Respondent alternatively asks that I consider suspending her registration instead of revoking her registration. This exact issue was addressed in *James L. Hooper, M.D.; Decision and Order.*[3] Dr. Hooper was subject to a one-year suspension of his state license to practice medicine after which his license would be automatically reinstated.[4] In comparison to *Hooper,* Respondent in this case has a less persuasive case as there is no guarantee that her advanced practice nurse prescriptive authority will be restored after 90 days. Dr. Hooper sought a suspension of his DEA Registration for the same time period his medical license was suspended. DEA Administrator Michele M. Leonhart agreed with Chief Administrative Law Judge John J. Mulrooney, II who did not find Dr. Hooper's argument persuasive. Administrator Leonhart, like Respondent in the case at hand, cited to *Anne Lazar Thorn, M.D.*[5] Administrator Leonhart cites the Acting Deputy Administrator's statement in *Thorn* that ''the controlling question is not whether a practitioner's license to practice medicine in the state is suspended or revoked; rather, it is whether the Respondent is currently authorized to handle controlled substances in the state.'' [6] In *Hooper,* Administrator Leonhart concludes that ''even where a practitioner's state license has been suspended for a period of certain duration, the practitioner no longer meets the statutory definition of a practitioner.'' [7] As detailed above, only a ''practitioner'' may receive a DEA registration. Therefore, I cannot and will not recommend the suspension of Respondent's DEA registration, but will instead recommend the registration be revoked.

Order Granting the Government's Motion for Summary Disposition and Recommendation

I find there is no genuine dispute regarding whether Respondent is a ''practitioner'' as that term is defined by 21 U.S. C. 802(21), and that based on the record the Government has established that Respondent is not a practitioner and is not authorized to dispense controlled substances in the state in which she seeks to practice with a DEA Certificate of Registration. I find no other material facts at issue. Accordingly, I GRANT the Government's Motion for Summary Disposition.

Upon this finding, I ORDER that this case be forwarded to the Administrator for final disposition and I recommended that Respondent's DEA Certificate of Registration should be REVOKED and any pending application for the renewal or modification of the same should be DENIED.

Dated: March 9, 2015

Christopher B. McNeil,

Administrative Law Judge

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[3] *James L. Hooper, M.D.; Decision and Order,* 76 FR 71371–01, 71371 (DEA Nov. 17, 2011).

[4] *Id.*

[5] *Anne Lazar Thorn, Revocation of Registration* M.D, 62 FR 12847, 12848 (DEA Mar. 18, 1997).

[6] *Id.* at 12848.

[7] *Hooper,* 76 FR at 71372.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Bobby D. Reynolds, N.P., Tina L. Killebrew, N.P. and David R. Stout, N.P.; Decision and Orders

On November 25, 2013, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued Orders to Show Cause to Bobby D. Reynolds, N.P. (hereinafter, Reynolds), of Limestone, Tennessee; Tina L. Killebrew, N.P. (hereinafter, Killebrew), of Kingsport, Tennessee; and David R. Stout, N.P. (hereinafter, Stout), of Morristown, Tennessee. GXs A, B, & C.

With respect to Applicant Reynolds, the Show Cause Order proposed the denial of his application for registration as a practitioner, on the ground that his registration ''would be inconsistent with the public interest'' as evidenced by his repeated violations of state and federal law in prescribing controlled substances to seven patients while employed as a nurse practitioner at the Appalachian Medical Center (AMC), a clinic located in Johnson City, Tennessee. GX A, at 1–2 (citing 21 U.S.C. 823(f)(2), (4) & (5)). The Show Cause Order alleged that he had made unintelligible entries in the medical records of three patients (N.S., T.H., and A.W.), that he had violated state law by referring N.S. to an unlicensed mental health counselor, that he had violated state law by making false entries in N.S.'s chart, that he had failed to maintain complete records for T.H., and that he failed to properly maintain the patient record of C.S. to accurately reflect nursing problems and interventions. GX A, at ¶¶ 5, 6, 7, 11, 12, and 15.

With respect to Applicant Killebrew, the Show Cause Order proposed the denial of her application for registration as a practitioner, on the ground that her registration ''would be inconsistent with the public interest'' as evidenced by her repeated violations of state and federal law in prescribing controlled substances to three patients while employed as a nurse practitioner at the AMC. GX B, at 1–2 (citing 21 U.S.C. 823(f)(2)(4) & (5)).

With respect to Registrant Stout, the Show Cause Order proposed the revocation of his practitioner's registration and the denial of his pending application to renew his registration on two grounds. GX C, at 1–2. First, the Order alleged that Respondent had materially falsified his renewal application when he failed to disclose that on March 10, 2010, the Tennessee Board of Nursing had summarily suspended his nurse practitioner's license and his Certificate of Fitness to prescribe legend drugs in Tennessee. GX C, at 13–14; *see also* 21 U.S.C. 824(a)(1). The Show Cause Order further alleged that Registrant Stout had failed to disclose that on September 3, 2010, he had entered into a Consent Order with the State Board, pursuant to which the suspension was terminated, but he was placed on probation for two years, his multistate privilege to practice in other party states was voided for the period of his probation, he was ordered to pay a civil penalty of $8,000, and other probationary terms were imposed. GX C, at 14. Second, the Show Cause Order alleged that Registrant Stout had ''committed such acts as would render his registration inconsistent with the public interest,'' in that he had violated state and federal law in prescribing controlled substances to five patients while employed as a nurse practitioner at the AMC.[1]

Following service of the Show Cause Orders, all three individuals timely requested a hearing on the allegations of the respective Order. The matters were then placed on the docket of the Agency's Office of Administrative Law Judges, and assigned to the Chief Administrative Law Judge, who consolidated the matters and proceeded to conduct prehearing procedures. However, after extensive prehearing litigation, each of the parties filed written notices waiving his/her respective right to a hearing, *see* GXs LL, MM, and PP, and the ALJ terminated the proceeding.[2]

[1] Each Show Cause Order made extensive and detailed allegations specific to each Applicant's conduct, as well as to Registrant Stout's conduct, in prescribing to the various patients. *See* GX A, at 2–26 (Reynolds OTSC); GX B, at 2–9 (Killebrew Order); GX C, at 2–14 (Stout Order). In its Request for Final Agency Action, the Government pursued only the allegations of unlawful prescribing by the three practitioners, as well as the allegations (which were raised in its prehearing statements) that Applicant Reynolds had made material false statements to a DEA Investigator.

[2] On March 27, 2014, NP Stout, through counsel, submitted a written request to the Government's counsel seeking to withdraw his application to renew his registration. GX RR. Government Counsel promptly forwarded the request to the Deputy Assistant Administrator. GX SS. According to Government Counsel, no action had been taken on the request as of September 16, 2014, the date on which the record was forwarded to this Office. *Id.* Nor has this Office been subsequently notified of any action having been taken on the request.

I conclude that granting Stout's request to withdraw would be contrary to the public interest and that he has otherwise failed to show good cause. Here, the Government has expended extensive resources in investigating the allegations, preparing for a hearing, and in engaging in pre-hearing litigation; it was also fully prepared to go to hearing on the allegations when Stout waived his right to a hearing. Moreover, Stout's counsel has made no offer as to how long he would wait before

Continued

Thereafter, the Government filed a Request for Final Agency Action and forwarded the entire record to my Office for review. Having reviewed the entire record, I find that the Government has established that Registrant Stout has committed such acts as would render his registration ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). Accordingly, I will order that the registration issued to Registrant Stout be revoked and that his pending application to renew his registration be denied. I further find that the Government has established that granting a new registration to Applicants Reynolds and Killebrew would be ''inconsistent with the public interest.'' *Id.* § 823(f). Therefore, I will also order that their respective applications be denied. I make the following findings of fact.

Findings

Jurisdictional Facts

In 2002, Applicant Bobby D. Reynolds II, FNP, founded the Appalachian Medical Center, a clinic located in Johnson City, Tennessee; Reynolds owned the clinic until 2010, when it was closed. GX 42, at 2–3. Reynolds employed both Applicant Killebrew and Registrant Stout at AMC. *Id.*

Reynolds was previously registered under the Controlled Substances Act as a Mid-Level Practitioner, with authority to dispense controlled substances in schedules II–V at the registered address of the AMC, which was located at 3010 Bristol Highway, Johnson City, Tennessee. GX 1, at 1. However, this registration expired on April 30, 2011. On May 19, 2011, Reynolds filed a renewal application; it is this application which is the subject of the Show Cause Order issued to him. *Id.*

Tina L. Killebrew, F.N.P., was employed as a nurse practitioner at AMC from approximately June 2006 through March 11, 2010. GX L, at 13–14 (Brief in Response to Amended Order December 30, 2013). She was also previously registered as a Mid-Level Practitioner with authority to dispense controlled substances in schedules II–V at AMC's address. *Id.* at 11. However, this registration expired on December 31, 2010. On or about August 30, 2011, Killebrew submitted an application for a new registration; it is this application which is the subject of the Show Cause Order issued to her. *Id.*

David R. Stout, N.P., currently holds DEA Certificate of Registration MS0443046, pursuant to which he is authorized to dispense controlled substances in schedules II–V as a Mid-Level Practitioner at the registered address of the AMC. GX 1, at 6. While his registration was due to expire on February 28, 2011, on February 16, 2011, Stout filed a renewal application. Accordingly, his registration remains in effect pending the final order in this matter. *Id.*

The Government's Evidence of Misconduct

In support of the allegations, the Government submitted patient files for seven patients, pharmacy records for four patients, along with various other documents. The Government also provided these materials to Amy Bull, Ph.D., a Board Certified Family Nurse Practitioner, who is licensed in Tennessee as both an Advanced Practice Nurse and Registered Nurse. GX 40, at 2–3. Dr. Bull is an Assistant Professor of Nursing at the Belmont University School of Nursing and previously taught at the Vanderbilt University School of Nursing, where she served as Director of the Family Nurse Practitioner Program, was the coordinator for courses in Advanced Pharmacotherapeutics and Health Assessment & Diagnostic Reasoning, and taught various courses. *Id.* at 1. Dr. Bull also continues to practice as a Nurse Practitioner at a clinic in Dickinson, Tennessee. *Id.* at 2.

Dr. Bull reviewed seven patient files. GX 68, at 6–7. Based on her review, Dr. Bull concluded that Reynolds, Killebrew, and Stout acted outside of the usual course of professional practice and lacked a legitimate medical purpose in prescribing controlled substances to the patients, *see* 21 CFR 1306.04(a), and also violated Tennessee Board of Nursing Rule 1000–04.08, which sets forth the standards of nursing practice for prescribing controlled substances to treat pain. *Id.* at 7–8. Dr. Bull specifically found that Reynolds, Killebrew and Stout ''repeatedly issued prescriptions . . . in the face of red flags that should have indicated to him [or her] that these individuals were abusing and/or diverting controlled substances and without taking appropriate action to prevent further abuse and/or diversion,'' and that in doing so, ''their conduct fell far below the standard of care in Tennessee and [was] contrary to generally recognized and accepted practices of a nurse practitioner in Tennessee.'' *Id.* at 8. What follows below is a discussion of the evidence with respect to patients N.S., T.H. and C.S.

N.S.

N.S.'s first visit to AMC was on June 8, 2004, when she presented complaining of neck and back pain. *See* GX 2, at 102. N.S. apparently was seen on this visit by a practitioner other than Mr. Reynolds,[3] Mr. Stout, or Ms. Killebrew. *See* GX 3, at 129–130. This practitioner specifically noted that N.S. had a ''tender neck and low back with decreased range of motion, low back tender to light touch'' and prescribed a thirty-day supply of thirty tablets of Avinza 60 mg (morphine, a schedule II drug), as well as Zanaflex, which is a non-controlled muscle relaxant. *See* GX 2, at 102; GX 3, at 129.

According to the Expert, the documentation contained in N.S.'s file did not support the prescribing of a thirty-day supply of Avinza 60 mg and the prescription was below the standard of care in Tennessee and outside the usual course of professional practice. GX 68, at 8. As the Expert noted, N.S.'s file contains radiologic reports (CT scans and plain radiographs of the neck and lower back) from June 28, 2001 which appear to have been generated in connection with N.S.'s prior visit to the emergency room (''ER'') due to a motor vehicle collision and which described previous surgery to the neck and degenerative changes in the lower back. *See id.* at 8–9; GX 2, at 116–120.

However, as the Expert then explained, these records were from examinations that were performed nearly *three years* before N.S.'s first AMC visit. GX 68, at 9. The Expert then observed that N.S.'s file lacked any documentation indicating what, if any, treatment she had received since the accident, nor contain any records of any prior treating physicians, nor any documentation relating to her substance abuse history. *Id.* Of further note, the Expert observed that N.S. did not list any medication she was then taking on the ''New Patient Information Sheet'' which she apparently completed at her first visit, *see* GX 2, at 9–10; and the record of her first visit does not document the she was taking any medications. *Id.* at 102; GX 68, at 9.

reapplying. *See* GX RR (''This proposal is in the public's interest because it saves time and money for valuable employees and staff. There will be no need to review documents, there will be no need to issue decisions and there will be no delay in Mr. Stout being able to show his good faith in hopes of someday being able to reapply.''). Finally, having reviewed the evidence, I conclude that the public interest would be ill-served by allowing him to withdraw his application and thereby avoid the findings of fact and conclusions of law which are clearly warranted by the evidence.

[3] According to the Expert, while Mr. Reynolds did not see N.S. at her June 8, 2004 visit, he had clearly reviewed the record of this visit as at the bottom of the visit note, there is a handwritten marking which, based on her review of the patient files, the Expert determined was the signature, or abbreviated signature of Reynolds. *See* GX 2 (ID) at 102; GX 68, at 10.

According to the Expert, the absence of this information in the file indicates that the AMC practitioner did not know what, if any, controlled substances N.S. was then being prescribed, her complete pain history, whether she was suffering from any coexisting diseases or conditions, who her prior treating physicians were, whether she had ever tried non-controlled substances, or whether she had ever received other treatment modalities to address her reported pain, such as physical rehabilitation. GX 68, at 9. The Expert then concluded that absent this information, N.S. should not have been issued a controlled substance prescription on her first visit, especially a schedule II controlled substance such as Avinza, which is a long-acting formulation of morphine. *Id.* The Expert further explained that if a controlled substance such as Avinza had been indicated, the starting adult dose would have been only 30mg daily (rather than 60mg which was prescribed).[4] *Id.*

On July 7, 2004, N.S. returned to AMC for a follow-up, but now was complaining of a migraine headache. *See* GX 2, at 101. Again, N.S. was seen by a practitioner other than Reynolds, Stout, or Killebrew. *See* GX 3, at 130.

Notably, the record states that N.S. displayed ''Slurred speech + Somnolence,'' which, according to the Expert was a potential red flag that N.S. was abusing prescription drugs.[5] GX 68, at 10. The Expert noted that the record indicated that N.S. had Tachycardia, as her pulse rate was above the normal rate for adults (60–100 beats per minute) and was nearly 20 beats higher than at her previous visit. *Id.* at 11. According to the Expert, while Tachycardia occurs for a variety of reasons, it can be caused by drug withdrawal. *Id.*

The Expert noted that the attending practitioner properly ordered a Urine Drug Screen (UDS) for N.S. *Id.* According to the Expert, a UDS is a particularly useful tool when the practitioner is presented with a red flag indicating that the patient may not be in compliance, such as when the patient presents at the office exhibiting the behaviors N.S. did on this visit. *Id.* As the Expert explained, a UDS can assist the practitioner in determining whether the patient has been taking the drug(s) that the practitioner has prescribed and if the patient was ingesting non-prescribed controlled substances, including illicit substances. *Id.* Thus, UDS results help practitioners to determine whether a patient is abusing and/or diverting controlled substances. *Id.*

While this other practitioner appropriately ordered a UDS, according to the Expert, he then inappropriately issued to N.S. another prescription for thirty tablets of Avinza 60 mg at this visit. *Id.* at 11–12. As the Expert found, at this visit, N.S.'s file still lacked any information of her prior treatment history and substance abuse history. *Id.* at 12. According to the Expert, in the absence of this information, and in light of the fact that N.S. presented at this visit demonstrating slurred speech and somnolence, the issuance of the Avinza prescription was below the standard of care in Tennessee and outside the usual course of professional practice and actually medically contraindicated given the mental status changes documented in her record. *Id.* at 12. The Expert further explained that under the circumstances presented by N.S., the standard of care and usual course of professional practice required that the practitioner refer the patient for a comprehensive evaluation (the emergency room) to determine the underlying cause of the symptoms of her increased heart rate, slurred speech, and somnolence. *Id.* Moreover, the patient should not have received prescriptions (of any type) at this visit until medical clearance was provided that she was not experiencing drug intoxication or an acute neurologic event. *Id.* Moreover, because N.S. was not referred or transferred for further evaluation, she should not have received any controlled medications until the urine drug screen results were available to the provider. *Id.*

Nearly three months later (on September 29, 2004), N.S. returned to AMC for her next visit and was seen by Mr. Reynolds. *See* GX 2, at 100; GX 3, at 71. Prior to this visit, AMC had received the report of the results of the UDS that had been administered to N.S. at her July 7, 2004 visit. *Id.* at 115. According to the Expert, on the date of the UDS, N.S. should have had Avinza left from the prescription issued at her first visit and should have still been taking the drug. *See* GX 2, at 102; GX 3, at 129; GX 68, at 12–13. However, the UDS was negative for opiates, positive for benzodiazepines, and positive for cocaine. *Id.;* GX 2, at 115.

According to the Expert, these results should have been a ''huge red flag of abuse and diversion'' for Mr. Reynolds because not only did N.S. test positive for cocaine, she also tested positive for three different benzodiazepines, none of which had been prescribed to her at her first visit. GX 68, at 13. The Expert further explained that the presence of the three benzodiazepines, in addition to the presence of cocaine, were consistent with the somnolence, slurred speech, and increased pulse rate that were documented during the July 7, 2004 visit. *Id.* The Expert also noted that N.S. tested negative for opiates, when she should have tested positive for the Avinza which she should have still been taking. *Id.*

The Expert also noted that as of this visit, Reynolds still had not acquired any information concerning N.S.'s prior treatment history or substance abuse history. *Id.* Also, the file contains no documentation that Reynolds had inquired of N.S. where she had been for the nearly three months since her July 7, 2004 AMC visit. *See generally* GX 2. According to the Expert, the standard of care required that Reynolds inquire about N.S.'s absence and determine what, if anything, she had been doing during this time to address her reported pain. GX 68, at 13. The Expert further noted that while the note for this visit was for the most part illegible, it appeared that Mr. Reynolds did not address N.S.'s absence. *See id;* GX 2, at 100.

Nonetheless, Reynolds issued N.S. another prescription for thirty tablets of Avinza 60 mg. *See* GX 2, at 100; GX 3, at 71. Based on the UDS results and notation in N.S.'s record that she displayed ''slurred speech & somnolence,'' the Expert concluded that Reynolds was on notice that she was likely diverting the Avinza she obtained at AMC for the purpose of obtaining the cocaine and the benzodiazepines. GX 68, at 14. The Expert also explained that at the time of these events, it was well known in the Tennessee health care community that prescription drug abuse and diversion was a problem that was plaguing East Tennessee. *Id.*

The Expert explained that the standard of care and usual course of practice under these circumstances

[4] The Expert acknowledged that as of the date of N.S.'s first visit, the Tennessee Board of Nursing had yet to adopt BON Rule 1000–04–.08, and that the Rule did not go into effect until January 1, 2005. GX 68, at 10. However, based on her knowledge and experience, the Expert explained that advanced nurse practitioners (''APNs'') in Tennessee were nevertheless employing the practices set forth in the Rule when they prescribed controlled substances for the treatment of pain. *Id.* Thus, the practices articulated in the guidelines reflected what, in her opinion, was the standard of care in Tennessee for family nurse practitioners as of June 2004. *Id.* The Expert explained that because of the lack of information of N.S.'s prior treatment history and substance abuse history, it was below the standard of care for a practitioner to issue N.S. a thirty-day supply of a schedule II controlled substance such as morphine at her first visit. *Id.*

[5] According to the Expert, these symptoms could represent several serious and even life-threatening medical conditions given N.S.'s complaint of a migraine headache. Also, N.S.'s slurred speech and somnolence could have been an indication that N.S. was having an acute neurologic event, such as a hemorrhagic stroke. GX 68, at 10–11.

would *not* have been to issue N.S. an additional thirty-day supply of morphine, because ''family nurse practitioners were not then, and are now not equipped, through their training and experience, to address the complex abuse and diversion issues N.S. was presenting.'' *Id.* According to the Expert, rather than continuing to issue N.S. prescriptions for more of the Avinza, the standard of care and usual course of practice required that Reynolds ''cease all controlled substances prescriptions to her, and instead referred [sic] her for a consultation with a pain management specialist who [was] equipped with the knowledge to treat a pain patient who has exhibited such aberrant behavior.'' *Id.* The Expert also explained that in the event that a local pain management practice did not have all of these specialists, Mr. Reynolds should have, in addition to sending her to a pain management specialist, referred her to a mental health specialist to address her possible psychological/drug abuse issues. *Id.* The Expert thus concluded that Reynolds' issuance of this prescription was below the standard of care in Tennessee, outside the usual course of professional practice, and for other than a legitimate medical purpose. *Id.*

N.S.'s file reflects that Reynolds, Stout, and Killebrew each continued to issue N.S. controlled substance prescriptions on multiple occasions subsequent to September 29, 2004. In fact, N.S. remained an AMC patient for over five more years and continued to receive numerous controlled substances prescriptions from AMC. *See generally* GX 2. Based on the evidence of N.S.'s abuse and/or diversion of controlled substances that was documented in her file, the absence of documentation of any prior treatment for pain, and the absence of any substance abuse history, the Expert opined that each and every controlled substance prescription that these three practitioners issued to N.S. from September 29, 2004 forward was below the standard of care, not for a legitimate medical purpose, and outside the usual course of professional practice. GX 68, at 15. However, ''because each of the three practitioners issued additional controlled substance prescriptions notwithstanding the existence of more red flags of N.S.'s abuse and/or diversion of controlled substances,'' the Expert addressed the invalidity of those prescriptions. *Id.*

On December 29, 2004, N.S. returned to AMC and saw Mr. Reynolds, who issued her a prescription for eight tablets of Avinza 60 mg. *See* GX 2, at 97; GX 3, at 76 According to the Expert, in addition to the previous evidence of N.S.'s abuse and diversion, Reynolds had received an admission report on December 3, 2004 from Johnson City Medical Center (''JCMC'') which notified him that N.S. was hospitalized for a drug overdose the same day. GX 68, at 15; GX 2, at 126–28. He also received notification from JCMC upon N.S.'s discharge on December 7, 2004. GX 2, at 158–61; GX 68, at 16. Reynolds evidently reviewed the report, as his signature marking appears at the bottom of the report's first page. GX 2, at 158. Notably, not only did the report state that N.S. had been admitted for a drug overdose, it also stated that N.S. had a history of multiple prior drug overdoses, the last one being in May 2004, one month before her first AMC visit, and a history of multiple suicide attempts. *Id.* at 126–27; 158–59.

Of further significance, the report listed two different primary care physicians for N.S., one of whom, Dr. Michael Dube, was not an AMC practitioner. *Id.* at 159. Also, the report stated that she was taking Lortab, a combination drug containing hydrocodone (which was then a schedule III controlled substance); Xanax, a schedule IV controlled substance; and Soma (carisoprodol), which was not federally scheduled at that time. *Id.* at 158. However, Reynolds had not previously prescribed any of these three drugs to N.S. *See generally* GX 2.

The report also stated that a urine toxicology test was performed on N.S. and that she tested positive for opiates and benzodiazepines. *Id.* at 159. However, as before, AMC had not prescribed any benzodiazepines to N.S. As the Expert explained, the report should have been another enormous red flag to Reynolds that N.S. was continuing to abuse and divert controlled substances and was engaging in doctor-shopping by obtaining controlled substances from multiple sources (AMC and Dr. Dube), another red flag of drug-seeking behavior. GX 68, at 16.

As of the December 29 visit, Reynolds also was aware that the physician who treated N.S. at JCMC had, three weeks earlier, discharged N.S. to Indian Path Pavilion (''IPP''), a local, in-patient mental health facility. *See* GX 2, at 160. In addition, on December 23, AMC received a fax showing that on December 21, N.S. had been admitted again to IPP for ''polysubstance abuse.'' *See* GX 2, at 153–56. Thus, as of N.S.'s December 29 visit, Reynolds was on notice that she may have suffered two overdoses in an approximately three-week period, that these would have been the latest of several overdoses she had suffered, and that she had been sent for mental health treatment on each of those two occasions. GX 68, at 17.

However, on reviewing N.S.'s patient file, the Expert found (as do I) that Reynolds did not contact: (1) The JCMC to obtain its records of N.S.'s multiple previous overdoses; (2) Dr. Dube to obtain records of the nature and extent of the treatment he had provided N.S., including the controlled substances he had prescribed her, (3) the IPP to obtain records regarding N.S.'s December 21, 2004 admission to that facility for polysubstance abuse; and/or (4) the pharmacy N.S. was using to fill her prescriptions to determine if she was obtaining controlled substances prescriptions from other practitioners. *Id.* According to the Expert, the standard of care and usual course of professional practice for a family nurse practitioner required that Reynolds obtain all of this information about N.S.'s history of overdoses, her suicide attempts, and her current hospitalizations, as well as information about other practitioners from whom she may have been obtaining controlled substance prescriptions, in order to determine the proper course to take in her care. *Id.*

As the Expert previously explained, a family practice nurse practitioner is not qualified to treat the complex issues presented by this type of patient. Thus, the Expert also explained that in light of the information contained in the December 3, 2004 JCMC and the December 21, 2004 IPP admission reports, the standard of care in Tennessee required that Reynolds cease all further controlled substance prescriptions (which he already should have), send N.S. to an out-patient or in-patient detoxification program and refer her to a pain management specialist. *Id.* at 18. Thus, the Expert concluded that the issuance of the December 29, 2004 Avinza prescription was outside the usual course of professional practice and lacked a legitimate medical purpose. *Id.*

Nevertheless, from January 2005 through June 2005, Reynolds continued to see N.S. at AMC on a monthly basis and continued to issue her monthly prescriptions for Avinza 60 mg. *See* GX 2, at 86–96; GX 3, at 76–79. According to the Expert, the issuance of each of these prescriptions was below the standard of care and outside the usual course of professional practice as well. GX 68, at 18. As the Expert explained, N.S. should not have been treated and prescribed controlled substances at a family practice in light of the drug abuse and diversion issues she presented, and

should have been referred to a specialist. *Id.*

According to the Expert, on January 1, 2005, the Board of Nursing's Rule 1000–04–.08 went into effect. *Id.* As a result, Reynolds was required to comply with the controlled substance prescribing guidelines contained in that Rule. However, as of January 6, 2005, Reynolds still had not obtained any information about her treatment history for the three years immediately preceding her first AMC visit on June 8, 2004. *See* TN BON Rule 1000–04–.08(4)(C)1; *see also generally* GX 2; GX 68, at 18. Moreover, Reynolds did not create a written treatment plan for N.S.; nor did he document that he had considered the need for further testing, consultations, referrals, or the use of other treatment modalities. GX 2; GX 68, at 18.

As the Expert explained, under the new Rule, Reynolds was required to create and maintain a ''written treatment plan tailored for the individual needs of the patient'' that ''include[d] objectives such as pain and/or improved physical and psychological function'' and was required to ''consider the need for further testing, consultations, referrals, or use of other treatment modalities dependent on patient response[.]'' GX 68, at 18 (quoting TN BON Rule 1000–04–.08(4)(c)2). As found above, in December 2004, the JCMC and IPP had forwarded to Reynolds information establishing that N.S. had a substantial history of substance abuse which had resulted in multiple drug overdoses and suicide attempts. Based on the results of the July 2004 UDS, he also had information that N.S. may not have been taking the Avinza and possibly was diverting the drug and that she was taking cocaine and benzodiazepines which had not been prescribed by his clinic. GX 68, at 19. The Expert thus concluded that Reynolds did not comply with the Rule and acted outside of the usual course of professional practice when he issued the Avinza prescription to N.S. *Id.*

The evidence further shows that beginning on February 8, 2005, Reynolds added Xanax 1 mg. to N.S.'s controlled substance regimen. *See* GX 2, at 94; GX 3, at 77–79. Reynolds issued this prescription after diagnosing N.S. with ''Major Depressive Disorder'' and ''GAD,'' the latter being an abbreviation for ''Generalized Anxiety Disorder.'' The Xanax prescription issued on February 8, 2005 was the first of numerous Xanax prescriptions N.S. received from Reynolds, Stout, and Killebrew over the course of the next five years. *See* GX 2.

According to the Expert, the decision of the nurse practitioners to address N.S.'s mental health issues by prescribing Xanax, was below the standard of care and outside the usual course of professional practice. GX 68, at 19. As support for her opinion, the Expert cited a treatise which she stated was generally recognized and accepted as authoritative by Tennessee family practitioners. *Id.* at 19–20 (citing Constance R. Uphold & Mary Virginia Graham, *Clinical Guidelines in Family Practice,* 4th Ed. (2003) (hereinafter, ''Uphold & Graham'')). This treatise was submitted as part of the record. *See* GX 41.

The Expert explained that ''according to Uphold & Graham, benzodiazepines, such as Xanax, are effective only for the *short-course treatment* of generalized anxiety disorder, or GAD, and family practitioners were cautioned against the use of this class of drugs for greater than a two week period because they carry 'the risk of dependence and withdrawal syndrome.' '' *Id.* at 20 (quoting GX 41, at 8). The Expert then noted that ''Uphold & Graham further instructs that if the patient's 'anxiety [is] associated with another psychiatric condition, most often depression,' the patient 'should be treated for the primary problem,' and 'most patients in this category should be referred to a specialist if possible.' '' GX 68, at 20 (quoting GX 41, at 9). Additionally, ''Uphold & Graham instructs that for 'patients with anxiety that is substance-induced' whether by licit or illicit drugs, family nurse practitioners are to 'provide the patient with counseling/referral to a drug detoxification program.' '' *Id.* According to the Expert, ''Uphold & Graham emphasizes that two of the 'categories of patients [who] should be referred to specialists for treatment' are '[t]hose with high suicide risk' and '[p]atients with comorbid conditions (primary anxiety disorder, substance abuse, dementia).' '' *Id.* (quoting GX 41, at 14).

Thus, based on Uphold & Graham, the Expert concluded that ''even assuming N.S. could have been treated for her purported major depressive order in a primary care setting, which she could not, she should *not* have been started on a benzodiazepine such as Xanax.'' *Id.* (citing GX 41, at 15). The Expert further noted that AMC asserted that its protocols were based on the Uphold & Graham Guidelines. *Id.* at 19–20 (citing GX 39).

According to the Expert, Reynolds, Stout, and Killebrew were required under Tennessee law to evaluate N.S. for a continuation or change of her medications at each periodic interval at which they evaluated her. GX 68, at 21; BON Rule 1000–04–.08(4)(c)4. However, while Xanax is a highly abused and diverted drug in Tennessee, Reynolds, Stout and Killebrew prescribed Xanax to N.S., ''at numerous periodic intervals over the course of the next several years and in the face of mounting evidence of her abuse of controlled substances, and without referring her for treatment by a specialist.'' GX 68, at 21. The Expert thus concluded that the prescriptions issued by the three nurse practitioners fell well below the standard of care and outside the usual course of their professional practice. *Id.*

On July 1, 2005, Reynolds issued N.S. prescriptions for 30 capsules of Avinza 60 mg and 60 tablets of Xanax 1 mg. *See* GX 2, at 86; GX 3, at 79. Reynolds issued these prescriptions even though he had not obtained the results of the UDS he ordered for N.S. during her June 1, 2005 AMC visit (and apparently never did based on a review of N.S.'s patient file). *See* GX 2, at 87. In fact, N.S.'s patient file does not contain any record of her even having been administered the UDS. GX 68, at 21; *see also* GX 2.

In the Expert's opinion, Reynolds' issuance of these prescriptions was below the standard of care and outside the usual course of professional practice. GX 68, at 21. Based on the evidence of N.S.'s abuse and diversion of controlled substances set forth above, and the fact that Reynolds had not obtained the results for the UDS he ordered at N.S.'s previous visit, the standard of care and usual course of professional practice under these circumstances would *not* have been to issue N.S. further controlled substances prescriptions. *Id.* at 22. Instead, it would have been to locate the results, and if she had not taken the UDS, which would be a red flag based on her history, require her to provide one and cease all further controlled substances prescribing until the results could be reviewed. *Id.* (citing Board Rule 1008–04–08(2) & (4) (c)(2)).

Likewise, on August 2, 2005, Mr. Reynolds issued N.S. prescriptions for 30 capsules of Avinza 60 mg and 60 tablets of Xanax 1 mg, each of which was for a thirty-day supply. *See* GX 2, at 85; GX 3, at 79. A note in the record of her August 2, 2005 visit states, ''Pt. called to request refill on Xanax. *Stated she had taken all she had before due date.* Script written for Xanax.'' GX 2, at 85 (emphasis added). Yet notwithstanding the extensive evidence that N.S. was abusing and diverting controlled substances, Reynolds issued her the prescription and did not refer her to an outside specialist to address her aberrant behavior. *See, e.g.,* GX 41, at 8–9, 14 (Uphold & Graham). The

Expert thus concluded that Reynolds' issuance of the prescription was below the standard of care and outside the usual course of professional practice. GX 68, at 22–23.

Twenty days later, on August 22, 2005, Mr. Reynolds issued N.S. a prescription for 20 tablets of Xanax 0.5 mg. *See* GX 2, at 84; GX 3, at 80. According to the Expert, this prescription was an extremely early refill, specifically, ten days early, in light of the fact that he had just issued N.S. a thirty-day supply of 60 tablets of Xanax 1 mg on August 2, 2005, and was further evidence that N.S. was either abusing the Xanax by taking extra pills in contravention of his directions, or was diverting the drugs he was prescribing to her. GX 68, at 23.

Moreover, on September 2, 2005, Mr. Reynolds issued N.S. prescriptions for 30 capsules of Avinza 60 mg and 60 tablets of Xanax 1 mg. *See* GX 2, at 82; GX 3, at 81. According to the Expert, Reynolds was then aware that N.S. had apparently not complied with his August 24, 2005 request for her to come into AMC for a pill count. *See* GX 68, at 24; GX 2, at 83. The Expert then explained that the failure of a patient to comply with a practitioner's request for a pill count, which is another tool utilized to monitor the patient's compliance with a controlled substances regimen, is another red flag of possible abuse and/or diversion. GX 28, at 24.

On October 3, 2005, Mr. Reynolds issued N.S. a prescription for 75 tablets of Xanax 1mg and 60 capsules of Kadian (a brand name for morphine) 30 mg. *See* GX 2, at 80; GX 3, at 81. N.S.'s file contains a handwritten note dated September 13, 2005, which was just *eleven days* after Reynolds had prescribed to her a thirty-day supply of 60 tablets of Xanax 1 mg, stating, ''Pt requested Xanax 1 mg TID for anxiety attacks.'' GX 68, at 25; GX 2, at 81. As of this date, Reynolds was aware that N.S. should have had 19 days of Xanax tablets remaining from the September 2nd prescription, and thus, she was requesting additional Xanax well before she should have consumed the prior prescriptions and was also requesting an increase from two (*i.e.,* ''BID'') to three tablets a day (*i.e.,* ''TID''). GX 68, at 25.

On November 1, 2005, Registrant Stout issued his first controlled substance prescriptions to N.S.; the prescriptions were for 75 tablets of Xanax 1 mg and 60 capsules of Kadian 30 mg. *See* GX 2, at 79; GX 3, at 82. According to the Expert, because this was N.S.'s. first visit with Stout, it was incumbent on him to review N.S.'s file before he issued her controlled substances prescriptions, so that he could determine the appropriate course of treatment. GX 68, at 26. Noting that under Board Rule 1000–04–.08, Stout was required to ''evaluate[ ] the patient for continuation or change of medications'' and to include in the patient record ''progress toward reaching treatment objectives, any new information about the etiology of the pain, and an update on the treatment plan,'' the Expert explained that an Advanced Practice Nurse cannot evaluate a patient for the continuation or change of medications, or determine the progress the patient is making towards reaching treatment objectives, or even know what the patient's treatment objectives are, without knowing the patient's treatment history. *Id.*

The Expert thus concluded that when Stout issued N.S. the Xanax and Kadian prescriptions, he should have been aware of N.S.'s prior abuse and diversion of controlled substances which was documented in her patient file. *Id.* Based on N.S.'s history, the Expert further concluded that the standard of care and usual course of professional practice under these circumstances would *not* have been for Mr. Stout to issue her further controlled substances prescriptions but to cease further prescribing and refer her to an outside specialist to address her aberrant behavior. *Id.* at 26–27 (citing GX 41, at 8–9, 14) (Uphold & Graham).

On July 20, 2006, Applicant Killebrew issued her first controlled substances prescriptions to N.S.; the prescriptions were for 75 tablets of Percocet 7.5/325 mg (oxycodone/acetaminophen, a schedule II controlled substance), and 60 tablets of Xanax 0.5 mg. *See* GX 2, at 76; GX 3, at 84. For the same reasons she identified in her discussion of the validity of Stout's initial prescriptions to N.S., the Expert found that Killebrew's prescriptions were below the standard of care and outside the usual course of professional practice. GX 68, at 27.

The Expert further noted that this was N.S.'s first visit to AMC in nearly eight months, (her last visit having been a Dec. 1, 2005 visit with Reynolds), and that Killebrew had noted in the record of this visit that N.S. was ''[j]ust released from jail 7/6/06 . . . requesting to be put back on pain meds she was on for back and neck pain.'' *Id.* at 27–28 (citing GX 2, at 76). The Expert noted, however, that Killebrew did not document having asked N.S. about the reason for her incarceration, specifically, whether it was drug-related, whether she was on probation, and, if so, whether her probationary status may have prohibited her from possessing controlled substances. GX 68, at 28. Nor did Killebrew document having asked N.S. about how she had addressed her alleged pain during her incarceration when she had told Killebrew that she was not receiving any pain medications. *Id.* According to the Expert, given N.S.'s history, the standard of care and usual course of professional practice under these circumstances, would *not* have been to issue her additional controlled substances prescriptions but to refer her to a pain management practice to address her purported back and neck pain and possible continuing substance abuse. *Id.* (citing GX 41, at 8–9, 14) (Uphold & Graham).

On August 17, 2006, Stout prescribed N.S. 75 tablets of Percocet 7.5/325 mg and 60 tablets of Xanax 0.5 mg. *See* GX 2, at 75; GX 3, at 87. According to the medical record, on July 19, 2006, less than a month before he issued N.S. these prescriptions, Stout had treated N.S. while he was working in the North Side Hospital emergency room (''ER''). *See* GX 16, at 2–3. According to North Side's records, N.S. presented to the ER on that date complaining of neck pain from a fall. Stout noted in the record for the ER visit that N.S. ''[r]efused meds . . . Wants stronger narcotics. Admits to having long history of drug abuse. . . .'' In the ''Impressions'' section of this report, Stout had also noted that N.S. displayed ''[d]rug seeking behavior.'' *Id.*

Moreover, N.S.'s AMC record included the note for her July 20 visit (the day after Stout saw her in the ER). Thus, the Expert found that Stout should also have been aware that N.S.'s previous visit was her first visit to AMC in seven months and that she had just been released from jail and had requested to be put back on pain medications. GX 68, at 29; GX 2, at 76. The Expert further explained that ''[a]s was the case with N.S.'s visit with Killebrew, Stout did not question N.S. as why she had been incarcerated . . . whether it was drug-related, whether she was on probation, and, if so, whether her probationary status may have prohibited her from possessing controlled substances. He also did not question N.S. about how she had been addressing her alleged pain during her incarceration when she, based on her own report to Killebrew, had not received pain medications.'' GX 68, at 29. Based on these circumstances (including the amply documented history of N.S.'s abuse and/or diversion), the Expert found that Stout's issuance of these prescriptions was below the standard of care and outside

the usual course of professional practice. *Id.*

On October 11, 2006, Stout again saw N.S. and issued her additional prescriptions for 75 tablets of Percocet 7.5 mg and 60 tablets of Xanax 0.5 mg. *See* GX 2, at 71, 73; GX 3, at 88. In addition to the previous documented incidents of N.S.'s abuse and/or diversion, N.S.'s file contained a note dated September 13, 2006, stating, ''[N.S.] selling perocet's (sic.).'' *See* GX 2, at 74. Moreover, in the record of the visit, Stout wrote, ''Confronted PT about ? selling meds. PT denies. States meds were stolen. Will do UDS today. Advised PT if UDS (-) drugs/abuse found would d/c. Has been taking meds for past week per pt.'' *See* GX 2, at 71, 73. Also, Stout had N.S. sign a Pain Management Agreement (''PMA''), which he and another AMC employee witnessed, and then issued her the controlled substance prescriptions. *See* GX 2, at 11–12.

According to the Expert, the fact that N.S. denied selling her drugs should not have overcome the evidence in her file, including the recent note of the report that she was selling her drugs and the extensive evidence of her history of abuse and/or diversion of controlled substances. GX 68, at 30. The Expert thus concluded that Stout's issuance of these prescriptions was below the standard of care and outside the usual course of professional practice. *Id.*at 29–30 (citing GX 41, at 8–9, 14 (Uphold & Graham)).

The UDS results showed that N.S. tested negative for oxycodone/oxymorphone, despite the fact that she had been receiving oxycodone (Percocet) prescriptions from AMC on a monthly basis since July 20, 2006. *See* GX 2, at 71–75, 105–107; *see also* GX 3, at 4–5. The results also showed that N.S. tested positive for hydrocodone/hydromorphone, even though no one at AMC had prescribed those drugs to her since she had returned to the practice. GX 2, at 107.

On November 10, 2006, Reynolds saw N.S. and issued her additional prescriptions for 75 tablets of Percocet 7.5 mg and 60 tablets of Xanax 0.5 mg. *See* GX 2, at 70; GX 3, at 91. In addition to the various recent notes in her file, Reynolds should have been aware of the October 18, 2006 results of the UDS administered to N.S. at the October 11, 2006 visit. As the Expert explained, based on the UDS results, Reynolds was aware that N.S. had lied to Stout during her October 11, 2006 visit when she told him that she was taking her pain medications, and that she was likely selling her Percocet because she tested negative for this drug. GX 68, at 31. In addition, Reynolds was aware of Stout's warning to N.S. during her October 11, 2006, visit that she would be discharged (''d/c'') if the results were negative (which they were for oxycodone), or if she was found to be abusing drugs, which was established by her testing positive for hydrocodone, a drug that she had not been prescribed at AMC. *Id.* at 32.

The Expert thus found that the UDS results were further evidence of N.S.'s continued abuse and/or diversion of controlled substances. *Id.* at 31. The Expert further opined that the standard of care and usual course of professional practice under these circumstances would *not* have been to issue N.S. further controlled substance prescriptions, but to discharge her from the practice and to refer her to a pain management practice to address her purported pain issues or a substance abuse/addiction specialist to address her likely substance abuse issues. *Id.* at 32. Thus, the Expert concluded that Reynolds' issuance of these prescriptions was below the standard of care and outside the usual course of professional practice. *Id.* at 31 (citing GX 41, at 8–9, 14) (Uphold & Graham)).

On December 11, 2006, Stout issued N.S. prescriptions for 75 tablets of Percocet 7.5 mg and 60 tablets of Valium 5 mg. *See* GX 2, at 69; GX 3, at 91. At the time of the visit, Stout had received the results of the UDS and was aware that N.S. had lied to him during her October 11, 2006 visit, when she told him she was taking her pain medications. N.S.'s patient record shows that Stout attempted to refer N.S. to two different pain management practices at this visit—''Appalachian Pain Rehab'' (Dr. Tchou) and ''Pain med associates.'' *See* GX 2, at 67. However, N.S. had apparently already been seen at those two practices and neither practice was willing to again accept her as a patient.[6] *Id.*

According to the Expert, this additional information should have been another red flag that N.S. was abusing and or diverting controlled substances. GX 68, at 33. The Expert thus concluded that under the circumstances, the standard of care and usual course of professional practice would *not* have been to issue N.S. more prescriptions, but to enforce the terms of the Pain Management Agreement and to follow through on the warning Stout had given N.S. during her October 11 visit that she would be discharged from AMC if she failed the UDS. *Id.* Additionally, the standard of care and usual course of professional practice would have been to attempt to refer N.S. to a mental health or an addiction specialist to address her purported pain issues and her likely substance abuse issues. *Id.* at 33–34 (citing GX 41, at 8–9, 14 (Uphold & Graham excerpts)). Yet Stout failed to either discharge her or refer her to a specialist.

On February 27, 2007, Reynolds issued N.S. prescriptions for 75 tablets of Percocet 7.5 mg and 60 tablets of Xanax .5 mg. *See* GX 2, at 66; GX 3, at 93. At the time of the visit, Reynolds was aware of the December 11, 2006 notes stating that neither Appalachian Pain Rehab nor Pain Med Associates would see N.S. *See* GX 2, at 67. For the same reasons discussed above, the Expert concluded that Reynolds' issuance of the prescriptions was well below the standard of care and outside of the usual course of professional practice. GX 68, at 32.

On June 1, 2007, Reynolds issued N.S. additional controlled substances prescriptions for 90 tablets of MS Contin 30 mg and 90 tablets of Xanax 0.5 mg. *See* GX 3, at 96. Notwithstanding that the quantity of both prescriptions had been increased by fifty percent from N.S.'s previous visit, her patient file does not contain a record of Reynolds having seen her on this date, nor any information as to why N.S. was not seen on this occasion. *See* GX 2, at 63–64. Based on the other documented evidence of N.S.'s abuse and/or diversion, the Expert concluded that Reynolds' issuance of these prescriptions was below the standard of care and outside the usual course of professional practice. GX 68, at 34–35 (citing Rule 1000–04–.08(4)(c) (requiring periodic re-evaluation for continuing or changing control substance prescriptions)).

On July 2, 2007, after N.S. called in and said she had run out of prescriptions the day before, Killebrew directed that prescriptions be called in for 40 tablets of Lortab 10 mg (hydrocodone/acetaminophen) and 30 tablets of Xanax 0.5 mg. *See* GX 2, at 63; GX 3, at 96. While Killebrew should have been aware of N.S.'s extensive history of abuse and diversion, according to N.S.'s patient file, she issued these prescriptions without requiring that N.S. come in for an office visit and after being notified that N.S. had called AMC and requested new prescriptions because she was out of her medications. *See* GX 2, at 63. The Expert further noted that N.S. evidently had not been seen at AMC since her May 3, 2007 office visit and that this

[6] Notes in the file state that N.S. ''has been double dotted'' at Appalachian Pain Rehab, which ''means won't see,'' and that N.S. ''already has been to Pain med associates + can't be seen there either!!'' GX 2, at 67.

was a further red flag given N.S.'s history. GX 68, at 35. Moreover, once again, there is no information in the file documenting why N.S. could not have been seen. *Id.* The Expert thus concluded that the issuance of the prescriptions was below the standard of care and outside of the usual course of professional practice. *Id.*

On November 16, 2007, Reynolds issued N.S. prescriptions for 30 tablets of Lortab 10 mg and 30 tablets of Xanax 0.5 mg. *See* GX 2, at 52; GX 3, at 102. The Expert found that N.S. was seeking an early refill of her controlled substances, because fifteen days earlier, Reynolds had prescribed her thirty-day supplies of 90 tablets each of Xanax 0.5 mg, MS Contin 30 mg, and Percocet 7.5/500 mg, each of which had a dosing of ''one po tid,'' or one tablet three times per day. *See* GX 68, at 36; GX 2, at 53–54; GX 3, at 102. N.S.'s early refill request presented another red flag of her potential abuse and/or diversion of controlled substances, which Reynolds ignored. GX 68, at 36. Moreover, N.S.'s Pain Management Agreement stated that ''medications taken early due to reasons not discussed with your provider [will not] be replaced early.'' GX 2, at 5. Yet Reynolds did not enforce the Pain Management Agreement. GX 68, at 36.

The Expert also concluded that given N.S.'s numerous prior red flags of drug abuse and diversion, Reynolds should have taken steps to determine if she was in fact taking the drugs he had been prescribing, or if she was diverting them. *Id.* at 37. The Expert explained that Reynolds should have required her to submit to a UDS, and that he also should have checked the Tennessee Controlled Substances Monitoring Database (''CSMD''), which became available on January 1, 2007, in order to determine if she possibly was doctor-shopping. *Id.* The Expert also noted that Reynolds did not ask why she was seeking an early refill. *Id.* The Expert thus concluded that Reynolds' issuance of these prescriptions was below the standard of care and outside the usual course of professional practice. *Id.* at 36–37 (citing Board Rule 1000–04–.08(4)(c) (2) & (4) and GX 41, at 8–9, 14 (Uphold & Graham)).

On January 3, 2008, Reynolds issued N.S. a prescription for 90 tablets of MS Contin 30 mg, 90 tablets of Xanax 0.5 mg, and 30 tablets of Percocet 7.5 mg. *See* GX 2, at 47–48; GX 3, at 103. According to her file, on November 30, 2007, N.S. had called and sought an early refill. Moreover, documentation in her file establishes that Reynolds should have known (having received reports on both December 22 and 26), that on December 22, N.S. had been admitted to JCMC and diagnosed with, among other conditions, ''polysubstance abuse.'' *See* GX 2, at 139–140. Here again, the Expert found that Reynolds' issuance of these prescriptions was below the standard of care and outside the usual course of professional practice and that she should not have been issued any further controlled substance prescriptions. GX 68, at 37 (citing GX 41, at 8–9, 14 (Uphold & Graham)).

On December 22, 2008, Killebrew issued N.S. prescriptions for 60 tablets of Lortab 7.5 mg and 30 tablets of Xanax 0.5 mg. *See* GX 2, at 40–41; GX 3, at 106. Notably, the chart indicates that this was N.S.'s first visit to AMC since February 2008 because she was pregnant, *see* GX 2, at 42–44, and that during the intervening ten months N.S had reportedly been receiving Suboxone/Subutex treatment from another practitioner and apparently had been able to function during the previous ten months without the need for Lortab and Xanax. *Id.* at 40.

According to the Expert, based on N.S.'s representations, Killebrew should have taken steps to determine whether N.S. had a legitimate medical need for these drugs prior to prescribing them. GX 68, at 38–39. The Expert explained that the usual course of professional practice would have been for Killebrew to determine the name of the practitioner who had provided Suboxone treatment to N.S. and contact that practitioner to determine the nature and extent of the treatment and to obtain a copy of the records. *Id.* at 39. The Expert also opined that given N.S.'s history of red flags, Killebrew should have run a check of the Tennessee CSMD to determine if her representations were accurate and to ensure that N.S. was not doctor-shopping. *Id.* However, according to N.S.'s file, Killebrew did not do so. GX 2. The Expert also found that Killebrew did not document any new illness or injury to N.S. as of this visit. GX 68, at 39. Also, on review of N.S.'s record, the Expert concluded that Killebrew had performed a cursory physical exam and that the lack of additional diagnostics or further evaluation by Killebrew further demonstrates that she failed to establish N.S.'s need for controlled substances at this visit. *Id.* Thus, the Expert concluded that Killebrew's issuance of these prescriptions was below the standard of care and outside the usual course of professional practice. *Id.* at 38–39 (citing TN BON Rule 1000–04–.08(4)(c)1, 2, and 4).

On June 4, 2009, Reynolds prescribed N.S. 60 tablets of MS Contin 30 mg, 30 tablets of Percocet 7.5 mg, and 90 tablets of Xanax 0.5 mg. *See* GX 2, at 38–39; GX 3, at 107. Significantly, Reynolds issued the prescriptions notwithstanding that N.S. had not been seen at AMC since her December 22, 2008 visit with Killebrew. *See* GX 2, at 40–41. Moreover, the record of the June 4, 2009 visit does not contain any documentation of what N.S. had been doing to treat her purported pain over the course of the previous five plus months. *Id.* at 38–39. The Expert also found that Reynolds should have been aware that N.S.'s December 22, 2008 visit had been her first visit to AMC since February 2008, after she had called AMC and informed staff that she was two months pregnant and had destroyed her medications. GX 68, at 39–40.

As with the previous visit, the Expert explained that the usual course of practice would have been for Reynolds take steps to determine whether N.S. had a legitimate medical need for the drugs prior to prescribing them. *Id.* at 40. These steps included asking N.S. what she had been doing over the past six months to address her purported pain and, given her history of abuse and diversion, running a check of the Tennessee CSMD to determine if she had been obtaining controlled substances from any other practitioners over the past six months. *Id.* However, according to N.S.'s file, Reynolds did not conduct such a check. GX 2. The Expert thus concluded that Reynolds' issuance of these prescriptions was below the standard of care and outside the usual course of professional practice. GX 68, at 39–40 (citing TN BON Rule 1000–04–.08(4)(c)(1, 2, 4)).[7]

[7] The Expert also explained that Reynolds' decision to issue N.S. controlled substances prescriptions on June 4, 2009 was contrary to the additional guidelines AMC was employing at that time as part of its practice protocols. GX 68, at 40. According to the Expert, she reviewed a February 23, 2010 letter Reynolds had sent to a Tennessee Department of Health Investigator, as well as several documents that were enclosed with the letter, including copies of AMC's practice protocols. *Id.; see also* GX 39. The Expert noted that Reynolds stated in his letter that one of the attached documents was ''a copy of the current treatment recommendations for chronic pain in the primary care setting as outlined by the *American Family Physician* in their [sic] November 2008 article 'Chronic Nonmalignant Pain in Primary Care' '' which was authored by R. Jackman, J.M. Purvis, and B.S. Mallett (hereinafter, ''Jackman article''). GX 68, at 40–41. According to Reynolds, AMC ''currently [is] referencing this article in our charting notes and intend to add these guidelines as an Addendum to our protocols when they are renewed in July 2010.'' GX 39, at 1. In his record of N.S.'s June 4, 2009 visit, Reynolds wrote: ''[t]his patient's pain has been approached with specific attention to the *American Family Physician's* November 2008 analysis that indicates nonmalignant pain should be addressed in the primary care setting.'' GX 2, at 38.

The Expert noted that her review of N.S.'s file found that Reynolds overlooked several recommendations contained within that article. GX

On November 11, 2009, Reynolds issued another prescription to N.S. for 14 tablets of Xanax 0.25 mg. *See* GX 2, at 25; GX 3, at 108. According to N.S.'s file, N.S. sought a refill claiming that the Xanax Reynolds had prescribed to her on October 29, 2009 had been stolen. GX 2, at 25. According to the Expert, a patient reporting that her controlled substances were stolen is another classic red flag of a patient's potential abuse and/or diversion of controlled substances. GX 68, at 43 (citing GX 39, at 11 (Jackman article's examples of aberrant behavior)).

According to the Expert, the standard of care and the usual course of professional practice would have been for Reynolds to enforce the terms of N.S.'s Pain Management Agreement, and refuse to provide her additional controlled substances. GX 68, at 43–44 (quoting GX 2, at 5; ''Lost or stolen medicines will not be replaced''). Also, according to the Expert, Reynolds should have required N.S. to submit to a UDS, and to run a check of the CSMD to determine if N.S. was engaged in diversion. GX 68, at 44. According to N.S.'s file, Reynolds did not take either action and simply issued her an additional Xanax prescription for 36 tablets of .25 mg. GX 2, at 25; GX 3, at 70. The Expert thus concluded that Reynolds' issuance of the prescription was below the standard of care and outside the usual course of professional practice. GX 68, at 43–44.

According to N.S.'s file, her visits to AMC ended in February 2010 after a nearly six-year relationship with the practice. GX 2. Summarizing her findings, the Expert noted that while during that time, N.S. presented numerous red flags of abuse and diversion, the monitoring of her controlled substances use by Reynolds, Stout, and Killebrew was woefully inadequate, and far below the standard of care in Tennessee. GX 68, at 44. The Expert also observed that over the course of nearly six years, N.S. was only asked to provide two UDSs, both of which she failed by testing positive for a drug she had not been prescribed at AMC (including cocaine on one of the tests), and testing negative for the drug which she had been prescribed. *Id.*

The Expert also noted that N.S. was required to come into AMC for but a single pill count, and there was no documentation showing that she even complied with the request. *Id.* The Expert then noted that even though the CSMD had been available since January 1, 2007, the only time N.S.'s prescription history had been checked was on the date of her last visit in February 2010. *Id.; see also* GX 2, at 129–131. The Expert also observed that there was no documentation that prior to the implementation of the CSMD, the practitioners had ever checked with N.S.'s pharmacy to ascertain whether she was engaged in drug-seeking or diversionary behavior. GX 68, at 44.

The Expert concluded by observing that none of these steps were taken, notwithstanding that: (1) N.S. showed up at her second visit exhibiting somnolence and slurred speech; (2) failed the UDS that was administered at that visit, and (3) several months later, suffered a drug overdose that the practitioners learned was the latest of several prior drug overdoses, in addition to multiple prior suicide attempts. *Id.* at 44–45. As the Expert found, Reynolds, Stout, and Killebrew ignored numerous warning signs that N.S. was abusing and/or diverting controlled substances that continued throughout her nearly six-year association with AMC, and they continued to provide her with controlled substances when they knew or should have known that she was acquiring the controlled substances for other than legitimate medical purposes. *Id.* at 45.

In a letter to a DEA Diversion Investigator, Reynolds addressed AMC's treatment of N.S. He asserted that N.S. was kept on the same medication that she had been prescribed by a neurosurgeon who had referred her to AMC. GX 42, at 7. Yet as the Expert noted, no such documentation exists in N.S.'s file.

Reynolds did acknowledge that on December 3, 2004, N.S. was admitted to a local hospital by a Dr. James for a drug overdose; he also stated that she was subsequently ''transferred to Indian Path Pavilion and continued on her then prescribed medications'' and that ''Dr. James added Soma and Lortab to the AMC regimen.'' GX 42, at 7. However, Reynolds also asserted that after this incident, N.S. ''never had another overdose incident while being treated at AMC'' and ''[s]he never again displayed signs of addiction to include requesting increases in medication without cause, going to numerous providers, aberrant behavior, contacting provider for medication after hours or on weekends, early refills, or refusal to follow plans of care.'' *Id.* Finally, Reynolds further asserted that ''[i]n October of 2006, she passed drug screens and observation by AMC providers.'' *Id.*

T.H.

T.H.'s initial visit was on October 3, 2005. *See* GX 17, at 4, 47. According to the record of this visit, T.H. was seen by an AMC practitioner other than Reynolds, Stout, or Killebrew. He reported that he was suffering from back pain, but said that it was not due to trauma or injury. *Id.* at 47; *see also id* at 4 (report of ''Back Pain''). T.H.'s record does not, however, quantify the extent of the pain he reported, nor document how long he had been suffering from back pain. *Id.* at 47. T.H. also reported a history of anxiety with panic attacks. *Id.* According to the intake paperwork that T.H. completed, he reported that he was not currently seeing any other provider, *id.* at 3, and also reported that he was not taking any drugs other than asthma medications. *Id.* at 4.

According to the Expert, the record of T.H.'s first visit is noteworthy for the absence of any information about his history and potential for substance abuse. GX 68, at 45; GX 17, at 47. Also, the record does not contain a written treatment plan that documents objectives for evaluating progress from the use of controlled substances. GX 68, at 45; GX 17, at 47. As the Expert explained, all of these issues were required to be, but were not addressed before T.H. was prescribed controlled substances. GX 68, at 46 (citing TN BON Rule 1000–04–.08(4)(c)1 and 2).

The Expert further found that the record of T.H.'s first visit revealed the first of several red flags of his potential abuse and/or diversion of controlled substances. *Id.* These included that on the initial intake form he completed,

68, at 41. These included the article's statement that ''[o]pioids pose challenges with abuse, addiction, diversion, lack of knowledge, concerns about adverse effects, and fears of regulatory scrutiny. These challenges may be overcome by adherence to the Federation of State Medical Board's guidelines, use of random urine drug screening, monitoring for aberrant behaviors, and anticipating adverse effects.'' *See id.* (quoting GX 39, at 5). The Expert further noted that the article also states that ''[w]hen psychiatric comorbidities are present, risk of substance abuse is high and pain management may require specialized treatment or consultation. Referral to a pain management specialist can be helpful,'' and that the evaluation of the patient must include ''[a] thorough social and psychiatric history [that] may alert the physician to issues, such as current and past substance abuse, development history, depression, anxiety, or other factors that may interfere with achieving treatment goals.'' *Id.*

The Expert also noted the article's statement that ''[f]or patients at high risk of diversion and abuse, consider *the routine use* of random urine drug screens to assess for presence of prescribed medications and the absence of illicit substances.'' GX 68, at 42 (quoting GX 39, at 9 of 22) (emphasis added). Finally, the Expert noted the article's statement that ''[a]berrant behavior that may suggest medication misuse includes use of pain medications other than for pain treatment, *impaired control* (of self or of medication use), compulsive use of medication . . . selling or altering medications, *calls for early refills, losing prescriptions, drug-seeking behavior (e.g. doctor-shopping),* or reluctance to try nonpharmacologic intervention.'' *Id.* (quoting GX 39, at 11) (emphasis added).

T.H. reported that he had ''frequent or recurring problems'' with alcohol. GX 17, at 4. He also reported that either he or a close family member had suffered from ''Alcoholism'' and ''Mental Illness.'' *Id.*

According to the Expert, T.H.'s disclosure of issues with alcohol abuse and mental illness were red flags of his potential drug abuse; she also noted that the Pain Management Agreements which T.H. was required to sign provided that ''[t]he use of alcohol and opioid medications is contraindicated.'' GX 68, at 46 (citing GX 17, at 5). According to the Expert, T.H.'s disclosures should have been explored further by the nurse practitioner who saw him, but according to the record were not assessed. *Id.* The Expert further opined that without a further evaluation of these issues, the practitioner should not have issued T.H. a prescription for controlled substances. *Id.*

The Expert also explained that if T.H. was in recovery from alcoholism, he should have been referred to a comprehensive pain specialist program, and should not have been treated by a primary care nurse practitioner. *Id.* As the Expert explained: '' '[p]atients who are alcohol dependent and who also have a psychiatric disorder should be referred for treatment for the underlying disorder as these patients are usually complex.' '' *Id.* (quoting GX 41, at 23 (Uphold & Graham)). Thus, according to the Expert, the decision to issue him any controlled substance prescriptions at this initial visit was contrary to the guidelines set forth in TN BON Rule 1000–04–.08(4)(c)1 & 2, and accordingly, below the standard of care in Tennessee and outside the usual course of professional practice. *Id.* at 46–47. Nonetheless, T.H. was issued prescriptions for 30 Lortab 7.5 mg and 30 Xanax .25 mg. GX 17, at 47.

During his second visit on October 25, 2005, T.H. reported that he had recently lost his job and was looking for a new one. He also reported increased stress, that he was not sleeping, and that he was having ''roller coaster feelings.'' *Id.* at 46. According to the Expert, ''the reported loss of income by a patient who is receiving opioids, such as hydrocodone (Lortab), is also a red flag of potential diversion. The practitioner must consider the risk that the patient may try to sell those drugs to generate the income he no longer is obtaining from his job.'' GX 68, at 47. The Expert noted, however, that there is no documentation in the visit note that the issue of how he was going to pay for his treatments and medications was discussed, nor is there any evidence that T.H. was asked to submit to a UDS to see if he was taking the drugs he had been prescribed. *Id.*

The practitioner also diagnosed T.H. as suffering from anxiety and depression. GX 17, at 46. According to the Expert, diagnosing the potential source of a patient's stress is critical in determining the appropriate course of treatment. GX 68, at 47. Thus, the decision to issue T.H. any controlled substance prescriptions at this visit based on the information he reported was contrary to the guidelines set forth in TN BON Rule 1000–04–.08(4)(c)1,2,4, and accordingly, below the standard of care and outside the usual course of professional practice. *Id.* (citing GX 41 (Uphold & Graham)). However, here again T.H. was issued prescriptions for 45 Lortab 7.5 mg and 30 Xanax .5 mg. GX 17, at 46.

At T.H.'s third visit on November 28, 2005, the practitioner noted that he discussed marriage counseling, thus indicating that he was having marital problems. *Id.* at 45; GX 68, at 47. According to the Expert, this was another potential red flag with respect to the prescribing of opioids given T.H.'s reports of anxiety and depression, as well as his prior report that he had lost his job. GX 68, at 47–48. T.H. was referred to another provider (Dr. Williams), and directed to return for a follow-up visit in ''2 months.'' GX 17, at 45. He was also issued prescriptions 60 Lortab 7.5 mg and 30 Xanax .5 mg. *Id.*

Nearly three months later on February 21, 2006, T.H. returned to AMC and saw Reynolds. See GX 17, at 43. In the interim, on December 5, 2005, T.H. was seen at Dr. T. Williams' pain clinic, Pain Medicine Associates. *See* GX 17, at 57–58; 45–46. John Powell, a Physician Assistant in Dr. Williams' clinic, identified a possible source of the ''mechanical low back pain'' that T.H. was reporting. GX 17, at 57. Notably, the pain clinic recommended that ''facet blocks should be undertaken as a diagnostic procedure followed by radiofrequency denervation if positive.'' GX 17, at 58. Also, the pain clinic recommended that T.H. be prescribed 90 tablets of Lortab 10 mg, one tablet three times a day, ''*until we can get the above accomplished.*'' *Id.* (emphasis added).

Based on her review of the pain clinic's letter, the Expert concluded that the clinic had issued T.H. a prescription for a thirty-day supply of Lortab 10 mg to hold him over until he received the facet blocks. GX 68, at 48. In addition, and significantly, Mr. Powell documented that T.H. had again disclosed that he ''had an alcohol problem in the past'' and ''still drinks occasionally.'' GX 17, at 57. Furthermore, Mr. Powell noted that T.H.'s ''chronic low back pain'' had been going on for ''two years.'' *Id.*

According to the record of his Feb. 21, 2006 visit, T.H. specifically ''Requested Bob.'' GX 17, at 43. The Expert found that the record of this visit is largely unintelligible due to Reynolds' incomprehensible handwriting. GX 68, at 48. However, there is no evidence in T.H.'s file that the facet blocks had been performed in the two and one-half months since he had seen Mr. Powell. *Id.; see also* GX 17. In fact, there is no evidence in the file that the facet blocks were ever done. GX 17. Also, there is no documentation of what, if anything, T.H. had been doing to address his pain for the past month when he would have been out of the drugs prescribed by Mr. Powell.[8] *See* GX 68, at 48–49; GX 17, at 43.

Nonetheless, at the visit, Reynolds issued T.H. prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 90 Xanax 1 mg. *See* GX 17, at 43; GX 5, at 13. According to the Expert, Reynolds' issuance of these prescriptions was contrary to the guidelines set forth in TN BON Rule 1000–04–.08 and, accordingly, below the standard of care in Tennessee and outside the usual course of professional practice. GX 68, at 49.

According to the Expert, Reynolds lacked ''an appropriate medical justification for adding a prescription for a schedule II controlled substance such as OxyContin 40 mg to treat [T.H.'s] purported pain,'' given that the pain specialist (Mr. Powell) was of the opinion that ''T.H. did not require anything more than a short-term prescription for Lortab [then a schedule III controlled substance], and for only as long as it took to get the facet blocks completed.'' *Id.* Also, even though Reynolds was now aware (based on Mr. Powell's report) that T.H. had been having back problems for two years, there was still no documentation or records of any prior treatments he had received before he started at AMC in October 2005. *See* GX 68, at 49–50 (citing TN BON Rule 1000–04–.08(4)(c)1 (requiring documentation of historical data that includes ''pertinent evaluations by another provider'')).

[8] In his letter to the DI, Reynolds asserted that TH ''returned to AMC on February 21, 2006 from pain management on long-term medication, Oxy[C]ontin, 40 milligrams, twice daily, and Lortab, 10 milligrams, #30. This medication was continued until the patient's death.'' GX 42, at 4. There is, however, no evidence in T.H.'s file (such as a discharge summary form Pain Medicine Associates) which supports this assertion.

The Expert also found that up to this point, neither Reynolds nor the AMC practitioner who had treated T.H. at his previous visits had adequately documented and evaluated his prior alcohol problems and the extent of his current consumption of alcohol. *Id.* at 49 (citing TN BON Rule 1000–04–.08(4)(c)1 (requiring documentation of historical data that includes ''history of and potential for substance abuse'')). The Expert also found it significant that neither Reynolds nor his colleague had sufficiently explored T.H.'s psychological problems, specifically, the anxiety and increased stress that T.H. previously had reported despite circling ''anxious'' and ''depressed'' in the examination section of the record of this visit. *Id.* at 49–50 (citing TN BON Rule 1000–04–.08(4)(c)1 (requiring documentation of historical data that includes ''pertinent coexisting diseases and conditions'' and ''psychological functions'')). And the Expert noted that Reynolds did not inquire about T.H.'s current employment status, which, in her view, could be significant if he was still unemployed. *Id.* at 49.

The Expert observed that Reynolds' failure to evaluate these issues prior to issuing the Xanax prescription was contrary to AMC's own practice guidelines. *Id.* at 50. Specifically, the Expert explained that according to Uphold & Graham, '' '[s]ubstance abuse can also produce anxiety. . . . Anxiety can also occur as part of the withdrawal from the following: alcohol, cocaine, sedatives, hypnotics, anxiolytics.' '' *Id.* (quoting GX 41, at 5). Continuing, the Expert explained that according to Uphold & Graham, '' '[a]nxiety associated with other psychiatric disorders (depression and alcohol dependence) is common. Discriminating between an anxiety disorder and a depressive illness is quite difficult because of the overlap in symptoms.' '' *Id.* at 50 (quoting GX 41, at 6.) The Expert thus concluded that ''without a detailed evaluation of T.H.'s anxiety and psychosocial history and substance abuse history (including a drug toxicology screen, or UDS), it was inappropriate for Mr. Reynolds to prescribe Xanax for the treatment for anxiety. He lacked any understanding of the etiology of that reported condition at that juncture.'' *Id.*

The Expert also explained that the combination and quantity of prescriptions Reynolds issued at the visit was further evidence that these prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose. *Id.* According to the Expert, ''the combination of OxyContin and Lortab together would not be the next step for a patient with uncontrolled pain. In this situation, the patient's medication [was] escalated to a long-acting opioid, such as OxyContin 10 mg twice daily, which is done when pain management is expected to be for a prolonged period of time.'' *Id.* at 50–51. The Expert then noted that Reynolds had prescribed a starting dose of 40mg twice daily, which is four times the normal starting dose, and that ''when starting a patient on a long-acting opioid, a short-acting opioid may be used for break-through pain, but not typically at the initial prescribing of the long-acting medication.'' *Id.* at 51.

The Expert also explained that Lortab and OxyContin given in combination ''may increase the risk of CNS and respiratory depression, profound sedation and hypotension,'' and that Lortab and Xanax in combination ''may increase risk of CNS depression and cause psychomotor impairment'' due to additive effects. *Id.* Also, according to the Expert, OxyContin given in combination with Xanax may result in ''vasodilation, severe hypotension, CNS and respiratory depression, [and] psychomotor impairment due'' to additive effects. *Id.* Finally, the Expert noted that the dose and the amount of Xanax prescribed was excessive as it was six times the total daily dosage of T.H.'s previous prescriptions and could be lethal, especially if taken in combination with two opioids. *Id.*

Citing Reynolds' failure to perform a proper evaluation of T.H., the illogical and potentially dangerous escalation of opioid and benzodiazepine dosages in the prescriptions he issued, and the red flags of potential drug abuse and diversion that T.H. presented, the Expert concluded that the prescriptions he issued to T.H. at this visit were below the standard of care for a primary care provider and outside the usual course of professional practice. *Id.*

On March 22, 2006, T.H. returned for a follow-up visit and saw Stout. *See* GX 17, at 42. The Expert found that the record of this visit was sparse, as ''Stout simply noted that T.H. was ''[h]ere for a follow-up. Denies recent trauma or illness. No fever, chills, nvd,'' and then circled entries on the record indicating that T.H. was anxious, depressed, and had lower back pain and cervical pain. GX 68, at 51.

Stout issued T.H. additional prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 60 tablets of Xanax 1 mg. *See* GX 17, at 42; GX 5, at 13. However, the Expert found that Stout did not document any evidence of the appropriateness of therapy by failing to quantify or evaluate T.H.'s pain and that there was also no information provided about the efficacy of the medications or the functionality of the patient. GX 68, at 52 (citing TN BON Rule 1000–04.08(4)(c)). The Expert also noted that while Stout acknowledged that T.H. was anxious and depressed, the visit notes had no additional information about the psychosocial situation of the patient. *Id.*

The Expert also observed that Stout did not generate a written treatment plan for T.H. and, as such, there was still no written treatment plan for T.H. *Id.* (citing TN BON Rule 1000–04.08(4)(c)2). Nor did Stout evaluate or assess T.H.'s history of, or potential for, substance abuse. *Id.* (citing TN BON Rule 1000–04.08(4)(c)1). The Expert thus concluded that these prescriptions were issued contrary to the guidelines set forth in TN BON Rule 1000–04–.08(4)(c) and, accordingly, below the standard of care and outside the usual course of professional practice. *Id.*

On April 21, 2006, T.H. returned to AMC and saw Reynolds, who issued him more prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 60 tablets of Xanax 1 mg. *See* GX 17, at 41; GX 5, at 13. Once again, the Expert found that the record for the visit was largely unintelligible. GX 68, at 52. She also observed that while Reynolds documented that T.H. was complaining of right upper quadrant pain and referred him for possible ventral hernia, there did not appear to be any documentation in the file that the prior deficiencies in complying with the guidelines of TN BON Rule 1000–04–.08 had been corrected. *Id.* at 51–52. Also, no AMC practitioner, including Mr. Reynolds and Mr. Stout, had created a written treatment plan for T.H, *id.* at 53 (citing TN BON Rule 1000–04.08(4)(c)2); and Reynolds still had not evaluated or assessed T.H.'s history of, or potential for, substance abuse. *Id.* (citing TN BON Rule 1000–04.08(4)(c)1).

According to the Expert, ''opioids typically would not be indicated in a case of new onset of abdominal pain, or even contraindicated pending an evaluation of the cause of the pain.'' *Id.* Given that T.H. had reported losing his job, the Expert also found it significant that the visit noted stated that he had a ''$310 balance; ins no pay.'' *Id.* (quoting GX 17, at 41). According to the Expert, this was a red flag for potential diversion which should have been explored because ''it indicates that T.H. [wa]s likely uninsured with increasing medical bills [and] [a] practitioner would have to be concerned about how T.H. was going to pay for not only the balance he owed to AMC, but also the drugs he was being prescribed in the

absence of insurance and possibly (still) a job.'' *Id.*

The Expert also found that T.H. presented another red flag in that, according to the visit note, he did not complain ''of constipation.'' *Id.* According to the Expert, ''[i]f T.H. actually was taking the amount of narcotics he had been prescribed, Mr. Reynolds should have expected T.H. to complain of constipation and need a prescription to treat this condition. Absence of a constipation complaint may be a signal [that] T.H. was NOT taking the drugs and instead was diverting them.'' *Id.*

The Expert then explained that under these circumstances, the standard of care and usual course of professional practice required that T.H. undergo a UDS to determine if he was taking the drugs that were prescribed and not diverting them. *Id.* However, the Expert found that there was no documentation in the visit note, or anywhere else in T.H.'s file, that he was asked to submit to a UDS at this visit. *Id.; see also* GX 17. The Expert thus concluded that Reynolds' issuance of the April 21, 2006 prescriptions was contrary to the guidelines set forth in TN BON Rule 1000–04–.08(4)(c) and, accordingly, below the standard of care and outside the usual course of professional practice. GX 68, at 53–54.

On May 22, 2006, T.H. returned to AMC and was seen by both Reynolds and Stout. *See* GX 17, at 40.[9] According to the Expert, the handwriting of both Stout and Reynolds appears on the record of this visit, even though the visit noted was signed by Mr. Stout. GX 68, at 54.

During the visit, Stout noted that T.H. reported that he had been seeing another practitioner at the same time that he was obtaining controlled substances from AMC. GX 17, at 40. Specifically, Stout wrote: ''[Patient] has spoken with Bob Reynolds about seeing Dr. Doobie [(sic)]. [Patient] states has not seen since 4/2006.'' *Id.*

As the Expert explained, this was another red flag for diversion and abuse, ''which is commonly referred to as 'doctor-shopping.' '' GX 68, at 54. Moreover, ''T.H.'s disclosure established that he had violated the Pain Management Agreement,'' which included the provision that he would '' 'use only one physician to prescribe and monitor all opioid medications and adjunctive analgesics,' '' and that '' '[a]ny evidence of . . . acquisition of any opioid medication or adjunctive analgesia from other physicians . . . may result in termination of the doctor-patient relationship.' '' GX 68, at 54–55 (quoting GX 17, at 5). Indeed, in his letter to a DEA Diversion Investigator, Reynolds acknowledged that T.H. had signed the Pain Management Agreement at his first visit to AMC. GX 42, at 4.

Notwithstanding T.H.'s clear violation of the Agreement, Reynolds issued him more prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 60 tablets of Xanax 1 mg. *See* GX 17, at 40; GX 18, at 30. As the Expert explained, when Reynolds issued these prescriptions, T.H. presented with multiple red flags in addition to that of doctor shopping. These included his financial, mental health, and alcohol issues. GX 68, at 55. However, ''T.H.'s file contains no indication that either Reynolds or Stout took the measures that a reasonable and prudent practitioner would have taken, such as to contact the other doctor [Dr. Dube] to confirm that he was no longer seeing T.H. and to ascertain the nature and extent of his treatment of T.H.'' *Id.* Also, neither Reynolds nor Stout took ''any other steps to ascertain the scope of T.H.'s abuse and/or diversion of controlled substances,'' such as by requiring him to provide a UDS. *Id.; see also* GX 17, at 5 & 40. Moreover, while in the Pain Management Agreement, T.H. had agreed to use only one pharmacy (the Hillcrest pharmacy), GX 17, at 5; neither Reynolds nor Stout checked with the pharmacy to determine if he was, in fact, presenting all of his AMC prescriptions there and if he was also presenting controlled substances prescriptions from other practitioners. *See generally* GX 17.

According to the Expert, ''each of these steps was an action that a reasonable and prudent family nurse practitioner would have taken when presented with this information, and was required by the standard of care in Tennessee.'' GX 68, at 55–56. The Expert thus explained that under the circumstances, the standard of care and the usual course of professional practice required the enforcement of the terms of the Pain Management Agreement, *see* GX 17, at 5 (pars. 1, 3, and 9); the cessation of the issuance of more controlled substances prescriptions; the taking of measures to ascertain whether T.H. was diverting the drugs he had been prescribed by requiring a UDS and contacting his pharmacy; and the referral of T.H to either a pain management specialist and/or a psychological/addiction specialist. GX 68, at 56.

On June 20, 2006, T.H. returned to AMC and was again seen by Reynolds. GX 17, at 39. Once again, Reynolds issued T.H. more prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 60 tablets of Xanax 1 mg. *See id.;* GX 18, at 30. Moreover, at this visit, T.H. presented a further red flag—specifically, Reynolds learned that T.H. was being treated with Suboxone, a schedule III controlled substance used to treat narcotic dependency, at the same time he had been receiving narcotics from AMC. GX 17, at 39. As the Expert found, the record of this visit contains an entry apparently made by A.N., a Registered Nurse, stating: '' 'observed note regarding Medicine Shoppe in Jonesboro TN & Suboxone 8 mg (Knoxville region) & Oxycodone 40 mg from Appalachian Med Center & will consult proprietor of Appalachian Med Center Bob Reynolds FNP regarding urine screen possibly needed & how to proceed in care of this pt. Contact person at Medicine Shoppe is Jeff Street.' '' GX 68, at 56–57 (quoting GX 17, at 39).

In reviewing T.H.'s file, the Expert observed that the note referenced by A.N. was not in the file. *Id.* at 57. The Expert also observed that T.H.'s file did not contain any documentation indicating that Reynolds had investigated the information documented by the RN, such as documentation that Reynolds had contacted the pharmacy about T.H.'s Suboxone treatment or obtained a record of the prescriptions T.H. had presented and filled at the pharmacy. *Id.* And the Expert further explained that the fact that the Medicine Shoppe had prescription information for T.H. was also a red flag because T.H. had agreed to use only the Hillcrest pharmacy to fill his prescriptions. *See id.* The Expert thus concluded that Reynolds' issuance of the prescriptions was outside of the usual course of professional practice.[10] *Id.* at 56–57.

On July 19, 2006, T.H. returned to AMC. Reynolds again issued him more prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 60 tablets of Xanax 1 mg. *See* GX 17, at 38; GX 18, at 29. And once again, Reynolds had received additional information indicating that T.H. was likely engaged in abuse. GX 68, at 58.

[9] The Expert based her conclusion on the fact that in course of reviewing the records, she had become familiar with the respective handwriting of Reynolds, Stout, and Killebrew. GX 68, at 54.

[10] The Expert further explained that the usual course of professional practice required that the Pain Agreement be enforced, the cessation of controlled substance prescriptions, that the Medicine Shoppe be contacted to follow-up on the items noted, that T.H. be required to submit a UDS, and that T.H. be referred to either a pain management specialist, and/or a psychological/addiction specialist. GX 68, at 57.

More specifically, T.H.'s file contains four documents that apparently were faxed to AMC from ''Northside Admin,'' and appear to have been faxed on the same date.[11] *See* GX 17, at 59–62. However, the date on the fax banner at the top of each page is cut-off. *See id.*

Notably, one of the documents was an April 21, 2006, letter from Dr. Michael Dube informing T.H. that he ''will no longer be treated as a patient at Medical Care Clinic and/or Watauga Walk-in Clinic.'' *See* GX 17, at 61. A second document showed that as of March 31, 2006, T.H. owed $230 to Medical Care Clinic. *Id.* at 59. A third document showed that as of June 6, 2006, T.H. owed $2,976 to Pain Medicine Associates (Dr. Williams' clinic), where T.H. was seen on December 5, 2005, having been referred by AMC. *Id.* at 60. The fourth document showed that on June 12, 2006, T.H. had received a prescription for Zoloft, a non-controlled drug used to treat depression, from a medical doctor in Knoxville, Tennessee. *Id.* at 62.

As the Expert explained, the letter from Dr. Dube confirmed the information that Reynolds and Stout received at T.H.'s April 20, 2006 visit, namely, that he was seeing another provider at the same time he was receiving controlled substances from AMC, and thus likely doctor-shopping. GX 68, at 58. The billing statements from Medical Care Clinic (Dr. Dube's practice) and Pain Medicine Associates (Dr. Williams' practice), ''provide[d] further evidence that T.H. was having significant financial difficulties.'' *Id.* at 58–59. According to the Expert, the fact that T.H. was approximately $3000 in debt to two medical practices should have been viewed as another red flag of his possible diversion of controlled substances. *Id.* at 59.

As for the Zoloft prescription, the Expert observed that this was evidence that T.H. was having his mental health issues addressed by another provider. *Id.* As such, it was also a red flag that T.H. was possibly obtaining controlled substances from another practitioner after he was discharged by Dr. Dube. *Id.* The Expert further explained that Reynolds should have been interested in knowing if the Zoloft prescriber was the same Knoxville-based practitioner who reportedly was providing T.H. with Suboxone as mentioned in the RN's note for T.H.'s previous visit. *Id.*

Noting that there was no evidence that Reynolds had contacted Dr. Dube, the Zoloft prescriber, the Hillcrest Pharmacy, or the Medicine Shoppe Pharmacy; nor evidence that he had required that T.H. provide a UDS; the Expert concluded that Reynolds' issuance of the prescriptions was below the standard of care and outside of the usual course of professional practice. *Id.* at 58–59. The Expert further opined that under the circumstances, the standard of care and usual course of professional practice would *not* be to issue T.H. additional controlled substances prescriptions but to enforce the terms of the Pain Management Agreement and cease further prescribing of controlled substances to T.H. *Id.* at 59.

On August 10, 2006, T.H. returned to AMC, even though this was just twenty-two days since his last visit. GX 17, at 37. Reynolds again saw T.H. and issued him prescriptions for 10 tablets of Lortab 10 mg and 15 tablets of Xanax 1 mg, which he authorized T.H. to fill on that date, as well as prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 60 tablets of Xanax 1 mg, which could not be filled until August 15, 2006. *See* GX 17, at 37; GX 5, at 13. Reynolds issued these prescriptions notwithstanding the evidence that T.H. was abusing and/or diverting controlled substances discussed above, and even though T.H. was seeking an early refill of his Lortab and Xanax prescriptions on this visit. GX 68, at 60. As the Expert explained, T.H. should have had eight days of Xanax tablets remaining on the prescription Reynolds issued him on July 19, 2006. *Id.* (citing GX 18, at 29).

Here again, T.H.'s early refill request was another red flag that T.H. was abusing and/or diverting the controlled substances that Reynolds was prescribing to him. *Id.* For the same reason as stated above, the Expert concluded that ''the standard of care and usual course of professional practice under these circumstances would *not* be to issue T.H. additional controlled substances prescriptions.'' *Id.* Rather, the standard of care and usual course of professional practice required that Reynolds ''enforce the terms of the'' Pain Contract, see GX 17, at 5 (par. 9), ''cease issuing further controlled substances to T.H., contact Hillcrest Pharmacy and Medicine Shoppe pharmacy to determine the prescriptions T.H. had filled, and order T.H. to take a UDS to determine if he was taking or diverting the controlled substances he had been issued or was taking controlled substances he had not been prescribed at AMC.'' GX 68, at 60.

On September 7, 2006, T.H. returned to AMC and was seen by Stout, who issued him prescriptions for 60 tablets of OxyContin 40 mg, 45 tablets of Lortab 10 mg, and 75 tablets of Xanax 1 mg. *See* GX 17, at 36; GX 18, at 8. According to the Expert, Stout noted in the record of this visit that ''[T.H.] got meds filled early on 08/10/06—Rx dated 08/15/06.'' GX 68, at 61. As the Expert explained, Stout was clearly aware of this red flag and should have questioned if T.H. was taking more than the prescribed amount or if he was selling the drugs. *Id.* Notwithstanding this, as well as the extensive other evidence in T.H.'s record that he was either abusing and/or diverting controlled substances, Stout issued the prescription. GX 18, at 8. For the same reasons set forth with respect to T.H.'s previous visit, the Expert concluded that Stout's issuance of the prescriptions was below the standard of care and outside of the usual course of professional practice. GX 68, at 61.

On September 29, 2006, T.H. returned to AMC and was seen by Reynolds, who issued him prescriptions for 60 tablets of OxyContin 40 mg, 75 tablets of Xanax 1 mg, and 45 Lortab 10 mg. GX 17, at 35; GX 18, at 8. Once again, T.H. presented a red flag in that he was seeking an early refill of both his OxyContin and Xanax prescriptions. GX 68, at 62. According to the Expert, T.H. should have had eight days left on the previous OxyContin prescription (which was for a thirty-day supply) and at least three days left on the previous Xanax prescription (which provided 75 tablets with a dosing of one tablet every 8–12 hours). *See* GX 68, at 62; GX 17, at 36; GX 18, at 8.

The Expert also noted that while T.H. had been receiving narcotics from AMC for nearly one year and had yet to be subjected to a UDS, and T.H.'s file documents that Reynolds sent him for blood work after this visit to check his blood counts, thyroid, and metabolic panel, *see* GX 16, at 50; Reynolds did not require that T.H. provide a UDS. GX 68, at 62. ''Based on this new red flag and the prior information indicating T.H.'s abuse and/or diversion of controlled substances,'' the Expert concluded that ''it was below the standard of care and outside the usual course of professional practice for Reynolds to issue these prescriptions without taking any steps to monitor his controlled substances use, including conducting a UDS and checking with

[11] The Expert acknowledged that the fax banner on the copies in T.H.'s file was cut off. However, the Expert explained that she had reviewed copies of the same four documents that were sent to another provider (*see* GX 22), which were provided by DEA, and that the date appearing on the fax banner was July 5, 2006. It is clear, however that these documents were faxed and received by AMC because the next day, one William Clever, another Advance Nurse Practitioner at AMC, wrote a letter to T.H. on AMC's letterhead that he was ''withdrawing from further professional attendance with you,'' suggested that T.H. find ''another provider without delay,'' and that ''after receipt of this letter, we will no longer be able to prescribe narcotics to you.'' GX 21, at 1.

his pharmacy for controlled substances prescriptions he was filling.''[12] *Id.*

On January 3, 2007, T.H. went to AMC and saw Killebrew, who issued him prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Percocet 10/325 mg, and 75 tablets of Xanax 1 mg. *See* GX 17, at 32; GX 18, at 28. Killebrew noted in the record of this visit that T.H. was ''[g]etting [d]ivorced,'' complaining of increased anxiety due to his divorce, and was crying. *See* GX 17, at 32. The visit note also documents that T.H. had lost six pounds since his last visit. *Id.*

According to the Expert, this may indicate that T.H. had depression given the information T.H. shared about his divorce and Killebrew wrote him a prescription for an antidepressant (Celexa) at this visit. GX 68, at 63 (citing GX 17, at 32). T.H. also reported that his pain was a seven out of ten, which indicates that the drug regimen he had been prescribed previously at AMC was not controlling his pain. *Id.* Killebrew also had T.H. sign a new Pain Management Agreement, which she witnessed. GX 17, at 2.

The Expert explained that based on the information T.H. reported at this visit, as well as the information in his file from prior visits, T.H. should have been considered a ''high-risk patient for managing chronic pain'' and whose ''care extend[ed] beyond the scope of'' a nurse practitioner engaged in family practice ''at this point.'' GX 68, at 63. The Expert further noted that a prudent practitioner would have considered T.H. to be ''a risk for suicide and diversion'' and would have referred him ''to a mental health specialist and a comprehensive pain management program.'' *Id.* Yet, the Expert found no evidence in the file that Killebrew did so. *Id.*

The Expert also noted that there was no documentation in T.H.'s file indicating that Killebrew had checked with the pharmacy T.H. had identified on his pain contracts as the sole pharmacy he would use to fill his prescriptions to determine if he still was engaging in doctor-shopping. *Id.* The Expert also found no evidence that Killebrew required him to submit to a UDS. *Id.* at 63–64. Based on the red flags T.H. presented and Killebrew's failure to take these steps to monitor T.H.'s use of controlled substances, the Expert opined that the issuance of the prescriptions was contrary to the Board's Rule 1000–04–.08(4)(c), and, accordingly, below the standard of care and outside the usual course of professional practice. *Id.* at 64.

On March 2, 2007, T.H. visited AMC and saw Stout, who issued him prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 75 tablets of Xanax 1 mg. *See* GX 17, at 29; GX 18, at 27. The Expert opined that Stout's notes for this visit were ''sparse, at best'' as they state only that T.H. was ''[h]ere for follow-up. Denies recent trauma or illness. Patient states pain medication is controlling his pain. Describes pain as 4/10 while on pain medication. Denies fever, chills, nvd.'' GX 68, at 64 (quoting GX 17, at 29). The Expert also observed that the visit notes contained no discussion of T.H.'s anxiety issues which Killebrew had documented during the January 3, 2007 visit. *Id.* The Expert also found that there was ''no documentation of any evaluation or assessment of the alcohol and financial red flags that were presented at several prior visits,'' that Stout ''neglected to inquire about whether T.H. was now employed or whether he was currently drinking alcohol'' even though the form contained a section for alcohol use (''ETOH''), nor elaborated on his purported finding that T.H. was ''anxious.'' *Id.*

The Expert also found that there was still no evidence that a written treatment plan was created for T.H. identifying objectives of treatment, or an update on the treatment plan as required by TN BON Rule 1000–04–.08(4)(c)2 & 4. *Id.* Moreover, the Expert found that while on January 1, 2007, the Tennessee prescription monitoring program (CSMD) had become available to practitioners to assist them in determining whether their patients were seeing other providers, there was no evidence in the file that Stout conducted a check on T.H. at this visit, even though T.H.'s record documented multiple instances in which AMC obtained information that T.H. was engaged in doctor-shopping. *Id.* at 64–65. Nor did the Expert find any evidence in the file that Stout had checked with the pharmacy T.H. identified on his pain contracts as the sole pharmacy he would use to fill his prescriptions to determine if he was doctor shopping. *Id.* at 65. The Expert thus opined that Stout's issuance of these prescriptions was contrary to the guidelines set forth in Tennessee BON Rule 1000–04–.08(4)(c), and, accordingly, below the standard of care in Tennessee and outside the usual course of professional practice. *Id.*

On May 1, 2007, T.H. visited AMC and saw Stout, who again issued him prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 75 tablets of Xanax 1 mg. *See* GX 17, at 27; GX 18, at 25–26. Once again, the Expert found that Stout's record of the visit was ''very sparse,'' as it stated only: ''Here for follow-up. PT denies trauma. Patient states back pain is controlled by pain medication. Denies radiation of pain or urinary incontinence. Denies chest pain or sob. Denies fever, chills, nvd.'' GX 68, at 65. Once again, the Expert observed that the visit note did not document that Stout had discussed with T.H. his use of alcohol (the ETOH portion of the form being blank), his anxiety,[13] and his employment and financial situation. *Id.*

The Expert also found that there was still no evidence of a written treatment plan for T.H. identifying treatment objectives, or an update on the treatment plan as required by TN BON Rule 1000–04–.08(4)(c)2, 4; she also found that Stout failed to quantify T.H.'s pain on this visit. *Id.* at 66. And once again, the Expert found that Stout did not take any steps to monitor whether T.H. was currently doctor-shopping and seeing other practitioners. *Id.* The Expert thus opined that Stout's issuance of these prescriptions was contrary to the guidelines set forth in Tennessee BON Rule 1000–04–.08(4)(c), and accordingly, below the standard of care in Tennessee and outside the usual course of professional practice. *Id.*

On June 26, 2007, T.H. visited AMC and saw Stout, who again issued him prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 75 tablets of Xanax 1 mg. *See* GX 17, at 23–24; GX 5, at 14–17. While the Expert noted that AMC had started using electronic medical records and that Stout had noted that T.H. ''is satisfied with the current treatment plan,'' she still found that there was no documentation in the record of a written treatment plan. GX 68, at 66 (citing TN BON Rule 1000–04–.08(4)(c)2). The Expert further noted that while Stout documented that T.H. reported he was having ''some increases [sic] problems situationally lately with their [sic] anxiety and depression,'' Stout again neglected to inquire about T.H.'s use of alcohol, which could have been the source of his anxiety and depression problems. *Id.* (quoting GX 17, at 23); also citing GX 41, at 6 (Uphold & Graham).

According to the Expert, Stout's failure to address this issue was contrary to the requirements of TN BON

[12] Reynolds also saw T.H. on November 6 and December 4, 2006; at each visit, Reynolds issued him prescriptions for 60 OxyContin 40 mg, 30 Percocet 10/325 mg, and 75 Xanax 1 mg. GX 17, at 33–34; GX 18, at 9–10.

[13] While the note stated that T.H. was ''anxious,'' the Expert explained that Stout ''failed to elaborate on his finding.'' GX 68, at 65.

Rule 1000–04–.08(4)(c)2 because ''[w]ithout knowing about the status of his alcohol issues, Mr. Stout was unable, and in fact did not 'consider [the] need for further testing, consultations, referrals, or use of other treatment modalities.' '' *Id.* at 67. Also, while Stout noted that T.H. was having ''work issues'' and ''financial problems,'' he failed to document whether T.H. was in fact now employed and capable of paying for his continued treatment (including medications). *Id.* Moreover, the Expert found no evidence that Stout took any steps to monitor whether T.H. was currently doctor-shopping and seeing other practitioners. *Id.* The Expert thus opined that Stout's issuance of these prescriptions was contrary to the guidelines set forth in Tennessee BON Rule 1000–04–.08(4)(c), and accordingly, below the standard of care in Tennessee and outside the usual course of professional practice. *Id.*

On July 24, 2007, T.H. returned to AMC and saw Killebrew, who issued him prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 90 tablets of Valium 10 mg. *See* GX 17, at 21–22; GX 18, at 24. T.H. reported that his pain was a 4 out of 10, that he was having problems with anxiety (which, according to the Expert indicated that the Xanax was not controlling his anxiety), and that he was trying to quit alcohol. GX 17, at 21. T.H. also reported that he had made an appointment with a local mental health facility. Killebrew noted that T.H. presented with ''Hand tremors, anxious today'' and that he had an elevated blood pressure. *Id.* According to the Expert, these findings may have been signs of anxiety or alcohol/drug withdrawal. GX 68, at 68.

According to the Expert, alcohol abuse was a red flag and Killebrew should have considered that if T.H. was abusing alcohol, he may also have been abusing opioids and/or illicit substances. *Id.* (citing GX 41, at 20–21 (Uphold & Graham)). Relying on Uphold & Graham, the Expert further noted that '' '[p]atients who are alcohol dependent and who also have a psychiatric disorder should be referred for treatment for the underlying disorders as these patients are usually complex.' '' *Id.* (quoting GX 41, at 23); *see also* GX 41, at 15 (stating that ''[p]atients with comorbid conditions (primary anxiety disorder, substance abuse, dementia)'' should be referred to a specialist). According to the Expert, ''Killebrew's findings on this visit are further evidence that T.H. required care that was beyond the scope of family practice nurse practitioners.'' GX 68, at 68.

While the Expert noted that Killebrew had documented in T.H.'s record that she had provided him with information on Alcoholics Anonymous and other recovery groups, *id.* (citing GX 17, at 21); the Expert then explained that ''a patient who is trying to quit alcohol is not an appropriate patient for [a] primary care nurse practitioner to attempt to manage his chronic pain'' *Id.* The Expert thus found that ''Killebrew should have ceased issuing T.H. further controlled substance prescriptions and sent him for evaluation by a mental health specialist,'' and further concluded that Killebrew's issuance of the prescriptions was ''contrary to the guidelines set forth in Tennessee BON Rule 1000–04–.08(4)(c), and accordingly, not consistent with the standard of care and outside the usual course of professional practice.'' *Id.*

On August 23, 2007, Killebrew again saw T.H. and issued him prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 90 tablets of Valium 10 mg. *See* GX 17, at 19–20; GX. 18, at 23. Killebrew noted in the visit record that T.H. had recently gone to the JCMC emergency room after injuring his left leg. *See* GX 17, at 19.

According to the Expert, this information was also a red flag suggestive of either abuse or an injury caused by over sedation, as the latter could have resulted from T.H.'s combined ingestion of Valium (which she had previously prescribed to him) and alcohol, or Valium alone, given the high dosage (10 mg three times per day) she had prescribed. GX 68, at 69 (citing GX 17, at 21–22; GX 18, at 24).

The Expert further noted that Killebrew neither asked T.H. if he had obtained any pain medications at his JCMC ER visit, nor obtained any records from the JCMC to determine whether T.H. had been given any prescriptions. *Id.* at 69. The Expert also found that Killebrew neither contacted T.H.'s pharmacy to obtain a recent dispensing history, nor conducted a check of the CSMD to see if he had been receiving controlled substances from other practitioners. *Id.*

While Killebrew again noted in the record that T.H. was ''trying to quit [alcohol]'' and ''[h]as made an appt. with Frontier Health,'' she did not document that she discussed with T.H. his efforts to quit alcohol since his previous visit or that she had discussed with T.H. whether he had been seen by the mental health clinic. GX 17, at 19. As the Expert found, Killebrew simply issued T.H. ''additional controlled substance prescriptions in the face of all of the red flags of T.H.'s abuse and diversion of controlled substances set forth in the paragraphs above.'' GX 68, at 69–70. The Expert thus concluded that Killebrew's issuance of the additional controlled substance prescriptions was contrary to the guidelines set forth in Tennessee BON Rule 1000–04–.08(4)(c), and accordingly, below the standard of care and outside the usual course of professional practice. *Id.* at 70 (citing Uphold & Graham, GX 41, at 14, 23).

On September 19, 2007, T.H. returned to AMC and saw Reynolds, who issued him prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Percocet 10/650 mg, and 90 tablets of Valium 10 mg. *See* GX 17, at 17–18; GX 18, at 23. According to the Expert, Reynolds issued these prescriptions without discussing with T.H. his visit at the mental health facility and did not obtain any records from the facility, even though the two previous visit notes mentioned that T.H. had made such an appointment. GX 68, at 70. Reynolds also did not acquire any information from T.H. about his efforts to quit alcohol, even though this was also mentioned in the two previous visit notes, and Reynolds did not document that he even addressed with T.H. his alcohol issues. *Id.;* GX 17, at 17–18. Nor is there any documentation that Reynolds discussed with T.H. his recent visit to the Emergency Room and T.H.'s file contains no record of his visit to the ER. GX 17, at 17–18.

The Expert further noted that Reynolds ''failed to take any other steps to monitor T.H.'s controlled substances use, despite the numerous red flags of potential drug abuse and diversion that T.H. had presented on prior visits.'' GX 68, at 70. The Expert thus concluded that ''Reynolds' issuance of the additional controlled substance prescriptions was contrary to the guidelines set forth in Tennessee BON Rule 1000–04–.08(4)(c), and accordingly, below the standard of care and outside the usual course of professional practice.'' *Id.*

On October 17, 2007, T.H. returned to AMC and again saw Reynolds, who issued him more prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Percocet 10 mg, 90 tablets of Xanax 1 mg, and Celexa 20 mg (a non-controlled anti-depressant). *See* GX 17, at 13–15; GX 19, at 2–6. In the visit note, Reynolds documented that T.H. ''has had increased problems with depression and had ran out of his Prozac, he is going to seek counseling at wmh and we will restart antidepressant today.'' GX 17, at 13.

Notably, T.H. had not previously been prescribed Prozac by anyone at AMC. *See generally* GX 17, at 17–47.

According to the Expert, this information should have placed Reynolds ''on notice that T.H. was seeing another practitioner, in particular a mental health specialist.'' GX 68, at 71. The Expert further explained that:

> [i]f a mental health specialist had taken over care for T.H. and his depression was worsening, as . . . Reynolds' notes of this visit reflect, then the usual course of practice would have been for the primary care nurse practitioner to contact the specialist and have the specialist manage T.H.'s care. Under these circumstances, Mr. Reynolds, as the primary care nurse practitioner, should not have changed T.H.'s antidepressant from Prozac to Celexa, and he should not have prescribed him Xanax and opioids, especially in the quantities he did, which have lethal potential in someone with increasing depression and history of alcohol use/abuse.

Id. at 71–72.

According to the Expert, Reynolds should also have asked T.H. about his use of Prozac, run a CSMD check, and required T.H. to submit to a UDS before issuing him more prescriptions. *Id.* at 71. However, according to T.H.'s record, Reynolds did none of these. *See* GX 17, at 13–15; GX 68, at 71. Moreover, according to the Expert, while T.H. would still have had several days left on his Valium 10 mg prescription, ''Reynolds should have, but according to the record did not'' instruct T.H. to stop taking the drug even though Reynolds had prescribed Xanax 1 mg along with the opioids (OxyContin and Percocet). GX 68, at 72 (citing GX 17, at 17–18; GX 18, at 23). According to the Expert, ''[a]dding 10 mg Valium to a drug regimen of OxyContin 40 mg, Percocet 10 mg, and Xanax 1 mg had the potential to be a lethal combination because of the respiratory depressing effects of these drugs.'' *Id.* The Expert thus concluded that Reynolds' issuance of the controlled substances prescriptions at this visit ''was contrary to the guidelines set forth in Tennessee BON Rule 1000–04–.08(4)(c), and accordingly, below the standard of care and outside the usual course of professional practice.'' *Id.*

T.H. died the following day. GX 24, at 2. According to the Medical Examiner's report, ''[p]ostmortem blood toxicology showed oxycodone (and its metabolite) in a supratherapeutic to potentially lethal concentration, alprazolam in a therapeutic to toxic concentration and diazepam (and its metabolite) in a therapeutic concentration.'' *Id.* at 1. The Medical Examiner thus concluded that ''[a]lthough the drugs may be present in therapeutic to potentially lethal concentrations, the combined/synergistic effects of the drugs caused death by central nervous system depression.'' *Id.*

Summarizing her findings, the Expert explained that during the two-year period in which T.H. went to AMC, he presented ''numerous red flags of abuse and diversion'' and yet he ''was never asked to take a UDS, nor was he ever asked to come into AMC for a pill count.'' GX 68, at 72. The Expert also explained that while ''the CSMD was available for the last ten months of his AMC visits, none of the practitioners ever conducted a CSMD check for him.'' *Id.* The Expert thus opined that ''the monitoring of [T.H.'s] controlled substances use by Mr. Reynolds, Mr. Stout, and Ms. Killebrew was woefully inadequate, and far below the standard of care in Tennessee.'' *Id.*

C.S.

On December 12, 2008, C.S. made her first visit to AMC and was seen by Reynolds. GX 26, at 45–46. C.S. completed a patient intake form stating that she had shoulder, knee, and back pain; she wrote that she had suffered injuries from a car accident which resulted in a metal rod in her femur and a plate and screw in her ankle. *Id.* at 10–11. Notably, on this form, C.S. stated that she did not have a current healthcare provider and did not list any medications that she was currently taking. *Id.* at 10, 11. C.S. also signed a Pain Management Agreement at this visit, which Reynolds also signed. *Id.* at 9. Reynolds prescribed a thirty-day supply of 90 tablets of Percocet 7.5/500 mg (oxycodone/acetaminophen, a schedule II drug) and 60 tablets of Valium 5 mg. *See* GX 26, at 45–46; GX 29, at 3.

The Expert observed that while Reynolds noted in the record that C.S. had ''a longstanding [history] of back pain,'' ''he did not have any information regarding treatment C.S. had been receiving for the fourteen months immediately preceding her first visit to AMC.'' GX 68, at 76 (citing GX 26, at 45). The Expert further observed that the only documentation of prior treatments in C.S.'s file were records Reynolds obtained from a physician who treated her between June 2007 and October 25, 2007.[14] *Id.* Significantly, that physician had noted that C.S. ''takes extra Rx pain pills in contrast to my recommendations'' and that he did ''not think she can self-medicate. . . .'' GX 26, at 58–61.

According to the Expert, this information ''should have been a red flag to Reynolds that C.S. misused and abused previous medications she had been prescribed.'' GX 68, at 76. Yet the Expert found that ''C.S's file indicates that Reynolds did not take any steps to follow-up on this information, such as contacting the previous physician about these entries and the nature, extent and duration of his treatment of C.S.'' *Id.* Nor, according to the Expert, did Reynolds ''obtain any other information related to C.S.'s history of[,] and potential for[,] substance abuse, despite being placed on clear notice of such issues.'' *Id.* The Expert also found that Reynolds ''failed to conduct a CSMD check, which would have provided him information about previous treatments with controlled substances and her substance use and abuse history.'' *Id* at 76–77.

The Expert further found that Reynolds ''failed to create a patient record that appropriately documented C.S.'s medical history and pertinent historical data, such as pain history, pertinent evaluations by other providers, history of and potential for substance abuse, and pertinent coexisting diseases and conditions. He also did not create a written treatment plan tailored for C.S.'s individual needs, nor did he consider the need for further testing, consultations, or referrals, or the use of other treatment modalities.'' *Id.* at 77 (citing Tenn. BON Rule 1000–.04–.08(4)(c)1 & 2. The Expert thus concluded that Reynolds' decision to immediately start C.S. on a controlled substances regimen contravened the guidelines of TN BON Rule 1000–04–.08. *Id.*

The Expert also noted that Reynolds had written in C.S.'s record that her pain was being treated in accordance with the guidelines in the Jackman article, which AMC had purportedly adopted for its treatment protocols.[15] *Id.* at 73. Consistent with her analysis and conclusions regarding N.S. and T.H., the Expert concluded that Reynolds ignored several recommendations contained within that article in his treatment of C.S. *Id.*

These included that ''[w]hen psychiatric comorbidities are present, risk of substance abuse is high and pain management may require specialized treatment or consultation. Referral to a pain management specialist can be helpful.'' *Id.* (quoting GX 39, at 5) As the Expert explained, the article then instructed that the evaluation of the

[14] The file does include records indicating that from June–October 2007 C.S. was taking Percocet and Ativan, as well as Effexor, a non-controlled drug prescribed to treat major depressive disorder, anxiety and panic disorder. GX 26, at 58–61.

[15] *See* Robert P. Jackman, M.D., *et al.,* ''Chronic Nonmalignant Pain in Primary Care,'' *American Family Physician* (Nov. 2008) (GX 39, at 5–12).

patient must include ''[a] thorough social and psychiatric history [that] may alert the physician to issues, such as current and past substance abuse, development history, depression, anxiety, or other factors that may interfere with achieving treatment goals.'' *Id.* at 74.

According to the article, ''[b]y identifying patients at risk of possible opioid misuse (*e.g.* persons with past or current substance abuse, persons with psychiatric issues), physicians can choose to modify the monitoring plan or to refer the patient to a pain specialist.'' GX 39, at 5. The article further stated that ''[f]or patients at high risk of diversion and abuse, consider *the routine use* of random urine drug screens to assess for presence of prescribed medications and the absence of illicit substances.'' *Id.* at 9 (emphasis added). The article also advised that ''[a]berrant behavior that may suggest medication misuse includes use of pain medications other than for pain treatment, *impaired control* (of self or of medication use), compulsive use of medication . . . selling or altering medications, *calls for early refills, losing prescriptions, drug-seeking behavior (e.g. doctor-shopping),* or reluctance to try nonpharmacologic intervention.'' *Id.* at 11 (emphasis added).[16]

Based on the guidance contained in the Jackman article, the Editorial, and the requirements set forth in TN BON Rule 1000–04–.08(4)(c), the Expert concluded that ''Reynolds[']issuance of the controlled substances prescriptions to C.S. at her first visit was below the standard of care and outside the usual course of professional practice.'' GX 68, at 75. Moreover, based on her review ''of C.S.'s patient file through her last visit on November 30, 2009,'' the Expert concluded that both Reynolds and Stout ''failed to comply with the Rule's guidelines on subsequent visits by C.S.'' *Id.* at 77. More specifically, the Expert found that Reynolds and Stout ''never acquired the information that was lacking at C.S.'s initial visit and, therefore, the controlled substances prescriptions they issued at subsequent visits were contrary to the Rule's guidelines for the same reasons as the prescriptions issued on the initial visit.'' *Id.*

The Expert also found that ''at each periodic interval, Reynolds and Stout failed to appropriately evaluate C.S. for continuation or change of medication, and include in the patient record her progress towards reaching treatment objectives, any new information about the etiology of the pain, and an update on the treatment plan.'' *Id.* at 77–78 (citing TN BON Rule 1000–04–.08(4)(c)4). The Expert thus concluded that on C.S.'s subsequent visits, such as those of March 12, 2009 and April 10, 2009, when Stout prescribed 90 tablets of Percocet 7.5/500 mg, 60 tablets of Valium 5 mg, and 30 tablets of Fastin 30 mg (phentermine, a schedule IV drug) to her, he acted in contravention of the Rule's guidelines, as well as the standard of care. *Id.* at 78 (citing GX 26, 28–37, 40; GX 27, at 2, 4, 5; GX 29, at 4).

The Expert also found that both Reynolds and Stout ignored red flags of abuse and diversion that were presented to them at C.S.'s subsequent visits, and did so even though C.S. had violated the terms of her Pain Management Agreement. *Id.* For example, on July 9, 2009, Reynolds issued C.S. prescriptions for 45 tablets of Roxicodone 15 mg (oxycodone), 60 tablets of Valium 5 mg and 30 tablets of Fastin 37.5 mg. *See* GX 26, at 29–30; GX 28, at 2. Reynolds issued these prescriptions even though on June 12, 2009, Reynolds documented that he had received a phone call from a person at ''Genesis Healthcare,'' which was a ''new practice in Boones Creek''; according to the note, Reynolds was informed that C.S. had told Genesis Healthcare that ''she did not have a family practice [and] was seeking to establish new [patient] care.'' GX 26, at 31. Reynolds was further informed that C.S. also used another name (''goes by [C.M.]).'' *Id.* Reynolds received this call three days after he had seen C.S. at AMC (on June 9, 2009), and had prescribed to her 45 tablets of Roxicodone 15 mg and 60 tablets of Valium 5 mg. *See* GX 26, at 33–34; GX 28, at 2. Of further note, the call from Genesis occurred two days after C.S. had called AMC seeking a refill of Fastin, which Reynolds refused to issue. GX 26, at 32.

According to the Expert, the telephone call from Genesis Healthcare was ''a huge red flag.'' GX 68, at 79. The Expert explained that it ''should have been alarming'' to Reynolds ''that C.S. told another practice that she did not have a family practice when she had been going to AMC monthly for the past seven months'' and that she was also using a second name. *Id.* As the Expert explained, after the phone call, Reynolds was aware that C.S. had misled both AMC and the other practitioner, and likely was doctor-shopping. *Id.* This was a violation of the terms of her Pain Management Agreement, which included the provision that: ''I will not attempt to obtain any controlled medicines, including opioid pain medicines, controlled stimulants, or anti-anxiety medicines from any other doctors.'' *Id.* (quoting GX 26, at 9).

Yet, at her July 9, 2009 visit, Reynolds did not discuss or otherwise confront C.S. about the information he had received from Genesis. *Id.* (citing GX 26, at 29–30). Moreover, C.S.'s patient record contains no documentation that Reynolds addressed C.S.'s violation of her PMA, even though its terms provided that if she broke the agreement, ''my provider will stop prescribing controlled substances immediately and only provide care for life threatening and chronic medical conditions'' and that she would ''either be discharged from th[e] practice or [o]ffered only alternative treatments such as non-narcotic medications and treatment center options.'' *Id.* at 79–80 (quoting GX 26, at 9); *see also* GX 26, at 29–30.

Moreover, the medical record contains no evidence that Reynolds took steps to monitor C.S.'s controlled substances use, such as by conducting a check of the CSMD before issuing the prescriptions. *Id.* at 79–80; *see also* GX 26. He also did not require her to submit to a UDS to determine if she was taking the drugs she had been prescribed at AMC and if there were any non-AMC prescribed drugs in her system. *Id.* at 80; GX 26.

''For all of these reasons,'' the Expert concluded that ''Reynolds' decision to continue issuing [C.S.] controlled substance prescriptions on July 9, 2009 was contrary to [the] guidelines set forth in Tenn. BON Rule 1000–.04–.08, and accordingly, below the standard of care and outside the usual course of professional practice.'' GX 68, at 80. Relying on the Jackman article and

[16] The Jackman article was supplemented in the same edition of *American Family Physician* by an Editorial, which provided additional guidance on the ''risk of drug misuse, abuse, and addiction'' that exists when treating patient with long-term opioids, a topic that was not fully explored in the Jackman article. *See* GX 49. The Editorial discussed the steps physicians should take to ''monitor'' these risks, including focusing on the patient's medical history, obtaining information from family members, focusing on physical signs of possible aberrant drug-taking behavior, such as slurred speech, small pupils, and unusual affect, and the use of urine drug screening that ''should be positive for prescribed medications, negative for medications that have not been prescribed, and negative for illicit drugs.'' *Id.* at 1–2. The Editorial, moreover, emphasized that ''[t]he current standard of care used by pain management specialists to treat patients with chronic pain and aberrant drug-taking behavior is an abstinence-oriented approach.'' *Id.* at 2. According to the Editorial, ''[i]n this approach, patients initially discontinue their opioid use for a 'drug holiday.' Formal inpatient or outpatient detoxification is sometimes required to stabilize opioid withdrawal syndrome. Following this, patients are given multidisciplinary treatment for opioid dependency and chronic pain, including cognitive behavior therapy (*i.e.* for chronic pain and a substance abuse disorder) that is concurrent with nonopioid pain management.'' *Id.*

accompanying Editorial, the Expert further concluded that ''the standard of care and usual course of professional practice . . . would have been to enforce the terms of C.S.'s [Pain Mgmt. Contract], cease prescribing her controlled substances, and refer her to a pain management specialist and/or addiction specialist to address her drug-seeking behavior.'' *Id.*

On August 4, 2009, C.S. returned to AMC and saw Stout, who issued her prescriptions for 45 tablets of Roxicodone 15 mg, 60 tablets of Valium 5 mg, and 30 tablets of Fastin 37.5 mg. *See* GX 26, at 27–28; GX 27, at 2; GX 28, at 2 & 14. Stout issued these prescriptions even though he had since received further evidence unequivocally showing that C.S. had engaged in doctor-shopping at both Genesis Healthcare and a third practitioner, as well as pharmacy-shopping. GX 68, at 80. Notably, on the date of this visit, AMC ran two CSMD queries to determine what controlled substances had been dispensed to C.S. during the period August 1, 2008, through August 4, 2009; the report was placed in C.S.'s AMC patient file. *Id.* (citing GX 26, at 54–57). The query was run using both of the names C.S. was known to have used when she sought controlled substances. *Id.* As the Expert explained, this demonstrates that AMC and Stout were aware of the fact that C.S. used multiple names. *Id.* at 80–81.

According to the Expert, the two CSMD reports revealed the following information:

(a) On June 3, 2009, C.M. received prescriptions for 56 oxycodone 7.5 mg and 15 Alprazolam 1 mg from the above-referenced practitioner in Boones Creek, Tennessee, which was six days before she visited AMC on June 9, 2009 and obtained prescriptions for 45 tablets of Roxicodone 15 mg and 60 tablets of Valium 5 mg from Reynolds.

(b) On June 15, 2009, C.S. received a prescription for phentermine 37.5 mg, another schedule IV controlled substance for weight loss, from a third different practitioner just six days after her June 9, 2009 visit to AMC, and five days after Reynolds refused her request to refill her prescription for Fastin.

(c) C.S. had been treated for narcotic dependence during the several months preceding her first visit to AMC. Specifically, the CSMP report shows that C.S. was treated with Suboxone throughout 2008. Significantly, the CSMP report showed that on October 10, 2008, just two months before C.S. began as a patient at AMC, she was issued a Suboxone prescription by Dr. Vance Shaw, AMC's Medical Director.

(d) C.S. was pharmacy shopping, in addition to doctor-shopping. On May 11, 2009, C.S. presented to Church Hill Drugs prescriptions for a thirty-day supply of oxycodone and alprazolam that she had obtained from AMC (Reynolds). Twenty-four days later, on June 3, 2009, C.S. presented to a different pharmacy, Wilson Pharmacy, the oxycodone and alprazolam prescriptions she obtained from the Boones Creek practitioner. Then, six days later, on June 9, 2009, which would have been the thirty-day expiration date of the May 11, 2009 prescriptions, C.S. returned to Church Hill Drugs to present the oxycodone and diazepam prescriptions she obtained from AMC (Reynolds). Thus, the CSMP report alerted Stout to the fact that C.S. was consciously selecting different pharmacies at which to present prescriptions for the same types of controlled substances so as to avoid being detected for doctor-shopping and to obtain early refills.

Id. at 81–82 (citing GX 26, at 49–57).

Thus, the CSMD reports clearly showed that C.S. had violated the terms of her Pain Management Agreement by both doctor shopping and pharmacy shopping (*i.e.,* filling her controlled substance prescriptions at multiple pharmacies).[17] *Id.* at 82. Notwithstanding the ''information showing that C.S. was seeing three different practices at the same time, was pharmacy-shopping, was in violation of her PMA, and was being treated for narcotics dependence for the several months leading up to her first AMC visit, which she had not disclosed to AMC, Stout issued her the above-referenced controlled substances prescriptions.'' *Id.*

Indeed, according to C.S.'s file, during the visit, Stout did not even discuss the CSMD reports with C.S. GX 26, at 27–28. Nor did he require her to provide a UDS or subject her to a pill count, which, according to the Expert, would have been reasonable responses to the red flag information he possessed. *Id.* The Expert thus found that Stout's decision to issue her more controlled substance prescriptions on August 4, 2009 was ''contrary to guidelines set forth in Tenn. BON Rule 1000–.04–.08, and accordingly, below the standard of care and outside the usual course of professional practice.'' GX 68, at 83.

Reynolds and Stout issued additional controlled substances prescriptions for oxycodone and benzodiazepines (Valium and Xanax) to C.S. on September 3, 2009, September 30, 2009, October 29, 2009, and November 30, 2009. *See* GX 26, at 19–26. For the reasons previously stated, the Expert found that Reynolds' and Stout's decisions to issuance C.S. more controlled substance prescription on these dates was contrary to AMC's professed protocols and the Board's Rule 1000–04.–.08(4)(c), and was therefore ''below the standard of care and outside the usual course of professional practice.'' GX 68, at 84.

Moreover, the Expert found that on September 30, 2009, another CSMD report was obtained on C.S., presumably by Stout who saw her on this date. GX 68, at 84; GX 26, at 49–52. Significantly, the report showed that on August 4–5, 2009, C.S. presented the prescriptions she received from Mr. Stout on August 4, 2005, *see id.* at 23–24; to two more pharmacies, Cave's Drugs and P&S Pharmacy. *See id.* at 49, 51. Stout, however, also ignored this additional violation of the Pain Management Agreement and issued C.S. prescriptions for 45 Roxicodone 15 mg and 60 Valium 5 mg. GX 68, at 84.

On October 29, 2009, Reynolds saw C.S. and actually increased her Roxicodone prescription from 45 to 60 tablets; he also issued her a prescription for 60 tablets of Valium 5 mg. GX 26, at 22. Not only did he ignore the information regarding C.S.'s doctor and pharmacy shopping, he also did so while noting in the visit record: ''No recent accidents or injuries and no significant changes in current medical condition. . . . Pt has no interest in further intervention and is satisfied with current treatment plan. . . .'' *Id.* at 21.

On November 30, 2009, C.S. made her last visit to AMC and saw Reynolds, who again prescribed to her 60 tablets of Roxicodone 15 mg. *Id.* at 20. Moreover, while the note contains the same statement that there were ''no significant changes in current medical condition'' and that the C.S. was ''satisfied with current treatment plan,'' Reynolds changed her prescription from Valium to 90 dosage units of Xanax .5 mg. *Id.* at 19–20.

To be sure, the visit note states her psychiatric condition as follows: ''Patient states that they [sic] have had some increases [sic] problems situationally lately with anxiety and depression. This seems to be related to social stressors such as family problems, work issues, financial stressors and sometimes for no reason to mention.'' *Id.* at 19. Yet this was the exact same statement that Reynolds provided in his documentation of C.S.'s psychiatric condition at her previous visit. *See id.* at 21. The record thus contains no explanation as to why Reynolds changed her prescription.

C.S. died the next day. Her death certificate lists the cause of death as ''multiple drug toxicity—oxycocodone, benzodiazepines, carbamates.'' [18] *Id.* at 5.

[17] In her Pain Management Agreement, C.S. had agreed to use only Church Hill Drugs to fill her controlled substance prescriptions. *See* GX 26, at 9.

[18] While not discussed above because it was not a controlled substance during the period in which

Summing up her conclusion with respect to the latter prescriptions, the Expert found that Reynolds and Stout acted below the standard of care and outside the usual course of professional practice. GX 68, at 84. Consistent with her conclusions regarding the previous prescriptions, the Expert concluded that Reynolds and Stout should have ''enforced the terms of the [Pain Management Agreement], ceased issuing her further controlled substances prescriptions, and immediately referred her to a pain management specialist and/or addiction specialist for treatment.'' [19] *Id.* at 85.

Discussion

As found above, each of the NPs has an application currently pending before the Agency, and by virtue of his having filed a timely renewal application, Mr. Stout also holds a registration. Pursuant to Section 304(a) of the Controlled Substances Act (CSA), a registration to ''dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). Thus, in determining whether the revocation of an existing registration is necessary to protect the public interest, the CSA directs that I consider the same five factors as I do in determining whether the granting of an application would be consistent with the public interest. These factors are:

(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).

''These factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem[ ] appropriate in determining whether a registration should be revoked.'' *Id.; see also Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009). While I must consider each factor, I am ''not required to make findings as to all of the factors.'' *Volkman,* 567 F.3d at 222; *see also Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). However, even where an Applicant or Registrant ultimately waives his right to a hearing on the allegations, the Government has the burden of proving, by substantial evidence, that the requirements are met for both the denial of an application and the revocation or suspension of an existing registration. 21 CFR 1301.44(d)–(e).

In this matter, I have considered all of the factors. Based on the Government's evidence with respect to factors two and four, I conclude that each practitioner has engaged in misconduct which establishes that granting his or her application, and in the case of Stout, continuing his registration, would be ''inconsistent with the public interest.'' [20] 21 U.S.C. 823(f) & 824(a)(4).

Factors II and IV—The Applicant's Experience in Dispensing Controlled Substances and Compliance with Applicable Laws Related to Controlled Substances

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

Fundamental to the CSA's scheme is the Agency's longstanding regulation, which states that ''[a] prescription for a controlled substance [is not] effective [unless it is] issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). This regulation further provides that ''an order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. 829] and . . . the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.'' *Id.*

As the Supreme Court has explained, ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006) (citing *United States* v. *Moore,* 423 U.S. 122, 135, 143 (1975)); *United States* v. *Alerre,* 430

C.S. was obtaining the prescriptions from AMC's practitioners, the evidence shows that she had also received Soma (carisoprodol) prescriptions at AMC on multiple occasions in the months prior to her death. *See* GX 26, at 20, 22–23, 26–27, 30. Carisoprodol is a derivative of carbamate. It has since been placed in schedule IV of the Controlled Substance Act because of substantial evidence of its abuse, particularly when taken in conjunction with narcotics and benzodiazepines. *See Placement of Carisoprodol Into Schedule IV,* 76 FR 77330 (2011).

[19] In reviewing C.S.'s medical record, the Expert also found that on the nine occasions on which Reynolds saw C.S. between December 12, 2008 and November 30, 2009, he created identical, verbatim records for each visit which included the following entries:

''Pt reports having increased pain with movement and decreased pain with rest'';

''Pt states their pain is a 4 out of 10 and that they have a better quality of life and are able to 'do more'";

''Patient states that they have had a headache for the last 1–2 days, radiating from their neck and around their temples. They relate it to increases in stressors such as home, work, financial, or problems with their family. They note some nause (sic), photophobia, and increased intensity with noise'';

''Anxiety and depression noted in patients (sic) mannerisms and actions during interview.''

GX 68, at 85 (quoting GX 26, at 19–46). Moreover, Reynolds and Stout documented the exact same physical exam findings at each of her visits. *See id.*

[20] As for factor one, the recommendation of the state licensing authority, while each of the practitioners apparently retains his/her Advanced Practice Nurse license, the Tennessee Board of Nursing has not made a recommendation to the Agency as to whether he/she should be granted a new DEA registration. Moreover, although each practitioner is currently licensed by the State and thus satisfies an essential condition for obtaining (and maintaining) a registration, *see* 21 U.S.C. 802(21) & 823(f), DEA has held repeatedly that the possession of state licensure '' 'is not dispositive of the public interest inquiry.' '' *George Mathew,* 75 FR 66138, 66145 (2010), *pet. for rev. denied Mathew* v. *DEA,* No. 10–73480, 472 Fed Appx. 453 (9th Cir. 2012); *see also Patrick W. Stodola,* 74 FR 20727, 20730 n.16 (2009); *Robert A. Leslie,* 68 FR 15227, 15230 (2003). As the Agency has long held, ''the Controlled Substances Act requires that the Administrator . . . make an independent determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest.'' *Mortimer Levin,* 57 FR 8680, 8681 (1992). Thus, this factor is not dispositive either for, or against, the granting of Respondent's application. *Paul Weir Battershell,* 76 FR 44359, 44366 (2009) (citing *Edmund Chein,* 74 FR 6580, 6590 (2007), *pet. for rev. denied Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008)).

Regarding factor three, there is no evidence that Reynolds, Stout, or Killebrew has been convicted of an offense related to the manufacture, distribution or dispensing of controlled substances. 21 U.S.C. 823(f)(3). However, as there are a number of reasons why a person may never be convicted of an offense falling under this factor, let alone be prosecuted for one, ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and thus, it is not dispositive. *David A. Ruben,* 78 FR 38363, 38379 n.35 (2013) (citing *Dewey C. MacKay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011)).

F.3d 681, 691 (4th Cir. 2005), *cert. denied,* 574 U.S. 1113 (2006) (stating that the prescription requirement likewise stands as a proscription against doctors acting not ''as a healer[,] but as a seller of wares.'').

Under the CSA, it is fundamental that a practitioner must establish and maintain a legitimate doctor-patient relationship in order to act ''in the usual course of . . . professional practice'' and to issue a prescription for a ''legitimate medical purpose.'' *Paul H. Volkman,* 73 FR 30629, 30642 (2008), *pet. for rev. denied,* 567 F.3d 215, 223–24 (6th Cir. 2009); *see also Moore,* 423 U.S. at 142–43 (noting that evidence established that the physician exceeded the bounds of professional practice, when ''he gave inadequate physical examinations or none at all,'' ''ignored the results of the tests he did make,'' and ''took no precautions against . . . misuse and diversion''). The CSA, however, generally looks to state law and standards of practice to determine whether a doctor and patient have established a legitimate doctor-patient relationship. *Volkman,* 73 FR at 30642.

Moreover, while a finding that a practitioner has violated 21 CFR 1306.04(a) establishes that the practitioner knowing and intentionally distributed a controlled substance in violation of 21 U.S.C. 841(a)(1), ''the Agency's authority to deny an application [and] to revoke an existing registration . . . is not limited to those instances in which a practitioner intentionally diverts a controlled substance.'' *Bienvenido Tan,* 76 FR 17673, 17689 (2011) (citing *Paul J. Caragine, Jr.,* 63 FR 51592, 51601 (1998)); *see also Dewey C. MacKay,* 75 FR at 49974. As *Caragine* explained: ''[j]ust because misconduct is unintentional, innocent, or devoid of improper motive, [it] does not preclude revocation or denial. Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify'' the revocation of an existing registration or the denial of an application for a registration. 63 FR at 51601.

''Accordingly, under the public interest standard, DEA has authority to consider those prescribing practices of a physician, which, while not rising to the level of intentional or knowing misconduct, nonetheless create a substantial risk of diversion.'' *MacKay,* 75 FR at 49974; *see also Patrick K. Chau,* 77 FR 36003, 36007 (2012). Likewise, ''[a] practitioner who ignores the warning signs that [his] patients are either personally abusing or diverting controlled substances commits 'acts inconsistent with the public interest,' 21 U.S.C. 824(a)(4), even if [he] is merely gullible or naïve.'' *Jayam Krishna-Iyer,* 74 FR 459, 460 n.3 (2009); *see also Chau,* 77 FR at 36007 (holding that even if physician ''did not intentionally divert controlled substances,'' State Board Order ''identified numerous instances in which [physician] recklessly prescribed controlled substances to persons who were likely engaged in either self-abuse or diversion'' and that physician's ''repeated failure to obtain medical records for his patients, as well as to otherwise verify their treatment histories and other claims, created a substantial risk of diversion and abuse'') (citing *MacKay,* 75 FR at 49974).

As explained by the Government's Expert, in 2004, the Tennessee Board of Nursing promulgated Rule 1000–04–.08, setting forth guidelines for determining whether the prescribing practices of Advance Practice Nurses are within ''the usual course of professional practice for a legitimate purpose in compliance with applicable state and federal law''; this rule became effective on January 1, 2005.[21] Board Rule 1000–04–.08(4); GX 68, at 10. This rule provided that the patient's medical record ''shall include a documented medical history and physical examination by the Advance Practice Nurse . . . providing the medication.'' Board Rule 1000–04–.08 (4)(c)(1). It further stated that the ''[h]istorical data shall include pain history, any pertinent evaluations by another provider, history of and potential for substance abuse, pertinent coexisting diseases and conditions, psychological functions and the presence of a recognized medical indication for the use of a controlled substance.'' *Id.*

The Rule also provided that ''[a] written treatment plan tailored for individual needs of the patient shall include objectives such as pain relief and/or improved physical and psychosocial function, and shall consider need for further testing, consultations, referrals or use of other treatment modalities dependent on patient response.'' *Id.* at 4(c)(2). Also, the rule provided that ''[a]t each periodic interval'' at which the patient is evaluated ''for continuation or change of medications, the patient record shall include progress toward reaching treatment objectives, any new information about the etiology of the pain, and an update on the treatment plan.'' *Id.* at (4)(c)(4). And the Expert also testified that Advanced Nurse Practitioners were employing the practices set forth in the guidelines in prescribing controlled substance before the Rule became effective on January 1, 2005.

As found above, the Government's Expert reviewed the medical records maintained by AMC on patients N.S., T.H., and C.S. and concluded that in issuing the prescriptions, Messrs. Reynolds and Stout, as well as Ms. Killebrew, failed to comply with the Board's Rule and the standard of care as set forth in various practice guidelines which the clinic asserted it followed. Most importantly, the Government's Expert concluded that Reynolds, Stout, and Killebrew had issued multiple controlled substance prescriptions without a legitimate medical purpose and outside of the usual course of professional practice and thus also violated 21 CFR 1306.04(a).

N.S.

N.S. was initially seen at AMC by providers other than Reynolds, Stout, and Killebrew. However, at the time of her first visit with Reynolds, the latter knew that N.S. has previously been subjected to a UDS and tested positive for several benzodiazepines, even though these drugs had not been prescribed to her by the other NPs at AMC, as well as cocaine. She also tested negative for opiates even though she had been prescribed Avinza (morphine) at AMC, and on the date of the test, she should still have been taking the drug. Reynolds also knew that at N.S's previous visit, she had shown signs of somnolence, slurred speech, and rapid heart rate. Finally, N.S.'s file still lacked information concerning her prior treatment history and substance abuse history, and given that three months had passed since N.S.'s previous visit, Reynolds should have asked N.S. where she had been, but failed to do so. Reynolds failed to refer her to a specialist who could have addressed her aberrant behavior, and instead, issued her another Avinza prescription.

As found above, throughout the lengthy course of her visits to AMC, N.S. continued to engage in aberrant behavior, which was largely ignored by Reynolds, Stout, and Killebrew, who continued to prescribe controlled substances to her. These episodes included overdoses resulting in multiple hospitalizations including for mental health treatment. Moreover, the discharge summary for the first of these, which occurred while N.S. was obtaining drugs at AMC, referenced her

[21] *See also* Board Rule 1000–04–.08(1)(d) (defining ''[p]rescribing pharmaceuticals or practicing consistent with the public health and welfare'' as ''[p]rescribing pharmaceuticals and practicing Advanced Practice Nursing for a legitimate purpose in the usual course of professional practice'').

history of multiple overdoses and suicide attempts; listed two physicians as her primacy care providers (one of whom was not affiliated with AMC); stated that N.S. was taking hydrocodone, Xanax, and carisoprodol, none of which had been prescribed to her at AMC; and reported the results of a UDS, which again showed she was positive for benzodiazepines.

Yet, notwithstanding these multiple red flags, Reynolds continued to prescribe Avinza to N.S. and did so without having obtained information about her treatment before coming to AMC, did not create a written treatment plan, and did not document that he had considered the need to refer her for further testing or consultations.

Thereafter, Reynolds added Xanax for N.S.'s anxiety, notwithstanding that because of her obvious psychiatric issues, she should have been referred to a specialist. As the Expert explained, this was contrary to the Uphold & Graham Guidelines, which Reynolds claimed were the protocols that AMC followed.

Following this, N.S. sought multiple early refills for Xanax; Reynolds also had directed her to come in for a pill count, but N.S. failed to comply. Yet Reynolds continued to issue her more Xanax, and even did so on an occasion when she should have had 19 days left on a prescription.

As for Stout, while he did not prescribe to N.S. until seventeen months into her visits to AMC, the Expert explained that because it was her first visit with him, he was obligated to review her patient file before prescribing controlled substances to determine whether it was appropriate to continue or change her medications. The Expert thus concluded that Stout should have been aware of N.S.'s history of substance abuse and diversion, which was documented in her file, and that Stout breached the standard of care and acted outside of the usual course of professional practice when he issued her Xanax and Kadian prescriptions, rather than cease further prescribing and refer her to a specialist who could address her aberrant behavior.

While Killebrew did not see N.S. until July 2006, when she had been going to AMC for more than twenty-five months, the Expert found that she too acted outside of the usual course of professional practice because she was obligated to review N.S.'s patient file and should not have prescribed controlled substances to her given her history of drug abuse and diversion. Moreover, this was N.S.'s first visit to AMC in seven months, and Killebrew noted that N.S. had recently been released from jail. However, Killebrew failed to ask why she had been incarcerated and how she had addressed her pain issues during that period. Killebrew nonetheless issued N.S. prescriptions for Percocet and Xanax.

Thereafter, N.S. continued to see Reynolds and Stout (and occasionally Killebrew) and repeatedly obtained more controlled substance prescriptions while the practitioners ignored additional red flags. For example, in August 2006, Stout prescribed Percocet and Xanax to N.S., even though the day before N.S.'s July 20 visit with Killebrew, he had treated her while working in a local emergency room and documented that N.S. had admitted ''to having a long history of drug abuse'' and displayed ''drug seeking behavior.'' Stout also failed to address with N.S. why she had been jailed and how she addressed her pain issues while she was incarcerated.

Two months later, Stout issued N.S. more Percocet and Xanax prescriptions, even though her file contained a note (dated one month) earlier stating that she had been selling Percocet. N.S. denied this, claiming her medications had been stolen, but then said she had been taking her medications for the past week. While Stout required that N.S. take a UDS, she tested negative for oxycodone (which she claimed she was taking) but positive for hydrocodone/hydromorphone, even though no one at AMC had prescribed those drugs to her. And notwithstanding these results, which showed that she was abusing and/or diverting, and demonstrated that N.S. had lied to him, Stout issued her more Percocet and Xanax prescriptions.

Several months later, Stout attempted to refer her to two different pain management practices. However, N.S. had already been seen at these practices and neither would accept her as a patient. Once again, Stout issued her more prescriptions for Percocet and Xanax, and several months later, Reynolds issued more of the same prescriptions, ignoring the evidence that N.S. was abusing and diverting, and acted outside of the usual course of professional practice in doing so.

Several months later, Reynolds increased the quantity of N.S.'s prescriptions (she had been switched from Percocet to morphine), by fifty percent from those issued at the previous visit, and yet there is no evidence that Reynolds saw her on this occasion and no explanation in her record as to why she was not seen. And the following month, N.S. called AMC and stated that she had run out of her prescriptions and Killebrew directed that prescriptions for Lortab and Xanax be called in for her; however, N.S. had not been seen at AMC in two months, which according to the Expert, also raised a red flag.

Thereafter, N.S's behavior continued to present red flags, such as in November 2007, when she twice sought refills of controlled substances, including refills which were fifteen days early; yet Reynolds issued her more prescriptions. And the following month, N.S. was admitted to a local hospital which sent AMC both admission and discharge summaries; notably, the summaries listed ''polysubstance abuse'' as one of her diagnoses. Yet, even after receiving this information, Reynolds prescribed more MS Contin, Xanax, and Percocet to her.

Thereafter, N.S. became pregnant and did not visit AMC between February and late December 2008, and apparently had received Suboxone or Subutex treatment from a physician (who was not affiliated with AMC) during her pregnancy. Yet, on N.S.'s return, Killebrew prescribed to her both 60 Lortab 7.5 mg and 30 Xanax .5 mg. However, Killebrew did not even obtain the name of the physician who had provided the Suboxone/Subutex treatment, let alone contact him/her. She also did not conduct a check of the State's prescription monitoring database, even though in the Expert's view, N.S's history of doctor shopping warranted this. Moreover, Killebrew did not document that N.S. had incurred a new illness or injury, and according to the Expert, performed a cursory physical exam. I thus adopt the Expert's conclusion that Killebrew acted outside of the usual course of professional practice and lacked a legitimate medical purpose in issuing the prescriptions. 21 CFR 1306.04(a).

Following this visit, N.S. did not return to AMC for more than five months. Yet on her return, Reynolds issued her prescriptions for even more potent controlled substances and in even greater quantities (60 MS Contin 30 mg, 30 Percocet 7.5 mg, 90 Xanax .5 mg). However, Reynolds did not document how N.S. had managed her purported pain since her last visit, failed to run a check on her with the CSMD, and failed to conduct a UDS on her. Once again, the Expert concluded that these prescription were issued in violation of 21 CFR 1306.04(a).

As the Expert explained, over the course of the nearly six-year period in which N.S. obtained controlled substances at AMC, she presented numerous red flags (including overdoses) and yet was subjected to only two UDSs, both of which she failed, and but a single pill count.

Moreover, the only time her prescription history was obtained from the CSMD was on the date of her last visit. Also, there were several episodes in which N.S. had not appeared at AMC for months on end, and yet was given more prescriptions without the treating practitioner even attempting to verify her explanation for her absence, asking her how she addressed her pain during her absence, contacting her purported treating physicians, or performing an adequate physical examination. I therefore conclude that all three practitioners acted outside of the usual course of professional practice and lacked a legitimate medical purpose when they issued controlled substance prescriptions to N.S. 21 CFR 1306.04(a).

I also conclude that all three practitioners acted outside of the usual course of professional practice and lacked a legitimate medical purpose in issuing multiple controlled substance prescriptions to T.H. As explained by the Expert, from T.H.'s initial visit, the practitioners knew that T.H. had problems with alcohol as well as mental health issues, and yet they failed to adequately evaluate his alcohol-related issues and refer him to a specialist who could properly address his mental health issues.

Moreover, while T.H. was referred to a pain management clinic, which recommended that he undergo facet blocks and that he take only three Lortab 10 mg per day and do so only for as long as it took to have the procedures performed, T.H. returned to AMC where he saw Reynolds, who failed to determine whether T.H. had ever undergone the procedures. Also, while T.H. should have been out of the controlled substance prescribed by the pain management clinic for a month, Reynolds made no inquiry as to how T.H. had managed his pain. Yet Reynolds then proceeded to escalate T.H.'s prescriptions to 60 OxyContin 40 mg, 30 Lortab 10 mg, and 90 Xanax 1 mg. As the Expert explained, there was no medical justification for adding OxyContin 40 mg to T.H.'s medications, which she explained was four times the normal starting dose. The Expert also explained that the amount of Xanax Reynolds prescribed was excessive as it was six times the daily dosage T.H. had previously received and could be lethal when taken with the narcotics that Reynolds prescribed. The Expert further noted that Reynolds did not properly evaluate T.H.'s alcohol-related problems or his anxiety. I agree with the Expert that Reynolds lacked a legitimate medical purpose and acted outside of the usual course of professional practice in issuing the prescriptions. 21 CFR 1306.04(a).

At the next visit, T.H. saw Stout, who issued him more prescriptions for the same three drugs. Yet as the Expert explained, Stout did not properly evaluate T.H.'s pain and psychosocial situation, the efficacy of the drugs on his ability to function, did not develop a written treatment plan, and did not evaluate T.H.'s history or potential for abuse. I agree with the Expert's conclusion that Stout lacked a legitimate medical purpose and acted outside of the usual course of professional practice in issuing the prescriptions. *Id.*

During the course of the two years in which T.H. visited AMC, he presented multiple red flags. These included that: (1) He was receiving high doses of narcotics and yet never complained of opioid-induced constipation; (2) he admitted that he was simultaneously seeing another physician, yet neither Reynolds nor Stout contacted the physician to determine the nature of the treatment T.H. was receiving; (3) a pharmacy reported that T.H. was receiving Suboxone treatment from still another physician (again, neither Reynolds nor Stout contacted the physician); (4) T.H. was clearly using multiple pharmacies notwithstanding that he had agreed to use only a single pharmacy; (5) AMC had received a fax which included various documents establishing that T.H. had been treated at three other clinics; (6) T.H. was being treated for depression by a physician; (7) T.H. owed approximately $3,000 to two medical practices; (8) T.H. sought multiple early refills; (9) and T.H. was trying to stop abusing alcohol.

However, T.H. was never required to provide a UDS, was never subjected to a pill count, and a CSMD report was never obtained on him. Moreover, according to the Expert, at no point did any of the three practitioners (including Killebrew, who saw T.H. and prescribed to him on several occasions) create a written treatment plan and properly evaluate his use of alcohol. Yet all three practitioners continued to prescribe both OxyContin and either Percocet or Lortab, as well as Xanax, to T.H., up until the day before he overdosed and died. Based on the Expert's extensive findings, I conclude that each of the practitioners acted outside of the usual course of professional practice and lacked a legitimate medical purpose when they issued T.H. the prescriptions for multiple narcotics and benzodiazepines.[22] 21 CFR 1306.04(a).

I also agree with the Expert's conclusions that both Reynolds and Stout acted outside of the usual course of professional practice and lacked a legitimate medical purpose when they issued various controlled substance prescriptions to C.S. As the Expert noted, C.S. claimed that she had suffered injuries in a car accident and suffered from back pain (at a level of 4 out of 10) as well as neck pain, although the records also state: ''Pt has no interest in further intervention and is satisfied with current treatment plan.'' The note for her first visit further stated that C.S. reported that she had ''increase[d] problems situationally lately with their anxiety and depression.''

According to the Expert, at C.S.'s first visit, Reynolds failed to create a patient record that appropriately documented her medical history, including her pain history, pertinent evaluations by other practitioners, her history of, and potential for, substance abuse, and pertinent coexisting diseases and treatments. The Expert also found that he did not create a treatment plan which was tailored for her individual needs.

[22] It is noted that Ms. Killebrew's involvement with T.H. was limited to only three visits and that the prescriptions she issued were generally the same as those issued by Reynolds and Stout. With respect to T.H.'s first visit with Killebrew, the Expert opined that the information he reported regarding his impending divorce and increased anxiety rendered him a ''high-risk patient for managing chronic pain and whose care extended beyond the scope of a nurse practitioner engaged in family practice,'' and that a ''prudent practitioner would have considered T.H. to be a risk for suicide and diversion and would have referred him to a mental health specialist and a comprehensive pain management program,'' which Killebrew failed to do. GX 68, at 63.

While the Expert's discussion sounds in malpractice, the Expert further noted that as of the date of his first visit with Killebrew, T.H.'s file contained extensive evidence that he was abusing and/or diverting controlled substances yet Killebrew failed to take steps to monitor his use of controlled substances. I thus agree with the Expert's conclusion that Killebrew acted outside of the usual course of professional practice when she prescribed to T.H. 60 OxyContin 40 mg, 30 Percocet 10 mg, and 75 Xanax 1 mg. *Id.* at 63–64.

Similarly, at T.H.'s second visit with her, he reported that he was having problems with anxiety, that he trying quit alcohol, that he had made an appointment at a mental health facility and had hand tremors; according to the Expert, the latter was a sign of anxiety or alcohol/drug withdrawal. Killebrew did not, however, refer T.H. for treatment by specialists as was called for in the Uphold & Graham practice guidelines which AMC had previously adopted as its practice protocols. GX 39, at 15. Instead, she issued him more prescriptions, these being for 60 OxyContin 40 mg, 30 Lortab 10 mg, while changing his prescription for Xanax to 90 Valium 10 mg. She also ignored other red flags which were documented in T.H.'s patient file. At T.H.'s next visit, Killebrew issued T. H. these same prescriptions, again ignoring the red flags he presented and AMC's practice protocols. Consistent with the Expert's testimony, I conclude that Killebrew acted outside of the usual course of professional practice and lacked a legitimate medical purpose in prescribing controlled substances to T.H. 21 CFR 1306.04(a).

While Reynolds made an entry in the medical record that he had performed a physical exam, notably, with the exception of her vital signs, the physical exam notes for each of her visits are repeated verbatim.

Notwithstanding that C.S. had reported increased problems with anxiety and depression, and according to the clinic's protocols, presented a higher risk of substance abuse, Reynolds did not refer her to a specialist and did not document that he had even considered doing so. Moreover, while C.S. had reported injuries, she also wrote on her intake form that she did not have a current health care provider. As the Expert explained, there is no evidence that Reynolds inquired as to how she had addressed her pain if she had no current provider. Moreover, while Reynolds could have run a CSMD check to verify if C.S. had, in fact, recently seen another provider, as well as obtain information as to her substance abuse history, he did not do so. Of note, that report would have shown that in the period preceding her visit, she had obtained Suboxone from three different physicians. Reynolds started her on Percocet and Valium. I agree with the Expert's conclusion that the prescriptions lacked a legitimate medical purpose and were issued outside of the usual course of professional practice. 21 CFR 1306.04(a).

At some point, Reynolds did obtain C.S's medical records from a physician who treated her over a five-month period, which had ended more than thirteen months before her first visit to AMC. Most significantly, the physician had documented that C.S. was taking more pain medications than he recommended and explained that he did not think that she could ''self-medicate.'' Yet both Reynolds and Stout continued to prescribe multiple controlled substances including Percocet, Valium, and phentermine to C.S. Moreover, there is no evidence that either Reynolds or Stout ever contacted that physician.

The Expert further found that neither Reynolds nor Stout properly evaluated C.S. at her follow-up visits to determine whether her medications should be continued or changed. Moreover, both Reynolds and Stout repeatedly ignored red flags that C.S. was engaged in both doctor and pharmacy shopping and thus violating her pain contract. These incidents included one in which Reynolds received a phone call from another clinic reporting that C.S. had sought to become a patient, claiming that she did not have a family practice, and that she also used two names at various practices. Neither Reynolds nor Stout documented having addressed this incident with her. Instead, they continued to issue her more prescriptions and never ran a UDS on her.

Moreover, while AMC eventually obtained CSMD reports on her (two months after the above report), they again ignored multiple items of information in those reports which showed that C.S. had been treated for narcotic dependency prior to her first visit at AMC (and had obtained Suboxone from three physicians), that she had recently obtained controlled substances from two other physicians, and that she had also filled prescriptions at multiple pharmacies in violation of her pain agreement. Yet Reynolds and Stout continued to issue her prescriptions for both oxycodone and benzodiazepines up until her death. I therefore agree with the Expert's conclusion that both Reynolds and Stout acted outside of the usual course of professional practice and lacked a legitimate medical purpose when they issued the prescriptions to C.S. 21 CFR 1306.04(a).

In summary, I find that the Government's evidence with respect to factors two and four establishes that each of the three practitioners issued prescriptions in violation of the CSA's prescription requirement and engaged in the knowing diversion of controlled substances. I further hold that the Government has established by substantial evidence that the misconduct of each practitioner is sufficiently egregious to conclude that he/she has committed acts which render his/her ''registration inconsistent with the public interest.'' 21 U.S.C. 823(f) & 824(a)(4). With respect to each of the three practitioners, these findings are sufficient to support the denial of their applications, and in the case of Stout, to revoke his registration.

Factor Five—Such Other Conduct Which May Threaten Public Health and Safety

The Government also contends that practitioner Reynolds engaged in actionable misconduct under this factor when he wrote a letter to a DEA Diversion Investigator which contained various material false statements regarding AMC's treatment of N.S. I agree with the Government.

As recognized by the Sixth Circuit, ''[c]andor during DEA investigations, regardless of the severity of the violations alleged, is considered by the DEA to be an important factor when assessing whether a [practitioner's] registration is consistent with the public interest.'' *Hoxie* v. *DEA,* 419 F.3d 477, 483 (6th Cir. 2005). To be actionable, the Government is required to show that the statement was false and material to the investigation. *See Roy S. Schwartz,* 79 FR 34360, 34363 n.6 (2014); *Belinda R. Mori,* 78 FR 36582, 36589 (2013). As the Supreme Court has explained, a false statement is material if it '' 'has a natural tendency to influence, or was capable of influencing the decision of the decisionmaking body to which it was addressed.' '' *Kungys* v. *United States,* 485 U.S. 755, 770 (1988) (quoting *Weinstock* v. *United States,* 231 F.2d 699, 701 (D.C. Cir. 1956)). The Court has further explained that:

> it has never been the test of materiality that the misrepresentation . . . would more likely than not have produced an erroneous decision, or even that it would more likely than not have triggered an investigation. Rather, the test is whether the misrepresentation . . . was predictably capable of affecting, *i.e.,* had a natural tendency to affect, the official decision.

485 U.S. at 770–71. ''It makes no difference that a specific falsification did not exert influence so long as it had the capacity to do so.'' *United States* v. *Alemany Rivera,* 781 F.2d 229, 234 (1st Cir. 1985).

The Government first argues that Reynolds made a materially false statement when he wrote that N.S. ''was admitted to JCMC on December 3, 2004 by Dr. . . . James with drug overdose. She was transferred to [IPP] . . . and continued on her then prescribed medications.'' Req. for Final Agency Action, at 42 (quoting GX 42, at 7). Based on an affidavit it obtained from Dr. James, the Government argues that Reynolds' statement was false because Dr. James ''did not continue N.S. on her then prescribed medications'' but ''ceased prescribing'' all controlled substances to her because she had ''been admitted [to JCMC] for a drug overdose, had a history of multiple overdoses and suicide attempts, and was [being transferred] to IPP for inpatient psychiatric treatment.'' *Id.* at 43.

Notwithstanding Dr. James' statement (which may well have reflected her instructions), the discharge summary for N.S.'s hospitalization (which was part of her patient file), lists Soma, Xanax, MSCN (morphine), and Lortab as ''medications to continue'' and is blank in the space for listing ''medications to discontinue.'' GX 2, at 160. While the form was apparently completed by a nurse and not Dr. James, absent proof that Reynolds had otherwise obtained knowledge that Dr. James had instructed that N.S.'s medications were to be discontinued, it was not unreasonable for him to conclude that the nurse had

accurately reflected Dr. James' instructions on the discharge summary. I thus reject the contention that Reynolds knowingly made a material false statement when he wrote that N.S. had been continued on her then-prescribed medications.[23]

Reynolds, however, also claimed that N.S. ''never had another overdose incident while being treated at AMC'' after a December 3, 2004 hospitalization at Johnson City Medical Center. GX 42, at 7. The Government, however, produced a copy of a report created upon N.S.'s admission to the Johnson City Medical Center on August 19, 2005, which clearly stated that ''[t]he patient was transferred from Northside Hospital because of unresponsiveness secondary to drug overdose.'' GX 14, at 29.

The report further stated that N.S. had told her mother that she had taken five Soma tablets, that her mother found her unresponsive on the floor, that she was taken to Northside Hospital where ''she was found unresponsive to painful stimuli . . . with pinpoint pupils,'' and that Narcan, a drug used to counter the effects of opioids, ''was not helpful.'' *Id.* The report also listed ''[d]rug overdose'' under the attending physician's impressions, and noted that she was to be admitted to the ICU. *Id.* at 30. Finally, the attending physician listed Reynolds as N.S.'s primary care provider and listed him as a recipient of a copy of the report. *Id.*

Based on the above, I conclude that Reynolds knew that N.S. had been hospitalized for a second overdose incident after the December 3, 2004 hospitalization and that his statement was false. I further conclude that the statement was material because it was clearly made by Reynolds to the DI in an attempt to excuse the misconduct he and his fellow practitioners engaged in when they continued to prescribe controlled substances to N.S. even when faced with knowledge that she was drug abuser. *See* GX 42, at 2 (Reynolds' letter to DI; ''I am including in this letter the documents that I have developed to explain my actions and the rationale behind the decisions that have been called into question by the Office of General Counsel of Tennessee and I assume the DEA.'') As explained above, that misconduct is clearly within the Agency's jurisdiction and his statement was clearly capable of influencing the decision of the Agency to pursue this matter.

[23] Even were I to hold that a negligently made false statement is actionable under factor five, no argument has been made as to why Reynolds was negligent when he relied on the discharge summary.

In his letter, Reynolds also stated that Dr. James (the physician who admitted N.S. to the JCMC for her December 2004) ''took the medical and social history from [N.S.'s] family [and] not the patient.'' GX 42, at 7. The Government notes that in the Admission Report, Dr. James documented that N.S. ''has had multiple episode of over dose in the past, the last one was in May 2004, when she was admitted to the Intensive Care Unit with drug overdose'' and that N.S.'s ''[h]istory [wa]s obtained mainly from the emergency room records and the patient's parents.'' Req. for Final Agency Action, at 45.

The Government argues that taken within the context of the letter, Reynolds' statement was materially false and was made ''for the purpose of demonstrating that the history noted by Dr. James . . . of 'multiple over dose in the past' was somehow inaccurate because'' it had not been obtained ''directly from N.S.'' *Id.* Notably, in his letter, Reynolds further asserted that when, after the overdose incident, N.S returned to AMC, ''[s]he argued with [him] that her overdose was a one-time mistake she had made'' which was caused by ''domestic issues at home'' and that he ''gave her the benefit of the doubt'' and prescribed more controlled substances to her. GX 42, at 7.

Here again, I agree with the Government that the statement was made to justify Reynolds' decision to ignore the clear evidence that N.S. was a substance abuser and to excuse his misconduct (as well as that of his fellow practitioners) in continuing to prescribing controlled substances to her. I further conclude that the statement was false and was capable of influencing the Agency's investigation and was therefore material.

Next, the Government argues that Reynolds made a material false statement when he wrote that after the December 3, 2004 hospitalization, N.S. '' 'never again displayed signs of addiction to include . . . aberrant behavior . . . [and] early refills.' '' Req. for Final Agency Action, at 44 (quoting GX 42, at 7). As found above, the record contains substantial evidence that N.S. displayed numerous signs of addiction and aberrant behavior. These included: (1) Her nearly eight-month absence from the practice (between Dec. 1, 2005 and July 20, 2006) and her reappearance at AMC during which she told Killebrew that she had been in jail; (2) Stout's having treated her the day before her reappearance at AMC at a local hospital's ER and noting that she wanted ''stronger narcotics'' and had ''displayed drug seeking behavior''; (3) a Sept. 13, 2006 report that N.S. was selling Percocet; (4) an Oct. 11, 2006 UDS which was positive for narcotics she had not been prescribed but negative for narcotics which she had been prescribed; (5) her false statement at that visit that she was taking the prescribed medications; (6) the December 2006 refusal of two different pain management practices, both of which had previously seen her, to accept her as a patient; (7) her having sought (in November 2007) a refill fifteen days early; (8) her admission to a local hospital in late December 2007, which diagnosed her with various conditions including poly-substance abuse; (9) the more than five-month gap between her December 22, 2008 and June 4, 2009 visit; and (10) her November 2009 claim that her drugs had been stolen and she needed a refill.

Here again, Reynolds clearly knew of these various incidents and his statement was clearly made to excuse the misconduct he and his fellow practitioners engaged in by continuing to prescribe controlled substances to N.S. in the face of her aberrant behavior. I therefore find that the statement was materially false.

Reynolds further stated that ''[i]n October of 2006, [N.S.] passed drug screens and observations by MC providers.'' GX 42, at 7. As found above, this statement was clearly false as N.S. tested positive for hydrocodone/hydromorphone, even though no one at AMC had prescribed these drugs to her, and tested negative for oxycodone/oxymorphone, even though she had received a Percocet prescription at her previous visit to AMC. Here again, Reynolds' statement was false and clearly made to excuse the misconduct that he and his fellow practitioners engaged in by continuing to prescribe controlled substances to N.S.

Based on the multiple materially false statements Reynolds made in his letter to a DEA Investigator, I further find that Reynolds has engaged in additional conduct which may threaten public health or safety. This finding provides a further reason to deny Reynolds' application.

Sanction

Under agency precedent, ''where a registrant [or applicant] has committed acts inconsistent with the public interest, [he or] she must accept responsibility for his [or her] . . . actions and demonstrate that he [or she] . . . will not engage in future misconduct.'' *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009); *see also Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008). Here, each practitioner has waived his/her right to a hearing and

therefore the opportunity to present evidence to refute the Government's showing that he/she has committed acts which render his/her registration ''inconsistent with the public interest,'' 21 U.S.C. 823(f), and the only evidence in the record relevant to these issues is Reynolds' letter to the DI.

Therein, Reynolds stated that he has closed his practice and would not re-open it; that he has taken 55 hours of continuing education in ethics, boundaries, pharmacology and pain; and offered to take ''other training'' to ensure the public safety and his ''compliance with DEA standards.'' GX 42, at 2. Even were I to give weight to Reynolds's unsworn statement regarding the remedial measures he has undertaken, I would still deny his application because he has presented no evidence that he acknowledges his misconduct. To the contrary, the multiple material false statements Reynolds made in his letter establish that he does not accept responsibility for his misconduct in prescribing to N.S. and others. Thus, I conclude that Reynolds has not refuted the Government's *prima facie* showing that granting his application would be ''inconsistent with the public interest.'' 21 U.S.C. 823(f). So too, because there is no evidence that either Stout or Killebrew has accepted responsibility for his/her misconduct, nor any evidence that either Stout or Killebrew has undertaken remedial measures to ensure that he/she will not re-offend in the future, I also conclude that neither one has refuted the Government's *prima facie* showing. Accordingly, I will order that the registration issued to Stout be revoked, and that the applications of Reynolds, Stout, and Killebrew [24] be denied.

Orders

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a)(4), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration MS0443046 issued to David R. Stout, N.P., be, and it hereby is, revoked. I further order that the application of David R. Stout, N.P., to renew his registration, be, and it hereby is, denied. This Order is effective June 18, 2015.

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b), I order that the application of Bobby D. Reynolds II, F.N.P., for a DEA Certificate of Registration as an MLP—Nurse Practitioner, be, and it hereby is, denied. This Order is effective June 18, 2015.

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b), I order that the application of Tina L. Killebrew, F.N.P., for a DEA Certificate of Registration as an MLP—Nurse Practitioner, be, and it hereby is, denied. This Order is effective June 18, 2015.

Dated: April 30, 2015.

Michele M. Leonhart,

Administrator.

[FR Doc. 2015–12038 Filed 5–18–15; 8:45 am]

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[24] While compared to Reynolds and Stout, Killebrew issued substantially fewer illegal prescriptions, her misconduct still involved the knowing diversion of controlled substances, and as such, is sufficiently egregious to support the denial of her application. *See Jayam Krishna-Iyer,* 74 FR at 464 (''[E]ven where the Agency's proof establishes that a practitioner has committed only a few acts of diversion, this Agency will not grant [an application for] registration unless [she] accepts responsibility for [her] misconduct.''); *see also MacKay* v. *DEA,* 664 F.3d 808, 822 (10th Cir. 2011) (sustaining agency order revoking practitioner's registration based on proof physician knowingly diverted drugs to two patients).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 13–35]

JM Pharmacy Group, Inc., d/b/a Farmacia Nueva and Best Pharma Corp; Decision and Order

On October 24, 2013, Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, ALJ), issued the attached Recommended Decision. Neither the Government nor the Respondents filed exceptions to the Recommended Decision.[1]

Having reviewed the entire record, I have decided to adopt the ALJ's findings of fact including his credibility determinations except as discussed below.[2] I also adopt the ALJ's

[1] All citations to the Recommended Decision are to the slip opinion as issued by the ALJ.

[2] In the Recommended Decision, the ALJ observed that his factual findings ''are entitled to significant deference.'' R.D. at 34 (citing *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951)). To make clear, the Agency is the ultimate factfinder and considers an ALJ's factual findings ''along with the consistency and inherent probability of testimony. The significance of [the ALJ's] report, of course, depends largely on the importance of credibility in the particular case.'' *Universal Camera,* 340 U.S. at 496. *See also Reckitt & Colman, Ltd.,* v. *Administrator,* 788 F.2d 22, 26–27 (D.C. Cir. 1986).

For reasons I have previously explained, *see Top Rx Pharmacy,* 78 FR 26069, 26069 n.1 (2013), I do not adopt the parenthetical following the ALJ's citation to *Paul Weir Battershell,* 76 FR 44359, 44368 n.27 (2011). *See* R.D. at 36.

In his discussion of factor two (''the applicant's experience in . . . dispensing controlled substances''), the ALJ explained that this factor manifests Congress's ''acknowledgment that the qualitative manner and *the quantitative volume* in which an applicant has engaged in the dispensing of controlled substances may be [a] significant factor'' in determining ''whether an applicant should be (or continue to be) entrusted with a DEA'' registration. R.D. at 37 (emphasis added).

It is certainly true that evidence as to the volume of dispensings (whether by a prescriber or a pharmacy) has been admitted in these proceedings, by both the Government to show the extent of practitioner's unlawful activities, and by practitioners to show the extent of their lawful activities. That being said, neither the text of factor two, nor the legislative history of the 1984 amendments which gave the Agency authority to consider the public interest in determining whether to grant an application or revoke (or suspend) an existing registration, compel the conclusion that Congress considered ''the quantitative volume'' of an applicant's or registrant's dispensings to be a significant factor in the public interest analysis.

The word ''experience'' has multiple meanings. Among those most relevant in assessing its meaning as used in the context of factor two are: (1) The ''direct observation of or participation in events as a basis for knowledge,'' (2) ''the fact or state of having been affected by or gained knowledge through direct observation or participation,'' (3) ''practical knowledge, skill, or practice derived from direct observation of or participation in events or in a particular activity,'' and (4) ''the length of such participation.'' *See Merriam-Webster's Collegiate Dictionary* 409 (10th ed. 1998); *see also The Random House Dictionary of the English Language* 681 (2d ed. 1987) (defining experience to include ''the process or fact of personally observing encountering, or undergoing something,'' ''the observing, encountering, or undergoing of things generally as they occur in the course of time,'' ''knowledge or practical wisdom gained from what one has observed, encountered, or undergone'').

None of these meanings compels the conclusion that Congress acknowledged that ''the quantitative volume'' of a practitioner's dispensing activity may be a significant consideration under this factor, and certainly none suggest that the Agency is required to count up the number of times an applicant or registrant has dispensed controlled substances in making factual findings under this factor as suggested by another ALJ. *See Clair L. Pettinger,* 78 FR 61592, 61597 (2013) (rejecting reasoning in ALJ's recommended decision that factor two ''requires evidence of both the qualitative and quantitative volume of the Respondent's experience'' and that ''[w]here evidence of the Respondent's experience . . . is silent with respect to the quantitative volume of the Respondent's experience, and requires speculation to support an adverse finding under Factor Two, this Factor should not be used to determine whether the Respondent's continued registration is inconsistent with public interest.'').

Prior to the 1984 amendment of section 823(f), the Agency's authority to deny an application or revoke a registration was limited to cases in which a practitioner: (1) Had materially falsified an application, (2) had been convicted of a State or Federal felony offense related to controlled substances, or (3) had his State license or registration suspended, revoked, or denied. *See* S. Rep. No. 98–225, at 266 (1983), *as reprinted in* 1984 U.S.C.C.A.N. 3182, 3448. Finding that the ''[i]mproper diversion of controlled substances'' was ''one of the most serious aspects of the drug abuse problem,'' and yet ''effective Federal action against practitioners ha[d] been severely inhibited by the [then] limited authority to deny or revoke practitioner registrations,'' *id.,* Congress concluded that ''the overly limited bases in current law for denial or revocation of a practitioner's registration do not operate in the public interest.'' *Id.*

The Senate Report thus explained that ''the bill would amend 21 U.S.C. 824(f) [sic] to expand the authority of the Attorney General to deny a practitioner's registration application.'' *Id.* The

Continued