

BILLING CODE: 4410-09-P

DEPARTMENT OF JUSTICE Drug Enforcement Administration

[Docket No. 11-48] Kevin Dennis, M.D., Decision and Order

On April 12, 2011, the Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause to Kevin Dennis, M.D. (hereinafter, Respondent), of Franklin, Tennessee. The Show Cause Order proposed the revocation of Respondent's DEA Certification of Registration and the denial of his application to renew his registration on the ground that his "continued registration is inconsistent with the public interest." ALJ Ex. 1, at 1 (citing 21 U.S.C. 823(f)).

More specifically, the Show Cause Order alleged that from September 2007 through July 2009, Respondent "prescribed controlled substances to individuals located in Colorado, Mississippi, North Carolina, South Carolina and Tennessee via the Internet based on online questionnaires, submissions of unverified medical records, and/or telephone consultations without a medical examination." Id. The Show Cause Order alleged that Respondent "failed to establish a valid physician-patient relationship" as required by various state laws and that in issuing the prescriptions Respondent violated Federal law because he acted outside of the usual course of professional practice and lacked a legitimate medical purpose. Id. at 2 (citing 21 CFR 1306.04(a); other citations omitted). The Show Cause Order further alleged that while Respondent is licensed to practice medicine in Tennessee, he violated multiple state laws because he prescribed controlled substances to residents of States where he is not licensed to practice medicine. Id. (citations omitted). Finally, the Show Cause Order alleged that Respondent violated Tennessee law by prescribing phentermine, a schedule IV controlled

substance, to members of his immediate family. <u>Id</u>. (citing Tenn. Code Ann. §§ 63-6-214(b)(1), (4) and (12)).

Respondent requested a hearing on the allegations and the matter was placed on the docket of the Office of Administrative Law Judges. ALJ Ex. 2. Thereafter, an Administrative Law Judge (ALJ) conducted a hearing on August 30 and 31, 2011, in Nashville, Tennessee. ALJ Recommended Decision (hereinafter, also ALJ), at 4. At the hearing, the Government elicited testimony from several witnesses and submitted various documents into the record; Respondent testified in his own defense and submitted his resume' for the record. Following the hearing, both parties filed briefs containing their proposed findings of fact, conclusions of law, and argument.

On November 3, 2011, the ALJ issued his recommended decision. Therein, the ALJ rejected the Government's allegations that Respondent had prescribed controlled substances over the internet to numerous persons who were not Tennessee residents, finding credible Respondent's testimony that he did not issue any of the prescriptions (and that the prescriptions were forged) and that the Government's contrary evidence was unsubstantiated hearsay. ALJ at 37-38. While there was also evidence that Respondent had issued prescriptions over the internet and without performing physical examinations, the ALJ found credible Respondent's testimony that he did so pursuant to an arrangement in which he was acting "as an on-call covering physician" for patients who needed a prescription refill when their doctor was unavailable. Id. at 39._The ALJ further found that the Government had failed to show that Respondent was required to perform a physical examination to prescribe to Tennessee residents, finding credible Respondent's testimony that "he did not give new diagnoses to the patients"; that he "only provided refills" and "did not prescribe new medications"; and that "he only issued prescription

refills after he conducted the telephone consultations with the patient, reviewed the patient's medical file and verified that the patient's primary care physician was unavailable to see the patient." <u>Id</u>.

The ALJ further found that Respondent had prescribed phentermine to family members, including his sister, wife and mother-in-law. <u>Id.</u> at 41. However, the ALJ also found credible Respondent's testimony that upon being confronted by a pharmacist that it was unlawful to prescribe to family members, he stopped doing so. <u>Id.</u> The ALJ also found that Respondent had provided a UPS box as the address of his registered location even though at the time he was practicing medicine at several physical locations and that this was a violation of 21 U.S.C. 822(e). <u>Id.</u> at 41-42.

Finally, the ALJ found that Respondent had fully accepted responsibility for his misconduct and demonstrated that he will not engage in future misconduct. The ALJ thus concluded that while the Government had established "a <u>prima facie</u> case that Respondent has committed acts inconsistent with the public interest by unlawfully prescribing controlled substances to immediate family members and by failing to maintain a proper registered practice location," he had rebutted the Government's prima facie case. Id. at 44.

The Government filed exceptions to the ALJ's recommended decision. Thereafter, the record was forwarded to me for final agency actions.

Having considered the entire record and the Government's Exceptions, I adopt the ALJ's findings that the Government proved that Respondent unlawfully prescribed a controlled substance to a family member and failed to update his registered location with the Agency. I also adopt the ALJ's finding that the Government did not prove that Respondent violated the CSA's prescription requirement by prescribing controlled substances through the Internet to

Tennessee residents because it did not establish that his conduct violated the State's regulation. However, for reasons explained below, I reject the ALJ's finding that the Government did not prove that Respondent improperly prescribed controlled substances without a valid doctor-patient relationship to persons who were not residents of Tennessee. Moreover, even were I to adopt the ALJ's finding that Respondent did not issue or authorize the issuance of the out-of-state prescriptions, under agency precedent - which was ignored by the ALJ - Respondent was nonetheless liable for them because he provided his registration number to Secure Telemed's employees and failed to exercise any supervision over their use of his registration. I further reject the ALJ's finding that Respondent has rebutted the Government's <u>prima facie</u> showing that his continued registrations would be inconsistent with the public interest.

FINDINGS OF FACT

Respondent is the holder of a DEA Certificate of Registration, which authorizes him to dispense controlled substances in schedules II through V as a practitioner. GX 1. Respondent's registration was due to expire on June 30, 2009. <u>Id</u>. However, on June 16, 2009, Respondent submitted a renewal application. GX 2. Accordingly, Respondent's registration remains active pending the issuance of this Decision and Final Order. 5 U.S.C. 558(c).

The Investigation of Respondent

Respondent came to the attention of the Agency in the spring of 2008, when DEA Investigators in Nashville, Tennessee started receiving complaints from other DEA offices, as well as pharmacies throughout the country, that the pharmacies were receiving prescriptions issued by Respondent which appeared to be suspicious. Tr. 115-16. Investigators eventually

determined that the prescriptions were being issued through an internet scheme known as Telemed Ventures.¹ Id. at 117.

Under the scheme, persons would go online and fill out a questionnaire, providing their name, address phone number, as well as their height, weight, and estimated blood pressure. <u>Id.</u> According to an Agency Investigator, sometimes patients would fax in their medical records; however, other patients said they did not do so. <u>Id.</u> at 119. Patients would then be put in touch with a physician, who would conduct a phone consultation with the patient and issue a prescription. <u>Id.</u> Initially, the prescriptions were transmitted either electronically or by fax to a fulfillment pharmacy, which dispensed the medication. <u>Id.</u> at 119-20. However, after DEA started cracking down on fulfillment pharmacies, the prescriptions were sent directly to the patients, who took them to their local pharmacies. Id. at 120.

During the course of the investigation, DEA Investigators conducted an inspection of Contract Pharmacy Services, a pharmacy located in Colorado, which filled prescriptions as part of the Secure Telemed scheme. <u>Id.</u> at 121. During the inspection, the pharmacist cooperated with DEA and identified the names of various physicians whose prescriptions he had filled, to include Respondent. <u>Id.</u> The pharmacist also provided the Investigators with a spreadsheet of various prescriptions he had filled which were attributed to Respondent. The spreadsheet listed several dozen controlled substance prescriptions for drugs (primarily for schedule III combination drugs of hydrocodone and acetaminophen), which the pharmacy dispensed to persons located in Mississippi and South Carolina between September 19 and October 30, 2007. <u>See</u> GX3.

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¹ The scheme was also known as Secure Telemedicine and Fortune Telemed. Tr. 117. Throughout the hearing, the parties referred to it as "Secure," "Secure Telemed," and "Secure Telemedicine," as does this Decision.

Using the spreadsheets, the Nashville-based Investigators asked other DEA offices to interview several of the persons who were listed as having had obtained controlled substances in October 2007, from the pharmacy, based on prescriptions issued by Respondent. Tr. 127. Those interviewed included K.S., a resident of Terry, Mississippi, and C.T., a resident of Clinton, Mississippi, to each of whom the pharmacy dispensed a prescription for 90 tablets of hydrocodone/apap 10/500mg; as well as A.L., a resident of Richland, Mississippi, to whom the pharmacy dispensed a prescription for 90 tablets of hydrocodone/apap 10/650mg. GX 3, at 1. Each of the interviews was conducted in the September/October 2009 timeframe. Tr. 73, 77, 81.

A Mississippi-based Investigator testified that she interviewed K.S., who related that she had obtained the prescription from an online pharmacy by filling out a form and that she had faxed her medical records to a website. K.S. further stated that she had "received a phone call from someone identifying [him]self as Dr. Dennis, contacting her about her online form." Tr. 73-74. According to the Investigator, K.S. further stated that she had never met Dr. Dennis and had not been physically examined by him. <u>Id</u>. at 74. K.S. further stated that she had received the prescriptions by e-mail and fax and that she had filled the prescriptions at a local Walgreens. <u>Id</u>. at 75.

The Investigator also interviewed A.L., who also told of filling out an online form through a website known as Fortune Telemed and faxing medical record to the website. <u>Id.</u> at 78-79. A.L. stated that she had "received a phone call from someone stating they were from Dr. Dennis' office," <u>id.</u> at 78, and that she had no personal contact with Respondent. <u>Id.</u> at 79. A.L. further stated that she received six to seven prescriptions from Respondent, some of which were filled at a pharmacy in Miami, and some of which she filled at a local Wal-Mart. <u>Id.</u> at 80-81.

The Investigator also participated in an interview of C.T., who also related that he had filled out a form at a website, faxed his medical records to the website, and "received a phone call from someone identifying [himself] as Dr. Dennis." <u>Id.</u> at 82. C.T. further stated that he never met Respondent, and that he had received two to three prescriptions from him which he filled at a local Walgreens. Id. at 84.

With respect to each of these three persons, the Investigator acknowledged that they did not volunteer Respondent's name and that she had told them that she was investigating a Dr. Dennis. <u>Id</u>. at 85. She further acknowledged that none of them would be able to identify Respondent if they testified in court. <u>Id</u>. at 87. Moreover, none of the witnesses identified an email address or fax number that was used to send them the prescriptions and the Investigator acknowledged that the prescriptions could have been created by Secure Telemed. <u>Id</u>. at 88.

An Investigator from the Columbia, South Carolina DEA office testified that on June 3, 2008, she was contacted by an Inspector from the South Carolina Bureau of Drug Control regarding two prescriptions issued under Respondent's registration (for 60 tablets of Valium and 60 tablets of hydrocodone/apap 10/325mg and dated May 30, 2008), which H.B., a resident of Chapin, South Carolina presented for filling at a local pharmacy. See Tr. 94-95; GX 14.

According to the DI, the pharmacy had contacted the state inspector because the prescriptions had been issued to a known drug seeker or doctor shopper and had been written by an out-of state physician. Tr. 95-96. The DI testified that she had spoken with both the pharmacist and a pharmacy technician regarding the prescriptions, and that the pharmacist told her that the pharmacy had a policy of contacting "every out-of-state physician." Id. at 97.

According to the DI, the pharmacist had initially attempted to call Respondent using the phone number which was listed on the prescription as Respondent's but was unable to reach him

because his mailbox was full. <u>Id</u>. at 98. However, the pharmacist looked for another phone number for Respondent and was eventually able to speak with him and did so on June 2, 2008.² Id. at 97.

The DI testified that the pharmacist told her that she asked Respondent if H.B. was his patient and to verify that he had written the prescriptions and the quantities; Respondent told the pharmacist that H.B. was his patient. <u>Id</u>. Moreover, the DI further testified that the pharmacist said that Respondent verified that he had written the prescription and the quantity. <u>Id</u>. at 99. And according to the DI, Respondent told the pharmacist that he "had a record on H.B." but "had never seen her in person." <u>Id</u>. at 98-99. Finally, the pharmacist told the DI that when she questioned Respondent about this, he stated that he had been "assured" by his Medical Director "that prescribing to out-of-state patients was legal in all except two states." <u>Id</u>. at 99. The DI further testified that the pharmacy had not filled the prescriptions.³ <u>Id</u>. at 96.

The DI further testified that she had compiled a spreadsheet based on data she obtained from the South Carolina Prescription Monitoring Program (PMP) of the prescriptions which were issued by Respondent and filled by South Carolina pharmacies, and that she had notated on

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² One of the prescriptions contains a different handwritten phone number with the same area code as that listed for Respondent's phone number. GX 14, at 2. According to the testimony of the DI, the phone number was on the document at the time she received it from the pharmacy. Tr. 103. The DI did not, however, know "where that number would call." Tr. 103. However, several other prescriptions in the record, which Respondent does not dispute having written, list the same phone number which was handwritten on the prescription issued to H.B. Compare GX 13, at 2-5, with GX 14, at 2. See also Tr. 215 (testimony of Nashville-based Investigator identifying phone number as Respondent's phone number at his Lebanon, Tennessee practice).

The DI further testified that she had received copies of the two prescriptions from the pharmacy on June 3, 2008. Tr. 94. Consistent with this testimony, both prescriptions have a fax header indicating that they were faxed from the pharmacy on June 3, 2008. See GX 14, at 1-2.

³ In her testimony, the DI stated that she had interviewed the pharmacist the week before the hearing. Tr. 99 & 103. The record does not, however, clearly establish that the statements attributed to Respondent were also related by the pharmacist to the DI in June 2008, after the DI had received the report from the State and contacted the pharmacy to obtain the prescriptions. See generally Tr. 93-103. Nor, with respect to the pharmacist's August 2011 statements, did the Government put on any evidence tending to show that the pharmacist had an accurate recollection of the 2008 incident and her phone conversation.

the document the distance between the patient's residence and Respondent's location. <u>Id</u>. at 105, 109; GX 17. The DI verified the data by contacting all of the pharmacies and asking whether the prescription had been presented and whether it had been filled. Tr. 107-08. She also stated that she had obtained a faxed copy of all of the prescriptions and that "[o]n many of" them, "there is a notation written on them from the pharmacists that were working that day that they were verified with Kevin Dennis." <u>Id</u>. at 111. The spreadsheet documents more than seventy controlled-substance prescriptions, nearly all of which were for hydrocodone, which were issued under Respondent's DEA registration and which were dispensed between January 2 and July 18, 2008. Consistent with the DI's testimony, the spreadsheet does not list the two prescriptions for H.B. as having been filled.

The Government also introduced into evidence copies of numerous other prescriptions which it alleged Respondent had issued through Telemed, as well as printouts from both the Tennessee and Mississippi prescription drug monitoring programs listing prescriptions which were dispensed and attributed to Respondent. GX 5 & 6. These included multiple prescriptions for 90 tablets of hydrocodone/apap 10/325 issued to K.P. of Fort Mill, South Carolina on December 13, 2007, as well as January 7, February 4, March 3, April 4, April 30, and May 23, 2008. GX 15, at 9-16. Each of the prescriptions included Respondent's cell-phone number, id., and the January 7 prescription bears the handwritten notation: "these are valid per Dr. Dennis" along with his DEA number. See id. at 10. Regarding this note, an Agency Intelligence Research Specialist, who obtained the prescriptions from the dispensing pharmacy, testified that she was told that the note was made "by the actual pharmacist after calling and confirming

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⁴ This exhibit also includes copies of prescriptions issued for Naproxen which were issued on the same dates as the hydrocodone ones were. <u>See GX</u> 15, at 1-8.

whether the prescription was valid or not." Tr. 59. The Research Specialist testified that she obtained these prescriptions from a K-Mart Pharmacy in North Carolina. Tr. 40.

These included multiple prescriptions for hydrocodone/apap 10/500mg. issued to patient E.F., who resided in the same town (Franklin, Tennessee) where Respondent practiced. GX12. According to the Government's lead Investigator, a local pharmacist had found the prescriptions to be suspicious⁵ and contacted a state drug task force because they contained a reference number and bar code and had been faxed into the pharmacy. Tr. 166.

The prescriptions were dated April 4, May 7, June 11, and July 10, 2008. GX 12. While the first three prescriptions contain the notation "filled" with a date, the latter prescription bears the notation "refused to fill 7/16 called Doctor & patient" and was marked with an x across the face of the prescription. <u>Id</u>. According to the Investigator, this note was written by the pharmacist. Tr. 167.

In addition, a report from the Tennessee PMP lists several other hydrocodone prescriptions which were dispensed by Tennessee pharmacies to E.F. pursuant to prescriptions attributed to Respondent; these include prescriptions which were dispensed on November 13 and December 11, 2007; January 29, and February 28, and August 4, 2008. See GX 6, at 9.

Notably, the PMP report does not list a dispensing as having occurred in July 2008. See id.

The DI further testified that in August 2008, after obtaining the prescriptions, he had contacted E.F. seeking to interview her. Tr. 170. The Investigator explained to E.F. that he had determined "that she was obtaining medications over the internet." <u>Id</u>. While E.F. initially

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⁵ According to the DI, the circumstances which raised the pharmacist's suspicion included that the prescriptions contained a reference number, a box with a bar code, and had been faxed into the pharmacy. Tr. 166. The DI testified that the reference number was "a way for Telemed to keep track of the prescription [it] sent." <u>Id</u>. at 253. Numerous prescriptions in the record contain these hallmarks.

⁶ The PMP report shows that E.F. filled her prescriptions at three different pharmacies.

offered to call the Investigator back to arrange for an interview, she ultimately became "very hard to get a hold of." <u>Id</u>. About a year later, the Investigator went to her house and found her. <u>Id</u>. at 171. E.F. eventually agreed to an interview which was conducted at her house. <u>Id</u>. at 172.

During the interview, E.F. stated that she had a long history of migraine headaches and admitted that sometime in late 2007, she had gone online and started ordering medications through a website which she referred to as "Telemed something." <u>Id</u>. She further stated that she had sent in medical records from both her primary care physician and neurologist and that after calling a 1-800 number for the website, she was told that she would be called by a physician. Id.

E.F. stated that she then received a phone call from a person who identified himself as Kevin Dennis and that she generally talked with Respondent whenever she needed a prescription.

Id. at 173. E.F. further stated that she had asked Respondent if she needed to be seen by him, and that Respondent stated that he did not need to see her as long as he was reviewing her medical records and talking to her on the phone. Id. at 174.

The DI also testified that a state investigator had provided him with a copy of the medical record E.F.'s primary care doctor maintained on her. <u>Id.</u> at 203. Upon reviewing the file, the Investigator found that there was no documentation that she was being prescribed controlled substances by another physician. <u>Id.</u> at 203-04; <u>see also GX 22</u>. Nor is there any evidence in the file of Respondent's having contacted E.F.'s primary care doctor. <u>See GX 22</u>.

The DI further testified that he had spoken with E.F.'s primary care doctor (Dr. B.) and asked him whether he had ever contracted with an organization to provide cross-coverage for his patients. Tr. 205. Dr. B. explained that because there are "numerous internal medicine physicians" at his practice, there would be no need to have a physician outside the practice cover for him. Id. Finally, Dr. B. said that he had never heard of Respondent. Id.

The Investigator also interviewed S.W., a Nashville resident, who according to the Tennessee PMP report, obtained prescriptions for hydrocodone and phentermine which were filled under Respondent's DEA registration. Tr. 135; GX 6, at 27. According to the PMP report, on December 17, 2007, as well as January 15 and February 14, 2008, Respondent issued to S.W. prescriptions for both 90 tablets of hydrocodone/apap 10/325 and thirty tablets of phentermine 30mg. GX 6, at 27. According to the Investigator, although S.W. acknowledged having ordered hydrocodone through Telemed she could not remember the name of the prescribing physician. Tr. 135, 164. However, the Investigator was eventually able to identify Respondent as the prescribing physician. Id. at 164.

During an interview, S.W. stated that she ordered drugs over the internet and had been doing so "for years" because it was "easier to get" some of the medications she wanted such as "diet pills" as "her primary care physician really didn't want to prescribe the type of things she wanted." <u>Id</u>. at 163-65. S.W. further stated that she never had a physical exam and never met the physician. <u>Id</u>. at 164. She also stated that she filled the prescriptions at a local Wal-Mart. Id.

S.W. provided the Investigator with the name of her primary care physician (Dr. H.). <u>Id.</u> at 165. Subsequently, the Investigator interviewed Dr. H. and asked him whether he would contract with an organization outside of his practice to provide on-call or cross-coverage for his patients. <u>Id.</u> at 207. Dr. H. explained that this would not occur because there were other physicians in his practice who covered for him if he was not available. <u>Id.</u> In addition, Dr. H. stated that he had never heard of Secure Telemedicine or any other organizations with a similar name. <u>Id.</u> at 207-08. Nor had Dr. H. ever heard of Respondent. <u>Id.</u> at 208.

During the investigation, the Government also found evidence that Respondent was prescribing controlled substances, specifically phentermine 37.5mg, to family members including his wife, sister, and mother-in-law. See GX 19, at 12-13, 17, 19, 21-23 (Rxs issued to wife); GX 20, at 2-6, 10-13 (Rxs issued to sister); GX 21, at 2, 4-10 (Rxs issued to mother-in-law); Tr. 175-79, 181-82, 201. The DI further stated that upon going to a Sam's Club Pharmacy in Franklin, Tennessee to retrieve the prescriptions which Respondent's wife and sister had filled there, the Pharmacy Manager related a 2009 incident in which he had challenged Respondent's wife and sister about the prescriptions. Tr. 185. According to the Pharmacy Manager, Respondent's wife and sister had filled prescriptions for diet pills at the pharmacy on several previous occasions and he had "always assumed that they were sisters." Id. However, upon reviewing the prescriptions, the Pharmacy Manager had "put two and two together" and concluded that one of the women "might be" Respondent's wife. Id.

When the women returned to pick up their prescriptions, the Pharmacy Manager confronted them, telling them that it was against state law and Medical Board policy for a physician to prescribe to a family member. <u>Id.</u> Respondent's wife became agitated and said that she would just "go get the doctor and we'll clear this up." <u>Id.</u> at 186. The women left and later returned with Respondent. The Pharmacy Manager, who declined to fill the prescriptions, explained the situation to Respondent, who stated that "he understood and left without incident." <u>Id.</u>

On June 26, 2009, Respondent went to the Nashville DEA office to discuss with the Investigator and his Supervisor why the Agency had not renewed his registration. <u>Id.</u> at 189, 421. After being advised of his right to remain silent and that he was not under arrest, Respondent was informed that DEA was investigating him for prescribing controlled substances

to persons in other States and with whom he did not establish a legitimate doctor-patient relationship. <u>Id</u>. at 190; <u>see also id</u>.at 422 (testimony of Supervisory Investigator: "I advised him that DEA was conducting an investigation of information we had received that he had been involved in issuing prescriptions to persons that he had never met, nor ever examined in other states and that it appeared that would be without a legitimate medical purpose, and that was the reason we were conducting the investigation. . . .").

Respondent stated that he "kind of knew what this was about" and pulled out of his pocket, "some sort of employment document with Secure Telemedicine." <u>Id</u>. at 190. However, the DI did not make a copy of the document. <u>Id</u>. at 357. According to Respondent, the document "was actually a liability form" that had the "name of [the] company, their malpractice insurance carrier, along with the name of seven other doctors," <u>id</u>. at 356, as well as the dates of its insurance policy. <u>Id</u>. at 358.

Respondent then volunteered that he quit working for Secure Telemedicine after receiving a phone call from a pharmacy in South Carolina questioning one of his prescriptions and after the entity's Medical Director "could not provide verification that he could do this legally in other states." Id. at 194; see also id. at 197 (testimony that Respondent "indicated that he left Secure Telemedicine because he didn't feel like it was the ethical thing to do and that they couldn't provide him the legal documentation to make him feel comfortable to continue working for them"); id. at 425 (Supervisory Investigator's testimony to same effect). Moreover, according to both Investigators, Respondent stated that he was surprised to receive the phone call from the South Carolina pharmacy because "it was his understanding that all these prescriptions went to a fulfillment [or clearinghouse] pharmacy." Id. at 198; see also id. at 424. According to the Investigator, Respondent never denied that he had issued prescriptions to out-of-state persons

during the interview and said he had worked for Secure Telemed from "around November [20]07 through March 2008." <u>Id</u>. at 195. However, in his testimony, Respondent denied ever having told the Investigators that he had issued prescriptions to out-of-state persons and asserted that he told them that he had limited his internet prescribing to Tennessee residents. Specifically, Respondent testified that:

I communicated to the investigators at that time that I was a Tennessee-licensed physician and that I was not authorized, and I was only notified by the South Carolina pharmacist that a prescription arrived in South Carolina. I did not communicate to the investigators that I had "prescribed or dispensed medications outside the State of Tennessee."

<u>Id.</u> at 396. According to Respondent, when he was confronted by an Investigator as to whether he had issued internet prescriptions for out-of-state patients, he stated that he did not "know of any online pharmacy activities," and added: "I don't know if it's an online pharmacy or not, but I've been associated with Secure Telemedicine. I've been an On-Call Coverage Consultant for that organization for a period of time." <u>Id.</u> at 397. Respondent again maintained that he told the Investigator that he "did not give Secure Telemedicine authorization to dispense or prescribe medications outside the State of Tennessee. I did not give them that authorization," <u>id.</u> at 398, and that at the time of the interview, he was unaware that any other prescription (beside the one that he was called about by the South Carolina pharmacist) had been issued to non-Tennessee residents using his DEA registration. <u>Id.</u> at 403.

According to the Investigator, Respondent further stated that "[i]t was his understanding that all these prescriptions went to a fulfillment [or clearinghouse] pharmacy. So, when he received a call directly from a pharmacy in South Carolina, it took him by surprise." <u>Id</u>. at 198. <u>See also id</u>. at 424 (testimony of Supervisory Investigator who also attended the interview: "he said that he had been contacted by a pharmacist from South Carolina concerning one of his

prescriptions and questioning that prescription and that he was surprised because he thought that all his prescriptions went through a clearinghouse pharmacy").

Respondent also stated that at the time he worked for Secure Telemedicine, he worked in an emergency room and had a practice in Lebanon and that he sent out his resume' online to "find some locum tenens work" to supplement his income. <u>Id.</u> at 195-96; 296. Respondent admitted that he never saw the patients to whom he prescribed and did not conduct physical examinations. <u>Id.</u> at 196. Rather, he would review a patient's record online and conduct a telephonic consultation with the patients before issuing a prescription; he further admitted that he prescribed such controlled substances as hydrocodone, Norco (a branded hydrocodone drug), and Xanax, as well as such non-controlled drugs as naproxen and ibuprofen. <u>Id.</u> at 196.

Respondent testified on his own behalf. Regarding his work for Secure Telemedicine, Respondent testified that he became aware of Secure Telemed through "a web search for locum tenens work" and that he did not interview "face-to-face" with them and had never been to its office, which he understood to be located in Miami; rather, he interviewed by phone. <u>Id</u>. at 295-97. Respondent nonetheless entered into an agreement with Secure towards the end of September 2007. Id. at 298.

Respondent maintained that he "was to become an on-call covering physician, considered under [Secure Telemedicine's] Consult-A-Doc program" and that he would provide shift coverage on an eight-hour basis. ⁷ <u>Id</u>. According to Respondent, he "would inform the company of the shifts that [he was] available in advance such that [he] would be available to cover on-call

Tennessee physicians contracted with Secure.

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⁷ In his letter requesting a hearing, Respondent asserted that "Secure contracted with primary care physicians in Tennessee and other jurisdictions to provide coverage by other licensed physician in their respective jurisdictions when the primary care physician was unavailable to attend to the needs of their established patients for ongoing conditions." ALJ Ex. 2. However, at the hearing, Respondent produced no evidence to support the assertion that

for physicians after hours or when a physician is just unavailable to be able to manage the care of their patients." <u>Id</u>.

Respondent further asserted that under the Consult-A-Doc program, patients would call into Secure Telemedicine, and that he would be notified through what was "called a dashboard" that a patient was seeking a consultation, and that he could either accept or decline the call. <u>Id.</u> at 299. Respondent maintained that if he accepted the call, his activities were limited to triaging a patient call in non-emergency situations and that if a patient's situation involved an emergency, he would direct the patient to go to the emergency room or an urgent care center. Id. at 299-300.

Respondent asserted that he would "never give a new diagnosis" to "any patient" and that upon completion of the call, he would update the patient's record in the electronic medical records system (EMR). <u>Id</u>. at 300._Respondent maintained that "if the patient requested and they were talking in a way such that they had a chronic ailment, such as a pain ailment," the patient was placed back in the queue because "there had to be verification of their records." <u>Id</u>. at 301. Respondent then asserted that he would then "[c]all the patient's primary care doctor, the doctor that's prescribing the medication, talk to that office, find out information about that office and find out about their unavailability." <u>Id</u>.; see also id. at 303.

Respondent maintained that "[s]ome doctors who are in private practice, mostly private practice, a lot of them don't have call coverage or they have problems finding physicians with call coverage." <u>Id</u>. Respondent then added that while working for Secure Telemedicine, he "really didn't have any contact" with any group practice where "they communicate to me that this program was part of them." <u>Id</u>.

Respondent asserted that with respect to solo practitioners, "if the office staff stated that Doctor ABC was actually on vacation and he will not be back for at least five days but be back

next week, that extended period of time then qualified the patient for that particular medication after reviewing the records with the staff." <u>Id</u>. at 302. Respondent stated that he would never initiate a new medication for a patient and that he would "always make sure that the doctor [was] truly unavailable" before prescribing a controlled substance. <u>Id</u>.

Respondent further testified that he only accepted on-call coverage for Tennessee physicians, and that he only consulted with the patients of Tennessee physicians. <u>Id</u>. at 303. He then explained that upon determining that a hydrocodone prescription needed to be refilled, he would update the EMR to note that he had reviewed the patient's record, that he had contacted the office of the patient's physician and determined that the "physician was not available to this patient" and that he would then push a button on a computer to send this information to Telemed, which would prepare the prescription. <u>Id</u>. at 304. In his testimony, Respondent emphasized that he did not actually prepare or sign the prescriptions. <u>Id</u>.; <u>see also id</u>. at 414. He also stated that he did not keep any records of his prescribing activities for Telemed, <u>id</u>. at 305, because they were the property of Secure Telemedicine. <u>Id</u>. at 384.

When asked to square his failure to retain patient files for those to whom he prescribed with his obligation as a physician to maintain a patient record, Respondent testified that:

I was not the [primary care physician]. I was only the on-call covering physician; therefore, it's not my responsibility at that time to have or operate in a fashion as though I am that patient's primary doctor. I was only an on-call covering physician.

Id. at 385.

Moreover, he did not forward a copy of the prescriptions he wrote to the patient's primary care physician claiming that this was the responsibility of Secure Telemedicine. <u>Id.</u> at 384. Asked by the Government whether he ever communicated with the patient's primary care physician regarding prescriptions he had written Respondent maintained that the information was

in the electronic medical record and was sent through Secure Telemedicine. <u>Id</u> at 388. And when asked whether he had ever verified with someone at Secure Telemedicine that it had notified a patient's primary care physician regarding his having written a prescription, Respondent replied: "I don't know of any instance where they did not. I was not told that information and I did not question that particular – I did not pose that question to them." <u>Id</u>. at 389. Strangely, Respondent acknowledged that he did not remember having ever been called by the primary care physician of a patient he had prescribed to through Secure Telemed, notwithstanding that his name would have been on the consult note. Id. at 408-09.

Respondent testified that on about April 4, 2008, he received a phone call from a South Carolina pharmacist, who he asserted was "a male pharmacist," Tr. 364, questioning a prescription that had his DEA number and information on it. <u>Id.</u> at 308. Respondent asserted that he "was not aware that [he] had written prescriptions for any patients outside the State of Tennessee" and that he "asked the pharmacist to not fill that prescription" and to send him a copy of it. <u>Id.</u>; see also <u>id.</u> at 368 ("I communicated with him [the pharmacist] that I was unaware that there was any patient I've ever prescribed any medication for or wrote a prescription for in the State of South Carolina."). According to Respondent, the pharmacist agreed not to fill the prescription. <u>Id.</u> at 308. Respondent did not, however, recall the name of the pharmacy or the city it was located in. <u>Id.</u> at 369. Moreover, Respondent did not notify DEA that his registration had been used to issue the prescription. <u>Id.</u> at 371, 374.

Respondent testified that "the same day," he contacted Secure Telemed's Medical

Director, and asked him "how is it that a prescription . . . 'has gotten outside the State of

Tennessee to a patient in South Carolina?" and said that he had "never approved anything like

that." <u>Id.</u> at 308. Continuing, Respondent testified that he asked Secure Telemed's Medical Director:

Can you give me some legalities or something in writing showing that, you know, this isn't happening or how is it happening? What are the laws concerning a doctor in Tennessee having the right to have a prescription written to a patient in any state outside of Tennessee?

I was very upset by that conversation, that this actually occurred, but I said I wanted to see a copy of it. I really wanted to see one, because I really hadn't seen any, because I hadn't produced any. I didn't know what they looked like.

And he stated he would get back with me, he would call me, he would investigate and research this, and he would provide some documents to me that protected me and protected the company pertaining to any Tennessee physician if they were to prescribe outside the State. I never received those documents from [him], and I discontinued providing any service for them probably within two weeks.

<u>Id</u>. at 308-09.

Respondent further acknowledged that he had provided Secure Telemedicine with his DEA registration number, as well as other documents, which had his signature on them. <u>Id.</u> at 310. He then expressly denied having told DEA Investigators that the reason he quit Secure Telemed was because they could not justify his continued prescribing of medications to out-of-state patients. <u>Id.</u> at 310-11. Rather, he reiterated that the reasons he quit Secure Telemed were for the reasons explained in the block-quote above. <u>Id.</u> at 311. Respondent did not, however, create any written correspondence documenting his decision to terminate his relationship with Secure Telemedicine. <u>Id.</u> at 375-77.

Respondent then denied having prescribed for "anybody other than patients that were treated by Tennessee physicians [that he was] on call for." <u>Id</u>. at 311. And when questioned by his counsel if "the one [prescription] in South Carolina, that's the first you heard about it?," Respondent replied "[t]hat is correct," then added: "And I had never seen a prescription as well."

<u>Id</u>. Respondent then maintained that he had never seen any of the prescriptions until the Government provided them following the initiation of this proceeding. <u>Id</u>.

After denying that he ever took a call from a patient that lived in South Carolina, Colorado or Washington State, <u>id</u>.at 305, Respondent then proceeded to deny having issued all but one all of the prescriptions for out-of-state patients.⁸ <u>Id</u>. at 312-23 (denying issuance of prescriptions in GXs 3, 5, 8, 9, 10 11); <u>id</u>. at _324-30 (denying issuance of prescriptions in GXs 12, 14); <u>id</u>. at 336-41 (denying issuance of prescriptions in GXs 16, 17, and 18)._ Moreover, he further denied having authorized Telemed to issue the various prescriptions. Id.

Regarding the hydrocodone prescriptions issued to E.F. (GX 12), who resided in Franklin, Tennessee, and which included a July 10, 2008 prescription with the notation that the pharmacist had "Refused to fill, 7/16, called doctor and patient," Respondent acknowledged that "[i]t's possible" he received a call about the prescription and that at the time, he was working in the ER and was "quite busy." Tr. 324-25. Respondent testified that he "tend[s] not to answer calls because of the nature of the hospital" and added that "[i]t's always possible that I could have received a call, and I could have answered this and spoken to this pharmacist, and told them not to fill the prescriptions." Id. at 325. However, Respondent did not have a "positive recollection" of the incident. Id.

Respondent then denied having issued, as well as having authorized anyone to issue, each of the prescriptions that E.F. obtained through Secure Telemed. <u>Id</u>. Respondent added that during the interview with DEA Investigators, he had told them that the only time he received a call regarding a prescription was for the call that came from the South Carolina pharmacist. <u>Id</u>. at 326; <u>see also id</u>. at 363 (acknowledging that it is "always possible" that he received a phone

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⁸ The only exception was for a prescription contained in GX 7. According to Respondent, although the patient provided a Colorado address, she was in the music business and had been a patient in Respondent's Tennessee practice. Tr. 314.

call from a pharmacist about E.F. but stating that he did not "have any recollection, and I've never seen this patient, I've never talked to this patient."); <u>id</u>. at 367. Later, on redirect examination, Respondent testified that he would not have issued prescriptions through the internet to E.F. because "[m]y office was available within a proximity where this patient can come right to my office so I can examine them physically, I can see what's going on with the medical conditions" and "I would have no need to do this." <u>Id</u>. at 404.

Regarding the May 30, 2008 prescriptions for hydrocodone and valium issued to H.B. of Chapin, South Carolina, and which were presented to the Chapin Pharmacy, Respondent denied writing them or issuing them in any way. Tr. 330. He also denied authorizing them "in any way." <u>Id</u>.

Respondent also denied writing, authorizing, or otherwise causing the issuance of the numerous hydrocodone prescriptions issued to K.P., of Fort Mill, South Carolina. <u>Id</u>. at 333-34. As found above, a January 7, 2008 prescription bears the handwritten notation: "These are valid per Dr. Dennis" along with his DEA registration number. GX 15, at 10. Respondent nonetheless denied having authorized or validated the prescription. Tr. 333-34. Moreover, on crossexamination, he denied having received any other phone calls from any pharmacists about prescriptions other than the phone call he claimed to have received from a South Carolina pharmacist in April 2008. <u>Id</u>. at 364. And when asked if he knew how the notation got on the prescription, Respondent testified:

I have no idea how the notation arrived there, but it doesn't appear to be a pharmacist. By pharmacy rule of law, any notation written on a prescription must contain their initials and it must contain the date of that communication and/or alteration of the prescription. By pharmacy law they must do this. This one does not contain any initials by a pharmacist, does not contain a date.

Id. at 334.

Respondent did not, however, cite to any specific provision of North Carolina law or the Pharmacy Board regulations in either his testimony or his brief, which requires that such a notation that a prescription has been verified must be initialed and dated. And even if the prescription should have been initialed and/or dated, given that Respondent has "no idea how the notation arrived" on the prescription, I find that the testimony of the Agency Intelligence Research Specialist, who obtained the prescription, that the note was made by "the actual pharmacist after calling and confirming whether the prescription was valid" to constitute substantial evidence that the note was made by the pharmacist, and consistent with pharmacy practice, was likely done so by the pharmacist in the process of reviewing the prescription and determining whether to fill it.⁹

Respondent further denied having issued any of the prescriptions listed on the spreadsheet of prescriptions which an Agency Investigator had compiled from the South Carolina PMP report. Tr. 339-40. Moreover, on cross-examination, the Government showed Respondent the printout from the Tennessee PMP (GX 6) showing the controlled substance prescriptions dispensed pursuant to prescriptions issued under his DEA registration and asked him to identify the patients he had prescribed to through Secure Telemedicine. <u>Id.</u> at 392. While a recess was then taken to allow Respondent to review the exhibit, upon the reconvening of the hearing, Respondent was "unable to identify any of those patients." Id. at 394.

Finally, Respondent asserted that the patients he prescribed to through Secure

Telemedicine were essentially one-time patients. As he testified, "The patients that I saw on this on-call coverage, the ones that I actually communicated with from what my recollection is was a

⁹ Respondent's counsel also attempted to call into question the notation by observing that it used "the plural 'these" and Respondent testified that he did no "know what 'these' mean." Tr. 334. However, as found above, the record also includes a copy of a Naproxen prescription which was issued on the same date as the hydrocodone prescriptions which bears the notation. See GX 15, at 2. Thus, K.P. had been provided with two prescriptions.

one-time call, because the patients had a doctor and I would not be responsible and I would not rewrite something for them. So I didn't expect to even see that patient or communicate with that patient again at any given time." <u>Id.</u> at 406. <u>See also id.</u> at 386 (testifying that "[t]he patient needed to see their own doctor and be seen by their primary care doctor. If I were to take on the responsibility to prescribe medication on a monthly basis, then I'm taking over the patient's primary care doctor's responsibility.").

Thus, other than the phentermine prescription he had issued for his former patient who had moved to Colorado, see GX 7, the only prescriptions in the record which Respondent admitted to issuing were the phentermine prescriptions for his wife, sister, and mother-in-law. Tr. 343-47. While Respondent questioned whether his mother-in-law came within the State's prohibition on prescribing to an immediate family member, he nonetheless ceased prescribing to her (as well as his wife and sister). Id. 347-48. He further testified that he understood the gravity of this situation. Id. at 348.

As for his internet prescribing, Respondent testified that he "will never get involved with any entity that even looked similarly as though they were doing business in any sort on the internet, ever." <u>Id</u>. at 349. He further stated that he had made mistakes, that the mistakes were apparent and clear, that he has learned from his mistakes and took responsibility for them. <u>Id</u>. Continuing, Respondent stated:

I in no way or form intended or willfully, knowingly participated in any situation that placed me or placed patients in particular at risk. I just didn't do that. I've learned today, throughout this whole process yesterday and today and throughout this whole investigation that you can't do these things. You have to be more diligent, you have to do some research, stay with those credible organizations like I'm currently with now . . . organizations where you can truly see how you're benefitting patients the right way with your gift of medicine.

* * *

More important than a DEA number is my name, my name, my credibility. My parents gave me that name and it's hard to see myself being so stupid to have participated with a company that misused and used me.

Id. at 349-50.

The Government's Exceptions

As discussed above, the ALJ found Respondent fully credible on all of the material issues including his testimony that he did not issue or authorize the issuance of the prescriptions to persons who resided outside of Tennessee and that his prescribing activities were limited to providing on-call services for Tennessee physicians. ALJ at 32-39. The Government takes exception to these findings. More specifically, the Government argues that the ALJ failed to give proper weight to the inculpatory statements Respondent made during the June 2009 interview with DEA Investigators. Exceptions at 5-7. The Government also takes exception to the ALJ's finding that the Secure Telemed prescriptions were issued without his knowledge or consent and argues that the ALJ ignored other evidence of record, including the statements of the South Carolina pharmacist regarding her June 2008 phone call to Respondent regarding the prescriptions issued to H.B., evidence showing that Respondent was called about a prescription for K.P., who was a South Carolina resident and verified the prescription, the phone number evidence, and the fact that Respondent never reported the misuse of registration. Id. at 7-19.

DISCUSSION

Section 304(a) of the Controlled Substances Act (CSA) provides that a registration to "dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . <u>has committed such acts</u> as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section."

21 U.S.C. 824(a)(4) (emphasis added). With respect to a practitioner, the Act requires the consideration of the following factors in making the public interest determination:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
 - (2) The applicant's experience in dispensing . . . controlled substances.
- (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety.Id. § 823(f).

"[T]hese factors are . . . considered in the disjunctive." Robert A. Leslie, M.D., 68 FR 15227, 15230 (2003). It is well settled that I "may rely on any one or a combination of factors and may give each factor the weight [I] deem[] appropriate in determining whether a registration should be revoked." Id.; see also MacKay v. DEA, 664 F.3d 808, 816 (10th Cir. 2010); Volkman v. DEA, 567 F.3d 215, 222 (6th Cir. 2009); Hoxie v. DEA, 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I "need not make explicit findings as to each one." MacKay, 664 F.3d at 816 (quoting Volkman, 567 F.3d at 222 (quoting Hoxie, 419 F.3d at 482)).

The Government has the burden of proving, by a preponderance of the evidence, that the requirements for revocation or suspension pursuant to 21 U.S.C. 824(a) are met. 21 CFR 1301.44(e). However, "once the [G]overnment establishes a prima facie case showing a

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¹⁰ In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct. Jayam Krishna-Iyer, 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. MacKay, 664 F.3d at 821.

practitioner has committed acts which render his registration inconsistent with the public interest, the burden shifts to the practitioner to show why his continued registration would be consistent with the public interest." MacKay, 664 F.3d at 817 (citing Medicine Shoppe-Jonesborough, 73 FR 364, 387 (2008) (citing cases)).

In this matter, it is undisputed that Respondent retains an active Tennessee Medical License (factor one) and that he has not been convicted of an offense related to the manufacture, distribution, or dispensing of a controlled substance (factor three). However, while I adopt the ALJ's findings of fact and legal conclusions that neither factor one (the recommendation of the state licensing board), nor factor three (Respondent's conviction record under laws related to the manufacture, distribution or dispensing of controlled substances), supports the revocation of Respondent's registration, it has long been settled that neither factor is dispositive. See MacKay, 664 F.3d at 817; see also Jayam Krishna-Iyer, 74 FR 459, 461 (2009); Edmund Chein, 72 FR 6580, 6593 n.22 (2007), pet. for rev. denied 533 F.3d 828 (D.C. Cir. 2008); Mortimer B. Levin, 55 FR 8209, 8210 (1990). Rather, the primary focus of this proceeding is whether, as alleged by the Government, Respondent violated the CSA's prescription requirement, 21 CFR 1306.04(a), as well as the laws of several States, by issuing prescriptions to patients he did not physically examine and with whom he did not establish a legitimate doctor-patient relationship, as well as by engaging in the unauthorized practice of medicine by prescribing to residents of States where he was not authorized to practice medicine. Gov. Br. at 23-24 (citations omitted). In addition, the Government alleges that Respondent violated Tennessee law when he issued phentermine prescriptions to his wife, sister, and mother-in-law. Id. at 24-25 (citing Tenn. Code Ann. §§ 63-6-214(b)(1), (4) and (12)).

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

Under a longstanding DEA regulation, a prescription for a controlled substance is not "effective" unless it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a). This regulation further provides that "[a]n order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. 829] and . . . the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." <u>Id.</u>

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." <u>Gonzalez v. Oregon, 546 U.S. 243, 274 (2006)</u> (citing <u>United States v. Moore, 423 U.S. 122, 135 (1975)</u>).

"Under the CSA, it is fundamental that a practitioner must establish a bonafide doctorpatient relationship in order to act 'in the usual course of . . . professional practice' and to issue a
prescription for a 'legitimate medical purpose.'" <u>Joseph Gaudio</u>, 74 FR 10083, 10090 (2009)
(citing <u>Moore</u>, 423 U.S. at 141-43). Moreover, at the time of the events at issue here, whether a
doctor and patient have established a bona fide doctor-patient relationship under the CSA was
generally a question of state law. <u>Id.</u>; see also <u>Kamir Garces-Mejias</u>, 72 FR 54931, 54935
(2007); <u>United Prescription Services</u>, <u>Inc.</u>, 72 FR 50397, 50407 (2007); <u>Dispensing and</u>
<u>Purchasing Controlled Substances Over the Internet</u> (DEA Guidance Document), 66 FR 21181,
21182-83 (2001).

"Moreover, '[a] physician who engages in the unauthorized practice of medicine' under state laws 'is not "a practitioner acting in the usual course of . . . professional practice'" under the CSA." Gaudio, 74 FR at 10090 (quoting United Prescription Services, 72 FR at 50407). As the Supreme Court explained shortly after the CSA's enactment, "[i]n the case of a physician," the CSA "contemplates that he is authorized by the State to practice medicine and to dispense drugs in connection with his professional practice." Moore, 423 U.S. at 140-41. This rule derives from the plain text of the statute which defines the term "practitioner" to mean "a physician . . . licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices . . . to . . . dispense . . . a controlled substance," 21 U.S.C. 802(21), and the term "dispense" to mean "to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner." 21 U.S.C. 802(10). Thus, a controlled-substance prescription issued by a physician who lacks the license or other authority necessary to practice medicine within a State is unlawful under the CSA. See 21 CFR 1306.04(a); cf. 21 CFR 1306.03(a)(1) ("A prescription for a controlled substance may be issued only by an individual practitioner who is . . . [a]uthorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession.").

The ALJ rejected all of the Government's contentions regarding Respondent's prescribing for Secure Telemed, apparently crediting his testimony denying having issued, as well as having authorized the issuance, of each of the Secure Telemed prescriptions presented by the Government. ALJ at 37. While the ALJ properly discounted some of the hearsay evidence relied upon by the Government to refute Respondent's denial of having issued the prescriptions, I find that there is sufficient other reliable evidence of record to support the finding that Respondent issued (or approved the issuance of) many of the prescriptions. Indeed, the evidence with respect to how Secure Telemed operated is consistent with what DEA has encountered in numerous other investigations of unlawful internet prescribing rings, and given

the absence of any evidence corroborating Respondent's testimony that he acted as an on-call physician, covering for other Tennessee physicians after hours or when they were unavailable to manage the care of their patients, I conclude that his testimony is so inherently implausible that no reasonable factfinder could find it to be credible.¹¹

As found above, with respect to the prescriptions issued to the three Mississippi residents, the Government elicited the testimony of an Agency Investigator regarding the statements they made during interviews to the effect that, after faxing their medical records to a website, they had received phone calls from someone identifying himself as Respondent, and were subsequently prescribed hydrocodone without meeting him and undergoing a physical exam. However, the Investigators conducted these interviews approximately two years after the prescriptions were issued and the Investigator who testified regarding the interviews acknowledged that none of these three persons initially named Respondent and none could identify an e-mail address or fax number that was used to send them the prescriptions. In addition, the Investigator offered no testimony that any of these individuals' statements were reduced to writing and sworn. Thus, by

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¹¹ I am mindful of the fact that the ALJ observed the demeanor of the various witnesses and found Respondent's testimony credible. However, as the Supreme Court has explained, "[t]he findings of the examiner are to be considered along with the consistency and inherent probability of [the] testimony." <u>Universal Camera Corp.</u>, v. NLRB, 340 U.S. 474, 496 (1951). As explained below, Respondent's testimony was contradicted by other evidence and contained numerous material inconsistencies. <u>Cf. Anderson v. City of Bessemer City</u>, 470 U.S. 564, 575 (1985) (challenge to district court finding under clearly erroneous standard) ("This is not to suggest that the trial judge may insulate his findings from review by denominating them credibility determinations, for factors other than demeanor and inflection go into the decision whether or not to believe a witness. Documents or objective evidence may contradict the witness' story; or the story itself may be so internally inconsistent or implausible on its face that a reasonable factfinder would not credit it."); <u>United States v. Lathern</u>, 665 F.3d 1351, 1354 (D.C. Cir. 2012).

Of course, the standard applicable in this matter is not the clearly erroneous standard, but rather, whether the Agency's decision is nonetheless supported by substantial evidence on the record as a whole. <u>Universal Camera</u>, 340 U.S. at 492 ("The responsibility for decision thus placed on the Board is wholly inconsistent with the notion that it has the power to reverse an examiner's findings only when they are 'clearly erroneous.'"); see also Chirino v. <u>NTSB</u>, 849 F.2d 1525, 1530 (D.C. Cir. 1988) ("In our view, the Board's determination that Chirino's testimony was 'inherently incredible' supplied the requisite basis under the NTSB's applicable rules to overturn the contrary findings of the ALJ.").

themselves, these statements do not bear sufficient indicia of reliability to be considered substantial evidence.

However, this is not the only evidence that supports a finding that Respondent did, notwithstanding his denial, issue prescriptions, through Secure Telemed, to out-of-state residents. As found above, the record contains seven prescriptions for 90 tablets of hydrocodone/apap 10/325 issued to K.P. of Fort Mill, South Carolina, each of which included Respondent's cell-phone number. Most significantly, a January 7, 2008 prescription bears the handwritten notation: "these are valid per Dr. Dennis" along with his DEA number. The testimony establishes that the notation was on the prescription when it was obtained by a DEA Intelligence Analyst, who was told that it was made by the actual pharmacist who called and verified the prescription. 12

While in his findings of fact, the ALJ found that Respondent "denied ever verifying that he issued the prescriptions to K.P., as indicated by [the] notation," ALJ at 24 (citing Tr. 333-34; GX 15, at 10), in his legal conclusions, the ALJ did not even mention the prescription and its notation, let alone explain why he apparently gave it no weight. However, I conclude that the notation is consistent with that which a pharmacist would make contemporaneously with having verified a prescription. And I further hold that the notation supports the inference that Respondent did not object to the dispensing of the prescription and that Respondent was engaged in issuing prescriptions through Secure Telemed for persons who resided outside of Tennessee.

¹² As found above, K.P. also obtained a Naproxen prescription which was dated January 7, 2008. Thus, the notation's use of the word "these" can be explained by the fact that pharmacist was verifying both prescriptions.

¹³ While at hearing, Respondent contended that the notation did not comply with law and regulations because it was not initialed and dated, he did not cite to any provision of either North Carolina law or the State's Pharmacy Board rules requiring that a pharmacist do this upon verifying a prescription. Nor does his brief cite to any such provision.

The Government also introduced into evidence controlled substance prescriptions for hydrocodone and Valium issued under Respondent's DEA registration to H.B., who was a resident of South Carolina, which were presented to the Chapin Pharmacy in Chapin, South Carolina. Regarding these prescriptions, the Government also elicited the testimony of a DEA Investigator regarding the out-of-court statements made to her by an Inspector for the South Carolina Bureau of Drug Control and the pharmacist. According to the DI, the State Inspector had contacted her shortly after he was contacted by the pharmacist about the prescriptions, because H.B. was a known doctor-shopper.

As found above, the DI testified that the pharmacist had told her that she attempted to call Respondent because the pharmacy had a policy of contacting "every out-of-state physician," and that when she initially attempted to call him using the phone number on the prescription, she received a message that his mailbox was full. The pharmacist, however, eventually reached Respondent on a different phone number and one of the prescriptions includes a hand-written phone number which matches the phone number listed on several of the prescriptions Respondent admittedly issued to family members.

According to the DI, Respondent verified that H.B. was his patient, that he had written the prescription and the quantity. Moreover, Respondent stated that while he had a record on H.B., he admitted that he "had never seen her in person." Respondent then stated that he had been assured by his Medical Director "that prescribing to out-of-state patients was legal in all except two states."

The ALJ found these statement did not constitute substantial evidence, reasoning that the Government had not shown a lack of bias on the part of the pharmacist, that the statements were neither signed nor sworn to, and that there was an absence of evidence "corroborating the

substantive content of the hearsay, namely that [the pharmacist] actually spoke with Respondent in or about June 2008." ALJ at 36. While I ultimately agree with the ALJ's conclusion that the statements cannot constitute substantial evidence, I disagree with much of his reasoning.

"[H]earsay may be substantial evidence depending on its truthfulness, reasonableness, and credibility; hearsay statements are highly probative where declarants are disinterested witnesses, statements are essentially consistent, and counsel had access to the statements prior to agency hearing") Bobo v. United States Dep't of Agric., 52 F.3d 1406, 1414 (6th Cir. 1995) (quoting Hoska v. United States Dep't of the Army, 677 F.2d 131, 138 (D.C. Cir. 1982)); Johnson v. United States, 628 F.2d 187, 190-191 (D.C. Cir. 1980). See also Echostar Comm.

Corp. v. FCC, 292 F.3d 749 (D.C. Cir. 2002) (hearsay can constitute substantial evidence where there are "satisfactory indicia of reliability" of statements).

Contrary to the ALJ's finding, the evidence shows that the pharmacist was a disinterested witness to the event. While the ALJ reasoned that the issue of bias is not entirely speculative because "[a] pharmacist would generally be motivated to inform DEA of compliance with applicable laws and regulations," ALJ at 35 (citing 21 CFR 1306.04(a)), the ALJ was unconvinced by the Investigator's testimony that the prescriptions were not dispensed. ALJ at 35. As reason for rejecting the Investigator's testimony, the ALJ observed that the prescriptions "bear no . . . objective markings consistent with a rejected prescription" and the absence of a notation on the prescriptions reflecting the substance of the pharmacist's "conversation with Respondent, to include such basic information as time, date, telephone number and signature of the pharmacist." Id. at 36.

However, the ALJ ignored the Investigator's testimony that as early as June 3, 2008, she was contacted about the prescriptions by the State Inspector, whom the pharmacist had initially

called about the prescriptions. In addition, the ALJ ignored the Investigator's testimony that she contacted the pharmacy and obtained the prescriptions that same day, which is corroborated by the fax header on the prescriptions.

As related by the Investigator, the contents of the pharmacist's conversation with Respondent clearly established that Respondent had failed to perform a physical examination on H.B. and that the two prescriptions lacked a legitimate medical purpose and were issued outside of the usual course of professional practice. See United States v. Nelson, 383 F.3d 1227 (10th Cir. 2004)._Thus, by relating the phone conversation the pharmacist had with Respondent to the Agency's Investigator, the pharmacist would have exposed herself to criminal (as well as administrative) liability if she had, in fact, filled the prescriptions. Beyond this, unexplained by the ALJ is why a person who had committed a criminal act by filling the prescriptions would then voluntarily (and without solicitation) report themselves to the law enforcers.

Here, the Investigator testified that the prescriptions were not filled. Moreover, the Investigator obtained from the South Carolina PMP a list of the prescriptions which were dispensed by South Carolina pharmacies which were issued under Respondent's registration. The Investigator testified that she then verified the data by obtaining the actual prescriptions from the respective pharmacies and prepared a spreadsheet. The spreadsheet does not, however, list any dispensings by the Chapin Pharmacy of prescriptions issued under Respondent's registration, let alone dispensings to this particular person (H.B.).

The ALJ discounted the clear and unequivocal testimony of the Investigator, reasoning that the prescriptions lacked any markings that they had been rejected (such as having been crossed-out), as well as any notations regarding the phone conversation. It is true that sometimes a pharmacist will line-through a prescription, or otherwise may note on it, that she has

pharmacist declines to fill a prescription, she is required under either the South Carolina Board of Pharmacy's regulations or the standards of pharmacy practice to either line-through the prescription or make a notation on it. Indeed, given the undisputed evidence that the pharmacist reported the incident to the State authorities contemporaneously with the incident and provided copies of the prescriptions to them at the time of her report, one must wonder why it would then be necessary to line out the prescriptions or document the phone conversation on them.¹⁵

The ALJ further surmised that that it was "uncertain as to which telephone number Ms. Owen used to confirm the prescription, leaving significant doubt as to whether a call was placed to Respondent or someone associated with Telemed." ALJ at 36. In support of this reasoning, the ALJ noted the testimony of the Investigator that the pharmacist was not sure which phone number she had used to reach Respondent. <u>Id.</u> The ALJ further explained that he gave "little to no weight to the telephone number written on the bottom of" one of H.B.'s prescriptions, because the DI testified that she did "not know specifically where that number would call." <u>Id.</u> at n.41 (quoting Tr. 103).

The ALJ's reasoning is simply a makeweight as only two phone numbers are listed on the prescriptions and there is substantial evidence that both phone numbers were used by Respondent. As for the number that was printed on the prescriptions, it was undisputed that this was either Respondent's (or his wife's cell-phone) number. And as for the number handwritten at the bottom of one of the prescriptions, notwithstanding the DI's testimony that she did "not know specifically where that number would call," Tr. 103, the record establishes that Respondent

¹⁴ The prescriptions were dated May 30, 2008, and the testimony indicated that the pharmacist was not able to speak to Respondent until June 2, 2008. According to a 2008 calendar, May 30th was a Friday, and June 2nd was a Monday.

¹⁵ Indeed, she may have done so after faxing the prescriptions to the Investigator.

used this number on the prescriptions he issued to family members. Given the absence of any other phone numbers on the prescriptions, I am reasonably confident that the pharmacist did, in fact, reach Respondent and not someone at Secure Telemed.

However, there are other reasons why the pharmacist's statements that Respondent verified writing the prescription for H.B. and did not physically examine her cannot be given weight. While the DI testified that she had contacted the pharmacy in June 2008 upon receiving the report from the State Inspector and that she obtained the prescriptions, she offered no testimony that she had interviewed the pharmacist on that occasion, and her testimony suggests that the pharmacist's statements were not made to her until the interview she conducted one week before the hearing, more than three years after the incident. Nor did the DI offer any testimony to support the conclusion that the pharmacist accurately recollected the incident, ¹⁶ and most importantly, the statements attributed to Respondent. Thus, the hearsay statements of the pharmacist cannot be deemed to be sufficiently reliable to constitute substantial evidence.

Nonetheless, there is other substantial evidence which supports the conclusion that Respondent, notwithstanding his denial of having done so, wrote or authorized the prescriptions issued to the non-Tennessee residents. The same DI testified that she had prepared a spreadsheet of the prescriptions that were filled by the South Carolina pharmacies (GX 17).

Moreover, the DI testified that while she initially obtained a printout from the South Carolina PMP, she then proceeded to obtain copies of the prescriptions from the pharmacies to verify the information contained in the PMP report. On cross-examination, Respondent's counsel asked the Investigator whether "other than [Respondent's] name being on those, you

State Inspector or better yet the pharmacist herself.

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¹⁶ It may be that the pharmacist made a record of the incident. However, no such evidence was put forward by the Government. It may also be that the circumstances of the incident were so unusual, that the pharmacist accurately recalled Respondent's statements. Yet no evidence was put forward to support such a finding. It may also be that the pharmacist related Respondent's statements to the State Inspector; if so, the Government could have called the

don't have any information from any other source that he actually personally issued those prescriptions?" Tr. 111. The Investigator testified that "[o]n many of the faxed prescriptions that [were] presented at my South Carolina pharmacies, there is [a] notation written on them from the pharmacists that were working that day that they were verified with" Respondent. Id. The ALJ entirely ignored this testimony.

In addition, according to both Agency Investigators who interviewed him in June 2009, Respondent volunteered information to the effect that following the receipt of a phone call from a South Carolina pharmacy questioning a prescription, he quit Secure Telemedicine after the entity's Medical Director "could not provide verification that he could do this legally in other [S]tates." Tr. 194; see also id. at 425 (testimony that Respondent said that "he had become concerned that . . . this wasn't right, . . . he was not involved in the right thing to do because Secure Telemedicine could not provide documentation to him that it was legal to operate in . . . the other [S]tates."). Obviously, if Respondent was only writing prescriptions for Tennessee residents, there was no need for him to verify with Secure's Medical Director whether it was legal to write prescriptions for patients in other States.

Both Investigators also testified that Respondent was told that he was under investigation for prescribing controlled substances to persons in other States and with whom he did not establish a legitimate doctor-patient relationship, and that Respondent replied that he "kind of knew what this was about." Tr. 190; see also id. at 422 ("I thought I knew why you wanted to talk to me."). In addition to Respondent's statement set forth above, the Investigators testified that Respondent admitted to having worked for Secure Telemedicine and stated that he was surprised to receive a phone call from a South Carolina pharmacy because it was his

¹⁷ To refute the DI's testimony, Respondent could have requested a subpoena requiring the Government to produce the actual prescriptions and sought a continuance of the proceeding. He did not.

understanding that all of the prescriptions were being filled by a fulfillment pharmacy.¹⁸ Moreover, according to both Investigators, at no point during the interview did Respondent claim that his internet prescribing activities were limited to Tennessee residents, <u>id</u>. at 423, or deny that he had prescribed to out-of-state patients. <u>Id</u>. at 195.

The ALJ declined to give weight to the testimony of the Investigators reasoning that "the Government presented no evidence that any of the investigators specifically asked Respondent whether he issued out-of-state prescriptions while he worked at Telemed." ALJ at 38. ¹⁹ In addition, the ALJ reasoned that "Respondent was not provided with any of the prescriptions in question during his . . . interview." Id.

Yet, the evidence is clear that Respondent was told that he was being investigated for prescribing controlled substances to out-of-state patients with whom he did not establish a doctor-patient relationship. While this statement may not have been framed as a question, it nonetheless was an accusation, and indeed, Respondent was under no illusion that it was not such, as immediately prior to it, he had been told that he had the right to remain silent and was not under arrest. And given its serious nature, one would expect that if it was not true, Respondent would have "clearly challenge[d] the accuracy of the accusation." McCormick on Evidence §160, at 426 (Edward W. Cleary, ed., 3d ed. 1984). Yet he did not do so.

¹⁸ Here again, if Respondent was writing prescriptions only for Tennessee patients, it begs the question of why it was his understanding that the Secure Telemed scheme was using a fulfillment pharmacy, such as the pharmacy which was located in Colorado. See Tr. 121. As the Agency's Investigator explained, the use of a fulfillment pharmacy was a common feature of unlawful internet prescribing schemes. Id. at 120.

¹⁹ The ALJ did not, however, find the testimony of either Investigator to be incredible. See generally ALJ at 36.

²⁰ Notably, Respondent did not remain silent in the face of the accusation. As for the ALJ's assertion that Respondent's failure to deny the accusations is not entitled to weight because the accusation was not framed as a question, the ALJ cited no authority to support this proposition. See <u>United States</u> v. <u>Ward</u>, 377 F.3d 671, 675 (7th Cir. 2004) ("[A] <u>statement</u> may be adopted as long as the statement was made in the defendant's presence, the defendant understood the statement, and the defendant has the opportunity to deny the statement but did not do so.") (emphasis added).

Moreover, the two Investigators further testified that Respondent volunteered that he quit working for Secure Telemed after its Medical Director "could not provide verification that he could do this legally in other states." Tr. 194; see also id. at 425. This testimony is entirely consistent with Respondent's failure to challenge the Investigators' accusation. Indeed, given the vehemence of his denial at the hearing of having written prescriptions for out-of state patients or having authorized their issuance, one must wonder why a similarly forceful denial did not occur during the June 2009 interview. And because it is clear that Respondent knew what the nature of the accusation was, it is of no consequence that the Investigators did not show him any specific prescriptions.

The ALJ likewise ignored the inherent implausibility of Respondent's testimony regarding his employment as "an on-call covering physician" under Secure Telemed's "Consult-A-Doc program." Tr. 298. According to Respondent, he would inform the company of when he was available "to cover on-call for physicians after hours or when a physician [was] just unavailable to manage the care of their patients." <u>Id</u>.

In his letter requesting a hearing, Respondent asserted that "Secure contracted with primary care physicians in Tennessee . . . to provided coverage by other licensed physicians in their respective jurisdiction when the primary care physician was unavailable to attend to the needs of their established patients." ALJ Ex. 2. Yet, if Tennessee physicians were entering into contracts with Secure, it begs the question of why Respondent was not informed, at the start of his shift, of the names of the doctors for whom he was providing on-call coverage. Notably, in describing his activities for Secure, Respondent offered no testimony to the effect that he was told at the start of his shifts the names of the physicians for whom he was providing on-call

coverage, and indeed, Respondent testified that he would review the patient's medical record and then verify with the office of the patient's primary care doctor that the latter was unavailable.

Respondent also testified that the patients had already provided their medical records to Secure Telemedicine at the time he took their phone call. Unexplained by Respondent is why the patients would have known to obtain their medical records if he was merely covering for a physician "after hours." Id. Likewise, Respondent testified that his activities were limited to "triag[ing]" patients in "non-emergency situations" and that he only issued refills for them. Id. at 299-300, 302. Yet if he was only providing coverage "after hours," it does not seem likely that he could have verified at that time with the office of the patient's primary care physician that the latter was unavailable and Respondent did not explain why, if he was only triaging patients "in a non-emergency situation," he did not simply instruct the patients to contact their primary care physician the next morning.

Respondent further asserted that there would be occasions where a patient's primary care physician would be on vacation and not be back until the "next week." <u>Id.</u> at 302. Given his testimony that he only issued refills for patients with "a chronic ailment," <u>id.</u> at 301, here again, Respondent offered no explanation as to why the patient's primary care doctor would not know in advance of when he/she would be on vacation and provide the patient with either a refill or an additional prescription to ensure that the patient had an adequate quantity of medication and did not run out.

Moreover, when confronted with evidence that the primary care physicians of two

Tennessee patients to whom he prescribed had never heard of him and that they had other

physicians in their group who would take calls for them, Respondent then denied either writing
the prescriptions or explained that he "really didn't have any contact" with any group practice.

<u>Id</u>. at 301. However, Respondent claimed that "[s]ome doctors who are in private practice . . . a lot of them don't have call coverage or they have problems finding physicians with call coverage." <u>Id</u>. Were I to credit Respondent's testimony, I would have to believe that the physicians he purportedly took calls for, had contracted with an entity that was not even located in Tennessee, and entrusted it to place the care of their patients in the hands of physicians they did not know, let alone had never met.²¹ And while Respondent maintained that he had prepared a consult note for each patient for whom he wrote a prescription, and asserted that Secure Telemed forwarded the note on to the patient's primary care physician, he did not recall having ever been called by the primary care physician of a Secure Telemed patient. <u>Id</u>. at 408-09. Nor did he testify that he called the patients' primary care physicians to inform them that he had issued a prescription to their patients.

Notably, Respondent produced no evidence to corroborate any of his far-fetched story. See Chirino v. NTSB, 849 F.2d at 1530. He did not maintain patient records, see Tenn. Comp. R. & Regs. R. 0880-02-.14(2)(b)(3), nor even document any of the phone calls he claimed to have made to the offices of the patient's primary care physicians. And when asked to review the Tennessee PMP report and identify any of the persons who were Secure Telemed patients, he could not identify a single one.

I therefore conclude that Respondent's testimony is so inherently implausible that no reasonable factfinder could find it to be true. <u>Anderson</u>, 470 U.S. at 575; <u>Lathern</u>, 665 F.3d at 1354; <u>Chirino</u>, 849 F.2d at 1530. I thus reject the ALJ's findings that Respondent credibly

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²¹ Also unexplained is why the physicians would entrust the care of their patients to physicians who were unlikely to have privileges at the same hospitals where they had privileges.

denied either issuing or authorizing the issuance of any controlled substance prescriptions to persons located outside of the State of Tennessee.²²

I therefore hold that because Respondent failed to perform a physical examination of the patients located in Mississippi, North Carolina, and South Carolina, he did not establish a legitimate doctor-patient relationship with them and thus lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing controlled substances to them.²³ See Miss. Code Ann. § 41-29-137; North Carolina Medical Board, Contact with patients before prescribing, at 1 (Nov. 1999); S.C. Code Ann. § 40-47-113.

Moreover, "[a] physician who engages in the unauthorized practice of medicine is not a 'practitioner acting in the usual course of . . . professional practice.' . . . A controlled-substance prescription issued by a physician who lacks the license necessary to practice medicine within a State is therefore unlawful under the CSA." <u>United Prescription Services, Inc.</u>, 72 FR 50397, 50407 (2007)) (citations omitted). <u>See also 21 U.S.C. 802(21)</u> ("[t]he term 'practitioner' means a physician . . . licensed, registered, or otherwise permitted, by the United States or the

²² The ALJ also found that while Respondent did not perform physical examinations on the Tennessee patients, the Government failed to prove that Respondent had violated Tennessee regulations because it did not show "that Respondent was not exempt under Tenn. Comp. R. & Regs. 0880-2-.14(7)(b)" from the requirements that he perform a physical examination. ALJ at 39. Under this provision, "[a] physician . . . may prescribe or dispense drugs for a person not in compliance with [the requirement that he perform a physical examination] consistent with sound medical practice . . . [f]or a patient of another physician for whom the prescriber is taking calls or for whom the prescriber has verified the appropriateness of the medication[.]" Tenn. Comp. R. & Regs. 0880-2-.14(7)(b).

The Government offered no expert testimony as to whether Respondent's internet prescribing was "consistent with sound medical practice." Id._Nor did it cite to any state authority such as a decision of either the Tennessee Courts or Board of Medicine explaining what constitutes compliance with the provision authorizing a prescription where "the prescriber has verified the appropriateness of the medications." Id. I therefore do not find the allegations of the Show Cause Order proved with respect to Respondent's Tennessee patients.

²³ The ALJ also noted that some of the signatures on the Secure Telemed prescriptions differed from those on the prescriptions Respondent issued to his family members. See ALJ at 33. Be that as it may, it provides no comfort to Respondent because he testified that he did not actually sign any of the prescriptions he approved for Secure Telemed but simply pushed a button on his computer approving the prescriptions, which was then prepared by someone at Telemed. Tr. at 304 & 414. Indeed, Respondent's failure to sign the prescriptions (even those he admits to issuing) is itself a violation of the CSA. See 21 CFR 1306.05(a) ("The prescriptions may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations.") (emphasis added).

jurisdiction in which he practices . . . to . . . dispense . . . a controlled substance."). As the Supreme Court has explained: "In the case of a physician [the CSA] contemplates that <u>he is authorized by the State to practice medicine</u> and to dispense drugs in connection with his professional practice." <u>United States</u> v. <u>Moore</u>, 423 U.S. 122, 140-41 (1975) (emphasis added) (quoted in <u>United Prescription Services</u>, 72 FR at 50407).

Here, it is undisputed that Respondent is licensed only in Tennessee. Accordingly, he engaged in the unauthorized practice of medicine by prescribing controlled substances to patients located in the States of South Carolina, North Carolina and Mississippi and therefore acted outside of the usual course of professional practice for this reason as well. See S.C. Code Ann. § 40-47-20(36) (b) & (e) (defining practice of medicine); id. § 40-47-200 (prohibiting practicing medicine without a license); N.C. Code Ann. § 90-1.1(5) (defining practice of medicine); id. § 90-18 (prohibiting practice of medicine without a license); Miss. Code Ann. § 73-25-33 (defining practice of medicine); id. § 73-25-34 (prohibiting practice of telemedicine without a state license).

Moreover, even were I to adopt the ALJ's finding that the Government did not prove that the "prescriptions were issued by Telemed with Respondent's knowledge or authorization," ALJ at 32, that would not be the end of the matter as far as the Secure Telemed prescriptions.

Contrary to the ALJ's understanding, DEA's authority to revoke a registration is not limited to those instances in which "Respondent knowingly issued . . . or . . . authorized Telemed to issue . . . prescriptions on his behalf." Id.

Rather, this Agency has long held that a registrant is strictly liable for the misuse of his registration by any person to whom he entrusts his registration. See Scott C. Bickman, 76 FR 17694, 17703 (2011); Harrell E. Robinson, 74 FR 61370, 61376-77 (2009); Paul Volkman, 73

FR 30630, 30644 & n.42 (2008); Rose Mary Jacinta Lewis, 72 FR 4035, 4040 (2007); Anthony L. Capelli, 59 FR 42288 (1994). Having provided his registration number to Secure Telemedicine, and having no effective means of supervising its employees to ensure that his number was not being misused, Respondent is liable for the issuance of all of the prescriptions Secure Telemedicine issued under his registration as if he had personally authorized them.²⁴

Moreover, Respondent testified that he never visited Secure's office nor interviewed face-to-face with principals. He also offered no testimony as to any due diligence he had performed. Respondent's total failure to take any steps to determine whether Secure was a legitimate enterprise manifests a level of irresponsible behavior that is fundamentally incompatible with holding a DEA registration.²⁵

The ALJ totally ignored this line of authority. <u>See ALJ 32</u>. I conclude, however, that this conduct is sufficiently egregious to warrant the revocation of Respondent's registration.²⁶

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Moreover, at the time Respondent entered into his contract with Secure Telemedicine, this Agency had already issued several final orders finding that the prescribing of controlled substances under similar circumstances (<u>i.e.</u>, through the internet and/or a telephone consultation) violated Federal law. <u>See, e.g., William R. Lockridge, M.D., 71 FR 77791, 77798 (2006)</u> (discussing expert testimony regarding steps necessary to establish a doctor-patient relationship, as well as guidelines published by the Federation of State Medical Boards and the American Medical Association, and DEA's 2001 Guidance Document, <u>Dispensing and Purchasing Controlled Substances Over the Internet</u>, 66 FR 21181). <u>See also Dale L. Taylor</u>, 72 FR 30855 (2007); <u>Mario Avello</u>, 70 FR 11695, 11697 (2005). So too, numerous States had issued pronouncements establishing that such prescribing was unlawful.

²⁵ In <u>Bickman</u>, I noted that "this is not a case where a practitioner simply provided his DEA registration to a health care facility as part of the credentialing process and a person at the facility subsequently used his registration for unlawful purposes." 76 FR at 17703 n.22. Given Respondent's total failure to perform due diligence, so too here.

²⁶ The evidence also showed that Respondent had prescribed phentermine to family members including his wife, sister, and mother- in-law. According to a Policy Statement of the Tennessee Board, "[t]reatment of immediate family members should be reserved only for minor illnesses or emergency situations," and "[n]o schedule II, III or IV controlled substances should be dispensed or prescribed except in emergency situations." Tennessee State Board of Medical Examiners, <u>Policy: Prescribing For Oneself And One's Family</u> 1 (Jan. 1997). The Board's statement does not, however, define the term "immediate family member," <u>see id.</u>, and the Government does not cite to any decision of either the Board or the Tennessee courts construing the term. While it would seem that Respondent's wife would fall within the definition, Respondent fully acknowledged his misconduct in prescribing phentermine to her. Thus, had this been the only allegation proven in the case, I would have adopted the ALJ's recommended sanction. For similar reasons, Respondent's failure to update his registered location would not warrant anything more than a reprimand.

Factor Five - Other Conduct Which May Threaten Public Health and Safety

Even were I to adopt the ALJ's findings and credit Respondent's testimony that he was unaware of the misuse of his registration until an April 2008 phone call from a South Carolina pharmacy, see ALJ at 37, the record supports a further finding that he engaged in other conduct which threatened public health and safety. While Respondent claimed that he reported the incident to the Tennessee Medical Board sometime in 2009 and well after the fact,²⁷ he did not notify DEA of the incident until the June 2009 interview.²⁸ Tr. 371-72. However, the record contains evidence establishing that numerous additional prescriptions were issued under his registration through Secure Telemed following the April 2008 phone call, many of which were filled. See GX 17, at 1 (spreadsheet listing multiple prescriptions filled by South Carolina residents); GX 8, at 5 (Pt. S.P.H.); GX 12, at 3-4 (Pt. E.F.); GX 14, at 1-2 (Pt. H.B.); GX 15, at 15 (Pt. K.P.); GX 6, at 9 (entry for patient for E.F. showing additional hydrocodone prescription filled on 8/4/08).

Thus, even crediting his testimony, Respondent was aware that his registration was being used for criminal purposes, and yet did nothing to prevent this. See 21 U.S.C. 822(a) (requiring registration to lawfully dispense a controlled substance) and § 841(a)(1) ("Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally . . . to . . . distribute[] or dispense . . . a controlled substance[.]"); see also id. § 843(a)(2) ("It shall be

²⁷ Respondent initially testified that he did not file the report with the State until June 2009 (the same month that he was interviewed by DEA Investigators). Tr. 372. Respondent then stated that he could not recall the exact month although it was sometime in 2009. <u>Id</u>. Respondent did not, however, maintain a copy of the report. <u>Id</u>.

²⁸ Contrary to the ALJ's understanding, <u>see ALJ</u> at 43-44, Respondent's claim that he reported the misuse of his DEA registration to the State authorities (approximately one year after the incident) neither mitigates his misconduct nor manifests that he accepts responsibility. State authorities did not issue his DEA registration and obviously have no authority to cancel a registration issued by an Agency of the federal government. Moreover, the lengthy delay in his reporting of the incident is consistent with the conduct of someone who has something to hide.

unlawful for any person knowingly or intentionally . . . to use in the course of the . . . distribution[] or dispensing of a controlled substance, . . . a registration number which is . . . issued to another person."). His failure to inform the Agency of the unlawful use of his registration²⁹ led to additional acts of diversion of controlled substances and constitutes "other conduct which . . . threaten[s] the public health and safety." 21 U.S.C. 823(f)(5).

I thus conclude that this factor also supports a finding that Respondent has committed acts which render his registration inconsistent with the public interest. 21 U.S.C. 824(a)(4).

SANCTION

Under Agency precedent, where, as here, the Government has made out a prima facie case that a registrant has committed acts which render his registration "inconsistent with the public interest," he must "'present[] sufficient mitigating evidence to assure the Administrator that [he] can be [en]trusted with the responsibility carried by such a registration." Samuel S.

Jackson, 72 FR 23848, 23853 (2007) (quoting Leo R. Miller, 53 FR 21931, 21932 (1988)).

"Moreover, because 'past performance is the best predictor of future performance,' ALRA Labs., Inc. v. DEA, 54 F.3d 450, 452 (7th Cir. 1995), this Agency has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct."

Medicine Shoppe-Jonesborough, 73 FR at 387. As the Sixth Circuit has recognized, this Agency also "properly considers" a registrant's admission of fault and his candor during the investigation and hearing to be "important factors" in the public interest determination. See Hoxie, 419 F.3d at 483.

²⁹ Had Respondent reported the misuse of his registration, the Agency could have - with his agreement - cancelled his number and posted this information in the database which the Agency makes available to other registrants for verifying the validity of another person's registration. However, short of issuing an Immediate Suspension Order, the Agency could not have indicated in the database that he did not have a valid registration.

More recently, the Tenth Circuit upheld the Agency's rule, explaining that:

When faced with evidence that a doctor has a history of distributing controlled substances unlawfully, it is reasonable for the . . . Administrator to consider whether that doctor will change his behavior in the future. And that consideration is vital to whether [his] continued registration is in the public interest. Without Dr. MacKay's testimony, the . . . Administrator had no evidence that Dr. MacKay recognized the extent of his misconduct and was prepared to remedy his prescribing practices.

MacKay, 664 F.3d at 820.

Here, the ALJ found that the Respondent "fully accepted responsibility" for his misconduct. ALJ at 43. Yet this conclusion was premised on the ALJ's finding that Respondent did not write any of the out-of-state prescriptions, a finding which I reject. As explained above, the record as a whole contains substantial evidence that Respondent, notwithstanding his testimony to the contrary, issued numerous controlled substance prescriptions to out-of-state patients, with whom he did not establish a legitimate doctor-patient relationship, and that he acted outside of the usual course of professional practice because he engaged in the unauthorized practice of medicine. Because Respondent failed to accept responsibility for this aspect of his misconduct, which was the most egregious of the various types of misconduct he engaged in, and continues to deny doing so, I conclude that he has not rebutted the Government's <u>prima facie</u> case. Accordingly, I will order that Respondent's registration be revoked and that any pending application be denied.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR

0.100(b), I order that DEA Certificate of Registration BD8297461, issued to Kevin Dennis,

M.D., be, and it hereby is, revoked. I further order that any pending application of Kevin

Dennis, M.D., to renew or modify his registration, be, and it hereby is denied. This Order is

effective [INSERT DATE THIRTY DAYS FROM DATE OF PUBLICATION IN THE

FEDERAL REGISTER].

Dated: August 17, 2013

Michele M. Leonhart Administrator

[FR Doc. 2013-20677 Filed 08/23/2013 at 8:45 am; Publication Date: 08/26/2013]

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