DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 09-50]

Robert Raymond Reppy, D.O.; Decision and Order

On March 31, 2011, Administrative Law Judge (ALJ) Timothy D. Wing issued the attached recommended decision. Neither party filed exceptions to the decision.

Having reviewed the entire record including the parties' briefs, I have decided to adopt the ALJ's recommended ruling, findings of fact, conclusions of law, and recommended order. Accordingly, I will order that Respondent's DEA Certificate of Registration be revoked and that any pending applications be denied.

As the ÅLJ found, between 2002 and 2006, Respondent wrote thousands of controlled- substance prescriptions (approximately 5000 each year) to patients who sought such drugs as hydrocodone and alprazolam through the internet, most of whom (at least 90 percent) he never physically examined, let alone met. ALJ at 12, 20–21.¹ Respondent wrote the prescriptions based on medical records which were sent to him not by the patients' doctors, but by the patients themselves, and a telephone consultation with the patients. Id. at 20–21. As the ALJ found, "Respondent rarely contacted a patient's primary care physician whose records he was reviewing" and had no way of verifying whether the person he prescribed to was the actual person whose record he was reviewing. Id. at 21

Respondent maintains that in 2002, when he agreed to write the prescriptions, the legality of prescribing controlled substances via the internet was "a gray area" and that the standards were not the same "as are agreed upon now." Tr. 64. Respondent further claims that he did his "due diligence," which included doing "a little research on [his] own," with the result being that he "couldn't find anybody saying * * * for definite that you cannot do this" and that he was even shown a letter from "DEA giving permission to do it." Id. at 60. Respondent was shown this letter by an attorney, Mr. Robert Carr, who happened to be the founder and President of United Prescription Services, a Tampa, Florida-based pharmacy which was to fill most of the prescriptions Respondent issued; Respondent knew that Carr had a

financial interest in United Prescription Services. *Id.* at 60–61, 151.

As for Respondent's assertion that he was unable to find "anybody" definitely saying that it was illegal to prescribe controlled substances over the internet to persons he never examined, this may be consistent with his claim that he did "*little* research." However, it clearly was not the case, as even by 2002, multiple States had enacted statutes, promulgated rules, or published policy statements to the effect that prescribing drugs in this manner was illegal. Moreover, as explained below, it was clearly unreasonable for Respondent to rely on Carr's purported advice.

In 2000, California enacted a provision which prohibits the prescribing or dispensing of a dangerous drug "on the Internet for delivery to any person in this state, without an appropriate prior examination and medical indication therefore." Cal. Bus. & Prof. Code § 2242.1. Moreover, as early as November 2001, the Medical Board of California (MBC) issued a citation order to an out-of-state physician for prescribing over the Internet to California residents. See Citation Order, Carlos Gustav Levv (Nov. 30, 2001). The MBC cited both the physician's failure to conduct "a good faith prior examination," as well as his lack of "a valid California Physician and Surgeon's License to practice medicine in California." Id. at 1. The Board further ordered Doctor Levy "to cease and desist from Internet prescribing to individuals in California without first performing a good faith prior examination, without having medical indication to prescribe such medication and without having a California Physician and Surgeon's License," and fined him \$25,000. Id. at 1-2. See also Citation Order, Martin P. Feldman (Aug. 15, 2003); see also Citation Order, Harry Hoff (June 17, 2003); Citation Order, Carlos Gustavo Levy (Jan. 28, 2003).

In addition, in January 2003 (and prior to much of Respondent's prescribing activity which continued until October 2006), the MBC revoked a physician's medical license when he engaged in practices similar to those of Respondent. *See In re Steven Opsahl, M.D.,* Decision and Order, at 3 (Med. Bd. Cal. 2003) (available by query at http:// publicdocs.mbc.ca.gov/pdl/mbc.aspx).

In *Opsahl*, the MBC held that "[b]efore prescribing a dangerous drug, a physical examination must be performed" and that a physician "cannot do a good faith prior examination based on a history, a review of medical records, responses to a questionnaire, and a telephone consultation with the patient, without a physical examination of the patient." *Id.* The MBC also held that a "medical indication" is determined only after the taking of a history, the conducting of a physical examination, and an assessment of "the patient's condition." *Id.* The MBC further explained that "[a] physician cannot determine whether there is a medical indication for prescription of a dangerous drug without performing a physical examination." *Id.*

In April 2001, Ohio enacted a statute which defines "telemedicine" as "the practice of medicine in this state through the use of any communication, including oral, written, or electronic communication, by a physician outside th[e] state" and also requires that a physician obtain a "telemedicine certificate" to lawfully prescribe within the State, id. § 4731.296 (effective 4-10-01), and a "special activity certificate." Id. § 4731.294 (effective 4-10-01). Moreover, in 2002, Ohio adopted a regulation which, except for in circumstances not at issue here, prohibits the dispensing of controlled substances "to a person who the physician has never personally examined and diagnosed." Ohio Admin. Code § 4731–11–09(A).

In 2002, Tennessee law prohibited (as it still does) the practice of medicine within the State without a license issued by the State. Tenn. Code Ann. §63–6–201(a) (2002); see also id. §63– 6-204 (2002) (defining "a person [who is] regarded as practicing medicine" as one "who treats, or professes to diagnose, treat, operate[] on or prescribes for any physical ailment or any physical injury to or deformity of another"). Like Ohio, Tennessee also provides for "restricted licenses and special licenses based upon licensure to another state for the limited purpose of authorizing the practice of telemedicine." *Îd.* § 63–6–209(b) (1996). See also Tennessee Board of Medical Examiners, Position Statement: Prerequisites to Prescribing or Dispensing Drugs-In Person, Electronically or Over the Internet (Sept. 2000) ("[I]t shall be a prima facie violation of [State law] for a physician to prescribe or dispense any drug to any individual, whether in person or by electronic means or over the Internet or over telephone lines, unless the physician has first done and appropriately documents, for the person to whom a prescription is to be issued or drugs dispensed, all of the following: (a) Performed an appropriate history and physical examination * * * ").²

¹ All citations to the ALJ's decision are to the slip opinion as originally issued.

² This statement likewise recognizes three situations in which a drug may be prescribed

Prior to Respondent's prescribing activity, Tennessee had also promulgated a regulation which provided clear notice that, before issuing a prescription for a controlled substance "by electronic means or over the Internet or over telephone lines," a physician must "[p]erform[] an appropriate history and medical examination," "[m]a[k]e a diagnosis based upon the examinations and all diagnostic and laboratory tests consistent with good medical care," "[f]ormulate[] a therapeutic plan," and "[i]nsure[] availability of the physician or coverage for the patient for appropriate follow-up care." Tenn. Comp. R. & Regs. 0880–2–14.(7)(a) (2002).

In April 2000, the Alabama State Board of Medical Examiners promulgated its "Contact with Patients before Prescribing" rule. The rule states the Board's position:

that prescribing drugs to an individual the prescriber has not personally examined is usually inappropriate. Before prescribing a drug, the physician should make an informed medical judgment based on the circumstances of the situation and on his or her training and experience. Ordinarily, this will require that the physician perform an appropriate history and physical examination, make a diagnosis, and formulate a therapeutic plan, a part of which might be a prescription.

Ala. Admin Code r.540–X–9.11(1). While the Alabama rule also recognizes that in certain situations a prescribing physician is not required to have performed a physical exam of the patient (such as admission orders for a newly admitted patient, where the prescriber is taking call for another physician, and where the prescriber continues medication "on a short-term basis for a new patient prior to the patient's first appointment"), none of these exceptions applied to Respondent's internet prescribing. *Id.* r.540–X–9.11(2).

In February 2002, the Georgia Composite State Board of Medical Examiners amended its regulation defining "Unprofessional Conduct" to include "[p]roviding treatment and/or consultation recommendations via electronic or other means unless the licensee has performed a history and physical examination of the patient adequate to establish differential diagnoses and identify underlying conditions and/or contra-indications to the treatment recommended." Ga. Comp. R. & Regs. 360–3–.02 (2002). While the regulation provided an exception in the case of a licensee who is on call or covering for another doctor, the exception did not apply to Respondent's internet prescribing. *See also* S.C. Code Reg. 81–28(A) (effective May 25, 2001) (requiring prescribing physician to "[p]ersonally perform an appropriate history and physical examination").

In addition, prior to Respondent's commencement of internet prescribing, numerous state boards had issued policy statements which made clear that this activity was unprofessional conduct and illegal. For example, in November 1999, the North Carolina Medical Board issued a position statement entitled "Contact With Patients Before Prescribing" (available at *http://www*. ncmedboard.org/position_statements/ detail/contact with patients before *prescribing/*). Therein, the Board stated "that prescribing drugs to an individual the prescriber has not personally examined is inappropriate" except in the case of admission orders for newly hospitalized patients, taking call for another physician, and on short-term basis prior to a patient's first appointment. The Board further explained that "[o]rdinarily, this will require that the physician perform an appropriate history and physical examination, make a diagnosis, and formulate a therapeutic plan, part of which might be a prescription.'

In December 1999, the Texas State Board of Medical Examiners issued its Internet Prescribing Policy. This Policy stated that "[i]t is unprofessional conduct for a physician to initially prescribe any dangerous drugs or controlled substances without first establishing a proper physician-patient relationship." Texas State Board of Medical Examiners, Internet Prescribing *Policy* (available at *http://www.tmb*. state.tx.us/rules/guidelines/ipp.php). The Policy further explained that "at a minimum," this requires, inter alia, "verifying that the person requesting the medication is in fact who they claim to be," and "establishing a diagnosis through the use of accepted medical practices such as a patient history, mental status exam, physical examination and appropriate diagnostic and laboratory testing." Id.

In May 2000, the Louisiana State Board of Medical Examiners issued a Statement of Position on Internet/ Telephonic Prescribing, which stated "the Board's view, [that] it is unlawful for a physician to prescribe medication, treatment or a plan of care generally if the physician has not examined the patient and established a diagnostic basis for such therapy." Louisiana State Board of Medical Examiners, *Statement of Position on Internet/Telephonic Prescribing*, at 2 (available at *http:// www.lsbme.la.gov/Statements* %20of%20position.html). The Board further explained that:

A physician establishes a physicianpatient relationship by:

• Verifying that the person requesting the medication is in fact who they claim to be;

• Conducting an appropriate examination of the patient;

• Establishing a diagnosis through the use of accepted medical practices, *i.e.*, a patient history, mental status, examination, physical examination and appropriate diagnostic and laboratory testing;

• Discussing with the patient the diagnosis, risks and benefits of various treatment options; and

• Insuring the availability for appropriate follow-up care. *Id.* at 2. The Louisiana Board further stated that "[a]s a matter of law, to be valid, effective and lawful, each prescription or order for medication must be issued or given by an authorized practitioner (*i.e.*, a Louisiana licensed physician) with respect to an individually identified patient, based on the practitioner's examination and diagnosis of the patient." *Id.* at 3. Finally, the Board explained that:

because the [State's] Medical Practice Act restricts the practice of medicine to persons possessing a license issued by [it,] [a]n individual who issues a prescription or orders medication for an individual who is a resident of or located in Louisiana, who does not possess a Louisiana medical license or other authorization to practice medicine in this state, is necessarily engaged in the unauthorized practice of medicine in contravention of the Medical Practice Act.

Id.

Moreover, in November 2000, the Oklahoma State Board of Medical Licensure and Supervision adopted its Policy on Internet Prescribing. The Oklahoma Board adopted most of the same standards as the Louisiana statement, including that "at a minimum," a physician must verify the identity of a patient requesting medication and "establish[] a diagnosis through the use of accepted medical practices such as a patient history, mental status exam, physical examinations and appropriate diagnostic and laboratory testing by the prescribing physician." Oklahoma State Board of Medical Licensure and Supervision, Policy on Internet Prescribing (available at http://www.

without the physician having performed a physical examination of the patient: (1) In admission orders for new admitted hospital patients, (2) when covering for another physician, and (3) on a shortterm basis for a new patients prior to the patient's first appointment. None of these applied to Respondent's internet practice.

okmedicalboard.org/download/308/ precribing+on+the+Internet.htm). The Oklahoma Board also stated that "[c]omplete management of a patient by Internet, e-mail, or other forms of electronic communications is inappropriate." Id.; see also Washington Medical Quality Assurance Commission, Position on Internet Prescribing (Winter 2001) (available at http://www.doh.wa.gov/hsqa/mqac/ policies.htm) ("The standard of medical practice in the state of Washington requires a physician, when prescribing medication to [inter alia,] verify that the person requesting the medication is in fact who he or she claims to be," and "establish a diagnosis through the use of accepted medical practices such as a patient interview, physical examination, and appropriate ancillary testing.").

To similar effect, in May 2000, the Mississippi State Board of Medical Licensure issued a policy statement on Internet Prescribing. The Mississippi policy stated that the "[e]ssential components of proper prescribing and legitimate medical practice require that the physician obtains a thorough medical history and conducts an appropriate physical examination before prescribing any medication for the first time." Mississippi State Board of Medical Licensure, *Internet Prescribing* (available at http://www.msbml.state. ms.us/regulations/

2004%20policy%20book.pdf). While the Mississippi Board recognized exceptions for admission orders for newly hospitalized patients, crosscoverage situations, and for short-term prescribing prior to a new patient's first appointment, as noted previously, none of these situations applied to Respondent's internet prescribing.

In December 2001, the Massachusetts State Board of Registration in Medicine amended its Prescribing Practices Policy and Guidelines to address the subject of Internet Prescriptions. The Board stated that "a prescription to be legally valid must be issued within the context of a physician-patient relationship under circumstances in which the physician has conformed to certain minimum norms and standards for the care of patients, such as taking an adequate medical history and conducting an appropriate physical examination." Massachusetts State Board of Registration in Medicine, Prescribing Practices Policy and Guidelines, Internet Prescriptions (available at http://www. mass.gov/Eeohhs2/docs/borim/policies guidelines/policy_03_06.pdf).³ The

Board further advised that "[p]rescribing over the internet while deviating from these requirements is therefore unlawful."⁴

At the instant hearing, Respondent did not testify as to any state laws or Board positions (with the exception of Florida) he found which authorized prescribing to patients he would not meet, based on a review of records and a telephone consultation. Instead, he maintained that "as part of [his] due diligence" in deciding whether to engage in Internet prescribing, he reviewed the Model Guidelines for the Appropriate Use of the Internet in Medical Practice (RX 9), a policy document issued by the Federation of State Medical Boards of the United States (FSMB). Tr. 76-77. Respondent testified that this document gave him the impression that Attorney Carr's advice that Internet prescribing was legal was accurate "because it specifically says the physician/patient relationships exists whether or not there has been a personal encounter between

⁴Other States adopted similar statutes, rules and/ or policy statements on Internet prescribing within the next several years and well before Respondent ceased his internet prescribing. See Colorado Board of Medical Examiners, Policy 40-9: Guidelines Regarding Prescribing for Unknown Patients (Nov. 16, 2003) (available at http://www.dora.state.co.us/ medical/policies/40-09.pdf) ; Ind. Admin Code 5-41 (Oct. 2003) ("Except in institutional settings, on-call situations, cross-coverage situations, and situations involving advanced practice nurses with prescriptive authority * * * a physician shall not prescribe, dispense, or otherwise provide, or cause to be provided, any controlled substance to a person who the physician has never personally physically examined and diagnosed."); New York State Board for Professional Medical Conduct, Statements on Telemedicine (Dec. 24, 2003) (available at http:// www.health.ny.gov/professionals/doctors/conduct/ telemedicine.htm.) ("All the current standards of care regarding the practice of medicine apply. The fact that an electronic medium is utilized for contact between parties or as a substitute for faceto-face consultation does not change the standards of care."). While these provisions were adopted after Respondent commenced his Internet prescribing, Respondent had a continuing obligation to keep track of the law as it changed.

In addition, as early as June 2001, DEA had revoked the registration of a physician whose state controlled substance registration and medical licenses had been suspended for prescribing over the Internet. See Rick Joe Nelson, 66 FR 30752 (2001). This same physician was ultimately indicted for conspiracy to distribute controlled substances outside of the usual course of professional practice, 21 U.S.C. 846, and convicted. See United States v. Nelson, 383 F.3d 1227 (10th Cir. 2004). Of note, his conviction was affirmed (in a published decision) on September 20, 2004, more than two years before Respondent left the clinic. See also Mark Wade, 69 FR 7018, 7021 (Feb. 12, 2004) (revoking registration of Internet prescriber and noting physician had pled guilty to violation of 21 U.S.C. 846).

the physician and the patient," and that this was "[b]lack and white."

The fact that a physician-relationship "is clearly established when a physician agrees to undertake diagnosis and treatment," RX 9, at 7, however, does not mean that a physician has established an adequate physicianpatient relationship sufficient to support the diagnosis of a patient and the issuance of a prescription. Indeed, the Guidelines further state that "[t]reatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional (face-to-face) settings." Id. at 8. At the hearing, Respondent offered no explanation as to what he thought this statement meant.

Just one page later, the Guidelines further state that "[p]hysicians who treat or prescribe through Internet Web sites are practicing medicine and must possess appropriate licensure in all jurisdictions where patients reside." Id. at 9. Respondent admitted that during the period of his internet prescribing, he was licensed only in the State of Florida. Respondent thus engaged in the unauthorized practice of medicine in numerous States. As the California Court of Appeals has explained, the "proscription of the unlicensed practice of medicine is neither an obscure nor an unusual state prohibition of which ignorance can reasonably be claimed, and certainly not by persons * * * who are licensed health care providers. Nor can such persons reasonably claim ignorance of the fact that authorization of a prescription pharmaceutical constitutes the practice of medicine." Hageseth v. Superior Court, 59 Cal. Rptr.3d 385, 403 (Ct. App. 2007).

Respondent's assertion that he relied on the FSMB Guidelines and yet 'couldn't find anybody saying * * * for definite that you cannot do this," Tr. 60, is especially remarkable given that the Guidelines included a list of References. RX 9, at 11. Among the authorities cited therein are the position/policy statements of the Boards of Louisiana, New York, North Carolina, Oklahoma, South Carolina, Texas and Washington State, each of which—as discussed above—provided ample notice that each of these Board's considered internet prescribing to violate the accepted standards of professional practice.⁵ In

³ The Board subsequently amended its policy on December 17, 2003; the amended policy did not change the requirement that the prescribing

physician must "conduct[] an appropriate physical" examination. If further stated that "[i]ssuance of a prescription, by any means, including the Internet or other electronic process, that does not meet these requirements is therefore unlawful."

⁵ In April 2001, DEA published a Guidance Document entitled *Dispensing and Purchasing Controlled Substances over the Internet*, 66 FR 21181 (2001). The Guidance explained that "[o]nly practitioners acting in the usual course of their professional practice may prescribe controlled substances. These practitioners *must be registered*

short, Respondent's assertion that he did "a little research" is an accurate statement only to the extent that emphasis is placed on the word "little."

Respondent also asserts that a February 27, 2002 letter from the Chief of the DEA's Office of Diversion Control's Liaison and Policy Section to Carr, "g[ave] permission to do it." Tr. 60; see also RX 4. According to Respondent, Carr showed him the letter which "seemed very convincing" and that the letter "basically said they [DEA] were okay with it." Tr. 90–91.

While the letter stated "[i]t appears that the submitted policies and procedures meet the federal requirements regarding controlled substances prescriptions," it further noted that the pharmacy had represented that under its policies, it "plans to verify the authenticity and legal authority to prescribe of each prescriber." RX 4, at 1. More specifically, the letter noted that "[m]anagement personnel will verify several elements including, but not limited to * * * [p]rofessional licensure, DEA registration, [l]egitimate patient/prescriber relationship, [p]rescriptions are issued in the usual course of professional practice, and [p]rescriptions are issued for a legitimate medical purpose." Id. (emphasis added). Continuing, the letter noted "valid controlled substance

In addition, the Guidance Document specifically stated that "Federal law requires that '[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'" *Id.* at 21182 (quoting 21 CFR 1306.04(a)). The Guidance explained that "[e]very state separately imposes the same requirement under its laws" and that "[u]nder Federal and state law, for a doctor to be acting in the usual course of professional practice, there must be a bona fide doctor/patient relationship." *Id.*

Continuing, the Guidance explained that "[f]or purposes of state law, many state authorities, with the endorsement of medical societies, consider the existence of the following four elements as an indication that a legitimate doctor/patient relationship has been established:

A patient has a medical complaint;

A medical history has been taken;

A physical examination has been performed; and Some logical connection exists between the

medical complaint, the medical history, the physical examination, and the drug prescribed.

Id. at 21182–83.

The Guidance further stated that "[c]ompleting a questionnaire that is then reviewed by a doctor hired by the internet pharmacy could not be considered the basis for a doctor/patient relationship." *Id.* at 21183.

While the DEA Guidance Document does not have the force and effect of law, it nonetheless provided an additional source of information as to the potential illegality of Respondent's Internet prescribing. prescriptions must be issued for a legitimate medical purpose," and that "this is usually defined and interpreted by the prescriber's respective state professional licensing board." ⁶ *Id.*

Thus, contrary to Respondent's claim, the DEA letter did nothing more than address the lawfulness of the pharmacy's dispensing of prescriptions and did so based on Carr's representation that the underlying prescriptions would be lawfully issued. The letter thus provides no comfort to Respondent.

As for his reliance on Carr's purported legal advice, Respondent stated that he "assumed the lawyer would give me his honest opinion and expertise and I wouldn't have to go around consulting three or four of them to get the same thing." Tr. 60-61. Yet Respondent acknowledged that he knew Carr had a financial interest in the pharmacy. Id. at 61. Given Carr's financial interest, and even assuming (without deciding) that Carr and Respondent entered into an attorney-client relationship, Respondent had ample reason to question whether Carr was capable of providing disinterested legal advice. Id. at 60-61. Moreover, Carr's advice was fundamentally at odds with various statements contained in the Model Guidelines, a document which Respondent purportedly read, including the statements that: (1) ''[t]reatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional (face-to-face) settings"; and (2) "[p]hysicians who treat or prescribe through Internet Web sites are

However, Respondent produced no evidence showing that Carr, in requesting DEA's review of its policies, disclosed to the Agency that the doctors whose prescriptions it filled would be practicing medicine across state lines. See RX 3. Moreover, even if Respondent relied on the Florida Telemedicine Regulation, and even conceding that the regulation did not clearly state on its face that the prescriber (as opposed to another doctor) must perform a physical exam, see Fla. Admin. Code r.64B15-14.008(2), having claimed to have reviewed the Model Guidelines (and having previously been licensed in other States), Respondent cannot credibly claim ignorance of the fact that the regulation of the practice of medicine is a state function and that each State has its own Board and set of rules with which he was required to comply. See, e.g., Hageseth, 59 Cal.Rptr.3d, at 403.

practicing medicine and must possess appropriate licensure in all jurisdictions where patients reside." RX 9, at 8–9. Thus, because it is clear that Respondent did not reasonably rely on Carr's advice, this is not a mitigating factor.

Finally, Respondent asserts that his cooperation in the proceeding involving *United Prescription Services, Inc.,* 72 FR 50397 (2007), should be considered as a factor in mitigation. Resp. Br. 25. The Government did not dispute that Respondent provided testimony and an affidavit in that matter that was of some benefit to the Government. Tr. 78.

That being said, I conclude that Respondent's cooperation is substantially outweighed by the extensive and egregious misconduct he committed. As the ALJ found, with the exception of a period of several months during which he was on a leave of absence, *see* GX 10, at 85; for more than four years, Respondent wrote thousands of controlled substances prescriptions outside of the usual course of professional practice and which lacked a legitimate medical purpose. ALJ at 54, 60; *see also* 21 CFR 1306.04(a).

While this is reason alone to reject's Respondent cooperation as a mitigating factor, in addition, the ALJ also found that Respondent flagrantly failed to supervise a Physician Assistant, who wrote thousands of controlled substance prescriptions under his registration. ALJ at 65. As the ALJ found, the PA wrote 14,000 prescriptions, many of which were for controlled substances, during the period in which Respondent was on leave of absence. Id. Upon his return in March 2004, Respondent discovered that the PA had written some controlled substance prescriptions in his name, Tr. 38, 139; a violation of both state and federal law. See Fla. Sta. Ann. §459.022(4)(e) (prohibiting PAs from prescribing controlled substances); 21 U.S.C. 843(a)(2) (prohibiting dispensing of a controlled substance by use of a registration number "issued to another person"); id. § 822(a)(2) (requiring '[e]very person who dispenses" to obtain a registration).

The evidence showed that Respondent was upset that the PA was writing prescriptions under his registration without complying with his instructions and could not be controlled. Tr. 139. Respondent complained to the clinic's owner "about [the PA's] prescribing patterns using [his] DEA registration," RX 12, at 4; and asked him to fire the PA several times; however, the clinic's owner refused to

with DEA and licensed to prescribe controlled substances by the State(s) in which they operate." Id. at 21181 (emphasis added).

⁶ As explained above, this was not an entirely accurate statement of the law with regards a physician's prescribing to patients who reside in a different State. As the Model Guidelines explained, most (if not all) States deem prescribing to a resident to be practicing medicine within the State, and thus, a physician doing so is subject to both the licensing and medical practice standards of the patient's State and the physician's State. *See* RX 9, at 9; *see also* discussion above.

do so.⁷ Tr. 37–38; *see* GX 10, at 106. Nonetheless, Respondent continued to work for the clinic and did so for more than another year. Notwithstanding Respondent's professed concern that the PA "was being pretty arrogant [and] doing a lot of things on his own," Tr. 121, and his awareness of the PA's prescribing irregularities, RX 12, at 4; Respondent offered no evidence that he had reported the PA to either law enforcement or regulatory authorities. This provides an additional reason to reject Respondent's cooperation as a ground for mitigating the sanction.

In conclusion, the record here establishes that over the course of more than four years, Respondent was responsible for the issuance of thousands of illegal controlledsubstance prescriptions. Respondent's misconduct was egregious, and the Agency's interest in deterring similar misconduct on the part of others provides ample justification to support the ALJ's recommended order. See Joseph Gaudio, 74 FR 10083, 10094 (2009); Southwood Pharmaceuticals, Inc., 72 FR 36487, 36504 (2007) (citing Butz v. Glover Livestock Commission Co., Inc., 411 U.S. 182, 187-88 (1973)).

Moreover, as the ALJ explained, while at the hearing, Respondent occasionally acknowledged some wrongdoing, most of his testimony was then spent on blaming others or offering absurd or disingenuous justifications for his egregious misconduct. See ALJ at 65 (discussing verification of internet customers' identities—"I'm relying on the state that issued their driver's license attesting their identity. If the state did not adequately check their identity before issuing them a driver's license, then * * * I had no way of determining that. * * * I used the same method of checking their identity' as I would if they were present in front of me."). See also id. at 66-67 (finding that "rather than admit that * * * his telemedicine practices were in clear violation of contemporaneous standards * * * Respondent * * * attempted to cast doubt on the clarity of the rules."); *id.* at 68 (comparing Respondent's testimony that he was "sorry" for the prescriptions but then stating that "if I thought I was doing anything wrong, I wouldn't have done it''); *id.* (stating that he was remorseful, but adding "I

sincerely wish I had never been duped into being any part of their operation at all").

In sum, as the ALJ found, Respondent "fail[ed] to sustain his burden to credibly accept responsibility for his misconduct and demonstrate that he will not engage in future misconduct." ALJ at 71. Accordingly, I will adopt the ALJ's recommended sanction.

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), I order that DEA Certificate of Registration BR5287342, issued to Robert Raymond Reppy, D.O., be, and it hereby is, revoked. I further order that any application for renewal or modification of such registration be, and it hereby is, denied. This Order is effective November 2, 2011.

Dated: September 19, 2011.

Michele M. Leonhart,

Administrator.

D. Linden Barber, Esq., for the Government.

A.S. Weekley, Jr., M.D., Esq., for Respondent.

Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge

I. Introduction

Timothy D. Wing, Administrative Law Judge. This proceeding is an adjudication pursuant to the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.*, to determine whether the drug enforcement administration (DEA) should revoke a physician's certificate of registration (COR) as a practitioner and deny any pending applications for renewal or modification of that registration. Without this registration the practitioner Robert Raymond Reppy, D.O. (Respondent or Dr. Reppy), of Tampa, Florida, will be unable to lawfully prescribe, dispense or otherwise handle controlled substances in the course of his practice.

On April 28, 2009, the DEA Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause (OSC) to Respondent, giving Respondent notice of an opportunity to show cause why the DEA should not revoke Respondent's DEA COR BR5287342 pursuant to 21 U.S.C. 824(a)(4), and deny any pending applications for renewal or modification pursuant to 21 U.S.C. 823(f), on the grounds that Respondent's continued registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 824(a)(4) and 823(f).

In substance, the OSC alleges as follows:

1. Respondent has a DEA COR scheduled to expire by its own terms on April 30, 2009;

2. Respondent issued prescriptions to Internet customers from early 2004 until October 2006;

3. Respondent allowed a physician's assistant (PA) to use Respondent's COR to issue purported prescriptions to Internet customers, in violation of 21 U.S.C. 846 and Fla. Stat. Ann. § 458.347 (2008);

4. The above-referenced prescriptions were issued without a legitimate medical purpose and outside the usual course of professional practice, in violation of 21 CFR 1306.04(a) and 21 U.S.C. 841(a)(1);

5. Respondent issued purported prescriptions of controlled substances to customers throughout the United States even though Respondent is licensed to practice medicine only in Florida;

6. The above-referenced prescriptions violated state laws prohibiting the unauthorized practice of medicine, including unlicensed, out-of-state physicians issuing controlled substance prescriptions to state residents. *See e.g.,* Miss. Code Ann. § 73–25–34; Cal. Bus. & Prof. Code § 2052; Ala. Code § 34–24–51; and

7. Respondent violated Florida law and regulations prohibiting licensed physicians from issuing controlled substance prescriptions in excessive or inappropriate quantities, from issuing prescriptions via the Internet without documented patient evaluation and without discussing treatment options with patients. Fla. Stat. Ann. § 458.331(q); Fla. Admin. Code Ann. r. 64B8–9.014.

On May 26, 2009, Respondent, through counsel, requested a hearing on the allegations in the OSC.⁸ Following prehearing procedures,⁹ a hearing was held on November 16, 2010, in Bradenton, Florida, with both the Government and Respondent represented by counsel. Both parties called witnesses to testify and introduced documentary evidence. After the hearing, both parties filed proposed findings of fact, conclusions of law and argument. All of the evidence and posthearing submissions have been considered, and to the extent the parties' proposed findings of fact have

⁷ In an affidavit given in the United Prescription Services proceeding, Respondent stated that the clinic owner removed the PA from the clinic. RX 12, at 4. However, in both the united and instant proceedings, Respondent testified that the clinic owner "would never fire [the PA], no matter how many times I requested it." GX 10, at 106; Tr. 37. Respondent also testified the PA "was kept away from me," TR.101, and that the PA would frequently work from home.

 $^{^8 \, \}rm Respondent$ submitted an application to renew his COR on April 6, 2009. (ALJ Ex. 3 at 1.)

⁹ This case was originally assigned to Administrative Law Judge Mary Ellen Bittner. (*See, e.g.*, OPHS May 27, 2009.) On January 15, 2010, Administrative Law Judge Gail A. Randall was assigned to the case. (Mem. Jan. 15, 2010.) Judge Randall reassigned the case to me on July 19, 2010. (Mem. Jul. 19, 2010.)

been adopted, they are substantively incorporated into those set forth below.

II. Preliminary Evidentiary Issues

Prior to discussing the evidence and reaching the substantive issues in this case, a threshold evidentiary issue is the weight to be given, if any, to (1) the Deputy Administrator's conclusions of law regarding Dr. Reppy's compliance with state law contained in United Prescription Services, Inc., 72 FR 50,397 (DEA 2007), a separate proceeding in which Dr. Reppy was a witness but not a party; (2) a transcript of Dr. Reppy's sworn testimony in that case, admitted without objection as Government Exhibit 10 in the present proceeding; and (3) affidavits of Respondent's current employees and patients offered as Respondent's Exhibit 19, and an affidavit of Respondent offered as Respondent's Exhibit 13.

A. The 2007 Final Order in United Prescription Services, Inc.

On August 23, 2007, the Federal **Register** published a final order in United Prescription Services, Inc., 72 FR 50,397 (DEA 2007). Therein, the then-Deputy Administrator made legal conclusions touching upon the conduct of Dr. Reppy, who testified in that case but was not named as a party. The Deputy Administrator found that "Dr. Reppy violated the laws of California, Tennessee, Indiana, and Louisiana' because ''[e]ven if Dr. Reppy's * * * conduct established a valid doctorpatient relationship under Florida law (a dubious proposition at that), [he] violated the laws of other States which clearly require that the prescriber personally perform the physical exam except in limited situations not applicable here." United Prescription Servs., 72 FR at 50,408 (internal citations omitted). The Deputy Administrator also concluded that Dr. Reppy's PA, Mr. Protheroe, "used Dr. Reppy's DEA registration while Reppy was on leave of absence and not supervising him * * *. These prescriptions violated the State of Florida's regulations' regarding Dr. Reppy's delegation of authority to a PA.¹⁰ Id. at 50,409.

In the "proposed conclusions of law" section of the Government's posthearing brief in the present case, the Government cites a number of such conclusions by the Deputy Administrator, apparently arguing that I should give weight to those conclusions here. (*See* Gov't Br. 5–6 (discussing Factors Two and Four of 21 U.S.C. 823(f)).)

At issue, therefore, is whether legal conclusions from a prior proceeding relating to the conduct of a non-party witness should be given weight or controlling effect in a subsequent proceeding against the witness. I note at the outset that Dr. Reppy was not named as a party in *United Prescription Services*, had not yet had any adverse action taken against him by the DEA with respect to his COR (*see* Gov't Ex. 10 at 61), and was apparently unrepresented by counsel at the time.

The APA provides that "[t]he transcript of testimony and exhibits, together with all papers and requests filed in the proceeding, constitutes the exclusive record for decision" in this administrative proceeding. 5 U.S.C. 556(e). The APA further defines "party" to include a person or agency named or admitted as a party, or properly seeking and entitled as of right to be admitted as a party * * *." 5 U.S.C. 551(3), amended by Public Law 111–350, Jan. 4, 2011, 124 Stat. 3677 (no relevant changes) ("party[] in an agency proceeding"). In the instant case, the final Agency decision in United Prescription Services cannot serve as substantial evidence because it is not part of the "exclusive record for decision" to which Dr. Reppy was a party.¹¹ I therefore find that the APA precludes me from considering the individualized legal conclusions on the ultimate issues¹² regarding Dr. Reppy contained in United Prescription Services as a potential basis for imposing a sanction in this case.¹³ See id. § 556(e).

I further find that the doctrine of *res judicata*, or collateral estoppel, provides no basis for adopting without analysis the Deputy Administrator's findings in *United Prescription Services* that Dr. Reppy violated state law. Under the doctrine of *res judicata*, (1) a final judgment (2) on the merits (3) between the parties is binding on the parties in

subsequent litigation. See, e.g., Restatement (Second) of Judgments § 24; Black's Law Dictionary (9th Ed.) (res judicata).¹⁴ Agency precedent has acknowledged the Supreme Court's recognition of the applicability of the res judicata doctrine in DEA administrative proceedings. Christopher Henry Lister, P.A., 75 FR 28,068, 28,069 (DEA 2010) (citing Univ. of Tenn. v. Elliot, 478 U.S. 788, 797-98 (1986) ("When an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata * *'')).

It is conceded that the Deputy Administrator's conclusions in United Prescription Services concerning Dr. Reppy's compliance with state law, including the extent of his supervision of his PA, went to the merits of that decision, and that the decision constituted the Agency's final order. However, Dr. Reppy was not a party to that proceeding. See 5 U.S.C. 551(3), amended by Public Law 111-350, Jan. 4, 2011, 124 Štat. 3677 (no relevant changes) (the term "party' includes a person or agency named or admitted as a party, or properly seeking and entitled as of right to be admitted as a party"). Indeed, as the United States Court of Appeals for the Fifth Circuit found before that Circuit split into the Fifth and Eleventh Circuits, "the offensive use of collateral estoppel calls for the courts to use special care in examining the circumstances to ascertain that the defendant has in fact had a full and fair opportunity to litigate and that preclusion will not lead to unjust results."¹⁵ Johnson v. United States, 576 F.2d 606, 614 (5th Cir. 1978). After carefully examining the circumstances, I conclude that when the Agency issued the final order in United Prescription Services, Dr. Reppy had not been afforded a full and fair opportunity to litigate whether he violated the laws of California, Tennessee, Indiana, Louisiana and Florida. Res judicata is therefore inapplicable. See East Main Street Pharmacy, 75 FR 66,149, 66,154

¹⁰ Specifically, United Prescription Services cites Fla. Admin. Code Ann. r. 64B8–30.008(2). See 72 FR at 50,409. As discussed below, that rule is inapplicable to Dr. Reppy because he is an osteopathic physician; the applicable rule (which is textually identical) is r. 64B15–6.0038. Infra text following note 63.

¹¹ Although the Government offered the United Prescription Services decision as an exhibit in its January 19, 2010 supplemental prehearing statement (Gov't Supp. PHS at 5), it withdrew the exhibit at hearing (see Tr. 6–7).

¹² As used herein, "ultimate issues," also called "mixed questions of law and fact" and "deep issues," are distinguishable from precedential holdings of general applicability.

¹³ I do not suggest that United Prescription Services is without binding effect as Agency precedent with respect to its holdings of general applicability. See, e.g., supra Section VI(C)(c) (citing United Prescription Services for the proposition that state law controls the question of whether a doctor-patient relationship exists).

¹⁴ Accord, e.g., Ritch v. State, 14 So.3d 1104, 1107 n.5 (Fla. App. 1 Dist. 2009) ("Collateral estoppel bars relitigation of an issue only when (1) an identical issue was presented in the prior proceeding; (2) the issue was a critical and necessary part of the prior determination; (3) there was a full and fair opportunity to litigate that issue; (4) the parties in the two proceedings are identical; and (5) the issue was actually litigated.").

¹⁵ In Bonner v. City of Prichard, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc), the United States Court of Appeals for the Eleventh Circuit adopted as binding precedent all decisions of the former Fifth Circuit handed down prior to October 1, 1981.

n.24 (DEA 2010) ("While I previously found [in a prior decision that a patient] had died of multiple drug intoxication and had both oxycodone and alprazolam in her system, Respondent was not a party to that proceeding. The Government was thus required to prove this fact anew * * *." (internal citations omitted)).

For the foregoing reasons, I find that the Deputy Administrator's finding in a prior case to which Dr. Reppy was not a party that "Dr. Reppy violated the laws of California, Tennessee, Indiana, Louisiana" and Florida, 72 FR at 50,408–09 (internal citations omitted), does not constitute substantial evidence in the above-captioned proceeding, and I give that finding no weight in this Recommended Decision.¹⁶

B. Respondent's Prior Testimony

In its January 19, 2010 supplemental prehearing statement (Gov't Supp. PHS at 5), the Government noticed its intention to offer into evidence a transcript of Dr. Reppy's testimony in United Prescription Services, Inc., 72 FR 50,397 (DEA 2007). Dr. Reppy was not a named party in that proceeding, had not yet had any adverse action taken against him by the DEA with respect to his COR (see Gov't Ex. 10 at 61) and at the time was apparently unrepresented by counsel. In the present case, on consent of the parties,¹⁷ I admitted the transcript of Dr. Reppy's former testimony. (Tr. 126–27.) A preliminary issue in this Recommended Decision is what weight, if any, to give to that testimony.

The APA provides that final determinations in Agency administrative proceedings must be based upon "reliable, probative and substantial evidence." 5 U.S.C. 556(d). In addition, I may consider "evidence that is competent, relevant, material and not unduly repetitious." 21 CFR 1316.59(a) (2010). Where prior testimony from a previous proceeding is reliable, probative, material and not unduly repetitious, Agency precedent supports the admission of such testimony. See United Prescription Servs., Inc., 72 FR 50,397, 50,403 (DEA 2007) (crediting documentary evidence containing substance of witness's prior testimony "[i]n another proceeding"); see also Nestor A. Garcia, M.D., 61 FR 30,099, 30,100 (DEA 1996) (giving weight to witness's testimony at hearing

that recounted witness's former testimony before state medical board).

Here, the transcript of Respondent's previous testimony in United Prescription Services is reliable insomuch as it contains Respondent's sworn testimony at a formal administrative hearing (see Tr.127 (referring to what Respondent said "under oath")) and Respondent testified at the present proceeding that his former testimony was accurate, true and correct.¹⁸ (Tr. 80.) Moreover, Respondent gave the prior testimony in 2007, closer in time to the events at issue in the present case, presenting an increased chance that his memory accurately reflected the events.¹⁹ The transcript of Respondent's prior testimony is probative and material to the extent it addresses matters at issue in the present proceeding, to include without limitation the state(s) in which Respondent held a medical license from 2004 to 2006 (Gov't Ex. 10 at 69); the relationship between witnesses and between the clinic and pharmacy at which Respondent allegedly worked and had prescriptions filled, respectively (Gov't Ex. 10 at 10, 42, 55, 65, 74–77, 82, 89); the evolving ownership and name of the clinic at which Respondent allegedly worked (Gov't Ex. 10 at 6, 9, 46); the extent of Respondent's supervision of a PA (Gov't Ex. 10 at 84-85, 95-97, 101, 106); the practices of Respondent with respect to patient evaluation and treatment (Gov't Ex. 10 at 12, 25–26, 30, 73–74, 77, 78– 80, 93–94); and other topics. Finally, although the transcript of Respondent's prior testimony covers many of the topics he addressed in his testimony at hearing, I find that it is not unduly repetitious and that any repetition is offset by its probative value.

For the foregoing reasons, I find it proper to give weight to relevant portions of the transcript of Respondent's prior testimony in University Prescription Services. (See Gov't Ex. 10.)

C. Affidavits of Respondent's Employees, Respondent's Patients and Respondent

The parties stipulated at hearing to the admission of affidavits of Respondent's employees Adele Durina and Janice Viscio and his patients "[C.K.]"²⁰ and "[D.C.]," who did not testify in person. (Tr. 166.) In addition, Respondent testified at hearing that, pursuant to his prior testimony in *United Prescription Services*, he provided an affidavit beneficial to the Government, which he signed. (Tr. 78.) Respondent further testified that Respondent's Exhibit 12 is an unsigned copy of that affidavit. (Tr. 78.) By stipulation of the parties, I admitted Respondent's affidavit. (Tr. 7–9; *see* Resp't Ex. 12.)

An issue is what weight, if any, to give these affidavits.

Because the patient and employee affidavits address Respondent's professional conduct since the conduct alleged in the OSC, they are relevant to the issue of whether Respondent is currently in compliance with state and federal standards for the prescribing and practice of controlled substances. Moreover, the contents of Respondent's affidavit also bear on matters directly relevant to this case, to include his employment and the extent of his supervision of his PA, John Protheroe, among other topics. Finally, the Government stipulates and does not object to the admission of any of the affidavits. I therefore find it proper to give weight to relevant portions of affidavits of Respondent and Respondent's employees and patients. See 5 U.S.C. 556(d); 21 CFR 1316.59(a) (2010).

III. Substantive Issue

Whether a preponderance of the evidence establishes that, pursuant to 21 U.S.C. 824(a)(4), Respondent's DEA COR BR5287342 should be revoked and any pending applications for renewal or modification denied, because Respondent's continued registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(f).

IV. Evidence and Incorporated Findings of Fact

I find, by a preponderance of the evidence, the following facts:

A. The Clinic and the Pharmacy

Significant testimony at hearing related to Respondent's connection with two entities: University Physicians Resources (UPR), a medical clinic, and United Prescription Services (UPS), a pharmacy. (*See, e.g.,* Tr. 23.)

¹⁶ Compare supra note 13.

¹⁷ Counsel for Respondent asked Respondent a series of questions regarding whether his former testimony included various topics and was accurate; Respondent answered in the affirmative. (Tr. 78–80.)

¹⁸ I draw a distinction between reliability, on the one hand, and accuracy, on the other. Although I find that Respondent's prior testimony in *United Prescription Services* is reliable, only a balancing of the transcript against other evidence in this case can shed light on whether it is accurate.

¹⁹ As noted throughout this Recommended Decision, I also find that statements contained in the transcript of Respondent's prior testimony are generally consistent with Respondent's testimony at hearing.

²⁰ To protect the privacy of Respondent's patients, only initials are used.

B. The Witnesses and Affiants²¹

Respondent Robert Raymond Reppy, D.O., is licensed as an osteopathic physician in the State of Florida pursuant to license number OS7246. (Tr. 20; Gov't Ex. 15 at 1.) His licensure status is Obligation/Active.²² (ALJ Ex. 3 at 1.) Although Respondent was previously licensed to practice medicine in Georgia, California and Hawaii, since 2000 he has only been licensed in Florida. (Tr. 20–21; Gov't Ex. 10 at 69.) Respondent is registered with the DEA as a practitioner in Schedules II through V pursuant to DEA COR BR5287342. (ALJ Ex. 3 at 1.) Respondent's COR was scheduled to expire by its terms on April 30, 2009. On April 6, 2009, DEA received Respondent's application for renewal.²³ (ALJ Ex. 3 at 1.)

Respondent's witness Robert Arthur Carr, Esq. (Mr. Carr) is an attorney who has worked in the area of medical malpractice for twenty years. (Tr. 143.) He is not a physician and has no medical training. (Tr. 156–57; see also Tr. 61.) Mr. Carr testified that he knew Respondent when he worked at UPS. (Tr. 142.) Mr. Carr stated that he had no ownership interest in UPR, but at one point he did have a financial interest in UPS.²⁴ (Tr. 151–52; see Resp't Ex. 5.) Every prescription filled by UPS represented revenue for Mr. Carr. (Tr. 152.)

Respondent's witness Melissa Messick, also known as Missy Messick

²² Respondent's Curriculum Vitae (CV) facially contradicts this stipulation, stating that Respondent's Florida medical license expired on March 31, 2008. The CV, however, appears to be outdated, notwithstanding Respondent's representation in his post-hearing brief that it is "accurate" (Resp't Br. at 2) and his argument that I accept evidence that is uncontroverted (Resp't Br. at 26-27). For instance, the CV indicates that Respondent is presently employed at UPR (Resp't Ex. 10 at 4), despite the otherwise uncontroverted testimony at hearing that Respondent stopped working at UPR in 2006. (Tr. 21–23, 51.) In light of this and other evidence concerning the status of Respondent's state medical license. I find that the weight of the evidence contradicts any inference that Respondent lacks state authority to handle controlled substances in Florida.

 $^{23}\,\rm Pursuant$ to 5 U.S.C. 558(c), Respondent's COR continues in effect until DEA takes final action on the renewal application. (See, e.g., ALJ Ex. 3.)

(see Tr. 67–68) (Ms. Messick), was employed by UPS from 2001 to 2005. (Tr. 129, 132.) She testified that she was in a position to observe Respondent's work. (Tr. 129.) Ms. Messick is not a medical practitioner and lacks legal or medical training. (Tr. 135.) In a prior proceeding, Respondent testified that a "Ms. Messich" presently owns UPR. (Gov't Ex. 10 at 10; see also id. at 76– 77.)

Respondent's affiant Janice Vischio (Ms. Vischio) has been a LPN ²⁵ for twenty years, of which she has spent fifteen years in Florida. Her license is in good standing with the Florida Department of Health. As of July 15, 2010, she had worked with Respondent for at least eighteen months. (*See* Resp't Ex. 19 at 2.) Ms. Vischio handles administrative work for Respondent and does not see patients. (*Id.* at ¶ 3.)

Respondent's affiant Adele Durina (Ms. Durina) has over twenty years of medical office experience and presently works as Respondent's Office Manager and Medical Assistant. (Resp't Ex. 19 at 6 ¶ 2.) As of as late as July 15, 2010, Ms. Durina had worked with Respondent since he began working at Cosmopolitan Clinic. (*Id.* at ¶ 3; *see also* Tr. 167.)

As of July 15, 2010, [C.K.] has been a patient of Respondent since Respondent began practicing in the local area and [D.C.] had been a patient of Respondent for approximately thirteen to fourteen months for the treatment of degenerative spondylosis. (Resp't Ex. 19 at 12 ¶ 2; *id.* at 9 ¶¶ 1–2.)

C. Respondent, the Clinic and the Pharmacy

Although he did not remember the precise dates, Respondent testified that he was employed at UPR, a medical clinic, for four years beginning in 2002 until approximately 2006. (Tr. 21–23, 51.) Respondent's salary at UPR was the same as his salary at his previous employer; he was paid by the hour or the day rather than by the number of prescriptions he wrote.²⁶ (Tr. 61, 79.)

When Respondent was first approached about working at UPR, he understood that customers would interact with UPR via the Internet. (Tr. 59–60.) Respondent testified that he was the only physician who worked at UPR. (Tr. 23.) This statement is somewhat inconsistent with testimony by Mr. Carr that the company worked in the mailorder pharmacy realm and acquired licenses to ship pain relievers to anywhere in the country by working with a number of physicians.²⁷ (Tr. 143; *see also* Resp't Ex. 5 \P 4.)

Before joining UPR, Respondent worked at Home Harbor Urgent Care Center. (Tr. 61.) After leaving UPR, Respondent worked at a clinic called Gulf Shore from 2007–2009; between 2009 and the present, he has worked at Cosmopolitan Clinic in Brooksville, presumably in Florida. (Tr. 56, 68, 107; Resp't Ex. 17.) Gulf Shore was a pain management practice run by an anesthesiologist. (Tr. 57.) Cosmopolitan is a combination family practice and pain management clinic. (Tr. 57.)

In his testimony in a prior proceeding, Respondent testified that UPR changed its name to MediHealth, which evolved into a general family practice. (Gov't Ex. 10 at 6, 9; *see generally* Tr. 107–08.) This testimony is consistent with Respondent's testimony in the present case that from 2007 to 2009 Respondent worked part-time at MediHealth, a clinic owned by Ms. Messick. (Tr. 67– 68.)

(a) The Connection between UPR and UPS

Respondent testified that UPS is a pharmacy. (Tr. 23.) UPR, by contrast, is a medical clinic. (Tr. 23.) The two organizations had close connections.

For instance, Respondent learned in 2006 that UPS owned UPR and that a Sam Bollinger ²⁸ (Mr. Bollinger) was the owner of both UPR and UPS.²⁹ (Tr. 22–23.) Respondent stated, however, that Mr. Bollinger "had always represented to me that no financial link was there." ³⁰ (Tr. 23.) In addition, Mr. Carr testified that he formed UPS in 2001 (Tr. 143; *see* Tr. 61; *see also* Resp't Ex. 5) and that UPS worked in the mail-order pharmacy realm and acquired licenses to ship pain relievers to anywhere in the

²¹ In its prehearing statement and supplements thereto, the Government identified Diversion Investigator Peter W. Flagg, Special Agent Daniel A. Forde, Diversion Investigator Deborah Y. Butcher, and Respondent as witnesses. At hearing, however, the Government rested upon the testimony of Respondent alone, along with the exhibits it introduced into evidence. Moreover, Respondent's counsel did not conduct a separate direct examination of Respondent during Respondent's case-in-chief. Instead, I permitted counsel to expand the scope of cross examination.

²⁴ In his testimony at a prior proceeding, Respondent testified that a Mr. Jerome Carr and a Mr. Rob Carr were listed as president of UPS in 2003. (Gov't Ex. 10 at 76, 89.) The inconsistency was never explained.

²⁵ Although the record in this case is silent, various provisions of federal law define the term "LPN" as "licensed practical nurse." *See, e.g.,* 32 CFR 199.2; 42 CFR 482.51(a)(2).

 $^{^{26}\,\}rm Respondent$ also testified that he did not have any ownership affiliation with UPS. (Gov't Ex. 10 at 46.)

²⁷ The contradiction is perhaps explained by Respondent's testimony in a prior proceeding that another physician worked at UPR before Respondent began working there. (*See* Gov't Ex. 10 at 65.) Moreover, the record contains no evidence that UPR was the sole clinic with which UPS worked.

²⁸ The transcript of hearing in the abovecaptioned case spells the name "Bollinger," (*e.g.*, Tr. 23) and that is the convention adopted here. *But see* Gov't Ex. 10 at 9 ("Ballinger"); Resp't Ex. 12 (same); Resp't Ex. 5 (same).

 $^{^{29}\,\}mathrm{Mr.}$ Bollinger is not a medical professional. (Tr. 24.)

³⁰ In his testimony in a prior proceeding, however, Respondent testified that Mr. Bollinger required Respondent to send his patients' prescriptions to UPS, that the vast majority of his prescriptions from 2005 and 2006 were filled at UPS, that most of the clerks and staff at UPR had at one time worked at UPS and that Mr. Bollinger "pretty much ran the show." (Gov't Ex. 10 at 42, 55, 74–76, 82.)

country by "working with a number of physicians." ³¹ (Tr. 143.)

In addition, Respondent testified that the UPS pharmacy filled the vast majority of the prescriptions Respondent wrote while at UPR. (Tr. Respondent testified that although he thought he was working for the clinic UPR, he inadvertently was working for UPS. (Tr. 94.) He then contradicted himself, stating that he wasn't working for UPS. (Tr. 94.) Mr. Carr stated that Respondent was not employed by UPS. (Tr. 151-52.) He denied supervising Respondent, and further denied having any say over Respondent's medical practice. (Tr. 152.) Ms. Messick testified that she was employed simultaneously by UPS and UPR from 2001 to 2005. (Tr. 129, 132, 133.) She described it as a "back and forth," and she observed what went on at UPS and UPR. (Tr. 133.) She confirmed that she observed Respondent's work at UPR, and stated that Respondent didn't work at UPS. (Tr. 133.) She had seen Respondent in the pharmacy at UPS only once. (Tr. 134.) She testified that she was in a position to observe Respondent's work, and that Respondent followed guidelines set by Mr. Carr. (Tr. 129.)

(b) Respondent's and Mr. Carr's Telemedicine Research

Respondent stated that when he began prescribing controlled substances to individuals who contacted him at UPR primarily via the Internet, telemedicine was a new practice; "the legal community was struggling in a gray area to determine what those [legal standards] would be * * *." (Tr. 64.) Consequently, Respondent viewed his work at UPR as an experiment involving new ways to use the Internet. (Tr. 31.) He had some concerns about the legitimacy of the practice, "[s]o I did my due diligence." (Tr. 60). He "did a little research on my own," consulted with the attorney Mr. Carr and relied on "a letter shown me from the DEA giving permission to do it." (Tr. 60; see also Tr. 89 - 92.)

The letter to which Respondent referred was preceded by a letter dated January 28, 2002, and signed by "Robert Carr/President/United Prescription Services, Inc." (Resp't Ex. 3.) Addressed to Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, DEA, Mr. Carr's letter describes the "Community Pharmacy" UPS and solicits Ms. Good's "views on whether any requirements or changes are warranted in our policy." (Resp't Ex. 3; Tr. 90.) Although the letter recites that a copy of UPS's policies is attached (Resp't Ex. 3), no policy pages are attached to the record copy (*see* Resp't Ex. 3) and Respondent testified that he never saw the policy pages.³² (Tr. 96.) Mr. Carr confirmed that he contacted the DEA on January 28, 2002, to inquire whether the policies of UPS were in conformity with the law. (Tr. 144–45.)

Slightly less than one month later, Mr. Carr received a response. (Tr. 146.) A February 27, 2002 letter by Ms. Good, addressed to "Mr. Robert Carr/ President/United Prescription Services, Incorporated" opined that "the submitted policies and procedures meet the federal requirements regarding controlled substance prescriptions." 33 (Resp't Ex. 4 at 1; see Tr. 91.) Mr. Carr testified that the DEA advised him that "there was no further things [sic] we had to be concerned with our physicians that were practicing telemedicine." (Tr. 146.) Respondent and Mr. Carr agreed that Mr. Carr advised Respondent that by following Mr. Carr's guidance, Respondent would be in compliance with state and federal law. (Compare Tr. 91, with Tr. 147.)

Respondent testified that Mr. Carr showed him Ms. Good's February 27, 2002 letter (Tr. 91) and that Respondent believed the letter gave Respondent permission to prescribe to patients in multiple jurisdictions who contacted him via an Internet web site but did not necessarily meet with him face to face. (See Tr. 59-60, 110.) Respondent conceded, however, that Mr. Carr's letter asks about the dispensing practices of the pharmacy, not the prescribing practices of physicians. (Tr. 97.) Respondent further conceded that he lacked specific knowledge of what policies Ms. Good approved for the pharmacy. (Tr. 96.) And in any event, the record reflects that Ms. Good's general expression of approval of the pharmacy came with a number of caveats: "Management personnel will verify several elements including professional licensure[,] DEA registration[, l]egitimate patient/ prescriber relationship[, p]rescriptions

are issued in the usual course of professional practice, and [p]rescriptions are issued for a legitimate medical purpose." (Resp't Ex. 4 at 1.)

Although Respondent now concedes that Mr. Carr's assurances that Respondent was complying with the law were inaccurate (Tr. 110–11), he devoted significant testimony to defending his reliance on Mr. Carr's advice. (*See* Tr. 64, 67, 98, 100–01.)

Mr. Carr also testified as to the legal status of Internet prescribing practices as well as his own role in establishing UPS. Mr. Carr stated that he researched the law regarding telemedicine and related prescribing practices, surveying the laws of all fifty states addressing the regulation of pharmacies, general medicine and pain medication. (Tr. 144.) He said he searched for anything in the telemedicine realm, compiling a file "well over a foot high of documents that I reviewed extensively from various states, various regulatory authorities." (Tr. 150.) He stated that in 2001 the statutes and regulations were very minimal on telemedicine. Mr. Carr testified that the only reference was a statute from an unidentified jurisdiction addressing neural radiology in telemedicine. (Tr. 144.)

Mr. Carr stated that "California is one of the states that we were prescribing to, or shipping drugs to." (Tr. 158.) He could not, however, identify the effective date of the California law requiring that a physician hold a California medical license before prescribing to people in California over the Internet. (Tr. 150, 157.) He moreover could not confirm whether he specifically researched California's law, stating only that "yes, there would have been a review of all California licenses * * * in 2002 * * * ." (Tr. 158.)

Mr. Carr also testified regarding the Model Guidelines for the Appropriate Use of the Internet in Medical Practice (Model Guidelines).³⁴ He did not recall seeing that document in particular during the course of his research of telemedicine. He stated, however, that if it was published in 2002, he would have reviewed it extensively. (Tr. 149–50.) He also stated that he was generally familiar with the document. (Tr. 155.)

Page nine of the Model Guidelines contains the following provision: "Physicians who treat or prescribe through Internet Web sites are practicing medicine and must possess appropriate licensure in all jurisdictions where patients reside." (Resp't Ex. 9 at 9; *See* Tr. 156.) Mr. Carr testified that he did not previously see that sentence.

³¹ In light of Respondent's testimony that he was the only physician employed by UPR between 2002 and 2006 (Tr. 21–23, 51), Mr. Carr's statement that UPS worked with "a number of physicians" (Tr. 143) may be explained by Respondent's testimony that a Dr. Long and a Dr. Ibanez previously worked at UPR (*See, e.g.,* Gov't Ex. 10 at 80–81). See note 27, *supra*.

 $^{^{32}\,\}rm Mr.$ Carr's description of the policies that he sent to DEA for review (see Tr. 145–46, 158–59) accordingly have little bearing, if any, on the question of what Respondent believed at the time he read the letter.

 $^{^{33}}$ Mr. Carr testified that he no longer has a copy of the policy documents he submitted to the DEA with his June 28, 2002 letter, explaining that he left them with UPS when he sold the company. (Tr. 158.)

³⁴ See Resp't Ex. 9.

(Tr. 156.) "I would not have advised [Respondent] of that" because "there wasn't to my knowledge any specific requirement in Florida as to determine the nexus of where physician/patient relationship was in fact occurring and where the medical practice was occurring." (Tr. 156.)

Mr. Carr further testified that he relied on statements, such as the one appearing in the Model Guidelines, that "the [physician-patient] relationship is clearly established when the physician agrees to undertake diagnosis and treatment of the patient * * * whether or not there has been a personal encounter between the physician * * * and patient." (Tr. 163; Resp't Ex. 9 at 7.) He did not recall, however, seeing that statement in particular during the course of his research of telemedicine. He could confirm only that "[s]omething like this was something I'd probably even send down to the doctors

to give them * * * assurances." (Tr. 163.)

Ms. Messick's testimony in this regard was consistent, if equally vague: Ms. Messick explained that Mr. Carr had provided statutes and regulations on practicing telemedicine and the physician-patient relationship to physicians at UPR.³⁵ (Tr. 134–35.) Ms. Messick testified that the guidance Mr. Carr provided to Respondent was legal, not medical, and dealt with telemedicine and how to maintain a physician-patient relationship. (Tr. 135.) Ms. Messick elaborated that this question was a controversial subject of much discussion in the office.³⁶ (Tr. 136.)

Mr. Carr testified that he relied on a Federal Register Notice entitled "Dispensing and Purchasing Controlled Substances Over the Internet." (Tr. 153; see generally Resp't Ex. 8.) That document provides that "practitioners must be registered with DEA and licensed to prescribe controlled substances by the state(s) in which they operate." (Tr. 154; see Resp't Ex. 8 at 3.) Yet, while UPS filled prescriptions written by Respondent and shipped them all over the United States, Respondent was not licensed to practice medicine in any state other than Florida. (Tr. 154.) Many of Respondent's patients did not come to Florida, but interacted with Respondent electronically. (See Tr. 25, 154.) Mr. Carr explained that he interpreted Respondent's Internet prescribing

practices as operating in the state of Florida. (Tr. 160–61.)

D. Respondent's Physician's Assistant (PA)

Significant testimony at hearing concerned actions allegedly taken by John Protheroe (Mr. Protheroe), a PA, and the extent, if any, of Respondent's supervision of Mr. Protheroe.

Mr. Protheroe began working for UPR a few months after Respondent started working there in 2002. (Tr. 37, 38, 120.) Respondent did not hire him, but he worked under Respondent's license. (Tr. 37, 131.) Respondent testified that "[Mr. Protheroe] was hired because * * * I was not making Mr. Bollinger happy with the amount of restrictions that I was placing on the patients and thus slowing everything down * * * he hired Mr. Protheroe to go behind my back and speed things up. He never discussed with me 'do you need one?'" (Tr. 120.)

Mr. Protheroe was not often present while Respondent was in the office, and frequently worked from home. (Tr. 37, 38, 41; Gov't Ex. 10 at 85 ("He was purportedly * * supposed to work under my license, submit himself to my review * * And yet he was allowed to review patients' charts from his own home, away from the office where no one could see him.").) Mr. Protheroe was a PA only to Respondent, and not to any other doctor. (Tr. 120.)

Respondent testified to having an antagonistic relationship with Mr. Protheroe (Tr. 37) and developing a number of concerns before November 2003. (Tr. 121.) Respondent accused Mr. Protheroe of exploiting Respondent's license "behind my back without my permission" (Tr. 37, 42), and failing to adhere to the criteria by which Respondent rejected patients (Tr. 122).

Mr. Protheroe's compensation was connected to the number of prescriptions Mr. Protheroe wrote, most of which were for controlled substances. (Tr. 79; Gov't Ex. 10 at 96–97; Resp't Ex. 12 at 2.) Ms. Messick testified that Mr. Protheroe was compensated at a rate of fifteen dollars per prescription. (Tr. 132.) According to Respondent, Mr. Protheroe "wrote so many prescriptions without my authorization using a stamp of my signature" that Respondent was uncertain whether Respondent had completed the conduct charged in an administrative complaint by the Florida Department of Health,³⁷ or whether Mr.

Protheroe had written the prescriptions in question. (Tr. 41.) Respondent testified that the number of prescriptions that Mr. Protheroe wrote without Respondent's authorization was at least 14,000. (Tr. 80; *see generally* Tr. 132; Gov't Ex. 10 at 84–85.) Respondent did, however, acknowledge occasions in which Respondent approved prescriptions written by Mr. Protheroe. (Tr. 38.) Respondent estimated the quantity as "only a few a day." (Tr. 42.) The vast majority of Mr. Protheroe's prescriptions, however, Respondent was unaware of. (Tr. 38.)

Respondent testified that Mr. Protheroe wrote the majority of the objectionable prescriptions while Respondent was away from the office from November 2004 to March 2005 after his wife was diagnosed with a serious health issue. (Tr. 121–22, 132; Gov't Ex. 10 at 85, 96, 101.) Mr. Protheroe's misconduct continued the entire time Mr. Protheroe worked there, until Mr. Protheroe left in 2005, shortly after Respondent returned from medical leave. (Tr. 138.) It was only after returning that Respondent complained about Mr. Protheroe to Ms. Messick, who recalled Respondent's complaint that Mr. Protheroe wrote prescriptions without accurately reading the diagnoses or medical records. (Tr. 131, 138-39.)

Respondent approached Mr. Bollinger several times and requested that Mr. Protheroe be fired. (Tr. 37; *see also* Tr. 131; Gov't Ex. 10 at 106.) Respondent said he did not need Mr. Protheroe, and that Mr. Protheroe "was put there by someone else and I had no power to remove him because I did not pay his salary. I could not tell him to leave." (Tr. 37; *see* Tr. 122.) In July 2005, Mr. Bollinger removed Mr. Protheroe from UPR. (Resp't Ex. 12 at 4.)

Respondent testified that he was precluded from a full right to supervise Mr. Protheroe, which he now regrets so much that "it's so soured me on the experience that I've never hired any physician's assistants since and I don't think I ever will." (Tr. 108–09.) But Respondent's testimony that he lacked the full authority to supervise Mr. Protheroe, including the right to fire him if necessary, is substantially undercut both by the relationship (Mr. Protheroe was the physician's assistant and Respondent was the *physician*), as well as by Respondent's affidavit, affirming that Respondent was medical director of UPR and its sole corporate officer beginning in 2004. (See Resp't Ex. 12 at 2.)

 $^{^{35}\,\}mathrm{He}$ did not provide them to Ms. Messick, however. (Tr. 135.)

³⁶ For instance, Ms. Messick cited the question of whether "the patient actually had to be seen by the physician or the physician's office [or] another physician." (Tr. 137.)

³⁷ As detailed below, the Florida Department of Health accused Respondent of prescribing controlled substances to a patient without: conducting a face-to-face meeting, performing an adequate physical exam, taking an adequate

medical history, documenting a treatment plan or making referrals, *inter alia*. (Gov't Ex. 14 at 4.)

Negligibly mitigating this contradiction is a statement by Respondent that he did not realize he was UPR's sole corporate officer until 2006, even though as early as 2004, he understood he was medical director:

In 2004, Mr. Bollinger asked me to sign some corporate documents for [UPR]. I understood that these documents would list me as the medical director of [UPR]. I learned in late 2006, that Mr. Bollinger made me the sole corporate officer and removed himself as a corporate officer of [UPR] by having me sign these documents. When Mr. Bollinger did this, Mr. Bollinger listed my address as 2304 East Fletcher Avenue, Tampa, Florida. That is not the address of [UPR], nor is it the address at which I worked. The address Mr. Bollinger listed for me on the corporate filings is the address for [UPS].

(Resp't Ex. 12 at 2.)

After carefully evaluating Respondent's testimony, other record evidence and Respondent's demeanor while testifying, I find that Respondent's testimony regarding the scope of his authority over Mr. Protheroe is not fully credible. For instance, to the extent that Respondent testified that he lacked the authority to supervise or fire Mr. Protheroe after 2004, this testimony stands in stark contrast with Respondent's own evidence that Respondent understood Respondent was medical director of UPR in 2004. Additionally, the evidence includes Respondent's concession that he had an obligation to properly supervise Mr. Protheroe (Tr. 101; see Resp't Ex. 9 at 5 ("physicians should * * [p]roperly supervise physician extenders")), and his assertion that he did, in fact supervise Mr. Protheroe "when he was in the office * * *." (Gov't Ex. 10 at 105.) For the foregoing reasons, I find that Respondent possessed both the obligation and the authority to supervise Mr. Protheroe.³⁸

E. Respondent's Prescriptions to Internet Customers, 2004 Through October 2006

(a) Respondent's Service to Internet Customers at UPR, Generally

Respondent testified as to how he handled prescription requests from customers when he worked at UPR. Respondent conducted a telephonic or in-person consultation with every person to whom he prescribed controlled substances. (Tr. 29.) Respondent would interview most patients over the phone and then determine whether to issue a prescription or order any "tests on further verifications that were necessary." (*See* Tr. 25.) Approximately ninety percent of the consultations occurred exclusively by telephone, without an in-person meeting. (*See* Tr. 26; *see also* Gov't Ex. 10 at 77 (ten percent or "[m]aybe less than five percent").) In approximately 2005, Respondent began encouraging more patients to come to the clinic in Florida. (*See, e.g.,* Gov't Ex. 10 at 93–94.)

Before phone consultations took place, patient records "were compiled by the customer and sent to me." ³⁹ (Tr. 34.) Other doctors did not send patient records to Respondent; patients sent them.⁴⁰ (Tr. 34, 79–80.) Respondent testified that "Patients did not make them up on their own." (Tr. 34.) Respondent's staff at UPR would initially "screen" patients and compile charts containing patients' contact information, diagnoses and medical documentation verifying their conditions. (Tr. 24–25, 37.) The staff would provide a chart "whenever I requested it." ⁴¹ (Tr. 70.)

During the four years that Respondent worked at UPR (Tr. 35–36, 51), other doctors referred approximately 300 patients to Respondent. (Tr. 35–36.) As for the rest of Respondent's thousands of patients (*e.g.*, Tr. 43), the physicians whose records Respondent relied on to justify prescribing controlled substances were not affiliated with Respondent and did not provide any medical services, testing or evaluation at Respondent's request. (Tr. 36.)

Respondent testified that to have a valid doctor-patient relationship, a servicing medical professional must have conducted a physical examination of the patient. (Gov't Ex. 10 at 79-80 ("Someone must have done [a physical examination]).") For follow-up consultations, Respondent did not require "a new physical exam with every consult. When it became, in my opinion, too dated, then I would demand another physical exam." (Gov't Ex. 10 at 79.) But Respondent performed physical examinations on only two percent of his patients in his first year of employment with UPR, a percentage which rose to no more than seven percent of patients in later years. (Tr. 25–26.) Moreover, in a given week,

Respondent rarely contacted a patient's primary care physician whose records he was reviewing. (Tr. 32, 34–35, 80; Gov't Ex. 10 at 30, 78.)

Although he sometimes would do so, Respondent did not always find it appropriate to tell customers that online communication cannot take the place of face-to-face communication. (Tr. 102– 03.)

(b) Extent of Respondent's Verification of Patient Identities at UPR

Respondent had no face-to-face interactions with as many as ninety percent of his patients. (Tr. 26, 55.) When ascertaining a patient's identity before issuing a controlled substance prescription, therefore, Respondent relied on representations made by the radiologist who read the patient's CAT scan or MRI, or the office notes of the physician who first saw the patient. (Tr. 54.)

As for how he verified the identity of patients with whom he never physically interacted, Respondent testified that "I used the same method of checking their identity as I would if they were present in front of me." (Tr. 54.) Yet Respondent conceded that he never looked at the face of the vast majority of people to whom he issued prescriptions. (Tr. 55.) He conceded that it was possible, therefore, that a family member could take the medical records and identification of a deceased person, and Respondent would have no way of knowing whether the person on the phone was actually the person whose medical records and identification Respondent was reviewing. (Tr. 55-56.)

Respondent explained that "I was rather good at detecting fraud" by comparing font and language in different parts of patient medical records. (Tr. 56.) Respondent added: "If the state did not adequately check their identity before issuing them a driver's license * * * I had no way of determining that." (Tr. 54.)

(c) Extent of Respondent's Patient Evaluation and Documentation Practices at UPR

When he worked at UPR, Respondent conducted physical examinations on some of the individuals who contacted him through Internet Web sites. (Tr. 25.) The percentage was very small. (Tr. 25.) "It went from about two percent in the beginning to six or seven percent towards the end." (Tr. 26.) Respondent did not conduct physical examinations on more than ninety percent of his patients. (Tr. 26.) Nor did other physicians perform examinations of those patients at Respondent's

³⁸ A later section of this Recommended Decision addresses whether Respondent had any legal obligation or authority in this regard, and if so, whether Respondent discharged it.

 $^{^{39}}$ See also Gov't Ex. 10 at 73 (''Usually it was the patient's job to gather the records and forward them to me.'').

⁴⁰ There is also evidence that an entity called FedexMeds.com was an occasional referral source of patients, which occasionally transmitted medical records to Respondent. (Gov't Ex. 10 at 73–74; *see generally* Resp't Ex. 12 at 3.)

⁴¹This testimony is consistent with Ms. Messick's testimony that she or her staff provided medical records to Respondent before he conducted telephone interviews with Internet patients or prescribed medication to them. (Tr. 130.)

direction.⁴² (Tr. 36.) Respondent elaborated that other physicians had already performed examinations or tests before the patient came into contact with Respondent, explaining "That's the whole point." (Tr. 36.) Respondent had no affiliation with the physicians whose records he relied on. (Tr. 36.) He admitted to prescribing hydrocodone to thousands of individuals without a faceto-face examination. (Tr. 43; *see* Tr. 53.)

Each day Respondent consulted with approximately thirty customers. (Tr. 26, 51.) He worked five days per week. (Tr. 35; 51–52.) On average, he issued controlled substances prescriptions to 150 patients per week. (Tr. 52.) Respondent worked at least forty weeks per year, usually more. (Tr. 52.) Thus, on approximately 5000 occasions per year or more, Respondent issued controlled substance prescriptions to new or repeat customers. (Tr. 53.)

Many patients came to him prediagnosed, and Respondent stated that they had to prove what the diagnosis was. (Tr. 29.) Although Respondent testified that he contacted a patient's primary physician whose medical records he was reviewing "on occasion" (Tr. 80) and "whenever it was necessary" (Tr. 32), he also testified that he only consulted one or two physicians out of the 150 patients he serviced in a given week, (Tr. 34, 35; see generally Gov't Ex. 10 at 30, 78 ("I generally did not have to do that on a regular basis. That was less than once a day. It was when I had specific questions.")). Respondent testified that it is not a common practice to speak with the medical professional who prepares medical records such as MRIs and radiology reports. (Tr. 32.)

Respondent stated that it would be inappropriate and "not smart medicine" (Gov't Ex. 10 at 26) to complete a firsttime diagnosis over the phone, but not necessarily a subsequent diagnosis.⁴³ (Tr. 29–30, 104.) Later, however, he stated that "I have enough expertise to know whether someone has a respiratory problem at the moment by how they're talking to me over the phone." (Tr. 115.)

Respondent conceded that it would be inappropriate to prescribe controlled substances to an individual who had not been diagnosed with having a legitimate medical need for the drugs. (Tr. 30.) The record also reflects allegations by the Florida Department of Health that Respondent failed to adequately discuss and document treatment options with patients (*see, e.g.,* Gov't Ex. 14 at 3–4), although these allegations were resolved by settlement agreement (Gov't Exs. 15 & 16).

At hearing, Respondent confessed that his evaluation of patients and documentation at UPR "is not considered adequate," and that "I have a different standard now because I've been educated about it." (Tr. 45-46.) "[T]he happy medium [in fighting controlled substance abuse] is to insist on proper documentation—and try to wean people off it when you can." (Tr. 66.) Reflecting on his current practice at Cosmopolitan, Respondent stated that he has been lowering patient dosages and "getting rid of the people who had abuse potential." (Tr. 66.) "I think I've done a good job where I am of * * cleaning up the practice." (Tr. 66.)

(d) Respondent's Internet Consulting and Prescribing Policies at UPR

Respondent testified to his belief that his patients' primary care physicians had undertaken personal encounters with patients, and therefore patients "were not placing their whole care in my hands." (Tr. 110.) He further testified that in 2002, the Federation of State Medical Boards stated that a faceto-face encounter was not necessary as long as the patient expected that the doctor would take over the treatment plan and review medical documentation. (Tr. 43–44.)

The Federation of State Medical Boards, however, is "a collection of licensing bodies from all the states." (Tr. 44.) Respondent testified that he did not initially know whether it is itself a licensing authority. (Tr. 45.) But he then conceded that "I realize now that it was a mistake after people with more legal expertise than I have told me" that statements by the Federation of State Medical Boards do not carry "legal weight."⁴⁴ (Tr. 45; *see also* Tr. 164.)

Respondent disputed the suggestion that he failed to adequately perform patient evaluations at UPR, testifying that his interaction with patients was adequate according to his understanding of what was required by the Federation of State Medical Boards. (Tr. 43.) He further stated that none of his patients for whom he prescribed over the Internet came to any harm: "there were no mortalities, no morbidity." ⁴⁵ (Tr. 116.) Asked whether any patient suffered an overdose death, Respondent answered that "I know none of them did while I was prescribing. If it happened since that time, then it happened because someone else was prescribing it. I can't be responsible for what some other doctor did." (Tr. 117.) "I'm sure there would have been a lawsuit if there was one and I never received any." (Tr. 123.) He conceded, however, that he has not stayed in touch with all of his UPR Patients since leaving UPR. (Tr. 117.)

(e) Location of Respondent's Customers

Respondent testified that most of the individuals to whom Respondent prescribed controlled substances became Respondent's customers through Internet Web sites. (Tr. 25.) Respondent testified that he issued prescriptions for controlled substances to people located all across the United States. (Tr. 27, 39.) Although he did not remember precisely how many different states, he said the list was "long." (Tr. 39; see Resp't Ex. 12 at 3 ("hundreds of patients who lived outside of Florida'').) For instance, in response to questioning by counsel for the Government, Respondent conceded issuing prescriptions for controlled substances to people in Tennessee, California, Illinois and North Carolina. (Tr. 38.) Respondent said that Kentucky and Mississippi were "off limits," but did not actually deny prescribing to individuals in those states. (Tr. 28.)

Respondent admitted that he was not licensed to practice medicine in all fifty states while he worked at UPR. (Tr. 28.) He presently understands that he has an obligation to prescribe or dispense controlled substances in accordance with all applicable state laws, and that prescribing across state lines sometimes includes the application of laws other than the laws of the State of Florida. (Tr. 63.) He concedes that, in hindsight, the prescriptions he issued at UPR to Internet customers "did not meet the highest standard * * * and I'm sorry." (Tr. 63–64.) In his post-hearing brief, Respondent states that he "now realizes that the prescriptions he issued at [UPR] to Internet patients were not issued in the usual course of professional practice * * ." (Resp't Br. at 17.) When asked whether he now knows that his Internet prescribing at UPR was not consistent with the law as it was at that time, Respondent answered "Absolutely." (Tr. 91-92.) Contradicting himself somewhat, Respondent also stated that

 $^{^{42}}$ As Respondent explained, "the physical examination has to be done by someone else in the case of telemedicine. [Patients] have to have seen a local doctor that actually saw them and performed the physical examination, and gotten those notes to me, so that I know what was seen and have the information available." (Gov't Ex. 10 at 25–26.)

⁴³ See also Gov't Ex. 10 at 12 ("it's certainly not considered appropriate to make new diagnoses in a telemedicine format").

⁴⁴ In any event, Respondent conceded that he personally has not received a license from the Federation of State Medical Boards. (Tr. 45.)

⁴⁵ This testimony is consistent with testimony of Ms. Messick, who stated that she was not aware of

any injuries or complaints by patients as a result of Respondent's prescribing practices. (Tr. 130.) She conceded, however, that she had not stayed in touch with the thousands of Internet patients with whom Respondent consulted. (Tr. 137.)

at the time he engaged in the prescribing practices that are the subject of the OSC, he wasn't doing anything wrong (Tr. 64– 65), explaining that "if I thought I was doing anything wrong, I wouldn't have done it." (Tr. 65.)

Significant testimony addressed the extent of Respondent's reliance on and understanding of the Model Guidelines. Respondent admitted that before accepting employment with UPR, he does not recall whether he read the provision from "Section Five[:] Guidelines for the Appropriate Use of the Internet in Medical Practice," entitled "Compliance with State and Federal Laws and Web Standards." (Tr. 105.) In pertinent part, that provision reads: "Physicians who treat or prescribe through Internet Web sites are practicing medicine and must possess appropriate licensure in all jurisdictions where patients reside." (Resp't Ex. 9 at 9.) Respondent admitted that he failed to comply with that provision. (Tr. 105.)

Asked if he was regretful and remorseful for the role he played at UPR in prescribing controlled substances, Respondent stated: "Yes, very much. I sincerely wish I had never been duped into being any part of their operation at all." (Tr. 92.) Respondent testified that in the future, he would not prescribe for patients in jurisdictions in which he lacks a medical license. (Tr. 111.) Asked by counsel whether he felt remorse for having done so, he said "Yes. Not only am I remorseful about it, but I feel rather foolish and stupid for doing so in retrospect." (Tr. 111.) He also deemphasized his own responsibility, stating "I was just an hourly employee. I was just a pawn in the machine." (Tr. 119.)

(f) Quantity of Prescriptions and Extent of Diversion Avoidance at UPR

On approximately 5000 occasions per year or more during his tenure at UPR, Respondent issued controlled substance prescriptions to new or repeat customers. (Tr. 53; *see also* Tr. 25, 32, 43.)

Most or many of the individuals who contacted Respondent at UPR sought and ultimately received a specific controlled substance. (Tr. 28, 36.) The most common request was for hydrocodone, a Schedule III narcotic. (Tr. 28.) Respondent testified that some patients also sought alprazolam, which he identified as a Schedule IV benzodiazepine trading under the brand name Xanax or Valium.⁴⁶ (Tr. 29.) Patients requested these drugs before Respondent consulted with them. (Tr. 29.) Respondent explained that patients "were just reiterating what their own physician had put them on." (Tr. 70.) Respondent testified that on many occasions, he reduced the amount of medications for some patients and suggested alternate treatment methods. (Tr. 79–80.)

In Respondent's professional medical opinion, the abuse of controlled substances is a significant problem. (Tr. 65.) Respondent testified that some people misuse and abuse the kinds of controlled substances that Respondent prescribed at UPR, particularly hydrocodone, alprazolam, oxycodone and methadone. (Tr. 65.) From time to time Respondent encountered patients who abused controlled substances and immediately dismissed them. (Tr. 65.) "I ferreted it out where I could." (Tr. 65.) Respondent, however, could not state how many of his patients were addicted to narcotics while he was prescribing to them. (Tr. 118.) Respondent is familiar with the rising rate of oxycodone overdose deaths, calls it a big problem and "I do best to make sure that doesn't happen." (Tr. 59.) Respondent stated that when physicians prescribe correctly, doctors who prescribe controlled substances to drug abusers do not themselves contribute to the pharmaceutical abuse problem. (Tr. 66.)

(g) The Florida Department of Health Administrative Complaint

Respondent testified that Florida instituted an administrative complaint (Complaint) against him arising out of his Internet prescribing practices at UPR.⁴⁷ (Tr. 40; Gov't Ex. 14.) The Complaint alleged, *inter alia*, that in 2004 Respondent repeatedly prescribed hydrocodone to patient [D.P.], a resident of Wyoming who had never had a face-

⁴⁷ Respondent stated that he never received correspondence from licensing boards in other states complaining of his practice. (Tr. 39.) He did, however, become aware of some such complaints in the context of a previous proceeding against UPS. (Tr. 40.) to-face meeting with Respondent. (Gov't Ex. 14 at 2, 3.) It further alleged that Respondent failed to perform an adequate evaluation of [D.P.], including an adequate medical history and an adequate physical examination to justify prescribing controlled substances; that Respondent failed to document discussing the risks and benefits with [D.P.]; that Respondent failed to prepare and document an adequate treatment plan or keep adequate medical records of his treatment of [D.P.]; and that Respondent failed to refer [D.P.] for additional consultations or diagnostic testing. (Gov't Ex. 14 at 4.)

Respondent could not confirm or deny whether he completed the conduct alleged in the Complaint because "this PA John Protheroe wrote so many prescriptions without my authorization using a stamp of my signature that it may well have been done under—under that process." (Tr. 41.) Respondent explained that when he received the Complaint, he had no way of looking into the patient records to determine whether it was Respondent or Mr. Protheroe who wrote the prescriptions in question. (Tr. 41–42.)

Respondent further testified that he did not know the identity of "[J.N.]," another patient. (Tr. 42.) The Complaint alleged that [J.N.] was Respondent's patient, located in Idaho, to whom Respondent allegedly prescribed hydrocodone, without conducting a face-to-face meeting or physical examination, discussing the risks and benefits of controlled substances, preparing and documenting an adequate treatment plan, keeping adequate medical records of treatment, or referring [J.N.] for additional consultations or diagnostic testing. (Tr. 42; see Gov't Ex. 14 at 4-6.) Respondent explained that when he received the Complaint, he did not have access to the records of patient [J.N.]. (Tr. 73-74.) Nor did Respondent have the opportunity to review the records of [S.J.], another patient listed in the Complaint, because Respondent lacked access to those records, as well. (Tr. 74.)

In short, Respondent does not know whether he issued any of the prescriptions alleged in the Complaint. (Tr. 42, 43.) Respondent conceded, however, that even if he did not personally issue the prescriptions, he did prescribe hydrocodone to thousands of individuals without conducting faceto-face examinations. (Tr. 43.) Respondent explained his belief that the patients for whom he was prescribing already had had a face-to-face meeting with their primary care physicians; Respondent believed he was merely renewing existent prescriptions,

⁴⁶Respondent's testimony that alprazolam is sold under the trade name Valium is incorrect. I take official notice that alprazolam sells under the trade name Xanax and that diazepam sells under the

trade name Valium. Under the APA, an agency ''may take official notice of facts at any stage in a proceeding-even in the final decision." U.S. Dept. of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is "entitled on timely request, to an opportunity to show to the contrary." 5 U.S.C. 556(e); 21 CFR 1316.59(e) (2010); see, e.g., R & M Sales Co., 75 FR 78,734, 78,736 n.7 (DEA 2010). Respondent can dispute the facts of which I take official notice by filing a properly supported motion for reconsideration within twenty days of service of this Recommended Decision, which shall begin on the date it is mailed. See, e.g., Joseph Gaudio, M.D., 74 FR 10,083, 10,088 (DEA 2009) (granting respondent opportunity to dispute officially noticed facts within fifteen days of service).

income and was unable to pay the \$3000 and \$5000 cost of the courses he

agreed to take. (Tr. 51.) Per the settlement agreement, Respondent agreed to pay his \$12,500 fine within two years of December 26, 2007. (Gov't Ex. 15; Tr. 49.) Respondent acknowledged that the settlement agreement and final order provided that Respondent would cease professional practice if he did not comply with the two-year deadline for paying the fine set therein. (Tr. 50; see Gov't Ex. 15 at 4.) Respondent testified that he has not yet paid the fine in full, but has practiced medicine continuously since the December 26, 2007 final order was issued, in part because he was unable to secure other employment, a problem he attributes partially to the DEA. (Tr. 49, 51.) Respondent testified that "unless I was ordered by the Department of Health I wasn't going to" cease practicing medicine, although he had agreed to do so in the October 2, 2007 settlement agreement. (Tr. 50.) The Florida Department of Health "agreed to the schedule that I'm paving it back on."⁴⁸ (Tr. 49.) In mitigation, Respondent stated that he reported to a compliance officer who was aware of Respondent's continued practice. (Tr. 70.)

F. Respondent's Family Practice at Cosmopolitan

(a) Generally

In July or August of 2010, after leaving UPR, Respondent placed an ad in the local newspaper advertising his new family practice at his current employer, Cosmopolitan Clinic. (Tr. 88; Resp't Ex. 17.) The ad resulted in Respondent acquiring new, non-pain management patients. (Tr. 88.) Respondent has acted to change his practice from a pain management practice to a family practice. (Tr. 88–89.)

Respondent testified as to his documentation practices at Cosmopolitan. (*See* Tr. 80–87; Resp't Ex. 15.) In pertinent part, he testified to using a Consent for Chronic Opioid Therapy, and later using a Controlled Substances Narcotic Agreement. These documents enable Respondent to summarily dismiss any patient who seeks controlled substances from other physicians (Tr. 84), or who fails to notify the clinic in writing upon switching pharmacies, (Tr. 86; Resp't Ex. 15.) Respondent testified that as of the date of the hearing, he understood that he is required to dispense or prescribe controlled substances only for a legitimate medical purpose in the usual course of his professional practice. (Tr. 62.)

At his current practice at Cosmopolitan, Respondent's most frequently prescribed controlled substances are methadone and oxycodone. (Tr. 57.) Respondent prescribes methadone to treat chronic pain conditions unlikely to improve without surgery, and oxycodone for conditions where a short-acting medication is more appropriate. (Tr. 58– 59.)

(b) Respondent's Current Patients at Cosmopolitan

[D.C.] has been a patient of Respondent for approximately thirteen to fourteen months for the treatment of degenerative spondylosis. (Resp't Ex. 19 at 9 ¶¶ 1–2.) During this time, Respondent met with [D.C.] approximately ten times. (*Id.* at ¶ 6.) Respondent physically examined [D.C.] at most visits and inquired whether [D.C.] was experiencing any new pain. (*Id.* at ¶ 7.) Respondent always took time with [D.C.] to discuss treatment options and [D.C.] never felt like the visit was rushed. (*Id.* at ¶ 9 & 10.)

[D.C.] believed [D.C.]'s former pain doctor was overmedicating [D.C.]. Respondent happily agreed to reduce the dosage of pain medication that [D.C.]'s former pain doctor was prescribing. (Resp't Ex. 19 at 9 ¶¶ 3–4.) Respondent gradually lowered the dosage over a period of months, ensuring that [D.C.] did not experience any new pain. (Id. at ¶ 5.) In fact, the reduction in [D.C.]'s pain has been dramatic. (Id. at ¶ 8.) Prior to treatment by Respondent, [D.C.] was taking 30 mg oxycodone five times per day, 10 mg methadone six times per day; and 2 mg Xanax two times per day. (Id. at ¶ 11.) Presently, however, [D.C.] considers [D.C.]'s pain to be under control and is taking 5 mg methadone once a day and one teaspoon of liquid oxycodone once a day. (Id. at ¶¶ 11 & 12.) The Xanax prescription is no longer needed. (Id. at ¶12.)

Another patient of Respondent, [C.K.], likes Respondent because he is a "straight up" sort of person; [C.K.] feels very comfortable with him. (Resp't Ex. 19 at 12 ¶ 3.) Respondent treats [C.K.] for back and neck pain stemming from an automobile accident, and also pain from a "bad knee," for which surgery has been recommended. (*Id.* at ¶¶ 4, 5 & 6.) Respondent examines [C.K.] on each visit and discusses treatment options. (*Id.* at ¶ 7.) Respondent has worked with [C.K.] to reduce the

continuing the course of care and not initiating the first treatment plan. (Tr. 109.) He conceded, however, that he had treated some patients who had been dropped by their providers, whether for lack of funds or another reason. (Tr. 113, 116.) "I was continuing the treatment plan that was first set up by their doctor who might no longer have been willing to continue that plan * * * So the patient had nowhere else to go." (Tr. 113.)

The Complaint resulted in a settlement agreement, dated October 2, 2007, implemented through a final order dated December 26, 2007. (Tr. 46-48; Gov't Exs. 15 & 16.) Respondent agreed to pay a fine of \$12,500, complete continuing medical education courses about prescribing controlled substances ("drug course"), maintaining medical records ("records course") and laws and rules ("laws and rules course"), perform 100 hours of community service and prepare a paper suitable for publishing in the Journal of the American Osteopathic Association. (Tr. 46; Gov't Ex. 15: see also Gov't Ex. 16.)

Respondent's community service was to be completed by December 30, 2009, but Respondent did not complete it until February 9, 2010. (Resp't Ex. 18 at 2; see also Tr. 72.) For instance, a February 2, 2010 letter from the Florida Department of Health states that "Dr. Reppy has not completed any term imposed by the final order and is considered out of compliance at this time." (Gov't Exs. 20 & 22.) At hearing, Respondent testified that he had since submitted the paper he was assigned. (Tr. 72.) The paper warns practitioners against the dangers of Internet prescribing, gives case histories and reflects on what happened to Respondent. (Tr. 93.)

Respondent's drug course was to be completed within one year of December 26, 2007, the date of the final order. (Tr. 48; Gov't Ex. 15.) Respondent did not complete the drug course until December 9 through December 11, 2009. (Tr. 48.) He did not complete the records course or the laws and rules course until after September 2010. (Tr. 48.) As of the date of the hearing, however, Respondent had complied with all of his continuing education requirements. (Tr. 71; Resp't Ex. 18 at 2.)

Explaining his failure to meet all the deadlines set by the settlement agreement, Respondent asserted that in 2006 DEA placed on the Internet information related to his reprimand. (Tr. 50.) Thereafter, Respondent "became essentially unemployable" at any hospital or large clinic. (Tr. 50.) Consequently, Respondent had no

 $^{^{48}}$ Respondent's Exhibit 18, dated October 20, 2010, indicates that Respondent made four periodic payments in February, May, July and September 2010, amounting to a total of \$1500 paid out of \$12,500 owed. (See Resp't Ex. 18 at 2.)

amount of [C.K.]'s pain medication. (*Id.* at ¶ 6.)

(c) Respondent's Current Employees at Cosmopolitan

Respondent's administrative employee Janice Vischio also submitted an affidavit. Although Ms. Vischio is not generally present when Respondent consults with patients, she does witness parts of some conversations. (Resp't Ex. 19. at 2 \P 4.) She states that Respondent personally sees patients, takes or reviews patient history and reviews patient office forms. (*Id.* at $\P\P$ 5–7.) Moreover, Ms. Vischio has seen Respondent's handwritten notes in patient files. (*Id.* at \P 7.)

Conceding that she has not personally seen Respondent examine patients, Ms. Vischio states that she has witnessed him performing exams on occasion and that Respondent documents exams in his files. (Id. at ¶ 8.) Respondent takes twenty minutes or more with each new patient, and ten minutes for a follow-up visit, and sometimes exceeds the allotted time limit. (Id. at ¶ 9.) Respondent discusses treatment plans with patients, returns their phone calls and discusses their options with them. (Id. at ¶ 10.) Ms. Vischio has worked with many physicians in a variety of medical settings, and calls Respondent thorough in his documentation and diligent in his examinations and followup. (*Id.* at ¶ 13.)

Ms. Vischio also addressed the new patient intake process. New patients must either obtain a referral for pain management or have a prescription history or list from six months to one year before seeing Respondent. (Resp't Ex. 19 at 3 \P 11.) New patients must fill out new patient packet forms, including medical history and treatment. They must also undergo an MRI or have had one within two years. (*Id.* at \P 11.) All MRIs are verified by the MRI facility before Respondent sees them. (*Id.* at \P 11.)

Ms. Vischio stated that when appropriate, Respondent has reduced the amount of pain medication prescribed; has instructed Ms. Vischio to advise patients of the same; and has heard patients complain that Respondent reduced their pain medication levels. (*Id.* at ¶ 12.)

Ms. Adele Durina, Respondent's office manager and medical assistant, submitted an affidavit stating she enjoys working with Respondent and has worked with him since he began working at Cosmopolitan Clinic because Respondent is considerate of his patients and office staff. (Resp't Ex. 19 at 6 ¶ 3; *see also* Tr. 167.)

When Respondent sees a new patient, he takes twenty to thirty minutes or longer and is very thorough. (Resp't Ex. 19 at 6 ¶ 4.) He conducts a physical examination and records the findings in the patient's chart. (Id. at § 5.) Followup visits are usually fifteen minutes but can be more. (*Id.* at ¶ 6.) Patients commonly comment that Respondent has taken an exceptional amount of time with them and answered questions and provided information that patients were unable to get from other doctors. (Id. at ¶ 7.) Respondent returns patient phone calls with unusual speed, which patients appreciate. (Id. at ¶ 8.)

Cosmopolitan Clinic often tests patients to ensure they are not taking medications that Respondent has not prescribed. (Resp't Ex. 19 at 7 ¶ 9; *see also* Tr. 167.) Patients who fail the screen are often dismissed immediately; others are given one, but only one, chance. (*Id.* at ¶ 9.)

V. The Parties' Contentions

A. The Government

The Government argues that Respondent prescribed controlled substances to thousands of individuals across the United States when he was only licensed to practice medicine in the state of Florida, thereby violating the laws of numerous states,49 in contravention of 21 CFR 1306.04 (2010). (Gov't Br. at 5; see Tr. 11.) Respondent often based his decision to prescribe solely on a review of medical records submitted by individuals who were seeking a controlled substance, usually hydrocodone, a Schedule III narcotic. (Tr. 11-12.) Respondent did not conduct physical examinations on the majority of these individuals. (Tr. 12.)

In addition, the Government argues that Respondent completed the conduct described above while employed by an Internet pharmacy "whose sole business was to allow people to visit a Web site, ask for a certain drug, get referred to a physician who would consult with them by telephone, look at medical records that had been submitted and then issue the prescribed drug to be filled by that pharmacy." (Tr. 12.) The Government urges that Respondent had a legal duty to supervise his PA, Mr. Protheroe, and as a last resort, Respondent should have withdrawn from his employment if Mr. Protheroe failed to comply with Respondent's instructions. (Gov't Br. at 6.) The Government argues that

Respondent's failure to do so "indicates Respondent is willing to permit the misuse of his DEA registration in order to maintain his employment," rendering Respondent's registration contrary to the public interest. (*Id.*)

Finally, the Government argues that Respondent's testimony and demeanor at hearing evinced a lack of remorse and an attempt to blame others for his misconduct. "Had Respondent accepted responsibility and demonstrated remorse for his conduct, his claims that he reformed his prescribing practices might portend a change in conduct." (Id. at 7.) Instead, the Government argues, registration is improper where "Respondent blames the legal community, a lawyer who had a financial interest in the pharmacy where Respondent's prescriptions were filled, a physician's assistant, the owner of [UPS], and even DEA for his failure to abide by the law." (Id.)

B. Respondent

Respondent disputes the quantity of controlled substances that Respondent prescribed. (Tr. 12-13.) Pointing to the practitioner manual distributed by the DEA (see Resp't Ex. 6 at 15), Respondent also argues that of the five grounds stated therein upon which a COR may be revoked, the only allegation that the Government has made is that Respondent committed an act that would render the DEA COR inconsistent with the public interest. (Tr. 14.) Noting that 21 U.S.C. §823 and 824 set forth factors for determining the public interest, Respondent argues that the Florida Board of Osteopathic Medicine has not made a recommendation regarding the issuance of a DEA registration. (Tr. 14; Resp't Br. at 21-22.) Moreover, Respondent argues that Respondent's experience in dispensing controlled substances has not been challenged, and in any event, Respondent has such experience. (Tr. 14; Resp't Br. at 22.) Additionally, Respondent has not been convicted under federal or state laws relating to the manufacture, distribution or dispensing of controlled substances. (Tr. 14; Resp't Br. at 22.)

As for the final factor, "such other conduct which may threaten the public safety," Respondent argues that he is no threat to the public safety. (Tr. 19.) As an initial matter, Respondent argues that he is remorseful, has been rehabilitated and that since discontinuing his Internet prescribing practices, "no conduct which might threaten the public health and safety has been charged and proved." (Resp't Br. at 22.) Respondent also notes that attorney Robert Carr assured Respondent that Respondent's

⁴⁹ The Government argues in part that I should give weight to findings in *United Prescription Services, Inc.*, in which "the Deputy Administrator found that Dr. Reppy violated the laws of California, Tennessee, Indiana and Louisiana * * *." (Gov't Br. at 5–6.)

prescribing practices at UPR were within the scope of permitted practice. (Tr. 16; Resp't Exs. 3 & 4.) Additionally, Respondent argues that many of the prescriptions attributed to him were either forged or written by a PA. (Tr. 16; Resp't Br. at 24.) Moreover, Respondent argues that he was acting as a consultant to primary care physicians and was merely extending prescriptions for drugs that had already been prescribed by other physicians. (Tr. 17.)

Respondent further contends that he acquired adequate medical history documentation from Ms. Messick, and that Respondent, "when necessary, would speak by telephone with either the patient or the patient's primary care physician." (Tr. 17–18.)

Respondent also notes that he was compensated on an hourly basis, so the number of prescriptions he wrote was not a factor in his prescribing habits. (Tr. 18.)

In addition, Respondent immediately terminated his Internet prescribing upon being notified that his actions were not in conformity with regulations. (Tr. 16.) He discontinued his prescribing habits far before any notice of these administrative proceedings. (Tr. 18.) He regrets his mistakes and apologizes for them. (Tr. 16, 18.)

In the nearly four years since Respondent engaged in Internet prescribing practices at UPR, Respondent argues that he has conformed his practice to meet all state and federal requirements, including requirements of the Florida Department of Health, Board of Osteopathic Medicine (Tr. 18, 19), and is converting his pain management practice to a family practice treating indigent and low-income patients. (Tr. 18.)

VI. Discussion and Conclusions

A. The Applicable Statutory and Regulatory Provisions

The Controlled Substances Act (CSA) provides that any person who dispenses (including prescribing) a controlled substance must obtain a registration issued by the DEA in accordance with applicable rules and regulations.⁵⁰ "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner" with a corresponding responsibility on the pharmacist who fills the prescription.⁵¹

It is unlawful for any person to possess a controlled substance unless that substance was obtained pursuant to a valid prescription from a practitioner acting in the course of his professional practice.⁵² In addition, I conclude that the reference in 21 U.S.C. 823(f)(5) to "other conduct which may threaten the public health and safety" would as a matter of statutory interpretation logically encompass the factors listed in § 824(a).⁵³

B. The Public Interest Standard

The CSA, at 21 U.S.C. 824(a)(4), provides, insofar as pertinent to this proceeding, that the Deputy Administrator may revoke a COR if she finds that the registrant's continued registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(f). In determining the public interest, the Deputy Administrator is required to consider the following factors:

(1) The recommendation of the appropriate state licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing or conducting research with respect to 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.

As a threshold matter, the factors specified in Section 823(f) are to be considered in the disjunctive: the Deputy Administrator may properly rely on any one or a combination of those factors, and give each factor the weight she deems appropriate, in determining whether a registration should be revoked or an application for registration denied. See David H. Gillis, *M.D.*, 58 FR 37,507, 37,508 (DEA 1993); see also D & S Sales, 71 FR 37,607, 37,610 (DEA 2006); Jov's Ideas, 70 FR 33,195, 33,197 (DEA 2005); Henry J. Schwarz, Jr., M.D., 54 FR 16,422, 16,424 (DEA 1989). Additionally, in an action to revoke a registrant's COR, the DEA has the burden of proving that the requirements for revocation are satisfied.⁵⁴ The burden of proof shifts to the registrant once the Government has made its prima facie case.55

C. The Factors To Be Considered

Factors 1 and 3: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority and Conviction Record Under Federal or State Laws Relating to the Manufacture, Distribution or Dispensing of Controlled Substances

In this case, regarding Factor One, it is undisputed that Respondent currently holds a valid medical license in Florida, but Respondent's medical license has been the subject of state disciplinary action in the past. As discussed in the Evidence and Incorporated Findings of Fact section of this Recommended Decision, the Florida Department of Health instituted an Administrative Complaint against Respondent in May 2007. (Tr. 40; Gov't Ex. 14.) The Complaint alleged, in sum and in substance, that Respondent repeatedly prescribed controlled substances without having face-to-face meetings with patients; without performing adequate patient evaluations, taking adequate medical histories, conducting adequate medical examinations, discussing the risks and benefits of the course of treatment, documenting treatment plans or making appropriate referrals. (*E.g.*, Gov't Ex. 14 at 2–3, 14.)

The Complaint resulted in a settlement agreement, dated October 2, 2007, implemented through a final order dated December 26, 2007. (Tr. 46–48; Gov't Exs. 15 & 16.) Respondent agreed to pay a fine of \$12,500, complete continuing medical education courses, perform 100 hours of community service and prepare a paper suitable for publication. (Tr. 46; Gov't Ex. 15; *see also* Gov't Ex. 16.)

Respondent failed to timely complete the deadlines set by the settlement agreement, but as of hearing had completed most of his requirements and was in the process of paying the assessed fine. (*See, e.g.,* Resp't Ex. 18 at 2 & Tr. 72 (community service); Tr. 48 & Gov't Ex. 15 (drug course); Gov't Ex. 15 & Tr. 49, 51 (\$12,500 fine).)

The most recent action by the Florida Department of Health reflects a determination that Respondent, notwithstanding findings of unprofessional conduct, can be entrusted with a medical license subject to probationary terms and conditions. While not dispositive,⁵⁶ this action by the Florida Department of Health does weigh against a finding that Respondent's continued registration

⁵⁰ 21 U.S.C. 822(a)(2); 21 U.S.C. 802(10). ⁵¹ 21 CFR 1306.04(a).

⁵²21 U.S.C. 844(a).

 $^{^{53}}See$ Kuen H. Chen, M.D., 58 FR 65,401, 65,402 (DEA 1993).

⁵⁴ 21 CFR 1301.44(e) (2010).

⁵⁵ Medicine Shoppe—Jonesborough, 73 FR 364, 380 (DEA 2008); see also Thomas E. Johnston, 45 FR 72,311, 72,311 (DEA 1980).

⁵⁶ Mortimer B. Levin, D.O., 55 FR 8209, 8210 (DEA 1990) (finding DEA maintains separate oversight responsibility and statutory obligation to make independent determination whether to grant registration).

would be inconsistent with the public interest under Factor One. *Cf. Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (DEA 2003) (under Factor One, prior suspension of respondent's state medical license held not dispositive where state license currently under no restrictions).

Regarding Factor Three, there is no evidence that Respondent has ever been convicted under any federal or state law relating to the manufacture, distribution or dispensing of controlled substances. I therefore find that this factor, although not dispositive, *see Leslie*, 68 FR at 15,230, weighs against a finding that Respondent's continued registration would be inconsistent with the public interest.

Factors 2 and 4: Respondent's Experience in Handling Controlled Substances; and Compliance With Applicable State, Federal or Local Laws Relating to Controlled Substances

Respondent argues that his experience in dispensing controlled substances has not been challenged. (Tr. 14; *see* Resp't Br. at 22.)

It has. As summarized above and discussed below, the Government challenges Respondent's supervision of his PA, his unauthorized practice of medicine, the legitimacy of his prescribing practices and his compliance with telemedicine standards, all applied to the dispensing ⁵⁷ of controlled substances.

(a) Adequacy of Notice of PA Supervision Issue

A threshold matter concerns whether the Government adequately noticed its contention that Respondent violated Florida law relating to the supervision of his PA, Mr. Protheroe.58 Before the Agency may properly impose a sanction on the basis of a given allegation, Agency precedent requires that a registrant be provided a "'full and fair opportunity' to litigate both the factual and legal bases of the Government's theory." CBS Wholesale Distribs., 74 FR 36,746, 36,750 (DEA 2009). As for the factual basis of the Government's theory, I find that the issue of Respondent's relationship with his PA was adequately noticed by the Government's supplemental prehearing statement.59

More complicated is whether the Government adequately noticed provisions of Florida law relevant to the supervision of PAs. The OSC alleges in pertinent part that Respondent violated Fla. Stat. Ann. §458.347 (2008) ("Physician assistants"), which sets forth a regulatory framework for the training, conduct and supervision of PAs.⁶⁰ (See ALJ 1.) That provision is codified in Chapter 458, entitled "Medical Practice." But Respondent is an osteopathic doctor (Tr. 20; Gov't Ex. 15 at 1), and not an allopathic doctor, so the standards of his practice are governed by Chapter 459 ("Osteopathic Medicine'') and not Chapter 458 ("Medical Practice"). See Fla. Stat. Ann. § 458.303 ("The provisions of * * * [the Florida statute noticed in the OSC, Section] 458.347 shall have no application to * * * [o]ther duly licensed health care practitioners * * * ."). As codified in Section 459.022, Chapter 459 contains a PA provision applicable to osteopathic doctors that substantially mirrors the PA provision applicable to allopathic doctors actually noticed by the Government. In fact, a word-by-word comparison of §458.347 (allopathic doctors) and §459.022 (osteopathic doctors), as codified during the relevant time period,⁶¹ reveals that the language from each provision governing a physician's duty of care with respect to supervising a PA is textually identical,62 and the remaining provisions contain no

 60 The version Fla. Stat. Ann. § 458.347 alleged in the OSC is from 2008, but the relevant time period of Respondent's conduct was from 2004 until approximately 2006. (ALJ Ex. 1.) Consequently, the following analysis concerns the 2004 through 2006 versions of that statute.

⁶¹ See Gov't Ex. 5 (collecting versions of Fla. Stat. Ann. § 459.022 from 2004–2006); see also supra note 60.

⁶² Compare Fla. Stat. Ann. § 459.022(3) ("Each physician * * * shall be * * * responsible and liable for the performance and the acts and omissions of the physician assistant."), with Fla. Stat. Ann. § 458.347(3) (same). Compare also Fla. Stat. Ann. §459.022(4)(e) ("A supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician's practice unless such medication is listed on the formulary created pursuant to §458.347 * A physician assistant must clearly identify to the patient that she or he is a physician assistant [and] inform the patient that the patient has the right to see the physician * * *."), with Fla. Stat. Ann. §458.347(4)(e) (same). The reference in Section 459.022(4)(e) to the location of the formulary of drugs a PA may not prescribe is consistent with the reference in Section 458.347(4)(e) to "the formulary created pursuant to paragraph (f)" because the formularies are identical. See Fla. Admin. Code Ann. rr. 64B15-6.0038 & 64B8-30.008.

differences relevant to this proceeding.⁶³

The OSC also alleges violations of Fla. Admin. Code Ann. r. 64B8-30.008(1)(a) (formulary requirements for PAs). That provision, which falls under the subtitle of regulations applicable to allopathic physicians, provides in pertinent part that PAs are not authorized to prescribe controlled substances. Fla. Admin. Code Ann. r. 64B8-30.008(1)(a). But because subtitle 64B8 of the Florida Administrative Code Annotated governs matters pertinent to the Board of [allopathic] Medicine, and Respondent is a doctor of osteopathy, the relevant Florida administrative provisions governing Respondent's conduct are located under subtitle 64B15 ("Board of Osteopathic Medicine"). As codified in Rule 64B15-6.0038, subtitle 64B15 contains a formulary provision that mirrors the formulary provision applicable to allopathic doctors actually noticed by the Government. A word-byword comparison of Rule 64B8-30.008(1)(a) (applicable to PAs under allopathic doctors) and Rule 64B15-6.0038 (applicable to PAs under osteopathic doctors) as codified during the relevant time period 64 reveals that the two provisions are textually identical.

As summarized thus far, the OSC in this case notices the Government's intention to litigate issues embracing supervision of Respondent's PA and related formulary provisions of Florida law. Although the provisions actually noticed by the Government pertain to allopathic doctors and not osteopathic doctors, two reasons compel the conclusion that the notice provided in this instance is sufficient to apprise Respondent "that this allegation would be litigated." *See CBS*, 74 FR at 36,749.

First, as discussed above, the pertinent operative sections of the provisions actually noticed in the OSC are literally identical to the duty-of-care provisions applicable to osteopathic doctors. Respondent therefore had not just substantial notice, but truly *actual* notice of the exact legal standards that the Government alleges that Respondent violated.

Second, DEA, to a certain extent, adopts a "notice pleading" model with respect to certain matters of law. *Cf.* 21 U.S.C. 823(f)(4) (requiring the DEA to assess a registrant's "[c]ompliance with

⁵⁷ Under the CSA, prescribing is included in the definition of "dispensing." 21 U.S.C. 802(10).

⁵⁸ The OSC alleges that Respondent violated Fla. Stat. Ann. § 458.347 (2008) ("Physician assistants"). (ALJ Ex. 1.)

⁵⁹ The Government noticed Respondent's testimony: "regarding his relationship with Physician's Assistant John Protheroe^{**} * He will testify generally to the manner in which he

supervised Mr. Protheroe as well as Mr. Protheroe's responsibilities * * * Mr. Protheroe issued prescriptions for controlled substances using Respondent's DEA registration number * * * with Respondent's consent and under his supervision." (Gov't Supp. PHS at 4.)

⁶³For instance, the addition of the word "osteopathic" in the legislative intent headings of Fla. Stat. Ann. § 459.022(1) cannot be considered a material difference from the text found in Section 458.347(1).

⁶⁴ See Gov't Ex. 3 (collecting Fla. Admin. Code Ann. rr. 64B15–6.0038 (2004), 64B8–30.008 (2005) and 64B15–6.0038 (2006)); see also supra note 60.

applicable state, federal or local laws relating to controlled substances''). I find that an otherwise adequate provision of notice of the substantive legal issues to be addressed is not undercut by an erroneous citation, when the text that should have been cited is literally identical to the erroneously cited text and is contained within a neighboring chapter of the same code of state law.

Therefore, although the Government's inaccurate noticing of the provisions of law upon which it intends to seek revocation of a COR could be misleading in some circumstances, I find that under the circumstances of this case Respondent received adequate and timely notice of the legal and factual issues surrounding Respondent's interaction with and supervision of his PA. I therefore conclude that Respondent's interaction with and supervision of his PA may properly be considered as a potential basis for revoking Respondent's COR and denying any pending applications for registration or renewal.

(b) Respondent's Supervision of His PA

An issue under Factors Two and Four of 21 U.S.C. 823(f) is whether Respondent adequately discharged his duty under Florida and federal law to supervise his PA, Mr. Protheroe. I find insofar as is pertinent to this proceeding that Florida law sets forth the duties and obligations of osteopathic physicians vis-à-vis PAs, as set forth below. *See generally* Fla. Stat. Ann. § 459.022; Fla. Admin. Code Ann. r. 64B15–6.0038.

A "physician assistant" is "a person who is a graduate of an approved program or its equivalent or meets standards approved by the boards and is licensed to perform medical services delegated by the supervising physician." Fla. Stat. Ann. §459.022(2)(e). "Supervision" means "responsible supervision and control. Except in cases of emergency, supervision requires the easy availability or physical presence of the licensed physician for consultation and direction of the actions of the physician assistant * * * 'easy availability includes the ability to communicate by way of telecommunication." Id. §459.022(2)(f). A physician "supervising a licensed physician assistant * * * shall be responsible and liable for the performance and the acts and omissions of the physician assistant." Id. § 459.022(3). Failing to adequately supervise a PA constitutes grounds for discipline. Id. § 459.015(1)(hh). Subject to certain limitations, "[a] supervisory physician may delegate to a fully

licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician's practice. * * *'' *id.* § 459.022(4)(e), but, as emphatically stated in the Florida Administrative Code:

PHYSICIAN ASSISTANTS APPROVED TO PRESCRIBE MEDICINAL DRUGS UNDER THE PROVISIONS OF * * 459.022(4)(E), F.S., ARE NOT AUTHORIZED TO PRESCRIBE THE FOLLOWING MEDICINAL DRUGS, IN PURE FORM OR COMBINATION: (a) Controlled substances.* * *"

Fla. Admin. Code Ann. r. 64B15-6.0038. In addition, a PA must "clearly identify to the patient that he or she is a physician assistant * * [and] must inform the patient that the patient has the right to see the physician prior to any prescription being prescribed or dispensed by the physician assistant." *Id.* § 459.022(4)(e)(1).

Federal law also bears upon a physician's supervision of a PA. As an initial matter, 21 U.S.C. 846, a provision noticed by the OSC in the abovecaptioned case, imposes liability for attempt and conspiracy to violate certain provisions of the CSA.⁶⁵ In pertinent part, the following statutory provisions are susceptible to the sweep of § 846. "Except as authorized by this title, it shall be unlawful for any person knowingly or intentionally * * * to * * * dispense[] a controlled

substance." 21 U.S.C. 841(a). Moreover, "[e]very person who dispenses * * * any controlled substance, shall obtain from the Attorney General a registration," ⁶⁶ 21 U.S.C. 822(a)(2), with the exception of "[a]n agent or employee of any registered * * * dispenser of any controlled substance if such agent or employee is acting in the usual course of his business or employment," § 822(c)(1). It is illegal "to use in the course of * * * dispensing of a controlled substance * * * a registration number * * * issued to another person." § 843(a)(2).

Read together, I find as a matter of statutory construction that 21 U.S.C. 822, 841, 843 and 846 impose on a practitioner an affirmative duty to supervise his or her PA to ensure that the PA dispenses ⁶⁷ medication only in accordance with the law, and to prevent the unauthorized use of the

practitioner's COR.68 See 21 CFR 1301.22 (2010) ("The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his/her business or employment."). This conclusion is consistent with Agency precedent holding that a registrant must adequately supervise his or her PA to prevent the unlawful issuance of prescriptions for controlled substances. As the Administrator recently explained, "a registrant is strictly liable for the misconduct of those persons who he authorizes to act under his registration." Scott C. Bickman, M.D., 76 FR 17,694, 17,703 (DEA 2011); see Robert G. Hallermeier, M.D., 62 FR 26,818, 26,820 (DEA 1997) (failure to supervise PA "permitted the prescribing of controlled substances by an unauthorized individual in violation of numerous provisions of Federal and state laws and regulations, including 21 U.S.C. 829(b) and 841 and 21 CFR 1306.03 and 1306.04(a) (1997) . * * *''); Jay Wheeler Cranston, M.D., 59 FR 36,786, 36,789 (DEA 1994) ("Respondent authorized physician assistants to issue and sign controlled substance prescriptions to patients without direct supervision of a physician in violation of 21 CFR 1306.03 and 1306.05(a) (1994)."). See generally Dan E. Hale, D.O., 69 FR 69,402, 69,406 (DEA 2004) (respondent's grant of permission to PA to "provide controlled substances to patients prior to the effective date of legislation permitting such activity * * * and unauthorized utilization of a physician assistant to provide controlled substances * * * to drug abusing patients so they would submit to unnecessary medical tests, violated laws relating to controlled substances * * * [and] weighs against registration").

Turning to the facts of the case at bar, the record reveals that Respondent's supervision of his PA, Mr. Protheroe, was virtually non-existent. Respondent testified that Mr. Protheroe worked under Respondent's license (Tr. 37, 131), giving rise to Respondent's legal duty to supervise him. *See* Fla. Stat. Ann. § 459.022(2)(e). Yet Respondent's testimony shows that Respondent did not supervise Mr. Protheroe. Respondent did not hire him (*see* Tr. 37 ("he was put there by someone else"), did not need him (Tr. 37), complained about him repeatedly to Mr. Bollinger

⁶⁵ Under 21 U.S.C. 846, "[a]ny person who attempts or conspires to commit any offense defined in this title shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy."

⁶⁶ See also 21 CFR 1301.11 (2010).

⁶⁷ Dispensing includes, *inter alia*, prescribing. 21 U.S.C. 802(10).

⁶⁸ See, e.g., 21 U.S.C. 820(3) (defining "agent" as "an authorized person who acts on behalf of or at the direction of a * * * dispenser").

and Ms. Messick (*see, e.g.*, Resp't Ex. 12 at 4; Tr. 131, 138–39), did not control Mr. Protheroe's hours (*see* Tr. 37 ("he was not even present most of the time I was there")), did not control Mr. Protheroe's work product (*see* Tr. 37 ("He ended up basically exploiting my license behind my back without my permission."); Tr. 122 (Mr. Protheroe failed to adhere to the criteria by which Respondent rejected patients); *see also* Tr. 131, 138–39) and did not believe he could fire him (Tr. 37 ("I had no power to remove him because I did not pay his salary. I could not tell him to leave.")).

I find that Respondent failed to exercise "responsible supervision and control" over Mr. Protheroe, in violation of Fla. Stat. Ann. § 459.022(2)(f), based in part on the uncontroverted evidence that Mr. Protheroe wrote at least 14,000 unauthorized prescriptions in Respondent's name (Tr. 80; see generally Tr. 132; Gov't Ex. 10 at 84-85), many of which while Respondent was away from the office for an extended period of time (Tr. 121-22, 132; Gov't Ex. 10 at 85, 96, 101). Because Respondent testified that he developed concerns regarding Mr. Protheroe's performance before November 2003 (Tr. 121), which was before Respondent went on leave in 2005 (see Tr. 121-22, 132), it cannot reasonably be questioned that Respondent is "responsible and liable for the performance and the acts and omissions of the physician assistant." Id. § 459.022(3).

Respondent's testimony that Respondent approved a few of Mr. Protheroe's prescriptions each day (Tr. 42) and supervised Mr. Protheroe during the limited times that the latter was in the office (see Gov't Ex. 10 at 105) does not satisfy Respondent's duty to supervise Mr. Protheroe, nor is there any evidence that Respondent adequately supervised Mr. Protheroe telephonically as would have been permissible under Fla. Stat. Ann. §459.022(2)(f). Respondent's failure to adequately supervise Mr. Protheroe constitutes grounds for discipline under Florida law. Id. § 459.015(1)(hh).

The evidence further reflects that the majority of prescriptions Mr. Protheroe wrote were for controlled substances. (*E.g.*, Resp't Ex. 12 at 2.) This evidence constitutes a flagrant violation of Florida law that unambiguously prohibits PAs from prescribing controlled substances under any circumstances. Under the Florida Administrative Code, "physician assistants * * are not authorized to prescribe * * * [c]ontrolled substances.

* * *''⁶⁹ Fla. Admin. Code Ann. r. 64B15–6.0038 (internal formatting omitted). Mr. Protheroe's illegal conduct is chargeable to Respondent because Respondent is ''responsible and liable for the performance and the acts and omissions of the physician assistant.'' Fla. Stat. Ann. § 459.022(3). Accord cf. Scott C. Bickman, M.D., 76 FR at 17,703 (holding registrant strictly liable for misconduct of ''those persons who he authorizes to act under his registration'').

Respondent's testimony that he approved a few of Mr. Protheroe's prescriptions each day (Tr. 42), read together with Respondent's admission that "[m]ost of the prescriptions written by Mr. Protheroe were for controlled substances" (Resp't Ex. 12 at 2), suggests Respondent attempted to confer upon Mr. Protheroe in some instances the authority to prescribe controlled substances. But Respondent lacked authority under Florida law to make such an authorization. "A supervising physician may delegate to a prescribing physician assistant only such authorized medicinal drugs as are * * * not" controlled substances. Fla. Admin. Code Ann. r. 64B15–6.0038.

To summarize, substantial evidence supports the conclusion that Respondent allowed a PA to use Respondent's COR to issue purported prescriptions of controlled substances to Internet customers, and that Respondent otherwise failed to adequately supervise his PA. Respondent's conduct in this regard violated Fla. Stat. Ann. §459.022; Fla. Stat. Ann. § 459.015(1)(hh) and Fla. Admin. Code Ann. r. 64B15–6.0038, as well as Respondent's duty under federal law to supervise his PA to ensure that the PA dispenses medication only in accordance with the law, and to prevent the unauthorized or unlawful use of Respondent's COR, e.g., Robert G. Hallermeier, M.D., 62 FR 26,818, 26,820 (DEA 1997); Jay Wheeler Cranston, M.D., 59 FR 36,786, 36,789 (DEA 1994).⁷⁰ This finding weighs strongly in favor of a finding under Factors Two and Four of 21 U.S.C. 823(f) that Respondent's continued registration would be inconsistent with the public interest.

(c) Unauthorized Practice of Medicine

Pursuant to 21 CFR 1306.03 (2010), "[a] prescription for a controlled substance may be issued only by an individual practitioner who is * * * authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession." The OSC in the abovecaptioned case alleges violations of the laws of Mississippi, California and Alabama relating to the unlicensed or long-distance practice of medicine. (*See* ALJ Ex. 1 at 2.)

First at issue is the law of Mississippi. As codified at Miss. Code Ann. § 73–25– 34(2), Mississippi has provided without amendment since 1997 that

no person shall engage in the practice of medicine across state lines (telemedicine) in this state, hold himself out as qualified to do the same, or use any title, word or abbreviation to indicate to or induce others to believe that he is duly licensed to practice medicine across state lines in this state unless he has first obtained a license to do so from the State Board of Medical Licensure.

See 1997 Miss. Laws 436.71

In this case, the record reflects that Respondent currently holds a medical license from the state of Florida. (Tr. 20.) Respondent was previously licensed in Georgia, California and Hawaii, but has not held medical licenses in any of those states since 1999. (Tr. 21.) Since 2000, Respondent has been licensed to practice medicine solely in Florida. (*See, e.g.,* Tr. 21.)

The record further reflects that during the relevant time period of 2004 to 2006 (ALJ Ex. 1 at 1), most of the individuals to whom Respondent prescribed controlled substances became Respondent's customers through Internet Web sites. (Tr. 25.) Respondent testified that he recalled issuing prescriptions for controlled substances to people located all across the United States. (Tr. 27, 39; see Resp't Ex. 12 at 3.) Although he did not remember precisely how many different states his client base represented, he said the list was long. (Tr. 39.) I therefore find that substantial evidence supports the OSC allegation that Respondent issued controlled substances to customers throughout the United States while licensed to practice medicine only in Florida.

This finding, however, does not end the inquiry. Respondent's testimony suggests that he did not issue prescriptions for controlled substances to individuals in Mississippi because that state was "off limits" in terms of what his telemedicine contract would permit. (Tr. 28.) The hearing transcript reads:

⁶⁹ In this context the term "controlled substances" is defined by Fla. Stat. Ann. §§ 893.02 (2004) and 893.03 (2004) and includes hydrocodone and oxycodone, among other drugs. *See* Fla. Stat. Ann. § 893.03(2)(a) (2004).

⁷⁰ See also supra text at notes 65 to 68.

⁷¹ See 1997 MS ALS 436 (on LexisNexis) (historical versions) and MS LEGIS 436 (1997) (Westlaw) (same).

Q: Dr. Reppy, the people that you provided service to when you worked at University, these were people from all over the United States, is that correct?

A: Yes.

Q: And in fact you serviced people in all 50 states, didn't you, during that time?

A: There were some states that were off limits because—like—like Kentucky was one of them and Mississippi was the other one. Those two states had stated that they would—were against any telemedicine-type of contract at all. Now, I was—I was represented by their legal counsel, by—by Mr. Carr that the—that the prescribing pharmacy was licensed in all 50 states and therefore that covered any legal issues with it. That—that wasn't true, but that's what I was told.

(Tr. 27–28.) The record reveals no other information specifically relating to Respondent's Mississippi prescribing practices,72 and the Government called no witnesses other than Respondent, even though DEA Diversion Investigator Peter Flagg, identified in the Government's supplemental prehearing statement as a witness, was present in the courtroom.⁷³ (Tr. 2; Gov't Supp. PHS at 1.) Although the second half of Respondent's testimony quoted above lends some support to the Government's allegation that Respondent prescribed to Mississippi residents, the first part of his statement, that Mississippi was off limits, cuts evenly in the other direction, leaving the evidence in equipoise.

Under the preponderance of the evidence test, the [party with the burden of proof] loses when the evidence is in equipoise because he did not present that slight quantum of evidence necessary to tip the balance from equipoise to his favor." United States v. Rodriguez, 406 F.3d 1261, 1300 (11th Cir. 2005) (Barkett, C.J., dissenting) (citing Nat'l Lime Ass'n v. EPA, 627 F.2d 416, 453 n.139 (D.C. Cir. 1980) ("The standard of ordinary civil litigation, a preponderance of the evidence, demands only 51% certainty.") and Black's Law Dictionary 1201 (7th ed. 1999)). I therefore conclude that substantial evidence does not support the conclusion that Respondent violated Miss. Code Ann. §73-25-34.74

Turning to California, the law of that state has provided in pertinent part without amendment since 2002 that

any person who practices or attempts to practice, or who advertises or holds himself or herself out as practicing, any system or mode of treating the sick or afflicted in this state, or who diagnoses, treats, operates for, or prescribes for any * * * physical or mental condition of any person, without having at the time of so doing a valid, unrevoked, or unsuspended [California medical license] is guilty of a public offense, punishable by fine, imprisonment or both. Cal. Bus. & Prof. Code § 2052(a).

As is true in most contexts, ignorance of the law is no defense. The California Court of Appeal has noted that the "proscription of the unlicensed practice of medicine is neither an obscure nor an unusual state prohibition of which ignorance can reasonably be claimed, and certainly not by persons * * * who are licensed health care providers. Nor can such persons reasonably claim ignorance of the fact that authorization of a prescription pharmaceutical constitutes the practice of medicine." *Hageseth* v. *Superior Court*, 59 Cal. Rptr. 3d 385, 403 (Ct. App. 2007).

Here, Respondent's unrebutted testimony confirms that he issued prescriptions for controlled substances to people in California while he was licensed to practice medicine solely in Florida. (Tr. 21, 28.) Respondent's witness Mr. Carr also testified that "I know California is one of the states that we were prescribing to—or shipping drugs to." (Tr. 158.) I therefore conclude that substantial evidence supports a finding that Respondent violated Cal. Bus. & Prof. Code § 2052(a) (prohibiting the unlicensed practice of medicine).

In addition, Mr. Carr testified that in 2001 or 2002 he researched the law of all fifty states regarding telemedicine (Tr. 144-45) and "left no stone unturned," compiling a file "well over a foot high of documents I reviewed extensively. * * *" (Tr. 150), finding that "the telemedicine * * * realm * * in 2001 was almost non-existent in any kind of regulations, statutes or anything." (Tr. 144.) He concluded that "the only reference you could really find back—back at that time was neural radiology in pain medicine." (Tr. 144.) He could not identify the effective date of California's statute related to Internet prescribing. (Tr. 150, 157.)

Although neither the Government nor Respondent addressed the matter in argument, in light of Mr. Carr's testimony, I find it notable that California in fact adopted an Internet prescribing statute at least as early as 2000. *See* Cal. Bus. & Prof. Code § 2242.1. Pertinent parts of that provision, with 2006 amendments noted,⁷⁵ reads:

No person or entity may prescribe, dispense, or furnish, or cause to be prescribed, dispensed, or furnished, dangerous drugs * * * on the Internet for delivery to any person in this state, without [a good faith] *an appropriate* prior examination and medical indication [therefor], except as authorized by Section 2242.

Id. Violators are subject to fines or civil penalties of up to \$25,000 per occurrence, *id.* § 2242.1(b) or, "[i]f the person * * * is not a resident of this state, a violation of this section shall, if applicable, be reported to the person's * * * appropriate professional licensing authority," *id.* § 2242.1(e).

In light of the existence of this statute prior to and during the relevant time period (see ALJ Ex. 1 (2004 to 2006)) and Mr. Carr's testimony that he shared his research on standards for Internet prescribing practices with Respondent before Respondent began working for UPR, Respondent's testimony that in 2003 "the legal community was struggling in a gray area to determine what [those standards] would be" (Tr. 64), at least with respect to California, is not credible. (Compare Tr. 60; see also Tr. 89–92.) When Respondent issued the prescriptions at issue here, numerous states had already adopted laws or regulations, or had issued policy statements making clear, that Respondent's Internet prescribing practices were illegal.⁷⁶ In addition, a 2001 Federal Register notice, offered as Respondent's own exhibit, makes clear that practitioners "must be licensed to prescribe controlled substances by the State(s) in which they operate."⁷ (Resp't Ex. 8 at 3.) And the Model Guidelines, offered as Respondent's Exhibit 9, cautions that "[p]hysicians who treat or prescribe through Internet Web sites are practicing medicine and must possess appropriate licensure in all jurisdictions where *patients* reside." (Resp't Ex. 9 at 12 (emphasis supplied).)

Moreover, Respondent's suggestion that a 2002 letter from the DEA (see Resp't Ex. 4) gave him permission to prescribe controlled substances to patients in states where he lacked a medical license (Tr. 60; see also Tr. 89–

⁷² Even the decision in *United Prescription Servs., Inc.,* 72 FR 50,397 (DEA 2007), which the Government withdrew as an exhibit, does not once mention the word "Mississippi."

⁷³ See supra note 21 (recounting the Government's withdrawal of its other witnesses).

⁷⁴ To summarize: the OSC alleges that Respondent violated Miss. Code Ann. § 73–25–34 (ALJ Ex. 1 at 2), but the Government offered no evidence to support this allegation other than the testimony of Respondent. *See supra* note 21.

⁷⁵ Added text is marked by *underlining* and deleted text is marked by [brackets].

⁷⁶ See, e.g., Cal. Bus. & Prof. Code § 2242.1(a); Tenn. Comp. R. & Regs. § 0880–2.14(7) (2003) ("Prerequisites to Issuing Prescriptions"); Ohio Admin. Code § 4731–11–09(A) (2003); Oklahoma State Board of Medical Licensure and Supervision, Policy on Internet Prescribing (Ratified 01/25/01).

⁷⁷ Although Mr. Carr testified that he interpreted Respondent's Internet prescribing practices as operating in the state of Florida (Tr. 160–61), Respondent offered no such testimony.

92) is misguided. First, the DEA letter addressed the dispensing practices of a pharmacy, not the prescribing practices of a physician. (Tr. 97; see Resp't Ex. 4.) Second, the letter cautioned that DEA's general expression of approval of the pharmacy came with a number of caveats: "Management personnel will verify several elements including * professional licensure[,] DEA registration[, l]egitimate patient/ prescriber relationship[, p]rescriptions are issued in the usual course of professional practice, and [p]rescriptions are issued for a legitimate medical purpose." (Resp't Ex. 4 at 1.) Respondent therefore could not reasonably have relied on the DEA's letter as authorizing him to prescribe controlled substances to patients in states in which he lacked a medical license.

Nor did Respondent reasonably rely on statements by Mr. Carr, given Mr. Carr's obvious financial interest in persuading Respondent to issue prescriptions. (Tr. 151-52.) Indeed, if nothing else, Respondent should have realized from reading a letter signed by, and another letter addressed to, "Robert Carr/President/United Prescription Services, Inc." (Resp't Exs. 3 & 4; Tr. 60, 89-92) that Mr. Carr could not be counted upon to act as a disinterested advisor to Respondent because as president he had a stake in the matter. To be certain, there is substantial evidence that Mr. Carr provided Respondent with incomplete information, and possibly inaccurate information, concerning the state of telemedicine law and the legality of Respondent's prescribing practices at UPR. Even so, ignorance of the law is no excuse, especially where the proscription of the unlicensed practice of medicine is hardly unique to California. See generally Hageseth, 59 Cal. Rptr. 3d at 403.

Turning to Alabama, the law of that state has provided since at least 1975 that "[a]ny person who practices medicine or osteopathy or offers to do so in this state without a[n Alabama medical license] * * shall be guilty of a Class C felony."⁷⁸ Ala. Code § 34–24– 51. Here, although Respondent admitted to prescribing controlled substances to people located all across the United States (Tr. 27, 39), and volunteered that the list of states in which his customers resided was "long" (Tr. 39), there is no testimony or other evidence relating to Respondent's Alabama prescribing practices, if indeed he had any.⁷⁹ In fact, the word "Alabama" does not appear in the entire hearing transcript.⁸⁰ I therefore find that substantial evidence does not support a finding that Respondent violated Ala. Code § 34–24– 51.

In its post-hearing brief, the Government identifies legal authority in Tennessee, Illinois and North Carolina that it alleges Respondent violated. (See Gov't Br. at 5.) Although Respondent did admit in response to questioning by counsel for the Government that he issued prescriptions for controlled substances to customers in these states while holding a medical license only in Florida (Tr. 38–39), I do not rely on these admissions as a potential basis for recommending imposition of a sanction because the issue of violations of the laws of Tennessee, Illinois and North Carolina was not noticed in the OSC,81 the Government's prehearing statement⁸² or the Government's supplemental prehearing statement. Respondent lacked adequate notice that violations of these states' laws would be at issue where the Government raised the factual basis of its theory for the first time at hearing, and raised the legal basis for the first time in its post-hearing brief. See CBS Wholesale Distribs., 74 FR 36,746, 36,750 (DEA 2009) (finding

⁸⁰ In addition, although the opinion in *United Prescription Servs., Inc.,* 72 FR 50,397 (DEA 2007) indicates that a Dr. Wayne Starks issued controlled substances prescriptions to a resident of Alabama in violation of 21 CFR 1306.04(a), *see* 72 FR at 50,408, that conclusion is not binding on Respondent in the above-captioned case, for the reasons discussed above; and in any event, there is no indication that Dr. Starks acted in conjunction with Respondent or at his direction.

⁸¹ The OSC alleges: "You violated state laws that prohibit the unauthorized practice of medicine, including unlicensed, out-of-state physicians issuing controlled substance prescriptions to state residents. See e.g. Miss. Code Ann. §73-25-34; Cal. Bus. & Prof. Code § 2052; Ala. Code § 34-24-51 (ALJ Ex. 1.) This language is too vague to notice violations of the laws of Tennessee, Illinois and North Carolina because the allegation of violations of "state laws" did not reasonably apprise Respondent of which other states' laws, if any. To be certain, the three states cited as exempli gratia (Mississippi, California and Alabama) could reasonably have apprised Respondent that other states laws might be in contention, too; but nothing in the OSC or other prehearing filings reasonably apprised Respondent of which ones

⁸² While the Government's prehearing statement notices its intent to offer into evidence controlled substances prescriptions to individuals in Illinois and Tennessee (Gov't PHS at 3), the Government withdrew that exhibit (Tr. 6–7). More importantly, the prehearing statement did not allege violations of Illinois, Tennessee or North Carolina law. that Respondent is entitled to a "'full and fair opportunity' to litigate both the factual *and legal* bases of the Government's theory" (emphasis supplied)).

I also decline, for reasons more fully discussed above,⁸³ the Government's invitation to recommend imposition of a sanction on the basis of "Respondent's violation of numerous state laws [as] explained in United Prescription Services, Inc., Revocation of Registration, 72 FR 50,397 (August 31, 2007)." (Gov't Br. at 5-6.) The APA, the doctrine of *res judicata* and principles of fair play and substantial justice foreclose the reliance on conclusions as to the legality of Respondent's conduct reached in a prior hearing where Respondent, a non-party in that proceeding, lacked both the motive and the opportunity to fully develop the relevant issues on cross examination and in fact cooperated with the Government.⁸⁴ See 5 U.S.C. § 551(3) (defining "party") and 556(e) (administrative record); see also Johnson v. United States, 576 F.2d 606, 614 (5th Cir. 1978) (cautioning against the use of offensive collateral estoppel). Cf., e.g., Fed. R. Evid. 804(b)(1) (former testimony hearsay exception).

To summarize, substantial evidence supports the conclusion that Respondent violated the laws of California by issuing prescriptions to customers across the country while licensed to practice medicine solely in the state of Florida, in violation of Cal. Bus. & Prof. Code § 2052(a) and 21 CFR 1306.03 (2010). This finding weighs in favor of a finding under Factors Two and Four of 21 U.S.C. 823(f) that Respondent's continued registration would be inconsistent with the public interest.

(d) Whether Respondent Issued Prescriptions for Controlled Substances Without a Legitimate Medical Purpose and Outside the Usual Course of Professional Practice

Another issue concerns whether Respondent conducted his prescribing practices pursuant to a legitimate medical purpose and within the usual

⁷⁸ A 2007 amendment made changes that are not pertinent to this Recommended Decision.

⁷⁹ In adversarial proceedings such as this one, "it is not the ALJ's role but rather that of the parties to develop the record; the ALJ's role is to ensure that the parties do so in accordance with the Agency's rules of procedure. * * *" *East Main Street Pharmacy*, 75 FR 66,149, 66,150 n.2 (DEA 2010).

⁸³ See supra Part II(A) (finding that the APA and negative implications stemming from the doctrine of offensive collateral estoppel preclude my reliance on conclusions of law regarding Respondent's conduct in a case in which he was not a named party).

⁸⁴ Tr. 78; *see* Resp't Br. at 17 ("Respondent's testimony [in the previous UPS proceeding] was beneficial to and supportive of the Government's position, and he also provided an affidavit of assistance to the Government."); *see also United Prescription Servs., Inc.,* 72 FR 50,397, 50,400 (DEA 2007) (citing affidavit by Dr. Reppy submitted as Government exhibit in prior proceeding).

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course of professional practice, consistent with 21 CFR 1306.04(a) and 21 U.S.C. 841(a)(1).85 To be effective, and lawful, a prescription for a controlled substance "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice * * * An order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription * * * and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances."⁸⁶ As the Supreme Court recently 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 (1975)).

As an initial matter, "[a] physician who engages in the unauthorized practice of medicine is not a practitioner acting in the usual course of * * * professional practice" as required by 21 CFR 1306.04(a) (describing requirements for lawful issuance of prescription). See, e.g. United Prescription Servs., Inc., 72 FR 50,397-01, 50,407 (DEA 2007). As noted above, I find that Respondent engaged in the unauthorized practice of medicine by issuing prescriptions for controlled substances to people in California while he was licensed to practice medicine solely in Florida, in violation of Cal. Bus. & Prof. Code § 2052(a). I therefore conclude that Respondent acted outside the usual course of professional practice, in violation of 21 CFR 1306.04(a).

Federal law further provides that revocation of a registration under the public interest standard of 21 U.S.C. 823(f) is not limited to practitioners who intentionally violate the prescription requirement, but also includes a "practitioner's failure to properly supervise her patients to prevent them from personally abusing controlled substances or selling them to others. * * *" *Jeri Hassman, M.D.,* 75 FR 8194, 8227 (DEA 2010). A practitioner must also "have established a bona fide doctor-patient relationship with the individual for whom the prescription is Turning to Florida, a state in which Respondent conducted business and has been licensed for at least ten years (*see*, *e.g.*, Tr. 20–23, 51, 56, 68, 107), the law of that state provided for part of the relevant time period ⁸⁸ that "gross or repeated malpractice or the failure to practice osteopathic medicine with that level of care, skill and treatment which is recognized by a reasonable prudent similar osteopathic physician as being accepted under similar conditions and circumstances, constitutes grounds for discipline." Fla. Stat. Ann. § 459.015(1)(x) (2001).

In addition, from March 2000 through November 2006,⁸⁹ Florida required that "complete medical history and physical examination must be conducted and documented in the medical record." Fla. Admin. Code Ann. r. 64B15– 14.005(3)(a) (2000) ("Standards for the Use of Controlled Substances for Treatment of Pain"). Osteopathic physicians have been required continuously since 1997 to "maintain written legible records on each patient. Such records shall contain * * * (a) Patient histories; (b) Examination results; (c) Test results; (d) Records of

⁸⁸ The quoted text that follows was the law in Florida from June 19, 2001, to June 20, 2005. *Compare* 2001 Fla. Sess. Law Serv. Ch. 2001–277 (C.S.S.B. 1558) (West) (2001 amendments enacting language cited), *with* 2005 Fla. Sess. Law Serv. Ch. 2005–266 (C.S.S.B. 940) (West) (substantially altering Fla. Stat. Ann. § 459.015(1)(x)).

⁸⁹ See Florida Department of State: State Library and Archives of Florida, Florida Administrative Weekly & Florida Administrative Code, http:// www.flrules.org/gateway/ RuleNo.asp?title=PRACTICE.

REQUIREMENTs&ID=64B15-14.005.

drugs prescribed, dispensed or administered; (e) Reports of consultations; and (f) Reports of hospitalizations." Fla. Admin. Code Ann. r. 64B15-15.004 (Dec. 22, 1997) ("Written Records; Minimum Content; Retention").90 Finally, Florida law has provided continuously since June 19, 2001,⁹¹ that prescribing controlled substances "inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the physician's professional practice, without regard to ĥis intent." Fla. Stat. Ann. §459.015(1)(t).92

The evidence at hearing regarding Respondent's prescribing practices included testimony from Respondent and Ms. Messick. As discussed above in the Evidence and Incorporated Findings of Fact section of this Recommended Decision, Respondent prescribed hydrocodone, a controlled substance, to thousands of patients over a four-year period from 2002 to 2006 (Tr. 21–23, 43, 51, 53) without examining as many as ninety percent of his patients (see Tr. 25–26). Despite his claim that his patients "were not placing their whole care in my hands" (Tr. 110), Respondent did not consult with the majority of his patients' primary care physicians. (See, e.g., Tr. 34, 35 (one or two physician consultations out of 150 patients serviced in given week); see also Gov't Ex. 10 at 30, 37). In fact, Respondent testified that he treated patients who had been discharged by their providers, whether for lack of funding or another reason: "I was continuing the treatment plan that was first set up by their doctor who might no longer have been willing to continue that plan. * * *" (Tr. 113; see also Tr. 116.) While legitimate reasons might have justified continuing a course of treatment in some instances where the primary care physician refused to do so,93 Respondent's

⁹² The OSC alleges violations of an identical provision of Florida law applicable to allopathic doctors, Fla. Stat. Ann. § 458.331(q). See ALJ. Ex.
1. For reasons discussed above, however, I find the provision applicable to osteopathic doctors was sufficiently noticed.

⁹³ For instance, read expansively, Respondent's testimony suggests a doctor might legitimately continue a medically sound treatment plan under which the previous provider ceased providing treatment due to a patient's inability to pay. (See Gov't Ex. 10 at 19 (testifying that certain pain management patients could not afford monthly office visits costing \$150); see also Tr. 79.) Respondent, however, did not offer evidence that Continued

⁸⁵ The OSC explicitly alleges violations of 21 CFR 1306.04(a) and 21 U.S.C. 841(a)(1). (ALJ Ex. 1.) ⁸⁶ 21 CFR 1306.04(a) (2010).

written." *Mohammed F. Abdel-Hameed, M.D.*, 66 FR 61,366, 61,369 (DEA 2009). At the time of the events at issue here, the CSA looked to state law to determine whether a physician has established a valid doctor-patient relationship.⁸⁷ United Prescription Servs., Inc., 72 FR 50,397, 50,407 (DEA 2007).

⁸⁷ On October 15, 2008, the President signed into law the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Public Law 110-425, 122 Stat. 4820 (2008). Section 2 of the Act prohibits the dispensing of a prescription controlled substance "by means of the Internet without a valid prescription," and defines, in relevant part, "[t]he term 'valid prescription' [to] mean[] a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by * * * a practitioner who has conducted at least 1 in-person medical evaluation of the patient." 122 Stat. 4820. Section 2 further defines "[t]he term 'inperson medical evaluation' [to] mean[] a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals." Id. See generally 21 U.S.C. 829 (incorporating amendments). These provisions do not, however, apply to Respondent's conduct, which predated them.

⁹⁰ The foregoing provisions of Florida law are prominently identified in the Florida Administrative Complaint against Respondent (Gov't Ex. 14), which was provided to Respondent as part of the Government's document exchange.

⁹¹ See 2001 Fla. Sess. Law Serv. Ch. 2001–277 (C.S.S.B. 1558) (West) (adopting quoted language).

conduct in many instances is inconsistent with a continuing course of treatment.

The evidence reflects Respondent did not consult with the majority of his patients' primary care physicians, and he had limited opportunity, if any, to independently confirm why those physicians stopped treating Respondent's patients. Florida law required Respondent to take and record a complete medical history and medical records, see Fla. Admin. Code Ann. r. 64B15-14.005(3)(a) (2000); Fla. Admin. Code Ann. r. 64B15–15.004. But the record is silent as to the steps Respondent took to independently verify most of his patients' histories. (See Tr. 32 ("not the common practice" for Respondent to confer with primary care physicians).) Indeed, Respondent testified that he took no additional steps: "If you have documentation in front of you that is signed by the primary care doctor * * * that is usually considered sufficient." (Tr. 32– 33.) He added: "the error rate in records is not particularly high." (Tr. 35.) As for those physicians he did consult, Respondent provided no details as to the contents of the conversations.

Respondent therefore had no way to verify, nor is his testimony consistent with his assertion, that his patients "were not placing their whole care in [Respondent's] hands." (Tr. 110.) The record reflects that other doctors referred no more than approximately 300 patients to Respondent over the course of a four-year period (Tr. 35-36), and that Respondent prescribed hydrocodone to thousands of individuals without a face-to-face interaction or physical examination. (Tr. 43; see Tr. 53.) I therefore reject in substantial part Respondent's argument that he merely acted as a consultant to a primary care physician and merely extended prescriptions for drugs that had already been prescribed by another physician. (Tr. 17.) Contrary to Respondent's claim, Respondent had no affiliation with most of the physicians whose records he relied on (Tr. 36) and should have proceeded as if the care of the majority of his patients was solely in his own hands because, as Respondent's own testimony shows, in a meaningful number of cases it was. His failure to do so raises the specter of diversion and improper treatment. It also constitutes a "failure to practice osteopathic medicine with [a reasonable] level of care, skill and treatment," which under Florida law from 2001 to 2005

constituted grounds for discipline.⁹⁴ See Fla. Stat. Ann. § 459.015(1)(x) (2001). His conduct was outside the usual course of professional practice. See 21 CFR 1306.04(a); 21 U.S.C. 841(a)(1).

In addition to testifying that he did not perform physical examinations on the majority of his patients (Tr. 25-26), Respondent also conceded that other physicians did not perform examinations of patients at Respondent's direction.⁹⁵ (Tr. 36.) And because Respondent acquired his patients' records directly from patients and not from medical professionals (see Tr. 34, 79–80), a practice that could lead to fraud (see generally Tr. 55-56), Respondent had no way to verify that anyone had ever actually conducted physical examinations on many of his patients, or that any such physical examinations were conducted recently enough to warrant a prescription for controlled substances. In light of Respondent's testimony that he had noticed fraudulent alterations in some of his patients' records (Tr. 56), there is insufficient evidence to substantiate Respondent's contention that "[p]atients did not make [their medical records] up on their own." (Tr. 34.) Respondent's conduct does not comply with Florida standards, as follows.

Although there appears to be some ambiguity in Florida law regarding whether a physical examination must be conducted by the prescribing physician, as opposed to a referring physician, there are indications that the prescribing physician must conduct the physical examination himself. A 2002 decision by the State of Florida Division of Administrative Hearings interpreting the state telemedicine rule applicable to osteopathic doctors observed that "assuming that the physician had complied with the [telemedicine rule, Fla. Admin. Code Ann. r. 64B15-14.008] by conducting a physical examination when the drug was prescribed, the requirement [of a documented patient evaluation, "including history and physical examination, adequate to establish the diagnosis for which any drug is prescribed"] would already be satisfied." Levy v. Dep't of Health, No. 02-2308RX, at *45, 2002 Fla. Div. Adm. Hear. LEXIS 1443 (Dec. 3, 2002).

Other Florida decisions interpreting Florida's nearly identical telemedicine rule (Fla. Admin. Code Ann. r. 64B8-9.014) 96 applicable to allopathic doctors are consistent with this conclusion. See, e.g., Dep't of Health v. Wise, No. 06-2014PL, at *20, 26, 2006 Fla. Div. Adm. Hear. LEXIS 530 (Nov. 9, 2006) ("simply relying upon what a patient reports is their blood pressure does not constitute a physical examination" and concluding "failure to conduct a physical examination * * * constituted the failure to practice medicine with that level of care, skill, and treatment which is recognized by reasonably prudent physicians as being acceptable under similar condition and circumstances"). I therefore find that Respondent violated applicable Florida rules regarding physical examinations.

Řespondent's conduct also does not comply with standards acknowledged by Respondent. Respondent testified that to have a valid doctor-patient relationship, a servicing medical professional must have conducted a physical examination of the patient. (Gov't Ex. 10 at 79–80 ("Someone must have done [a physical examination]).") For follow-up consultations, Respondent would not require "a new physical exam with every consult. When it became, in my opinion, too dated, then I would demand another physical exam." (Gov't Ex. 10 at 79.) Yet there is substantial evidence, summarized above, that on numerous occasions Respondent failed to ensure that these requirements were met. "Respondent thus routinely prescribed without any independent assessment and verification of his patients' medical complaints." Ladapo O. Shyngle, M.D., 74 FR 6056, 6057, 6058 (DEA 2009) (holding that Florida physician failed to establish bona fide doctor-patient relationship where he "prescribed on the basis of a telephonic consultation and did not personally conduct a physical exam and take a medical history from the patients").

Respondent's failure to supervise his PA, John Protheroe, also bears on the reliability of Respondent's medical records. Respondent repeatedly suggested that Respondent was part of a process at UPR over which he lacked control. For instance, Respondent testified that he could not differentiate between prescriptions issued by Mr. Protheroe in Respondent's name and prescriptions that Respondent issued himself.⁹⁷ (*E.g.*, Tr. 41–43.) Asked

most or even many of his patients were in this situation.

⁹⁴ See supra note 88.

⁹⁵ As Respondent explained in his testimony in a prior proceeding, "the physical examination has to be done by someone else in the case of telemedicine. [Patients] have to have seen a local doctor that actually saw them and performed the physical examination, and gotten those notes to me, so that I know what was seen and have the information available." (Gov't Ex. 10 at 25–26.)

 ⁹⁶ See supra text at notes 99 to 101.
 ⁹⁷ Respondent testified that he did not know the

identity of "[J.N.]," a patient identified in the Florida Administrative Complaint. (Tr. 42.)

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whether Respondent completed the conduct charged in Florida's Administrative Complaint against him, Respondent stated:

I actually don't know if I did or not, because as I said, this PA John Protheroe wrote so many prescriptions without my authorization using a stamp of my signature that it may well have been done under under that process.

(Tr. 41.) Yet, in prescribing to his own repeat patients, Respondent's testimony shows he relied on medical records containing previous prescriptions bearing his signature without knowing whether he or Mr. Protheroe issued those prescriptions. Respondent's testimony that he couldn't distinguish whether he or his PA had treated a patient, combined with his willingness to nevertheless issue follow-up prescriptions, is further evidence of Respondent's failure in many instances to establish and maintain a valid doctorpatient relationship.

In addition to the problems noted above, Respondent's verification of patient identity was patently inadequate. Respondent had no face-toface interactions with as many as ninety percent of his patients. (Tr. 26, 55.) When ascertaining a patient's identity before issuing a controlled substance prescription, therefore, Respondent relied almost exclusively on documents submitted by the patient with no concurrent verification of identity such as comparing a photo identification with the person presenting it.

As for how he verified the identity of patients with whom he never physically interacted, Respondent testified that "I used the same method of checking their identity as I would if they were present in front of me." (Tr. 54.) Yet Respondent conceded that he never saw most of the people to whom he issued prescriptions (Tr. 55), undermining the basis for his claim.

Respondent explained that "I was rather good at detecting fraud" by comparing font and language in different parts of patient medical records. (Tr. 56.) Respondent added: "If the state did not adequately check their identity before issuing them a driver's license * * * I had no way of determining that." (Tr. 54.) Respondent's explanation entirely misses the point. The question Respondent should have cared about, but apparently did not, was whether the person receiving treatment was actually the person described in the medical records. A patient referral provides at least some degree of identity verification. But given the low rate at which doctors referred patients to Respondent (Tr. 35–36 (approximately 300 patients over four years)) compared with the total number of Respondent's patients (Tr. 52–53 (150 patients per week, constituting at least 5000 controlled substances prescriptions per year)), verifying that the patient fit the records should have been a great concern for Respondent.

Respondent testified that some people misuse and abuse the kinds of controlled substances that Respondent prescribed at UPR, particularly hydrocodone, alprazolam, oxycodone and methadone. (Tr. 65.) From time to time Respondent encountered patients who abused controlled substances and immediately dismissed them. (Tr. 65.) "I ferreted it out where I could." (Tr. 65.) Respondent, however, could not state how many of his patients were addicted to narcotics while he was prescribing to them. (Tr. 118.)

Without the face-to-face meetings that Respondent conducted in no more than approximately ten percent of consultations (*e.g.*, Tr. 26, 55)), Respondent could not objectively assess whether a person's appearance as recited in photo identification and medical records (to include height, weight, sex, hair color and the like) matched the person presenting as a patient over the telephone. Because patients submitted their own medical records to Respondent's clinic (Tr. 34; 79-80), and thus had both the opportunity and the inclination to fraudulently modify them (see generally Tr. 56), Respondent's nearly exclusive reliance on his own ability to detect fraudulent modifications (see Tr. 56), even if Respondent was quite skilled in this regard, was unreasonable under the circumstances. Indeed, Respondent conceded that it was possible that a person posing as a patient could take the medical records and identification of a deceased person, and Respondent would have no way of knowing whether the person on the phone was actually the person whose medical records and identification Respondent was reviewing. (Tr. 55–56.) Respondent's testimony suggesting that an unspecified percentage of his patients could not afford traveling to visit Respondent in person (*e.g.*, Tr. 79, 116) does not substantially mitigate the potential for diversion inherent to Respondent's Internet prescribing

practices.⁹⁸ I find it more likely than not that Respondent failed "to properly supervise [his] patients to prevent them from personally abusing controlled substances or selling them to others. * * *" *Jeri Hassman, M.D.,* 75 FR 8194, 8227 (DEA 2010).

In sum, Respondent did not verify that the majority of the individuals to whom he prescribed controlled substances were actually the patients listed in the medical records associated with their files, constituting a departure from the usual course of professional practice. Any quantity of controlled substances Respondent prescribed to these patients was therefore "inappropriate." See Fla. Stat. Ann. § 459.015(1)(t). In addition to falling below Florida standards of professional practice, Respondent's identity verification practices also raise the specter of the diversion of controlled substances, given that most or many of the individuals who contacted Respondent at UPR sought and ultimately received controlled substances. (Tr. 28, 36.)

There are further examples in the record indicating significant deviations in Respondent's prescribing practices from the usual course of professional practice, but further elaboration is unnecessary. Respondent "voluntarily and openly admit[s] that he had issued prescriptions to individuals via the Internet whom he had not examined and who were residents of states other than a state in which Respondent was licensed. * * *" (Resp't Br. at 23.) Respondent concedes, and I so find by a preponderance of the evidence, that "the Government has established the fact that the majority of the prescriptions by the Respondent during his work at [UPR] were not valid." (Resp't Br. at 23.)

In partial mitigation, Respondent recognizes both that his reliance on Mr. Carr's advice was misplaced and also that Mr. Carr's 2002 correspondence with the DEA does not excuse his prescribing of controlled substances to patients residing in states where he was not licensed. (Id.) But even if Respondent's reliance on Mr. Carr's advice were deemed to be reasonable, and I do not so find, such reliance would not outweigh the significant weight properly given to his issuance of thousands of controlled substances prescriptions to patients across the country while he was licensed to practice medicine solely in Florida; his

Respondent does not know whether he issued any of the prescriptions alleged in the Complaint, a situation he attributes to the sheer number of prescriptions his PA wrote without authorization. (Tr. 41–42.)

⁹⁸ Moreover, the weight given to Respondent's testimony in this regard is diminished by Respondent's admission that he does not know how much UPR charged. (Tr. 119.)

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routine failure to either conduct physical examinations or consult with a patient's primary care physician to ensure that a physical examination was conducted recently enough to sustain a diagnosis justifying controlled substances; his misplaced confidence in his own ability to detect fraud in medical records, which he obtained directly from patients, when he could have required the records be sent directly from other practitioners; and his related failure to acknowledge his failures to sufficiently verify the identity of most patients.

For the foregoing reasons, I find by substantial evidence that Respondent issued a substantial number of prescriptions for other than a legitimate medical purpose or outside the usual course of professional practice and without establishing a bona fide doctorpatient relationship, in violation of Florida law, see Fla. Stat. Ann. §459.015(1)(x) (2001); Fla. Stat. Ann. §459.015(1)(t) (2001); Fla. Admin. Code Ann. rr. 64B15-14.005(3)(a) and 64B15-15.004, and federal law, see 21 CFR 1306.04(a); 21 U.S.C. 841(a)(1); Mohammed F. Abdel-Hameed, M.D., 66 FR 61366, 61369 (DEA 2009) and Ladapo O. Shyngle, M.D., 74 FR 6056, 6057, 6058 (DEA 2009). This finding weighs heavily in favor of a finding under Factors Two and Four of 21 U.S.C. 823(f) that Respondent's continued registration would be inconsistent with the public interest.

(e) Adequacy of Notice of Florida Telemedicine Issue

Next at issue is whether the Government adequately noticed its contention that Respondent violated Florida standards for telemedicine prescribing practice.⁹⁹

Regarding the factual basis of the Government's theory, the Government's prehearing statement calls into issue "the process by which [Respondent] authorized Internet requests for drugs" including the information he collected, the basis of his diagnosis, his communication with patients and full disclosure, among other things. (*See* Gov't PHS, Jun. 18, 2010, at 2–3.) Moreover, the Government's prehearing statement also notices its intent to introduce as documentary evidence a copy of Florida Administrative Code Rule 64B8–9.014 ("Standards for Telemedicine Prescribing Practice"), consistent with the OSC. (*Id.* at 3; ALJ Ex. 1.) I therefore find that the factual issue of Respondent's compliance with applicable Florida telemedicine practices was adequately noticed.

More complicated is whether the Government adequately noticed its intent to rely on provisions of Florida law relevant to standards for telemedicine in seeking the revocation of Respondent's COR. As noted above, the Government's prehearing statement noticed the issue of Respondent's compliance with Florida Administrative Code Rule 64B8-9.014. That provision, which falls under the subtitle of regulations applicable to allopathic physicians, sets forth standards for telemedicine prescribing practice in Florida. Fla. Admin. Code Ann. r. 64B8-9.014. But because subtitle 64B8 of the Florida Administrative Code governs matters pertinent to the Board of [allopathic] Medicine, and Respondent is a doctor of osteopathy, the relevant Florida administrative provisions governing Respondent's conduct are located under subtitle 64B15 ("Board of Osteopathic Medicine"). Rule 64B15-14.008 in that subtitle contains a telemedicine provision that mirrors the telemedicine provision applicable to allopathic doctors that was actually noticed by the Government. A word-byword comparison of Rule 64B8–9.014 (telemedicine standards for allopathic doctors) and Rule 64B15-14.008 (telemedicine standards for osteopathic doctors), as codified during the relevant time period of 2004 through 2006¹⁰⁰ (see ALJ Ex. 1) reveals that the two provisions are substantially identical.¹⁰¹ Because Respondent thus had actual notice of the legal standards that the Government alleges that Respondent violated, I find that the notice provided in this instance was sufficient to apprise Respondent "that this allegation would be litigated." *See CBS*, 74 FR at 36749.

(f) Respondent's Compliance with Florida Telemedicine Standards

On October 16, 2001, Florida enacted a rule applicable to osteopathic doctors

entitled "Standards for Telemedicine Practice." 102 Fla. Admin. Code Ann. r. 64B15–14.008. The spirit of the rule is to prevent physicians from prescribing medications with only minimal diagnosis and documentation. In addition to constituting grounds for disciplinary action under Fla. Stat. Ann. § 459.015(1)(x) and (t),

[p]rescribing medications based solely on an electronic medical questionnaire constitutes the failure to practice osteopathic medicine with that level of care, skill and treatment which is recognized by reasonably prudent osteopathic physicians as being acceptable.

Fla. Admin. Code Ann. r. 64B15–14.008. Before an osteopathic physician may "provide treatment recommendations, including issuing a prescription, via electronic or other means," the rule requires:

(1) A documented patient evaluation, including history and physical examination, adequate to establish the diagnosis for which any drug is prescribed.

(2) Sufficient dialogue between the osteopathic physician and the patient regarding treatment options and the risks and benefits of treatment.

(3) Maintenance of contemporaneous medical records meeting the requirements of Rule 64B15–15.004, F.A.C.

Id. In addition to an emergency services provision not applicable here, the rule finally states that it "shall not be construed to prohibit patient care in consultation with another physician who has an ongoing relationship with the patient, and who has agreed to supervise the patient's treatment, including the use of any prescribed medications. * * *" *Id.*

As discussed supra, Respondent on numerous occasions (Tr. 53 (5000 controlled substances prescriptions per year)) "provide[d] treatment recommendations, including issuing a prescription, via electronic or other means" without conducting patient evaluations to include physical examinations or ensuring that such examinations were reliably conducted by other qualified medical professionals (see, e.g., supra text at note 95) and without maintaining medical records meeting the requirements of Rule 64B15–15.004 (see supra text at notes 93 to 94). Nor did Respondent in more than approximately 300 cases (see Tr. 35-36) out of thousands (Tr. 53) ever act in a

⁹⁹ The Government's prehearing statement alleges violations of Florida telemedicine standards, as discussed below. Before the Agency may properly impose a sanction on the basis of a given allegation, Agency precedent requires that a registrant be provided a "'full and fair opportunity' to litigate both the factual and legal bases of the Government's theory." *CBS Wholesale Distribs.*, 74 FR 36746, 36750 (DEA 2009).

¹⁰⁰ See Gov't Ex. 4 (collecting versions of Fla. Admin. Code Ann. r. 64B15.4008 from 2004–2006); see also supra note 60.

¹⁰¹ The only notable differences are as follows. First, r. 64B15–14.008 inserts the word "osteopathic" at various points to reflect that the actor contemplated is an osteopathic physician and not an allopathic physician. Second, r. 64B8–9.014 explicitly contemplates that PAs may participate in telemedicine practices, whereas r. 64B15–14.008 does not. Finally, r. 64B8–9.014, but not r. 64B15– 14.008, explicitly defines "telemedicine" as including prescribing via the Internet, telephone or facsimile. *Compare* Fla. Admin. Code Ann. r. 64B8– 9.014, *with id.* r. 64B15–14.008.

¹⁰² See Florida Department of State: State Library and Archives of Florida, Florida Administrative Weekly & Florida Administrative Code, https:// www.flrules.org/gateway/ruleNo.asp?id=64B15-14.008 (listing enactment date as October 16, 2001, and identifying sole alteration or variance since that time as a variance granted to a Virtual Medical Group, Inc. on May 26, 2006).

consultative capacity "with another physician who ha[d] an ongoing relationship with the patient, and who ha[d] agreed to supervise the patient's treatment, including the use of any prescribed medications," Fla. Admin. Code Ann. r. 64B15–14.008. I therefore find that Respondent failed to comply with Fla. Admin. Code Ann. r. 64B15– 14.008 ("Standards for Telemedicine Practice"). This finding weighs in favor of a finding under Factors Two and Four of 21 U.S.C. § 823(f) that Respondent's continued registration would be contrary to the public interest.

Factor 5: Such Other Conduct Which May Threaten the Public Health and Safety

Under Factor Five, the Deputy Administrator is authorized to consider "other conduct which may threaten the public health and safety." 5 U.S.C. 823(f)(5). The Agency has accordingly held that "where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for his or her actions and demonstrate that he or she will not engage in future misconduct. Patrick W. Stodola, 74 FR 20,727, 20,734 (DEA 2009).¹⁰³ A "[r]espondent's lack of candor and inconsistent explanations" may serve as a basis for denial of a registration. John Stanford Noell, M.D., 59 FR 47,359, 47,361 (DEA 1994). Additionally, "[c]onsideration of the deterrent effect of a potential sanction is supported by the CSA's purpose of protecting the public interest." Joseph Gaudio, M.D., 74 FR 10,083, 10,094 (DEA 2009).

As discussed above, the substance of Respondent's conduct between 2004 and 2006 is relatively uncontroverted. Respondent issued, permitted his PA to issue or failed to prevent his PA from issuing in Respondent's name thousands of controlled substances prescriptions to patients around the country while Respondent was licensed to practice medicine only in Florida. Many of these prescriptions issued without Respondent or a physician acting at Respondent's direction ever conducting a physical examination, let alone seeing the patient. Respondent infrequently consulted with his patients' previous doctors, and routinely accepted medical records sent in by patients, without requiring that records be sent by medical professionals. Moreover, Respondent was aware that some of his patients, or people posing

as his patients, fraudulently altered medical files in order to obtain controlled substances. Respondent's actions constituted clear violations of state and federal law.

In light of these essentially uncontroverted facts, a remaining issue in this case is whether Respondent has adequately accepted responsibility for his past misconduct such that his continued registration might nevertheless be consistent with the public interest. See Patrick W. Stodola, 74 FR 20,727, 20,734 (DEA 2009). Respondent argues that he has "expressed considerable regret and remorse for his Internet prescribing and acknowledged its impropriety. * (Resp't Br. 22.) But across various dimensions, the record reveals that Respondent has not sustained his burden in this regard.

As an initial matter, I reject Respondent's contention that "no conduct which might threaten the public health and safety has been charged and proved." (Resp't Br. at 22.) Indeed, Respondent's failure to verify the identity of the majority of his patients (see Tr. 26, 54-56), as detailed above, raises dual specters of diversion and polypharmacy, both of which threaten the public interest. Respondent testified that "I used the same method of checking [new patients'] identity as I would if they were present in front of me." (Tr. 54.) To the contrary, Respondent never saw most of the people to whom he issued approximately 5000 prescriptions for controlled substances per year. (Tr. 52-53, 55.) Moreover, patients submitted their own medical records to Respondent's clinic (Tr. 34; 79-80), and they thus had both the opportunity and the inclination to fraudulently modify them (see generally Tr. 56). I find that Respondent's failure to consistently verify patient identities and secure the integrity of patient records weighs in favor of a finding that Respondent's continued registration would be contrary to the public interest.

Respondent has not demonstrated a credible acknowledgment of his inadequate patient identity verification practices, nor has he demonstrated that he will not engage in similar future misconduct. For example, Respondent's sole comment in this regard at hearing offers valuable insight into his outlook: "If the state did not adequately check [his patients'] identity before issuing them a driver's license * * * I had no way of determining that." (Tr. 54.) Respondent's testimony misses the point and offers no support for a finding that he has accepted responsibility for his prior misconduct. To the contrary,

Respondent's testimony supports an inference that he would continue the same unreliable and dangerous identity verification practices if permitted to maintain his registration in the future. *See Alra Laboratories, Inc.* v. *DEA*, 54 F.3d 450, 452 (7th Cir. 1995) (an "agency rationally may conclude that past performance is the best predictor of future performance").

Respondent's flagrant failures to supervise his PA also bear upon a Factor Five analysis. Respondent, who was Medical Director of UPR in 2004 (Resp't Ex. 12 at 2), possessed both actual authority and the legal duty to exercise "responsible supervision and control" over Mr. Protheroe. See, e.g., Fla. Stat. Ann. § 459.022(2)(e); see also, e.g., Dan E. Hale, D.O., 69 FR 69,402, 69,406 (DEA 2004); Robert G. Hallermeier, M.D., 62 FR 26,818, 26,820 (DEA 1997); Jay Wheeler Cranston, M.D., 59 FR 36,786, 36,789 (DEA 1994). As chronicled earlier in this Recommended Decision, Respondent failed to exercise this supervisory authority, and at times failed to acknowledge that he had it. He permitted Mr. Protheroe to work under Respondent's license but did not control Mr. Protheroe's hours; he did not control Mr. Protheroe's work product; he did not hire him and did not believe he could fire him. (Tr. 37.) Mr. Protheroe wrote at least 14,000 unauthorized prescriptions in Respondent's name (Tr. 80; see generally Tr. 132; Gov't Ex. 10 at 84-85), many of which for controlled substances (e.g., Resp't Ex. 12 at 2), while Respondent was away from the office for an extended period of time (Tr. 121-22, 132; Gov't Ex. 10 at 85, 96, 101), in violation of Fla. Stat. Ann. § 459.022(4)(e) (prohibiting PAs from prescribing controlled substances), as well as other provisions of law.

Respondent fundamentally failed to take responsibility for his failure to supervise Mr. Protheroe. Respondent conceded at hearing that he had an obligation to properly supervise Mr. Protheroe (Tr. 101; see Resp't Ex. 9 at 5 ("physicians should * * * [p]roperly supervise physician extenders")), and stated that he supervised Mr. Protheroe during the limited times "when he was in the office. * * * " (Gov't Ex. 10 at 105) and not working from home. Although these statements show that Respondent was aware of his unfulfilled supervision obligation, they reveal no acceptance of responsibility for Respondent's failure to discharge it. To the contrary, Respondent's testimony is consistent with blame-shifting:

Q: And so you had an obligation to properly supervis[e] Mr. Protheroe?

¹⁰³ See also Hoxie v. DEA, 419 F.3d 477, 484 (6th Cir. 2005) (decision to revoke registration "consistent with the DEA's view of the importance of physician candor and cooperation.")

A: Yes, sir. I freely admit that he was not adequately supervised. But he was kept away from me and I did not hire or fire him. I supervised him as much as I could to my ability. But, yes, I agree that it wasn't enough. (Tr. 101.)

Respondent testified that he regrets his relationship with Mr. Protheroe. "[I]t's so soured me on the experience that I've never hired any physician's assistants since and I don't think I ever will." (Tr. 108–09.) But even viewed in a light most favorable to Respondent, this statement offers no credible basis to conclude that Respondent acknowledges and accepts responsibility for his failure to supervise, nor is there any basis to conclude that if again confronted with the challenges of supervising a contumacious PA, Respondent would adequately discharge his supervisory obligations.

Respondent's testimony also consistently downplayed any personal role that Respondent played in failing to comply, or that he should have played in complying, with state and federal PA supervision requirements. Even if Respondent felt he couldn't supervise Mr. Protheroe, as a last resort Respondent could have withdrawn from his employment if Mr. Protheroe failed to comply with Respondent's instructions. Respondent's failure to do so indicates Respondent is willing to permit the misuse of his DEA registration in order to maintain his employment, rendering Respondent's registration contrary to the public interest. See Alra Laboratories, 54 F.3d at 452.

There are additional areas in which Respondent could have accepted responsibility for his misconduct, but didn't. For instance, rather than admit that, as concluded above, his telemedicine practices were in clear violation of contemporaneous standards (see, e.g., supra text at notes 75–76), Respondent at hearing attempted to cast doubt on the clarity of the rules. Commenting on his understanding of the patient evaluation standard of care for Internet prescribing practices in 2002 and 2003, for instance, Respondent opined that today's standard is different, but that previously "the legal community was struggling in a gray area to determine what those [standards] would be and now they have decided." (Tr. 64.) Somewhat contradicting himself, Respondent also testified that he presently understands that he has an obligation to prescribe or dispense controlled substances in accordance with all applicable state laws, and that prescribing across state lines sometimes includes the application of laws other

than the laws in the State of Florida. (Tr. 63.) That Respondent eventually chose to discontinue his illegal Internet prescribing practices (Tr. 91; *see also* Resp't Br. at 24) does not, without more, show that Respondent's continued registration would be consistent with the public interest.

Respondent also attempted to shift responsibility for his own professional misconduct to Mr. Carr. As an initial matter, Respondent's claim that he reasonably relied on "a letter shown me from the DEA giving permission to" engage in the controversial telemedicine practices here at issue (Tr. 59-60, 110; see also Tr. 89–92) is not credible. The reasonableness of Respondent's reliance on the DEA letter is undermined by the fact that the letter concerned the dispensing practices of a pharmacy, not the prescribing practices of a physician. The letter moreover contained caveats that "[m]anagement personnel will verify several elements including * professional licensure[,] DEA registration[, l]egitimate patient/ prescriber relationship[, p]rescriptions are issued in the usual course of professional practice, and [p]rescriptions are issued for a legitimate medical purpose." (Tr. 97; Resp't Ex. 4 at 1.) Additionally, Respondent's unquestioned reliance on legal advice from Mr. Carr, who Respondent also knew to be president of UPS, undermines the credibility of Respondent's testimony on this issue.

Further defending his reliance on Mr. Carr's advice, Respondent pointed to the Model Guidelines, published by the Federation of State Medical Boards in 2002. (See Resp't Ex. 9 at 3, 7.) Paraphrasing a sentence from that document, Respondent stated that "the physician/patient relationship exists whether or not there has been a personal encounter between the physician and the patient." (Tr. 76; see Resp't Ex. 9 at 7.) But the Model Guidelines go on to state that "[p]hysicians who treat or prescribe through Internet Web sites are practicing medicine and must possess appropriate licensure in all jurisdictions where patients reside." (Resp't Ex. 9 at 12.) At hearing, Respondent conceded that "given hindsight * * * I don't think I did fully understand" the Model Guidelines when he read them. (Tr. 98.) Respondent, however, contradicted his former testimony and stated that he could not confirm that he actually reviewed the Model Guidelines before accepting his position with UPR. (Tr. 100-01.) In any event, Respondent ultimately conceded that he was mistaken, and that statements by the Federation of State Medical Boards do not carry legal weight. (Tr. 45; see also

Tr. 164.) Respondent ultimately conceded in his testimony that Mr. Carr's assurances were inaccurate. (Tr. 110–11; *see* Resp't Br. at 25.)

But Respondent's acknowledgements are too little; and because many of them precede or follow Respondent's own contradictory testimony, they arrive too late. On the topic of telemedicine standards, for example, even if Respondent's equivocal statements are read to acknowledge that Florida had enacted a telemedicine regulation as early as 2004, Respondent still has not demonstrated that he accepts responsibility for his failures to comport with those standards. For instance, Respondent conceded that in hindsight, the prescriptions he issued at UPR to Internet customers "did not meet the highest standard * * * and I'm sorry." (Tr. 63–64.) Similarly, when his attorney asked him whether he now knows that his Internet prescribing at UPR was not consistent with the law as it was at that time, Respondent answered "Absolutely." (Tr. 91-92.) But Respondent undercut his own display of contrition, elaborating that when he engaged in the prescribing practices that are the subject of the OSC, he wasn't doing anything wrong. (Tr. 64-65.) "[I]f I thought I was doing anything wrong, I wouldn't have done it." (Tr. 65.) Based on Respondent's demeanor while testifying, I find that this statement, along with other similar statements, undermines the sincerity of Respondent's contrition.

Indeed, Respondent's feelings of regret are best characterized not as regret that he acted contrary to the public interest, but regret that his poor choices led to undesirable personal ramifications. Asked if he was regretful and remorseful for the role he played at UPR in prescribing controlled substances, Respondent stated: "Yes, very much. I sincerely wish I had never been duped into being any part of their operation at all." (Tr. 92.) Moving forward, Respondent promised not to prescribe for patients in jurisdictions in which he lacks a medical license. (Tr. 111.) Asked by counsel whether he felt remorse for having done so, he said "Yes. Not only am I remorseful about it, but I feel rather foolish and stupid for doing so in retrospect." (Tr. 111.) This last statement, self-serving though it is, arguably cuts in Respondent's favor. But it is outweighed by Respondent's subsequent de-emphasis of his own responsibility. I give significant weight to Respondent's candid statement that "I was just an hourly employee. I was just a pawn in the machine." (Tr. 119.) This admission belies Respondent's belief that actors other than Respondent

are responsible for Respondent's misconduct. Such a belief is inconsistent with Agency precedent requiring a registrant to accept responsibility for his actions and demonstrate that he will not engage in future misconduct. *See Patrick W. Stodola*, 74 FR 20,727, 20,734 (DEA 2009).

Respondent contends in mitigation that "no patient for whom Dr. Reppy prescribed over the Internet suffered any damage or harm and there were no mortalities or morbidities, and none of them suffered overdose deaths while he was treating them." (Resp't Br. 6 (citing Tr. 117, 118).) Although Respondent has not stayed in touch with all of his patients since he left UPR (Tr. 117), no record evidence contradicts this assertion. Asked whether any patient suffered an overdose death, Respondent answered that "none of them did while I was prescribing. If it happened since that time, then it happened because someone else was prescribing it. I can't be responsible for what some other doctor did." (Tr. 117.) "I'm sure there would have been a lawsuit if there was one and I never received any." (Tr. 123.) Respondent ignores the possibility that his provision of controlled substances to his former Internet patients could lead to adverse health consequences, for which Respondent might ultimately share responsibility.

Respondent also downplays the extent to which he could have known of patient addictions, arguing that "[t]here is no way to know whether or not patients became addicted" to controlled substances, suggesting he had only a passive role in the process. (Resp't Br. 6.) Respondent's testimony reflects a misunderstanding of his affirmative responsibility as a prescribing practitioner "for the proper prescribing and dispensing of controlled substances." ¹⁰⁴

In mitigation, more recent conduct does weigh in Respondent's favor. First, substantial evidence supports a finding that a significant period of time has elapsed without incident since the period of time embracing the unlawful conduct at issue here. Two of Respondent's employees and two of his patients affirmed that Respondent: personally sees patients and reviews patient records (Resp't Ex. 19. at 2 ¶¶ 5–7); requires that new patients produce recent prior medical records (Resp't Ex.

19. at 3 ¶ 11); performs physical examinations (E.g., Resp't Ex. 19. at 2 ¶ 8; id. at 6 ¶ 3, 5; id. at 19 ¶ 7); discusses treatment plans and spends between fifteen and thirty minutes with patients (Resp't Ex. 19. at 2 ¶ 10; *id.* at 6 ¶ 4, 7; *id.* at 9 ¶ 9, 10); reduces patient pain medication levels and suggests alternate treatment methods (Resp't Ex. 19 at 3 ¶ 12; *id.* at 9 ¶¶ 3–4; *see also* Tr. 66, 79– 80); and dismisses patients who fail to pass drug screens (Resp't Ex. 19 at 7 ¶ 9.) Insomuch, therefore, as Respondent's current practice is relevant, Respondent has painted a generally positive picture. See Paul J. Caragine, Jr., 63 FR 51,592, 51,601 (DEA 1998) (citing Norman Alpert, M.D., 58 FR 67,420 (DEA 1993)) ("[W]hile passage of time alone is not dispositive it is a consideration in assessing whether Respondent's registration would be inconsistent with the public interest."). Viewed in isolation, Respondent's medical practice from approximately 2006 to the present weighs somewhat in favor of a finding that Respondent's continued registration would be consistent with the public interest. That said, absent acceptance of responsibility for the misconduct, the passage of time alone precludes the issuance of even a restricted registration. "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." Robert L. Dougherty, M.D., 76 FR 16,823, 16,835 (DEA 2011) (citing Leonardo v. Lopez, M.D., 54 FR 36,915, 36,915 (DEA 1989) and Robert A. Leslie, M.D., 68 FR 15,227, 15,227 (DEA 2003)).

To be certain, Respondent's voluntary retreat from a telemedicine pain practice in favor of his current practice provides at least some indication that Respondent will avoid, or limit, the circumstances underlying the misconduct alleged in the instant case. But beyond stating that the prescriptions he issued at UPR to Internet customers "did not meet the highest standard * * * and I'm sorry" (Tr. 63–64), Respondent provides limited credible assurance that if given the opportunity he would not simply repeat the same mistakes he made in the past.

In light of the foregoing, Respondent's evidence as a whole fails to sustain his burden to credibly accept responsibility for his misconduct and demonstrate that he will not engage in future misconduct. I find that Factor Five weighs in favor of a finding that Respondent's continued registration would be inconsistent with the public interest.

VII. Conclusion and Recommendation

After balancing the foregoing public interest factors, I find that the Government has established by substantial evidence a prima facie case in support of revoking Respondent's COR, based on Factors Two, Four and Five of 21 U.S.C. 823(f).

Once DEA has made its prima facie case for revocation or denial, the burden shifts to the respondent to show that, given the totality of the facts and circumstances in the record, revoking or denying the registration would not be appropriate. *See Morall* v. *DEA*, 412 F.3d 165, 174 (D.C. Cir. 2005); *Humphreys* v. *DEA*, 96 F.3d 658, 661 (3d Cir. 1996); *Shatz* v. *United States Dep't of Justice*, 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston*, 45 FR 72, 311 (DEA 1980).

Additionally, where a registrant has committed acts inconsistent with the public interest, he must accept responsibility for his actions and demonstrate that he will not engage in future misconduct. See Patrick W. Stodola, 74 FR 20,727, 20,735 (DEA 2009). Also, "[c]onsideration of the deterrent effect of a potential sanction is supported by the CSA's purpose of protecting the public interest." Joseph Gaudio, M.D., 74 FR 10,083, 10,094 (DEA 2009). An agency's choice of sanction will be upheld unless unwarranted in law or without justification in fact. A sanction must be rationally related to the evidence of record and proportionate to the error committed. See Morall v. DEA, 412 F.3d 165, 181 (D.C. Cir. 2005). Finally, an "agency rationally may conclude that past performance is the best predictor of future performance." Alra Laboratories, Inc. v. DEA, 54 F.3d 450, 452 (7th Cir. 1995).

I recommend revocation of Respondent's COR BR5287342 and denial of any pending applications for renewal or modification, and any applications for a new COR. I find the evidence as a whole demonstrates that Respondent has not accepted responsibility, and Respondent's continued registration would be inconsistent with the public interest.

Dated: March 31, 2011

Timothy D. Wing,

Administrative Law Judge. [FR Doc. 2011–25229 Filed 9–30–11; 8:45 am] BILLING CODE 4410–09–P

¹⁰⁴ 21 CFR 1306.04(a) (2010); see also Fla. Admin. Code Ann. r. 64B15–14.005(3)(a) (2000) ("complete medical history and physical examination must be conducted and documented in the medical record."). See generally Fla. Admin. Code Ann. r. 64B15–15.004 (Dec. 22, 1997) ("Written Records; Minimum Content; Retention").