BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **Kevin Sanford Smith** **Physician's and Surgeon's Certificate No. G 70647** **Respondent.**	**Case No. 800-2016-025316**

DECISION

The attached Proposed Decision is hereby amended, pursuant to Government Code section 11517(c)(2)(C) to correct technical or minor changes that do not affect the factual or legal basis of the proposed decision. The proposed decision is amended as follows:

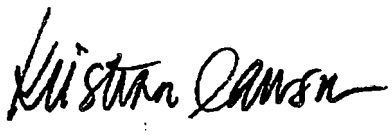
Page 110, paragraph 1, 1st line: "G 7047" is changed to "G 70647".

The attached Proposed Decision is hereby adopted as the Decision and Order of the Medical Board of California, Department of Consumer Affairs, State of California.

This Decision shall become effective at 5:00 p.m. on December 16, 2020.

IT IS SO ORDERED: November 16, 2020.

MEDICAL BOARD OF CALIFORNIA



Kristina D. Lawson, J.D., Chair
Panel B

BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation against:

KEVIN SANFORD SMITH, M.D., Respondent

Case No. 800-2016-025316

OAH No. 2019110287

PROPOSED DECISION

Mary Agnes Matyszewski, Administrative Law Judge, Office of Administrative Hearings, State of California, heard this matter on September 21, 22, 23, and 24, 2020.[1]

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[1] In light of the Governor's proclamation of a State of Emergency and Executive Orders N-25-20, N-33-20, and N-63-20 arising out of the COVID-19 pandemic; the declarations of county and city public health emergencies throughout the State; the directives from state and local officials to ensure and facilitate physical distancing and to shelter-in-place; and in order to protect the health and safety of all public and OAH personnel; this matter was conducted telephonically.

LeAnna E. Shields, Deputy Attorney General, Department of Justice, State of California, represented complainant, William Prasifka, Executive Director, Medical Board of California, Department of Consumer Affairs, State of California.[2]

Robert W. Frank, Attorney at Law, Neil, Dymott, Frank, McFall, Trexler, McCabe & Hudson APLC, represented respondent, Kevin Sanford Smith, M.D., who was present.

The matter was submitted on September 24, 2020.

PROTECTIVE ORDER SEALING CONFIDENTIAL RECORDS

Exhibits 4, through 16, inclusive, 18, 19, 20, 22, F, G, H, and I, medical reports and records, were received and contained confidential information. Exhibit D was offered but not received and also contained confidential information. It is impractical to redact the information from these exhibits. To protect patients' privacy and confidential personal information from inappropriate disclosure, those exhibits are ordered sealed. This sealing order governs the release of documents to the public. A reviewing court, parties to this matter, their attorneys, and a government agency decision maker or designee under Government Code section 11517 may review the documents subject to this order, provided that the documents are protected from release to the public.

[2] Kimberly Kirchmeyer was the Executive Director when the accusation was filed.

SUMMARY

Dr. Smith treated three pain patients, during different periods of time, between 2013 and 2017. Pain management is an evolving field of medicine and Dr. Smith has made changes to his practice because of recent developments. Dr. Smith presented as a caring and knowledgeable physician.

However, complainant established by clear and convincing evidence that during the time he treated these three patients, he was grossly negligent and committed repeated negligent acts when he prescribed a combination of high-dose opioids and Soma, failed to adequately modify the patients' controlled substance regimens; failed to obtain sufficient CURES[3] reports; failed to order urine drug screens, or follow-up on those that were ordered; and failed to adequately document detailed physical examinations. Dr. Smith repeatedly documented that he "did not recommend" the very high-dose opioid therapy he routinely prescribed and he made no changes to the patients' prescriptions despite his notations in the charts that he would.

Complainant did not establish by clear and convincing evidence that Dr. Smith failed to maintain timely medical records; or that he failed to obtain adequate consultations; or that he failed to adequately document his treatment objectives.

Based upon totality of the evidence presented, Dr. Smith's license will be placed on probation with terms and conditions that address the allegations proven.

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[3] CURES is the acronym for Controlled Substance Utilization Review and Evaluations System, a database of all Schedule II, III, and IV controlled substance prescriptions dispensed in California. (See Health & Saf. Code, § 11165 et seq.)

FINDING OF FACTS

Dr. Smith's Licensing History

1. The board issued Physician and Surgeon's Certificate No. G 70647 to Dr. Smith on January 14, 1991. That certificate was in full force and effect at all times herein and will expire on June 30, 2022, unless renewed.

2. On July 25, 2013, the board issued a public letter of reprimand[4] to Dr. Smith, in Case No. 10-2011-213184, arising out of his care and treatment of one patient. Dr. Smith was publicly reprimanded for committing repeated negligent acts in violation of Business and Professions Code section 2234, subdivision (c), for failing to "properly assess and treat chronic pain" and "adequately document the patient's medical records." That decision is now final and is incorporated by reference as if fully set forth herein. No facts regarding that matter were offered at this hearing.

Jurisdictional Background

3. The accusation was signed by the complainant, the former Executive Director, in her official capacity on January 3, 2019. Complainant alleged Dr. Smith violated Business and Professions Code sections 2227 and 2234, subdivision (b), by committing gross negligence in his care and treatment of three patients (First Cause for Discipline); violated Business and Professions Code sections 2227 and 2234, subdivision (c), by committing repeated negligent acts in his care and treatment of the three patients (Second Cause for Discipline); and violated Business and Professions

[4] Business and Professions Code section 2233 authorizes the board to issue a public letter of reprimand, rather than filing a formal accusation, for "minor violations."

Code sections 2227 and 2234, subdivision (a), violating or attempting to violate the Medical Practice Act (Third Cause for Discipline).[5] Complainant alleged Dr. Smith's letter of reprimand as a disciplinary consideration.

4. Dr. Smith timely submitted a notice of defense, and this hearing followed.

Dr. Smith's Education, Background, and Medical Practice

5. Dr. Smith obtained a Bachelor of Science degree in zoology from Marshall University in 1980. He obtained his medical doctor degree from Marshall University in 1986. From 1986 to 1990 he did a residency at the University of Louisville Affiliated Hospitals. Dr. Smith is board certified in Anesthesiology by the American Board of Anesthesiology. He was board certified in Pain Management by the American Board of Anesthesiology in 1978 and recertified in 2010.

Dr. Smith was a clinical instructor in anesthesia at the University of Louisville School of Medicine from 1990 to 1991. He practiced as an anesthesiologist from 1991 to 2002 at San Diego's Anesthesia Service Medical Group, Inc. He was a pain management specialist at Interventional Pain Specialist of Southern California from 2002 to 2006. Since 2006, he has been a pain management specialist at Integrated Pain Specialists of Southern California, where the three patients at issue in this matter were treated. Dr. Smith has privileges at several facilities, has served on numerous

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[5] Complainant also alleged that Dr. Smith's acts subjected him to the provisions of Business and Professions Code section 2228.1, which requires additional notification to patients if the physician caused harm. However, at hearing complainant's expert withdrew his opinions that Dr. Smith caused harm and complainant withdrew this allegation.

committees, is a member of many professional organizations, and has given multiple presentations on pain management issues.

6. Dr. Smith began his medical practice as an anesthesiologist. As pain management was evolving as a specialty practice, anesthesiologists were the ones leading and developing this practice. Dr. Smith and his colleague began practicing both anesthesia and pain management while at Anesthesia Service Medical Group, Inc. Dr. Smith served as the chairman of the Chronic Pain Management Committee for the group. Because of the litigation involved and the liability for pain management, the anesthesia group, which was self-insured, was concerned about costs. As a result, the group asked the pain management physicians to start their own practice. Dr. Smith and his colleague amicably left the group to form their own pain management practice, Interventional Pain Specialist of Southern California. The anesthesia group's attorneys helped Dr. Smith and his partner form the new pain management practice and the anesthesia group referred patients to Dr. Smith and his colleague. As Dr. Smith testified, the anesthesia group was "one of my biggest referrals" and he still remains close with his former colleagues.

In 2006 Dr. Smith and his partner ended their partnership and Dr. Smith formed Integrated Pain Specialists of Southern California, where the treatment at issue in this case was provided. The structure of Dr. Smith's pain management practice has been the same since the business model he and his ex-partner established when they created the practice: one treating physician, two or three medical assistants, and one physician assistant. At times, there has been a second part-time physician assistant and Dr. Smith had a nurse practitioner for short period of time, but no longer.

7. Dr. Smith described the evolving nature of pain management. Initially when he opened his practice, he was one of only two or three pain management

practices in San Diego County. Back then, insurance companies did not authorize monthly visits, so patients were only seen every two to three months, and given prescriptions for two to three month supplies. This "changed rapidly" to the current model where insurance companies now authorize patients to be seen on a monthly basis with 30-day prescriptions of opioids and other pain management medications, which is how Dr. Smith operates his practice. Dr. Smith continues to make changes to his practice as standards of care evolve.

Dr. Smith described how his medical assistants take the patient's vital signs and review information with the patient before he or the physician assistant meets with the patient. The information obtained by the medical assistant is not in the chart when Dr. Smith sees the patient, it is entered later. Dr. Smith relies upon the medical assistant or physician assistant to bring any significant findings, such as inconsistent urine drug screens (UDS), elevated blood pressure readings, or other concerns to his attention. He also relies on his office staff to obtain the UDS reports and advise him when they are received. When Dr. Smith found out that these three patients were not following his instructions or violating office policies, he discharged them. He attributed his lack of knowledge regarding violations that took place long before he discharged the patients to the failure of his staff to bring it to his attention.

Dr. Smith testified about each patient's care, his rationale for treatment ordered, and the reasons for decisions made as charted in the records. Dr. Smith's testimony is incorporated in the findings reached below. He also introduced notes documenting weekly staff meetings and weekly meetings with his physician assistants and nurse practitioner to review patients' care, which were considered herein.

Physician Responsibility for Physician Assistants

8. It was suggested at hearing that because many of these patients were seen by the physician assistants, that Dr. Smith was somehow not responsible for any care provided at those visits. That suggestion is rejected. Business and Professions Code section 3502, subdivision (a)(1), authorizes a physician assistant to perform medical services "under the supervision of a licensed physician." California Code of regulations, title 16, section 1399.540, subdivision (a), allows a physician assistant to "only provide those medical services which he or she is competent to perform and which are consistent with the physician assistant's education, training, and experience, and which are delegated in writing by a supervising physician who is responsible for the patients cared for by that physician assistant." Accordingly, despite who rendered the treatment, Dr. Smith was responsible for all medical care provided to the patients.

Expert Witnesses

COMPLAINANT'S EXPERT

9. Complainant retained Foead Geula, M.D., who authored a report, two supplemental reports, and testified at this hearing. Dr. Geula obtained his Bachelor of Science in biochemistry and cell biology from the University of California, San Diego in 1999; his medical degree from Washington University in St. Louis, Missouri in 2004; and his Master of Arts degree from Washington University in 2002. He did an internal medicine internship at University of California, Los Angeles from 2004 to 2005. He did an anesthesiology residency at University of California, San Francisco from 2005 to 2008, and a pain management fellowship at University California, San Francisco from 2008 to 2009. He was board certified in both anesthesia and pain medicine by the American Board of Anesthesiology. Since 2009 he has been a clinical instructor at

Overview-UCLA Medical Center; from 2008 to 2009 he worked per diem at Kaiser Permanente Medical Center in San Francisco; and from March 2012 to the present he has been in private practice. He has been an expert for the board since 2013, but took himself "off of availability" in 2019 or 2020 because his practice has gotten very busy.

From 2012 to 2018 Dr. Geula had both a pain management and an anesthesia practice of "varying percentages." Since closing the pain management portion of his practice in 2018, he has "exclusively" performed anesthesia. Dr. Geula explained that when he was providing pain management, he performed interventional treatment at various ambulatory surgical centers in Los Angeles, performing trigger point injections, epidurals, facets, blocks, injections and spinal cord stimulator trials. He prescribed controlled substances, generally short acting opioids of low dosage, although occasionally he inherited patients with high-dose prescriptions, referred to in this hearing as "legacy patients," and he adjusted those prescriptions by lowering them.

During the time he was practicing pain management, Dr. Geula worked alone, he did not supervise physician assistants or other staff, and did not operate a practice similar to that operated by Dr. Smith. When he was practicing pain management, Dr. Geula kept current on the standard of care through continuing education and online courses, attending conferences, and reading periodicals. Dr. Geula acknowledged asking the board's investigator whether he was qualified to be an expert in this case since he no longer practiced pain management. The investigator advised him that since he practiced pain management during the years at issue in this matter, he could render opinions on the applicable standard of care.

RESPONDENT'S EXPERT

10. Dr. Smith retained Standiford Helm, II, M.D. Dr. Helm authored a report and testified at this hearing. Dr. Helm graduated with a Bachelor of Arts degree from Harvard College in 1972. He obtained his medical degree from Tufts University in 1977. Dr. Helm did an internal medicine internship at Boston City Hospital from 1977 to 1978. He did a residency in anesthesiology at the University of California, Los Angeles from 1978 to 1980. He obtained his Master's in Business Administration from Pepperdine University in 1988. Dr. Helm is a diplomat of the American Board of Anesthesiology with a subspecialty certification in pain medicine. He is certified in addiction medicine by the American Board of Preventive Medicine. He is a diplomate of the American Board of Pain Medicine. He is a diplomate of the American Board of Interventional Pain Physicians with competency certification in Regenerative Medicine in Interventional Pain Management. He is also a Fellow of Interventional Pain Practice.

Dr. Helm has served on the editorial board of numerous pain management publications, has staff privileges at several medical centers, is a member of many medical societies where he has held multiple leadership roles, and has authored numerous publications. Dr. Helm is the medical director of The Helm Center for Pain Management, a private practice treating pain management patients. Dr. Helm has overseen physician assistants and other staff and treated patients similar to the ones at issue here. Dr. Helm's practice is very similar to Dr. Smith's practice.

Dr. Helm began his career as an anesthesiologist and as the pain management field developed, he "did with it." He successfully passed the first board certification for pain medicine. Dr. Smith also had this matter reviewed by Timothy Deer, M.D., D.A.B.P.M., F.I.P.P., a nationally recognized pain management expert. After he wrote his report, Dr. Helm reviewed Dr. Deer's report and was "pleased to see Dr. Deer's

impressions and my impressions were very closely aligned." Because Dr. Helm had not reviewed and relied upon Dr. Deer's report when forming his opinions, complainant's objection to the introduction of Dr. Deer's report was sustained. However, Dr. Helm was asked specific questions about findings contained in Dr. Deer's report and he agreed with the opinions and conclusions Dr. Deer reached. As noted during that questioning, these two experts expressed similar opinions.

Dr. Helm has treated thousands of patients like the ones at issue here for more than 20 years. He has reviewed hundreds of pain management cases for the board, attorneys, and physicians. He has acted as an expert or consultant "in a variety of different roles" for the board.

Dr. Helm explained how pain management for treating patients with opioids has evolved from 2010 to the present. In 2016 when the Center for Disease Control (CDC) came out with its morphine equivalent dosage of 90, that was a significant change in the pain management practice and led to many changes, including increased referrals from primary care physicians and opioid weaning.

Evaluation of the Experts

11. In determining the weight of each expert's testimony, the expert's qualifications, credibility and basis for his opinions were considered. California courts repeatedly underscore that an expert's opinion is only as good as the facts and reason upon which that opinion is based: "Like a house built on sand, the expert's opinion is no better than the facts on which it is based." (*Kennemur v. State of California* (1982) 133 Cal.App.3d 907, 923.)

Dr. Geula gave very careful, measured responses, even researching during breaks to verify or correct his testimony. He based his opinions on specific entries in

the medical records. However, he often testified about chart entries that "concerned" him, what he "would have liked" to see, what he "would have wanted" Dr. Smith to do at the visits, or how the patient's findings "could be" related to various medical conditions. Dr. Geula did not specifically testify that these concerns meant Dr. Smith fell below the standard of care and it often appeared that much of Dr. Geula's testimony centered on "best practices" and not the standard of care.

Dr. Geula only spent a few years practicing pain management part-time and did not supervise physician assistants or operate the kind of practice at issue here. Dr. Geula primarily provided interventional pain management treatment as opposed to prescribing the long-term, long acting opioid medications that Dr. Smith and Dr. Helm have prescribed. Dr. Helm, much like Dr. Smith, had extensive pain management experience and has operated a pain management practice for decades similar to the one Dr. Smith operates. Dr. Helm's vast experience doing the type of pain management Dr. Smith provided made some of Dr. Helm's opinions more reliable than Dr. Geula's to the contrary. Dr. Helm also repeatedly cited to published studies, articles and authorities as the basis of his opinions, making them founded upon and supported by outside sources, unlike Dr. Geula who did not specifically cite to such authorities during his testimony.

However, Dr. Helm took a more global approach to each patient's care, agreeing that there were areas where Dr. Smith could have made better choices, but ultimately concluding that, overall, he met the standard of care. Dr. Helm opined that he did not see anything in these three patients' records where Dr. Smith fell below the standard of care. Dr. Helm tended to gloss over entries in the records that Dr. Geula had concerns about and seemed to take a no harm, no foul approach, which made many of Dr. Helm's opinions unpersuasive. Dr. Helm's credibility was also questionable

because in other disciplinary matters where he was complainant's expert, he opined that the board's pain management guidelines were the standard of care as opposed to those cases as a respondent's expert where he opined that the guidelines were not the standard of care, like he did here. Dr. Helm has also testified consistently in other disciplinary matters with the opinions he offered here, so the concerns raised about his credibility were not sufficient to discount all of his opinions offered at this hearing, especially given Dr. Geula's lack of experience both in years of treating pain patients and the types of pain management he rendered, which was a factor affecting the reliability of his opinions.

12. Complainant's request for judicial notice of a previously adopted board decision containing findings critical of Dr. Helm's credibility was denied because that decision was not precedential, so is not controlling here. Moreover, the two experts referenced in that decision were equally qualified and experienced, unlike the two experts here.

Pain Management Guidelines

13. The board created Pain Management Guidelines which have been revised several times. The most recent version was revised in 2014. Although not offered at hearing, both experts referred to these and earlier guidelines when rendering opinions. The main contention between the experts was whether the guidelines were the standard of care.

14. Official Notice is taken of the board's preamble in the 2014 Pain Management Guidelines, pursuant to Government Code section 11515. The preamble states in part:

> These guidelines are intended to help physicians improve outcomes of patient care and to prevent overdose deaths due to opioid use. They particularly address the use of opioids in the long-term treatment of chronic pain. . . . These guidelines underscore the extraordinary complexity in treating pain and how long-term opioid therapy should be conducted in practice settings where careful evaluation, regular follow-up, and close supervision are insured. . . . **These guidelines are not intended to mandate the standard of care.** The board recognizes the deviations from these guidelines will occur and may be appropriate depending upon the unique needs of individual patients. Medicine is practiced one patient at a time and each patient has individual needs and vulnerabilities. . . . (Emphasis added.)[6]

15. No evidence was introduced that the board has ever stated that its pain management guidelines are the standard of care.

16. Dr. Geula's initial report was written in the format of the guidelines. He based his opinions upon violations of the guidelines. Dr. Helm testified that the guidelines were not the standard of care and that the board's former Executive Director confirmed this in discussions he had with her. Dr. Helm criticized Dr. Geula for opining that violating the guidelines equated with violating the standard of care. Dr.

[6] The 2014 preamble was consistent with the board's prior statements regarding earlier versions of the guidelines and the standard of care.

Helm also opined that the guidelines are "directed to primary care physicians." Setting aside the credibility issues noted above, Dr. Helm's opinion that the guidelines were not the standard of care was consistent with the board's published position. Dr. Geula's report stated that the guidelines were "fully consistent" with the standard of care; to the extent he opined that the guidelines were the standard of care, those opinions are not accepted.

Dr. Smith's Care and Treatment of Patient A

17. Patient A, a 59-year-old female, first presented to Dr. Smith on October 10, 2013, for pain management of chronic pain in her face, lower back and knees. She described the pain as "pulsing, throbbing, pounding, aching, radiating, penetrating, shooting, tender, tight, squeezing, tiring, pinching, cramping, pulling, tingling, intense, unbearable" with a severity of 6-7 out of 10. There was no precipitating event or trauma and she was status post bilateral total knee replacements. She had numbness and tingling on the right side of her head, weakness, and bladder leaks. Her condition improved with pain medications and was aggravated by activity. Other therapies she had tried were TENS unit,[7] chiropractor, biofeedback/relaxation training, bedrest, physical therapy, and pain clinic treatments. Patient A indicated on her questionnaire

[7] TENS is the acronym for Transcutaneous Electrical Nerve Stimulation, a non-invasive device used for nerve related pain conditions.

she was a "Prop 215 patient," information that Dr. Smith circled[8] and that "in the 90s [Patient A] overdid drinking."

Dr. Smith reviewed Patient A's lumbar spine MRI. Dr. Smith's chart note thoroughly documented Patient A's current medications, past medical history, surgical history, history of present illness, vital signs, family history, social history, allergies, review of systems, and hospitalizations. Dr. Smith performed an extensive physical examination. His assessments were trigeminal neuralgia; osteoarthritis, generalized; knee pain, degeneration of lumbar disc(s); displacement of lumbar disc without myelopathy; facet joint syndrome, lumbar spine; spinal stenosis, lumbar spine; and long-term use meds nec.[9] Included among the current medications Dr. Smith noted she was taking OxyContin, Oxycodone, Dilaudid, Soma, Klonopin, Xanax[10] as needed, and medical marijuana, as well as other controlled substances.

In his treatment plan for the trigeminal neuralgia, Dr. Smith noted the patient's significant medical history which included a cerebral tumor removed in 1994 and that her history was "significant for chronic opioid dependency, but patient wishes to be weaned and or detoxed from opioids when appropriate." He noted that despite the

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[8] Proposition 215 exempted patients who possess marijuana used for medical treatment recommended by a physician from criminal laws. Dr. Geula did not know what "Prop 215 patient" meant; Dr. Smith and Dr. Helm did.

[9] No testimony defining "nec" was offered, presumably it meant "necessary."

[10] All of these medications are controlled substances. OxyContin, Oxycodone, and Dilaudid are opiates; Soma is a muscle relaxant; Klonopin and Xanax are benzodiazepines.

findings on her lumbar spine MRI, she had not received any diagnostic/therapeutic injections of her lumbar spine. Patient A wished to discontinue Dilaudid and admitted to using recreational/medicinal marijuana. Dr. Smith documented: "Patient understands I do not recommend controlled substance use with recreational drug use, and one would need to be discontinued. Patient understands I do not recommend chronic oral systemic opioid therapy nor high-dose oral systemic opioid therapy for her condition. Patient understands she is currently receiving high-dose oral opioid therapy."

Patient A also reported she was being treated for anxiety and depression, was on benzodiazepines, and was currently stable from that condition. Dr. Smith wrote:

> Patient was warned and understands I do not recommend opioid therapy mixed with benzodiazepine therapy due to the increased risk of respiratory depression and death. Patient is motivated today and wishes to discontinue her opioid therapy when her knees feel better. She is hopeful that she can be off of his [*sic*] medications by January 2014. Patient understands I do not recommend OxyContin as a sustained-release medication. I recommend discontinuing OxyContin and trialing MS Contin 60 mg b.i.d. I recommend continuing oxycodone 30 mg tablets 6 per day. I recommend continuing Soma 350 mg t.i.d. p.r.n. spasm. I recommend discontinuing hydromorphone. I recommend proceeding with diagnostic/therapeutic injections of her lumbar spine that may include epidural steroid therapy,

> facet injections, facet rhizotomies, and a MILD[11] procedure for spinal stenosis due to ligamentum flavium hypertrophy. These treatments could help significantly improve her low back pain while her knee pain improves, and enable us to wean her from opioid medications. Patient understands I do not perform detox, but she is willing to enter and entertain a detox program in order to get off of her opioids. Patient may also benefit from a referral to either a neurosurgeon or and oral facial pain specialists for treatment of trigeminal neuralgia pain.

Patient A reported seeing a neurosurgeon "many years ago and would consider a reevaluation. A medication management agreement was discussed and "signed by the patient today." The medication management agreement stated the patient agreed to follow Dr. Smith's pain program procedures, including taking prescriptions exactly as prescribed, utilizing only one pharmacy to fill the prescriptions for opioids, maintaining a relationship with the patient's primary care physician, and understanding that the patient may be terminated from the program for violating the agreement. The chart also contained a "Bowel Regimen" document that provided ways to prevent and treat constipation which was a "common and serious side effect associated with long-term and even short-term opioid usage."

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[11] MILD is the acronym for Minimally Invasive Lumbar Disc procedure, an FDA-approved, minimally-invasive treatment to remove excess tissue in the spinal canal, with the goal of relieving pressure on the spinal nerves.

Dr. Smith provided a 30-day supply of medication and Patient A "understands the risk of continued oral medication management." Dr. Smith started Patient A on 60 mg of extended release MS Contin, to be taken twice a day; refilled her 30 mg of Oxycodone, two tablets to be taken every four to six hours as needed for pain, with a maximum of six tablets per day; and refilled her 350 mg of Soma to be taken three times a day for spasms. Patient A would follow-up in one month for a medication management visit and to discuss lumbar epidural steroid therapy. There was no documentation of reviewing CURES and no urine drug screen (UDS) was ordered.

18. An October 31, 2013, telephone note indicated that Patient A's husband called advising Patient A "was on a CAP machine,"[12] was experiencing aerophagia,[13] and her home treatment of standing in the shower was not helping. Dr. Smith advised Patient A to go to the Emergency Room (ER), and explain she was on "high dose opioids."

19. Patient A was next seen by a physician assistant on November 4, 2013. In her questionnaire Patient A reported severe stomach cramping, distension, "over the top pain," with "severe vomiting lasting all day to dry-heaving." She had 75 percent pain relief and her current pain was 6 out of 10. She had been to the ER on three occasions, including today. She reported that she had not taken Xanax since October

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[12] Presumably this referred to a C-PAP machine that is used to treat sleep apnea, a condition noted in Patient A's records.

[13] Aerophagia is a condition where an individual swallows air.

10, 2013.[14] The physician assistant documented Patient A's referral by her primary care physician for an endoscopy. Patient A admitted to using medical marijuana and the physician assistant noted that Patient A's use of marijuana violated the medication management agreement which may result in her being discharged. Patient A reported that she was no longer using benzodiazepines; however her daily use of Klonopin, a benzodiazepine, was documented in the "Current Medications Taking" section of the chart at this visit and at each visit thereafter. There was no documentation of this inconsistency or any documentation that using Klonopin was contrary to the "warning" Dr. Smith gave her at the first visit about the risks of combining benzodiazepines with opioids. The physician assistant reviewed Dr. Smith's "medication management philosophy" of using "medicine as a bridge to more appropriate therapies" and that Dr. Smith "doesn't recommend chronic oral systemic opiate therapy nor high-dose oral systemic opioid therapy for her condition." The physician assistant continued Patient A on the MS Contin, Oxycodone, and Soma, and Patient A agreed to take her medications as prescribed. Patient A would be seen in one month for medication management and a urine drug screen "NOV" was noted.[15] No testimony regarding what NOV meant was offered. There was no documentation of a CURES report being reviewed.

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[14] Dr. Geula opined that her gastrointestinal issues could be due to the medication changes Dr. Smith made at the first visit so should "certainly be on the differential."

[15] Although Dr. Geula testified that a UDS was not ordered at this visit, "UDS NOV" was noted in the plan.

20. Patient A was next seen by a physician assistant on December 2, 2013. She reported receiving 50 percent relief with her current treatment but had increased right shoulder pain and difficulty sleeping or eating because of the severity of her pain. The physician assistant documented in the medications section of the chart the numerous medications Patient A was taking, including Klonopin, despite her prior representation she was no longer taking benzodiazepines. No further inquiry regarding this inconsistency was documented. The physical examination documented was extremely cursory. Patient A's medications were refilled with no changes, a UDS was ordered, and she was referred back to her neurosurgeon for follow-up on her trigeminal neuralgia.

21. A lab report documented a urine collection on December 2, 2013, which was faxed to Dr. Smith's office on December 30, 2013. The report was positive for marijuana metabolite which was inconsistent with Patient A's report of no longer using marijuana. The results were also negative for opioids which was inconsistent with the medications Dr. Smith was prescribing.

22. At her next visit on December 30, 2013, with a physician assistant, Patient A reported no change in her chronic pain and continued to receive approximately 55 percent pain relief with her current treatment. She reported a flareup of her gastrointestinal issues for which she was seeing a physician and her primary care physician had taken x-rays of her right shoulder and referred her to an orthopedist. She reported difficulty sleeping and eating due to her pain. The physical examination documented was very brief. The physician assistant noted that Patient A was a candidate for diagnostic/therapeutic injections of her lumbar spine that may include epidural steroid therapy and that option would be discussed with her after "most intense abdominal issues have been treated." The patient verbalized her

understanding of this plan. The physician assistant reviewed the patient's inconsistent UDS results with her. As noted, Patient A "swears" she was not using marijuana and was taking her morphine as prescribed. The physician assistant explained that this inconsistent UDS was a violation of Patient A's medication management agreement and further violations may result in her being discharged. The patient agreed to comply. The physician assistant documented that since Patient A was "stable and tolerating her medication without difficulty, no change was made to her prescriptions today." In the medications section the physician assistant documented patient A's daily use of Klonopin but, again, no inquiry regarding this was documented. A follow-up UDS was not ordered and there was no documentation of a CURES report being reviewed.

23. At Patient A's next visit on January 27, 2014, with a physician assistant, her blood pressure was recorded at 164/100. She reported 50 percent pain relief with her current treatment and was working with her orthopedic provider regarding "her frozen shoulder." Her abdominal pain, nausea and vomiting had resolved. She was working with her primary care physician regarding her sleep apnea. The physical examination documented was brief and did not reference an examination of Patient A's back. Given her low back complaints, an epidural steroid injection was recommended and the patient agreed to contact the office when she "desires to proceed." The physician assistant documented: "In the meantime, the patient would like to continue medication management with her current regimen." Her medications were refilled with no changes. The "Current Medications Taking" section of the note documented that Patient A was taking Klonopin once a day, but again, there was no inquiry charted regarding her use of this benzodiazepine. Patient A agreed "to continue to work with her medical providers to optimize her general health and well-

being as well as her elevated blood pressure obtained at the visit today." There was no UDS ordered or documentation of CURES being reviewed.

24. The chart entry for Patient A's February 24, 2014, visit with a physician assistant, were almost identical to the entries made on January 27, 2014, including the brief physical examination and Patient A's daily use of Klonopin. Her medications were refilled and a UDS was ordered.

25. A March 18, 2014, telephone encounter note documented a call from Patient A advising that because of her "extreme nausea with stomach pain" and throwing up, Patient A was going to be out of medication by the end of the week and wanted to know if she could get an early refill. The patient was reminded to take her medications as prescribed per the signed medication management agreement and "further violations may result in discharge from our office." An appointment was rescheduled for this week and she was advised to consider the Sharp pain program if she did not "want to proceed with interventionals." The note documented "UDS NOV" but there was no documentation of any inquiry into why the UDS ordered at the prior visit was not done. There was no documentation of reviewing CURES.

26. At her March 20, 2014, visit with a physician assistant, Patient A reported an increase in her right shoulder and arm pain and more consistent chronic lower back pain. She was "currently receiving no relief with current treatment." She reported that her orthopedic provider diagnosed a rotator cuff tear that would require surgery and that her gastrointestinal issues made it difficult for her to keep her medications down. She was working with her gastroenterologist for abdominal issues and with her primary care physician for her sleep apnea. The physical examination documented was brief. Patient A was again informed that she was a candidate for lumbar spine epidural steroid injection therapy which she wanted to undergo. A referral to a neurosurgeon

or specialist for her facial pain was recommended and Patient A agreed to pursue that care. Patient A continued to take Klonopin daily, but there was no documentation regarding any discussion about this with the patient. It was again documented that "[i]n the meantime" Patient A would continue with her current medication regimen and "since [she] is adequately functioning and tolerating her medication without difficulty, no change was made to her prescriptions today." Patient A was advised of other interventional procedures to consider, including facet injections, facet rhizotomies, and a MILD procedure for spinal stenosis. Patient A understood that she would need to coordinate her pain management with her shoulder surgeon. A UDS was ordered, but there was no documentation regarding the UDS previously ordered nor documentation of reviewing CURES.

27. On April 14, 2014, Dr. Smith performed a lumbar epidural steroid injection and lumbar epidurography for Patient A's lumbar degenerative disc disease.

28. Patient A was next seen by a physician assistant on April 17, 2014, reporting no pain relief from the procedure as of yet. Patient A may benefit from additional injection therapy and would be reevaluated at the next office visit.[16] Patient A reported an increase in her chronic pain generators: aerophagia, right shoulder and arm pain, both knees, trigeminal neuralgia and fibromyalgia. She was receiving 25 percent relief with her current treatment. A brief physical examination was documented. She was continuing to treat with her orthopedic provider, gastroenterologist, and primary care physician. She continued to use Klonopin daily. It was again recommended that Patient A transition her care to the Sharp pain program

[16] Both experts agreed that it is not uncommon for patients not to receive any relief from epidural injections; the results from these injections can vary.

which "provides a comprehensive approach to managing chronic pain that we do not offer through our office as well as helping her to build additional tools and techniques to manage and cope with her pain and address the significant psychological component to her chronic pain along with water therapy to reduce/eliminate her need for daily oral analgesics." The chart note indicated that "In the meantime" Patient A would continue with her current medication regimen until she established care with the Sharp pain program. Patient A was reminded that she must complete her UDS when requested per her signed medication management agreement and that further violations may result in discharge. The UDS was again ordered, she was referred to the Sharp pain program, and she was to follow-up in one month for medication management if needed. There was again no documentation of reviewing CURES.

29. The lab report for Patient A's urine collected on April 17, 2014, which was reported to Dr. Smith's office on April 26, 2014, was positive for the presence of marijuana metabolite, which was inconsistent with Patient A's report that she was not taking marijuana. Her levels of morphine and oxycodone were both reported as high. Her urine was negative for the presence of benzodiazepines which was inconsistent with Dr. Smith's chart notes but consistent with the patient's report of no longer taking benzodiazepines.

30. At Patient A's May 15, 2014, visit with a physician assistant, she reported 50 percent pain relief from the lumbar epidural steroid injection. She reported increases in her activity but no change in her chronic pain generators. She continued to treat with other providers for her planned shoulder surgery, her sleep apnea and her gastrointestinal issues. She agreed to have her MRI results sent to Dr. Smith. A brief physical examination, similar to the one documented at the prior visit, was performed. Patient A continued to use Klonopin daily which was inconsistent with her

recent UDS, but no documentation of discussing this inconsistency was charted. Patient A admitted "having a difficult time with her goal to reduce her oral analgesics use due to the severity of her pain as well as stress level, so she would like to discuss other pain management options." Patient A reported that she was contacted by the Sharp pain program and canceled her appointment because she "realized she had been there years ago with no benefit." It was still recommended that she transition her care to that program. "In the meantime" Patient A would continue with her current medication regimen until she could establish care with the Sharp pain program, and no change was made to her medications. She was again encouraged to consult with her neurosurgeon to address her facial pain. The physician assistant reminded Patient A that she must "perform her UDS when requested" per her medication management agreement and that further violations may result in her discharge.[17] Patient A agreed to comply. There was no documentation of reviewing CURES and no UDS ordered.

31. Patient A was next seen on June 12, 2014, and reported 25 percent relief with her current treatment regimen. She was still obtaining "great relief" from the lumbar epidural storied injection and able to perform many activities without pain. She was continuing to treat with three other physicians for her right shoulder pain, sleep apnea and gastrointestinal issues. The brief physical examination documented was similar to the ones previously documented. She continued to use Klonopin daily. It was again documented that Patient A had canceled her Sharp pain program appointment because she had treated there previously with no benefit. Patient A was again

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[17] This entry was confusing because there was a lab report for the UDS ordered at the prior visit, indicating Patient A did comply with the prior instruction to have a UDS performed.

encouraged to transition her care to the Sharp program. It was again documented that she should follow up with her neurosurgeon for her facial pain complaints. It was again documented that she would have her MRI scan results sent to Dr. Smith's office. Patient A's medications were refilled without any changes. There is no documentation of reviewing CURES and no UDS was ordered.

32. Patient A was next seen by a physician assistant on July 10, 2014. She reported 25 percent pain relief with her current treatment and the effectiveness of the lumbar epidural steroid injection had remained. She would be undergoing right shoulder surgery next month, her neurosurgeon did not recommend surgery for her facial pain, and she continued to work with her primary care physician and gastroenterologist for her sleep apnea and abdominal issues. Again, the brief physical examination documented was similar to the ones previously charted. Patient A's cancellation of her appointment at the Sharp pain program, the recommendation that she transition her care to that program, her promise to have her MRI scan results sent to Dr. Smith's office, and her daily use of Klonopin were again documented. Her medications were refilled with no changes. There was no documentation of a CURES report being reviewed and no UDS ordered.

33. In the August 7, 2014, questionnaire she completed at her next visit, Patient A noted that she was being referred to a pulmonologist because her C-PAP was not working. Patient A was seen by a physician assistant who documented that Patient A reported 25 percent pain relief with her current treatment, that the lumbar epidural steroid injection had started to lose its effectiveness, that she was undergoing shoulder surgery the next day, and that she would like to repeat the steroid injection after she recovers from her shoulder surgery. The physical examination documented was brief and similarly worded to prior chart entries. She continued to use Klonopin

daily. Since Patient A was "adequately functioning and tolerating her medications," no changes to her prescriptions was made and all her medications were refilled. Patient A was instructed to have her surgeon contact Dr. Smith to discuss post-operative pain control if Dr. Smith's office would be managing her medications.

34. At Patient A's September 4, 2014, visit, she was seen by a physician assistant. She reported 25 percent relief with her current treatment and that the epidural injection had started to lose his effectiveness. This last entry was clearly a cut-and-paste from prior visits because the injection had "started" to lose its effectiveness the month prior. The patient was four weeks post-operative from her shoulder surgery and was doing well. She was continuing to treat with providers for her gastrointestinal and sleep apnea issues. She was continuing to take Klonopin daily. Her medications were refilled with no changes. Despite the entry at the prior visit that the patient's orthopedic surgeon should contact Dr. Smith to discuss post-operative pain management, there was no documentation in the chart of that ever occurring and no documentation regarding whether Patient A received additional pain medication from her orthopedic surgeon. There was no documentation of CURES being reviewed and no UDS ordered.

35. Patient A was next seen by a physician assistant on October 2, 2014. Again it was documented that the lumbar epidural steroid injection "has started" to lose its effectiveness, but "not enough that she is interested in a repeat injection." Patient A reported 50 percent relief with her current treatment and was undergoing physical therapy with good progress following her right shoulder repair surgery. She continued to treat with specialists for her facial pain, gastrointestinal and sleep apnea issues. She continued taking Klonopin daily. There was no change made to her

medications and they were refilled. No UDS was ordered and there was no documentation of reviewing CURES.

36. Patient A was next seen by a physician assistant on October 30, 2014. She reported no change in her chronic back pain, felt it was stable, and she was not interested in an injection at this time. She reported 50 percent relief of her pain with her current treatment. She had completed physical therapy for her right shoulder and was doing her home exercise programs without difficulty. She was scheduled to undergo a workup for her gastrointestinal issues on November 4, 2014, and was continuing to work with her primary care physician for her sleep apnea, as well as beginning to see "a new sleep doctor." She continued taking Klonopin daily. All of her medications were refilled with no changes. There is no documentation of a CURES report being reviewed or a UDS being ordered.

37. At Patient A's next visit on November 25, 2014, she was again seen by a physician assistant. Patient A reported feeling ill and had been vomiting since the morning. She had recently been diagnosed with severe irritable bowel syndrome and thinks this is a flareup of that condition. She reported no change in her chronic back pain and felt it was stable. She reported no relief of her pain without her medications. She continued to work with her physicians regarding her gastrointestinal and sleep apnea issues. She continued taking Klonopin daily. Her medications were renewed with no changes. It was recommended she be seen by her primary care physician or go to the urgent care or the ER for her elevated blood pressure reading of 202/114. Patient A stated that she took her blood pressure medication earlier, but has been vomiting, so it likely did not stay down. There was no documentation of reviewing CURES and no UDS was ordered.

38. Patient A was next seen on November 23, 2014, by a physician assistant. She reported two episodes of severe pain that required her to go to the ER where she was admitted for a few days and treated for a fecal impaction. She followed up with her gastroenterologist. She was still receiving 25 percent pain relief with her current treatment. She continued to work with her primary care physician and her "sleep doctor" and had recently been placed on oxygen at night to help with her sleep apnea. Patient A reported that "[e]very aspect of her life had been adversely affected due to her recent hospitalization, severity of her pain, and stress level." Patient A continued with her daily Klonopin use. The physician assistant documented that the patient wished to continue with her medication management regimen but due to her recent bowel obstruction and supplemental oxygen for her sleep apnea, "she is not a candidate for continued oral opioid therapy" and "was advised to coordinate detox that we do not provide through our office." Resources were given to the patient but since she was "adequately functioning and tolerating her medication without difficulty, no change was made to her prescriptions today" and her medications were refilled. No documentation about any discussion of the risk of taking high dose opioids, which depress respirations, given Patient A's sleep apnea was charted. There was no documentation of reviewing CURES and no UDS was ordered.

39. Dr. Smith saw the patient on January 15, 2015, to discuss treatment options. The patient reported being under extreme mental stress due to an abusive son and advised that the police were now involved. Patient A had an appointment with a psychiatrist the following week. She was continuing to take Klonopin daily. Dr. Smith noted that once the situation with her abusive son was stabilized, "I recommend proceeding with detox from chronic high-dose oral systemic opioid therapy and possibly proceed with intrathecal drug delivery system therapy if psychological clearance can be obtained." Dr. Smith noted further, "Patient understands I do not

recommend chronic high dose oral systemic opioid therapy for her condition. I also recommend obtaining a repeat urine drug screen today." Dr. Smith refilled the patient's medications with no changes and ordered a UDS.

40. The lab report for Patient A's urine collected on January 15, 2015, documented as having been reported to Dr. Smith's office on January 24, 2015, was negative for benzodiazepines, which was consistent with her prior report to Dr. Smith's office, but inconsistent with his chart notes. The lab results were positive for marijuana metabolite, negative for the presence of opioids, including morphine, and positive for the presence of oxycodone, all of which were inconsistent with the medications Dr. Smith was prescribing and the marijuana she claimed to no longer be taking.

41. At Patient A's next visit on February 12, 2015, with a physician assistant, she was complaining "of her usual and familiar pain." She reported being under "severe mental strain due to some family issues." She was "seeing a psychiatrist and a counselor to help her cope." She reported undergoing recent blood work that showed she had anemia so she was taking iron. She was continuing to take daily Klonopin. The physician assistant wrote: "Due to the patient's symptoms, and continued pain I recommend she temporarily continue with the current medications."[18] Patient was recommended to continue working with authorities regarding her abusive son and seeing her psychiatrist and counselor. The physician assistant charted: "Once the situation is stabilized, Dr. Smith recommends proceeding with detox from chronic high dose oral systemic opioid therapy and possibly proceed with intrathecal drug delivery system therapy if psychological clearance can be obtained." The patient wished to

[18] Presumably this meant the medications that were being prescribed at every visit with no changes.

continue with oral medications at this time and those were refilled with no changes. There is no documentation of reviewing CURES and no discussion documented regarding the inconsistent January 15, 2015, UDS and no repeat UDS was ordered, nor was there a discussion charted that her UDS results violated her medication management agreement.

42. Patient A was next seen on March 12, 2015, by a physician assistant and continued to have high anxiety, panic attacks, headaches, and abdominal pain due to her "high stress family situation despite working with her psychologist and psychiatrist routinely." She was taking iron for her anemia and Klonopin daily. The physician assistant documented: "Due to the patient's symptoms of chronic pain and with the direction of Dr. Smith, her medication management with her current regimen will be continued until her family situation is resolved." It was again documented that Dr. Smith recommended proceeding with detox from chronic high-dose oral systemic opioid therapy and possibly proceed with intrathecal drug delivery system therapy if psychological clearance can be obtained, but there was no charting of how or where Patient A was to detox and this note was confusing given that Dr. Smith never tapered her medications, but, instead, continued to refill them at each visit with no changes. Patient A showed "no diversionary nor aberrant behavior with medications" which was an inaccurate entry given Patient A's January 15, 2015, UDS results. There was no documentation of reviewing CURES, no documentation of the inconsistent UDS obtained January 15, 2015, and no UDS ordered.

43. Dr. Smith saw Patient A at her April 8, 2015, visit. She reported 25 to 50 percent pain relief with her current treatment and continued to take Klonopin once a day. Dr. Smith refilled her medications with no changes. He did not document reviewing CURES, or discussing Patient A's January 15, 2015, inconsistent UDS results.

Dr. Smith did not document that his office had not received that UDS report and he did not order a repeat UDS.

44. In her May 26, 2015, patient questionnaire, Patient A reported that she had "another attack that began 4:30 am with [illegible] so high I passed out. This attack lasted about 15-16 [illegible]." Patient A was seen by a physician assistant who documented the patient's report of "a flareup of severe abdominal pain with nausea and vomiting" that lasted 15 to 16 hours. She was receiving 50 percent pain relief with her current treatment. She continued to take Klonopin daily. Patient A's medications were refilled with no changes and the physician assistant documented: "Due to the patient's symptoms of chronic pain and with the direction of Dr. Smith, her medication management with her current regimen will be continued until her family situation is resolved." Patient A would continue working closely with her psychiatrist, counselor, and authorities. There was no documentation of reviewing CURES and no UDS was ordered.

45. Patient A was next seen on June 30, 2015, by a physician assistant and reported having been seen by an endocrinologist. She had a flareup of her abdominal condition which required her to go to the hospital where she was treated and released. She was currently receiving 75 percent relief with her current treatment. She was taking Klonopin once a day. Her medications were refilled with no changes. There was no documentation of reviewing CURES, no UDS ordered, and no documentation of whether she received any medication at the hospital.

46. Patient A was seen by a physician assistant on July 1, 2015, and reported a flareup of her lower back pain three weeks ago that continued to persist. She was receiving 50 percent pain relief with her current treatment. She reported that her

endocrinologist ordered "additional tests to rule out pheochromocytoma[19] because the initial test was inconclusive." The patient was continuing to take Klonopin once a day. Dr. Smith continued to recommend detox once the patient's family situation stabilized. A random drug screen was performed and the UDS dipstick results obtained in the office were positive for opioids, oxycodone and benzodiazepines which was "consistent with the medication list that was verified today." The urine specimen would be sent out to the lab for further evaluation. There was no documentation that the presence of benzodiazepines in the dipstick was inconsistent with Dr. Smith's original note that he would not prescribe opioids if Patient A continued to take benzodiazepines; no documentation that the presence of benzodiazepines was inconsistent with Patient A's earlier report that she was no longer taking benzodiazepines; and no documentation reconciling her prior UDS that was negative for the presence of benzodiazepines with this one that was positive. There was no documentation of reviewing CURES.

47. Patient A's lab report for urine collected on July 1, 2015, and reported to Dr. Smith's office on July 4, 2015, was positive for the presence of marijuana metabolite, and negative for the presence of opiates, which were inconsistent results. The lab results were also positive for the presence of benzodiazepines, which was consistent with the chart note entries, but contrary to Dr. Smith's original notations that he would not prescribe high dose opioids if the patient was taking benzodiazepines. The records also did not document any type of inquiry into the fact that the patient originally stated she was no longer on benzodiazepine therapy but

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[19] Pheochromocytoma is a tumor originating in the adrenal gland cells that causes overproduction of certain hormones.

then reported taking Klonopin daily at each successive visit, or had a prior UDS that was negative for the presence of benzodiazepines.

48. Patient A was next seen on July 29, 2015, by a physician assistant. She reported no flareups of her chronic intermittent abdominal symptoms but admitted that her chronic trigeminal neuralgia had been more apparent. She was receiving 50 percent pain relief with her current treatment and was treating with an endocrinologist. She continued to have sleep and stress issues because of her family stress, but her mood had improved with the Paxil and Lamotrigine[20] her psychiatrist had prescribed. She continued to take Klonopin once a day. The results of the UDS, which were positive for marijuana and negative for the opioids that Dr. Smith's office prescribed, were reviewed with the patient who was surprised by the results and reported that she took her medication as prescribed and had not used marijuana since January. Patient A was advised that these UDS results "are another violation of her medication management agreement, so Dr. Smith will review her chart to determine further care with our office." "The patient was given contact information to coordinate detox from chronic high-dose oral systemic opioid therapy, as previously discussed." A two week refill of her medication was given and she was to follow-up with Dr. Smith regarding her continued medication management with the office.

49. An August 7, 2015, telephone note documented the call to Patient A to inform her that Dr. Smith had decided to discharge her "due to her multiple medication management violations." A final two week supply of her medications would

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[20] These drugs are controlled substances. Paxil is an anti-depressant; Lamotrigine is an anti-convulsant used to treat seizures and extreme mood swings for adults with bipolar disorder.

be provided to her and a formal letter of discharge would be sent to her via regular and certified mail.

50. A letter dated August 10, 2015, formally discharged Patient A from Dr. Smith's care due to "violation of your pain management treatment." In his letter, Dr. Smith recommended that Patient A "seek care through a comprehensive treatment program for detoxification as well as to address potential opioid withdrawal type of symptoms."

51. An August 18, 2015, telephone note documented that Patient A called advising she had received her formal letter of discharge but would be out of medications tomorrow and was requesting a refill, despite having been provided a two week supply just one week ago. Dr. Smith's office inquired as to why she was out of medications after being given a two week supply. Patient A denied she ever "over medicated" and was confused why she could not get a refill because the discharge letter advised that she could come for one final appointment to get medication to tide her over until she saw a new provider.

52. The CURES reports obtained by complainant as part of the investigation documented the medications prescribed by Dr. Smith's office and the Clonazepam (Klonopin) prescribed by Patient A's primary care provider, that Dr. Smith's records continuously documented she was taking. Contrary to Patient A's claim of being "off benzodiazepines," the CURES report revealed her monthly prescriptions for Clonazepam throughout the entire time she was treating with Dr. Smith. Dr. Smith produced copies of CURES reports that he testified had been scanned into the patient's file but did not print out when his office produced copies of his records to the investigator. Those reports contained handwritten notations questioning the reason medications had been prescribed, stating "too much" oxycodone was being

taken, which demonstrated Dr. Smith had concerns, but then he did not follow up and document reviewing CURES at each patient visit.

Evaluation of Dr. Smith's Care and Treatment of Patient A

GROSS NEGLIGENCE ALLEGATIONS

Combination of Medications

53. Dr. Geula opined that Dr. Smith was grossly negligent in his care and treatment of Patient A when he prescribed a combination of high dose opioids and Soma to her. Dr. Geula was critical of the amount of morphine equivalent, 390, that Dr. Smith prescribed at the first visit. Dr. Geula opined that at the first visit, Patient A was on high doses of opioids which are "a pretty big red flag and when combined with Soma it is pretty alarming." High dose opioids can cause respiratory depression. Dr. Geula explained that the synergistic effect of opioids and Soma, a muscle relaxer that metabolizes similar to a benzodiazepine, increases the risk of cardiopulmonary complications and respiratory depression, which is increased even more when Xanax, a benzodiazepine Patient A used in the past, is added.[21]

Dr. Geula opined that Patient A's use of a C-PAP was significant because it is used for obstructive sleep apnea and prescribing opioids and benzodiazepines poses a significant risk for an apneic event, especially for this patient who was at risk for apnea. Dr. Geula did not believe there was any indication for the Soma prescription because there was no documentation of muscle spasms during Dr. Smith's initial exam.

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[21] There was no evidence patient A was prescribed Xanax by Dr. Smith or was taking it when treating with him.

Dr. Geula did not believe that Dr. Smith evaluated Patient A for substance abuse and although Dr. Smith noted that the patient was aware he did not recommend high-dose opioids, he continued to prescribe them. Dr. Smith also advised Patient A of the risk of combining benzodiazepines and opioids and to discontinue using marijuana, but did not take any action when she did not follow his advice.

Dr. Helm opined that combining Soma and opioids was not an extreme departure from the standard of care. There have been some very good population-based studies showing that the risk of higher doses and combination therapy may have adverse effects including respiratory issues and death, so lowering the risk means decreasing the medications. But, subsequent to this time when Dr. Smith saw Patient A in 2013, the Food and Drug Administration (FDA) had the manufacturers of sustained-release opioids do an opioid pain consortium study to evaluate patients receiving these amounts of opioids, but the study was pulled before it was completed. However, one fact that came out from the study is that although these were not common doses, it was well-known in the pain management community that there were patients taking these amounts of opioids. Moreover, the morphine equivalent opinions Dr. Geula gave were based on the CDC guidelines issued in 2016, several years after Dr. Smith treated and discharged Patient A.

Dr. Helm opined that Dr. Smith did chart that the patient had spasms because his description of her pain as being "pulsing, throbbing, pounding, aching, radiating, penetrating, shooting, tender, tight, squeeze, tiring, pinching, cramping, pulling, tingling, intense, [and] unbearable" our adjectives consistent with spasm. Dr. Smith also documented that the Soma was being prescribed for "spasms."

Patient A was being treated for sleep apnea and Dr. Smith prescribed high dose opioids and Soma, greatly increasing the risk of respiratory depression in a patient

who already was at risk for an apneic event. Dr. Helm's opinion, which was supported by Dr. Smith's documentation, that Patient A had muscle spasm, is accepted, but his opinions that combining high dose opioids with Soma was within the standard of care is rejected. Complainant established by clear and convincing evidence that Dr. Smith was grossly negligent in his care and treatment of Patient A when he prescribed a combination of high dose opioids and Soma to her.

Failure to Modify Controlled Substance Regimen

54. Dr. Geula opined that Dr. Smith was grossly negligent in his care and treatment of Patient A for failing to adequately modify her controlled substance regimen. There were no changes made to the patient's medication regimen, despite her statements that her pain was improving, or even during those times when she had advised that her pain was increasing. Instead, her medications were simply refilled at each visit without taking her condition, and changes to it, into account.

Dr. Helm opined that the types and amounts of medications prescribed were within the standard of care. Efforts to find alternatives or to wean are judgment calls and Dr. Smith's decisions were within the standard of care. Dr. Helm opined that Dr. Smith stopped the patient's benzodiazepines early on and lowered her morphine equivalent dosage, increasing it thereafter for reasons that were documented in the chart.

It is not enough for a physician to simply document that he has told the patient what he does not recommend; the physician must actually follow through on those recommendations. Here Dr. Smith merely charted his philosophy but then did not follow it and he and his physician assistants continued to prescribe high dose opioids to Patient A, with no end in sight. Moreover, contrary to his philosophy, he prescribed

those high dose opioids despite Patient A's daily use of benzodiazepines, and her use of medical marijuana. Dr. Geula's opinions were more persuasive than Dr. Helm's and Dr. Helm's testimony about weaning the patient and lowering her doses was contrary to what was charted. Complainant established by clear and convincing evidence that Dr. Smith was grossly negligent in his care and treatment of Patient A for failing to adequately modify her controlled substance regimen.

Failure to Review CURES Reports

55. Dr. Geula opined that Dr. Smith was grossly negligent in his care and treatment of Patient A for failing to review her CURES report. Dr. Geula explained that CURES is a tool to help the prescriber ensure that the patient is only getting prescriptions from one physician. It was especially important to obtain them in this case when the patient's UDS showed potential diversionary behavior and she had a history of substance and alcohol abuse.

Dr. Helm opined that Dr. Geula's opinion that CURES be obtained at every visit was an example of "best practices" and not standard of care. The standard of care when Dr. Smith treated Patient A did not require CURES be obtained at every visit. In 2018, it has been mandated by law that physicians must review CURES at every visit, but not when Dr. Smith treated her. Dr. Helm opined that the standard of care when Dr. Smith was treating this patient was to obtain CURES "intermittently," but he did not define what that meant.

Given the many medications identified in the records that Dr. Smith and his staff were not prescribing, her inconsistent UDS, and the inconsistent chart entries regarding Klonopin, it was imperative Dr. Smith review CURES at the visits so he could confirm the medications Patient A was reporting and to ensure there were no other

medications she was taking that she was not reporting. Although the CURES reports Dr. Smith introduced at hearing documented the concerns he had about Patient A's medications, he failed to document a review of CURES at any of the visits and failed to review a sufficient number of CURES given Patient A's inconsistent UDS results and medications that other treaters were providing. Complainant established by clear and convincing evidence that Dr. Smith was grossly negligent in his care and treatment of Patient A for failing to review her CURES report.

Failure to Obtain More Frequent UDS

56. Dr. Geula opined that Dr. Smith was grossly negligent in his care and treatment of Patient A for failing to obtain more frequent urine drug screens. The patient had inconsistent drug screens, was being prescribed "very, very high doses of opioids" with Soma, had numerous risk factors, and had a history of abuse. All of those facts warranted close monitoring to ensure the proper use of the prescriptions for this patient.

Dr. Helm agreed the standard of care required obtaining UDS, but noted Dr. Smith was not personally seeing the patient when the UDS came back, the patient was being seen by physician assistants. Also, literature on using UDS "dates back to the early 2000's and none has ever been published setting out how frequently UDS must be ordered." When the UDS was inconsistent, there was documentation of a discussion with Patient A regarding her medication management agreement and she was warned not to violate it again. Dr. Helm explained that these are very complex patients, it is an education process, and the physician does not abandon the patients when they have a violation. The physician will try to work with them, try to educate them, but "if they refuse to learn, you have to act, but first you have to educate them." Dr. Smith's records show that he was practicing very conservatively, his office was not a "pill mill,"

and he was monitoring the patients. Dr. Helm saw "a great deal of monitoring in these records." Dr. Helm did not believe that Dr. Smith violated the standard of care for failing to obtain more frequent UDS.

Dr. Smith explained that lab results were received at his office via fax. The medical assistant would obtain those reports, review them, and provide them to the physician's assistant or "physician extender" in the office.[22] If there were issues with the UDS results, they would be brought to Dr. Smith's attention. The lab used for UDS testing varied based on the patient's insurance company. Dr. Smith explained that there was a period of time when the Sharp Medical Group was requiring his office use Quest for UDS testing and there were lots of issues with that lab. Dr. Smith explained that initially he preferred using a dipstick and then sending the sample to the lab for confirmation, but Sharp would not allow that. He then learned that there were other physicians in San Diego who were allowed to use the dipstick and he called Sharp out on that and, eventually, they allowed him to use dipsticks. Another problem with Quest was that the lab did not want to test for all the drugs that Dr. Smith wanted to test for, tested for drugs that his office had not requested, or did not test for drugs that his office had requested. There were also numerous problems with getting reports faxed back to Dr. Smith's office. Even though the UDS reports state they were "faxed" or "reported" to Dr. Smith's office on a given date, often they were not sent to the office. Dr. Smith testified that this happened "for lots of labs" and "went on for years." His office would send out UDS requests and not see the results back and would have to call the lab in order to obtain results. Dr. Smith had numerous meetings with Sharp

[22] It was unclear what Dr. Smith meant by the "physician extender" in his office and no testimony explaining it was offered.

and Quest about these issues and finally had to meet with the medical director at Sharp to get the issue resolved. Dr. Smith explained to the Sharp director that this UDS issue was below the standard care in the community and "really needs to change." After Dr. Smith mentioned the standard of care, "that is when things started to change."

The difficulties Dr. Smith was having with the labs did not absolve him of his responsibility to follow up on the results of labs he ordered at visits before simply refilling the patient's prescriptions with no changes. There was no documentation of these lab difficulties nor any documentation that he was aware of having ordered a UDS at a prior visit and still not having the results. Again, simply ordering a test is not enough, a physician should follow up on tests ordered and, at a minimum, document that he has done so, even if his documentation is that the results are not yet back. Given the high-dose opioids he was prescribing, and the inconsistent UDS results, it was incumbent upon him to obtain more frequent UDS testing and follow-up on testing previously ordered.

Dr. Geula's opinions are accepted over those of Dr. Helm to the contrary. Contrary to Dr. Helm's testimony, these records did not show "a great deal of monitoring." Complainant established by clear and convincing evidence that Dr. Smith was grossly negligent in his care and treatment of Patient A for failing to obtain more frequent urine drug screens.

Failure to Maintain Timely Medical Records

57. Dr. Geula opined that Dr. Smith was grossly negligent in his care and treatment of Patient A for failing to adequately maintain timely medical records. He noted that many of the records were "electronically signed" on December 11, 2017,

which was months, and sometimes years, after the dates of treatment. Dr. Geula assumed that Dr. Smith and the physician assistants signed the chart on the dates noted as being "electronically signed." Dr. Geula had "heard of" the electronic medical record system Dr. Smith used, eClinicalWorks, but had never used that program and had no "hands-on familiarity" with it.

Dr. Smith testified that he is not "an expert" on his electronic medical record system, but has learned that unless the records are "locked," the date they are "electronically signed" will be the date they are printed. He does not routinely lock records as it causes issues for his staff when they are processing bills and performing other administrative tasks, although there have been occasions when he does lock records, but overall, he does not because of the many issues this caused in his office.

Complainant obtained authorizations to obtain the three patients' medical records. The records were printed and the "Certification of Records" for each chart was signed by Dr. Smith's custodian of records on December 11, 2017. Dr. Smith explained that any unlocked records would have been "electronically signed" on December 11, 2017, when they were printed for the investigator. Dr. Smith's explanation was credible, consistent with the statements he gave at his board interview, and no evidence to the contrary was introduced. Although there were a few records that were "electronically signed" after the dates of service but on dates other than December 11, 2017, given Dr. Smith's testimony regarding sometimes locking the records, his explanation for these dates is also accepted. Complainant did not establish by clear and convincing evidence that Dr. Smith failed to adequately maintain timely medical records for Patient A.

REPEATED NEGLIGENT ACTS ALLEGATIONS

Failure to Obtain Consultations

58. Dr. Geula opined that Dr. Smith was negligent in his care and treatment of Patient A for failing to obtain adequate consultations for her complex pain issues. Dr. Smith should have been referring Patient A to other specialists. Dr. Geula opined that the consults referred to in the records were not ones Dr. Smith initiated, but treatment Patient A sought on her own.

Dr. Helm opined that the records documented the therapies being attempted, the outside consultations and treatment Patient A was receiving, as well as previous therapies and consultations that did not resolve her pain complaints. The pain management specialist is a consultant and pain patients are sent to a pain management specialist for treatment. The patient is being sent to the pain management specialist for consultation, so the pain management specialist does not need to consult with others as he or she is the consultant. It is a judgment call to refer the patient to other consultants, and here Dr. Smith made appropriate decisions regarding when and to whom he should refer the patient to another provider.

Dr. Helm's opinions, which were supported by the records, were more persuasive than Dr. Geula's to the contrary. Complainant failed to establish by clear and convincing evidence that Dr. Smith was negligent in his care and treatment of Patient A for failing to obtain adequate consultations.

Failure to Document Detailed Physical Examinations

59. Dr. Geula opined that Dr. Smith was negligent in his care and treatment of Patient A for failing to adequately document a detailed physical examination of all

areas of Patient A's pain complaints. Dr. Geula noted that several of the entries in the chart notes were merely cut and pasted from previous visits. He believed the physical exams documented were cursory and that it "would have been nice" to have an examination of the cranial nerves at the initial visit. The follow-up visits did not examine the strength or mobility of the patient's lower extremities even though she had low back pain complaints.

Dr. Helm opined that the physical examinations documented in the records were sufficient and met the standard of care. There is no need to perform a complete physical examination at follow-up appointments where the same pain complaints are being addressed.

Many of the entries were cut-and-paste, physical examinations were cursory and there was no documentation of examining areas of the body where there were pain complaints. Dr. Geula's opinions were persuasive and supported by the records. Complainant established by clear and convincing evidence that Dr. Smith was negligent in his care and treatment of Patient A for failing to adequately document a detailed physical examination of all areas of her pain complaints.

Failure to Document Treatment Objectives

60. Dr. Geula opined that Dr. Smith was negligent in his care and treatment of Patient A for failing to adequately document treatment objectives of continued opioid therapy. Dr. Geula opined that objectives should be documented in the medical records and there were none. There were notations that the current course of treatment would be continued due to the patient's family issues, but there was no discussion of what was hoped to be gained by the use of opioid therapy.

Dr. Helm opined that a review of the records showed that the objectives were clearly documented and the modalities for treating the pain were provided. There were discussions regarding therapies previously tried, notes regarding therapies being considered, and the personal stress issues for Patient A that led Dr. Smith to maintain her on her current regimen. Dr. Helm opined that the notes clearly document the whole process of caring for this patient and the decisions being made. There was no violation of the standard of care.

Dr. Helm's opinions were more persuasive and supported by the records. Complainant failed to establish by clear and convincing evidence that Dr. Smith was negligent in his care and treatment of Patient A for failing to adequately document treatment objectives of continued opioid therapy.

Dr. Smith's Care and Treatment of Patient B

61. Patient B, a 50-year-old male, was first seen by Dr. Smith for a "New Patient" consult on July 8, 2014. Patient B complained of low back and neck pain with intermittent parathesias in both hands and feet. His pain severity was 9 out of 10. He described his pain as "throbbing, dull, radiating, penetrating, numb, tearing, pinching, pulling, stinging, [and] debilitating." In his questionnaire, Patient B wrote that he had experienced "many injuries." He listed the many therapies he had undergone including a TENS unit, chiropractor, massage, bed rest, trigger point injections, steroid injections, physical therapy, and ice packs. He used marijuana "to help control pain" and identified a history of drug addiction from 1977 to 2007 that was "Not part of my life anymore." Patient B's past medical history included current high blood pressure, palpitations from 1982 to 1994 that he explained as "don't know, just stopped," chest pain, shortness of breath, asthma or wheezing from smoking one-half to three-quarter packs of cigarettes per day for "35+ years."

Dr. Smith documented: "drug addiction – 1977 to 2007 . . . Per Dr.'s progress note,[23] He last used methamphetamine about 18 months ago." An MRI of the lumbar spine performed on March 27, 2014, showed a severe L4 compression fracture. Dr. Smith performed an examination, documenting his findings and assessed the patient with a fractured vertebral column lumbar, degeneration of lumbar disc(s), low back pain, cervical spine pain, degenerative disc disease cervical spine, and long-term use "meds nec." Dr. Smith identified his treatment for each condition, noting that he recommended a repeat MRI with thoracic spine and STIR imaging[24] because Patient B's MRI had been performed one year ago and was incomplete because he could not tolerate the noise. Dr. Smith also recommended a cervical spine MRI due to the positive objective findings of midline tenderness associated with reduced range of motion. As noted:

> Patient understands we will see him for an office visit once we have obtain [*sic*] results of the studies. Patient understands I do not recommend chronic oral systemic opioid therapy for this condition nor do I recommend high dose oral systemic opioid therapy for this condition. Patient understands we will recommend treatment in order to help his pain that we may minimize, eliminate, or significantly reduce his daily oral analgesic requirements.

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[23] It was not clear what "Dr.'s progress note" Dr. Smith reviewed.

[24] STIR is the acronym for Short-TI Inversion Recovery and is typically used during an MRI to null the signal from fat.

Patient B reported taking Percocet six times per day but recently reduced to four per day trying to extend his medications until this appointment. Patient B requested to increase back to six per day. He reported taking Soma three times per day. Patient B's history suggested rheumatoid arthritis, osteoarthritis, peripheral neuropathy, and history of substance abuse in remission the past 18 months. He was taking Neurontin and Lyrica and "appears to be taking" Elavil.[25] Patient B was "referred here for continued opioid med management." Dr. Smith recommended restarting MS Contin, continuing Oxycodone, continuing Soma but "consider switching to Zanaflex in the near future." Patient B signed a medication management agreement like the one Patient A signed, and UDS screening was ordered. A "Bowel Regimen" document, like the one in Patient A's chart, was also in the chart. Patient B would follow up in one month and Dr. Smith would help him obtain authorization and schedule cervical and lumbar spine MRIs. There was no documentation of reviewing CURES.

62. Patient B's UDS collected July 8, 2014, and reported to Dr. Smith's office on July 16, 2014, was positive for marijuana metabolite, negative for opiates, including morphine, both of which were noted to be "inconsistent" results. However, the morphine would not be an inconsistent result because Dr. Smith prescribed MS Contin at the first visit; Patient B reported that he was not taking morphine at the time he first visited Dr. Smith. Patient B's oxycodone levels were listed as being extremely high.

63. At Patient B's next visit on August 5, 2014, with a physician assistant, he reported no change in his chronic pain except the rheumatoid arthritis pain in his hands had increased. He was receiving 45 percent relief with his current treatment. His

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[25] These medications are controlled substances. Neurontin and Lyrica are anti-convulsant drugs used to treat neuropathic pain; Elavil is an anti-depressant.

pain improved with medication and rest. Much of this note appears to be cut-and-paste from the initial visit. The physical examination does not document the examination of Patient B's lower back. The patient had "not had the MRI scans at this point, but plans to schedule." "They have tried to contact him to schedule," but it was unclear to whom "they" referred. Again, even though it was documented that Patient B understood Dr. Smith's office would see him once they obtained the results of his MRI studies, his medications were refilled. It is unclear why he was seen when Dr. Smith charted at the initial visit that he would see Patient B once his MRI studies were obtained. There was documentation the physician assistant reviewed the results of the UDS obtained at the first visit. Despite those inconsistent results, the physician assistant documented that Patient B "showed no diversionary or aberrant behaviors with medications." Given the inconsistent UDS results and the fact that no CURES report was documented as having been reviewed, it is unclear how the physician assistant could reach that conclusion. Patient B was continued on his current therapy, his medications were refilled and it was again noted, "Patient understands I do not recommend chronic oral systems opioid therapy for this condition nor do I recommend high dose oral systemic therapy for this condition. Patient understands we will recommend treatments in order to help his pain so that we may minimize, eliminate, or significantly reduce his daily oral analgesic requirements." Patient B understood not to use alcohol or recreational drugs with his medications. No UDS was ordered and there was no documentation that CURES was reviewed.

64. At Patient B's next visit on September 2, 2014, with the physician assistant, he reported 25 percent pain relief with current treatment. He had some increased pain recently since purchasing an RV. No physical examination was documented. He had cervical and lumbar MRIs performed, had brought the scans with him, and wanted to discuss the results. The "lumbar MRI results were reviewed and

discussed" with Patient B and showed no significant changes from his 2014 films. The cervical MRI scans showed a 5 mm disc protrusion at C5-6, which was larger compared with the prior exam, moderate spinal stenosis and bilateral moderate foraminal stenosis; mild spinal stenosis and bilateral mild foraminal narrowing at C6-7; right posterior pre-foraminal 2 mm disc protrusion at C7-T1, mild right foraminal narrowing and no spinal stenosis; there was no evidence of cord edema or myelomalacia. "Based on the patient's symptoms, MRI results outlined above, and failure of conservative therapies, I recommend moving forward with a C7-T1 translaminar ESI."[26] The risks and benefits were explained and the patient elected to proceed. Patient B was stable on his current medications, showed no diversionary nor aberrant behaviors, denied adverse side effects, so was continued on his current therapy. It was again documented that Dr. Smith did not recommend chronic oral systemic opioid therapy for this condition nor did he recommend high dose oral systemic opioid therapy, but the patient's medications were refilled. There was no documentation of a discussion regarding the UDS ordered at Patient B's initial visit, no UDS was ordered at this visit, and no CURES reviewed.

65. At Patient B's next visit on September 30, 2014, he was seen by a physician assistant. He reported no change in his chronic pain, was receiving 65 percent pain relief with his current treatment, and planned to try acupuncture. Much of the note is copied over from previous visits. The physical examination did not document examining the patient's low back. Patient B reported receiving insurance approval for his injection, presumably this referred to the translaminar injection that was recommended at the prior visit. Patient B's blood pressure was 138/102 so he was

[26] ESI is the acronym for epidural steroid injection.

advised to follow up with his primary care physician regarding his elevated blood pressure. The chart note again documented that Dr. Smith did not recommend chronic oral systemic opioid therapy or high dose oral systemic opioid therapy for Patient B, but his medications were refilled, nonetheless. There was no documentation of a UDS being ordered, a discussion of the UDS previously ordered, or a CURES report being reviewed. The medications Patient B was receiving from his primary care physician were identified and Dr. Smith's office would "consider switching Soma to Zanaflex in the near future," but this never occurred.

66. At his next visit on October 24, 2014, with a physician assistant, Patient B wrote in his questionnaire that his pain had increased and he listed the many treatments he needed, including injections, chiropractic care, acupuncture, an implanted pain machine, and "an electric wheel car." He reported receiving 30 percent relief with his current treatment and planned to try acupuncture, but had not scheduled an appointment. Patient B felt that his "restless leg syndrome had increased," and he was working with his primary care physician to obtain a motorized scooter to use for long distances. Patient B also reported shortness of breath. There was no physical examination documented. There was no review of CURES documented and no UDS ordered. The chart note again noted that Dr. Smith did not recommend this high-dose therapy, but, again, Patient B's medications were refilled. Patient B was "very emotional about his chronic pain" adversely affecting his life. It was suggested that he meet with a therapist and he was provided with contact information for a pain psychologist. Patient B agreed to coordinate an appointment with that provider. Patient B was referred to a surgeon for evaluation of his lumbar spine, the cervical epidural steroid injection was scheduled, a TENS unit was ordered, and he was to return in one month for medication management.

67. A November 4, 2014, telephone encounter documented that Patient B called asking for his prescriptions to be filled. The office spoke with the pharmacist who advised the patient should still have medication left and that the pharmacist would not refill the medication until the next day at the earliest. Patient B was advised of the pharmacist's answer and "was very upset." He wanted to know if Dr. Smith could write a prescription for one week for the MS Contin, "so that it is all on the same schedule as the Percocet." Patent B did not want to change his appointment that was set for November 21, 2014, and he would talk to the provider at that time.

68. On November 21, 2014, Patient B met with Dr Smith. He reported 70 percent pain relief with his current treatment, but otherwise had no changes. The physical examination documented was extremely brief. Patient B's medications were refilled with no changes. Dr. Smith did not document reviewing CURES, did not order a UDS, did not document discussing the previously ordered UDS, and did not document discussing the phone call seeking early refills.

69. On November 26, 2014, Dr. Smith performed a cervical epidural steroid injection on Patient B.

70. At Patient B's December 19, 2014, follow-up visit with a physician assistant, he advised that he had fractured his ribs on December 11, 2014, when he fell off his bike. He brought his hospital records documenting that injury to the visit. He reported that his neck pain decreased after the steroid injection, but his pain had now increased because of his bike accident. He was currently receiving 50 percent relief with the treatment and planned to try acupuncture, but he had not yet scheduled an appointment. The physical examination documented was cursory. Despite the same chart entry that Dr. Smith did not recommend high-dose opioid therapy, Patient B's medications were refilled but his MS Contin was increased from twice a day to three

times a day, but there was no documentation for why this increase was given, presumably it was to treat the fractured ribs. However, Dr. Geula opined that MS Contin is a long acting medication and if the increase was because of the rib injury, an acute process, it would make more sense to increase the patient's Percocet for any breakthrough pain caused by the rib injury. Thereafter, Patient B's MS Contin prescriptions remained at this increased level of three times per day.

The chart again documented "consider switching Soma to Zanaflex in the near future," but there was no documentation for why the switch had not yet occurred since this same note had been entered at prior visits. Patient B was instructed to follow up with his primary care physician because of his 140/80 elevated blood pressure. The same note was again entered regarding being given contact information for a pain psychologist because he was "very emotional about his chronic pain adversely affecting his life." The follow-up plan was a repeat steroid injection and medication management in one month, no UDS was ordered, no CURES review was documented, and there was no documentation regarding inquiry into whether Patient B received pain medication at the hospital following his bike fall.

71. On January 14, 2015, Dr. Smith performed a second cervical epidural steroid injection.

72. Patient B wrote in his January 20, 2015, patient questionnaire that his "100% improvement" from the injections was "starting to fade." Both experts agreed that patients obtain variable results from injections, so this report was not unusual. During his visit with the physician assistant, Patient B reported 15 to 40 percent relief with the injection but felt it was slowly wearing off. He was receiving 50 percent relief from his current treatment. He was having less pain in the morning due to the MS Contin increase. He planned to try acupuncture, but had not yet scheduled an

appointment. He had "not received a call to schedule an appointment from the surgeon," but it was not clear to what this note referred. His rib fractures were healing well and he was interested in a pain pump. The physical exam documented was similar to the brief ones previously charted. Although it was again noted that Dr. Smith did not recommend long-term high-dose opioid therapy, Patient B's medications were refilled. He was to follow up with his primary care physician "regarding his overall health and well-being, and recent rib fracture." The follow-up was to return in one month for medication management and check the TENS unit approval.

73. On February 17, 2015, Patient B was seen by Dr. Smith. He reported his pain was most severe in his neck and his orthopedic spine surgeon was planning surgery on his cervical spine. Dr. Smith recommended that the surgeon also evaluate the patient's severe chronic compression fracture of his lumbar spine. Patient B reported 30 percent relief with his current pain treatment. Dr. Smith wrote that the patient "shows no aberrant behavior," but it was unclear how he made that determination since there was no documentation of any UDS performed nor documentation of reviewing CURES. Patient B requested changing from Percocet to Oxycodone and was interested in an intrathecal drug delivery system therapy in the future should his pain continue to be refractory. Dr. Smith refilled the patient's prescriptions except he stopped the Percocet and started Patient B on Oxycodone. Other than the patient requesting this change, Dr. Smith documented no rationale for doing so. Additionally, Dr. Smith noted shortness of breath and chest pain, but no evaluation or follow-up for those conditions was documented.

74. Patient B's next visit on March 24, 2015, was again with Dr. Smith. The patient reported 30 percent pain relief with his current treatment, which Dr. Geula

noted is where this patient began. The patient's medications were refilled with no changes. No UDS was ordered and no CURES was reviewed

75. An April 10, 2015, telephone note documented that Patient B called wanting to change his medications. He did "not want to take Naproxen anymore because his heart beats more often and can hear it in his ears." He wanted to go back on Percocet. Patient B advised that he has tinnitus which was why he hears his heartbeat in his ears. The "Action Taken" portion of the telephone note indicated that Patient B was on Oxycodone so was not a candidate for Percocet unless he wanted to switch from Oxycodone to Percocet. "Naproxen is an anti-inflammatory and works very differently than the opioids. His Naproxen can be switched to a different anti-inflammatory if he is having difficulty tolerating this medication. Please clarify message with patient and patient will need office visit to discuss medication adjustments." A message was left for the patient and the office was "waiting to hear back."

76. A March 17, 2015, telephone note advised Patient B that because of changes to his insurance, Dr. Smith's office was no longer able to accept his current insurance because they were not contracted with that carrier. The patient was going to follow-up with his insurance carrier and borrow money to pay for his next office visit.

77. Patient B was next seen on April 21, 2015, by the physician assistant. He continued to receive 30 percent relief with current treatment. He had stopped taking his Naproxen and had some improvement in his tinnitus. He requested switching back to Percocet in place of the Oxycodone as it had not been as effective for his breakthrough pain. The physical examination documented was brief. The patient's medications were refilled, except he was switched back to the Percocet and his Oxycodone was stopped. A UDS was ordered. There was no documentation of reviewing CURES.

78. Patient B's April 21, 2015, UDS results, reported to Dr. Smith's office on April 26, 2015, were positive for marijuana metabolite, opiates, hydrocodone and hydromorphone, and morphine, all of which were noted to be inconsistent results. It is unclear why the morphine was listed as an inconsistent result because Dr. Smith was prescribing MS Contin and that medication was noted on the requisition sheet ordering the UDS.

79. At his next visit on May 19, 2015, Patient B was seen by a physician assistant. He was currently receiving 75 percent pain relief. In what appears to be another copy and paste from prior notes, the note indicates that Patient B reported stopping his Naproxen with some improvement in his tinnitus and requesting a switch back to Percocet in place of the Oxycodone, both of which had been reported and addressed at the previous visit. Patient B had slurred speech at the visit and the results of his April 21, 2015, UDS were documented as being "not available as yet." Patient B was sent for another UDS. The physical examination documented was brief. He reported using lidocaine patches in the past for his back pain that were prescribed by his primary care physician. He had found five patches in his closet and asked for a prescription. He was told to try the patches he has, and if they help, that prescription would be renewed on his next visit. Patient B had an appointment to meet with his psychiatrist on May 27, 2015, in order to proceed with cervical spine fusion at C5-6. He needed to stop smoking before surgery as advised by his spine surgeon, to aid in his surgical healing. Patient B was again given contact information for a pain psychologist to optimize his pain management and to assist with smoking cessation. There was no documentation of reviewing the results of the UDS ordered at the prior visit. Patient B's medications were refilled, again a note was made that Patient B "continues his change to Percocet from Oxycodone" and the Oxycodone was stopped. Inexplicably the physician assistant wrote that Patient B "shows no diversionary nor aberrant

behaviors with medications," despite his slurred speech, and his using lidocaine patches he found in his closet. A UDS was ordered but there was no documentation about why the prior UDS results, which were inconsistent, were not available. No CURES was documented as having been reviewed.

80. Patient B's UDS specimen, received by the lab on May 20, 2015, and reported to Dr. Smith's office on May 22, 2015, was positive for marijuana metabolite, an inconsistent result. The results were also positive for morphine, oxycodone, noroxycodone, and oxymorphone.

81. A May 29, 2015, telephone note documented that Patient B was sent for a UDS at the last visit due to slurred speech and the medical assistant "felt he smelled of alcohol." UDS results on July 8, 2014, April 21, 2015, and May 19, 2015, had all been positive for marijuana metabolites. The "Action Taken" was: "Information sent to Dr. Smith for a violation of his medication management agreement and if patient needs to be discharged from practice. No documentation of Patient B being notified could be found for the UDS dated 7/8/14 and the other two have just become available."[27] Dr. Smith instructed his office to call Patient B and inform him of the repeated violations of his medication management agreement and discharge him from the practice. The patient was so notified and informed that he would receive a formal letter of discharge with the names of other pain practices. If he needed one more prescription while he transitioned, Dr. Smith's office would accommodate him.

[27] There was no explanation charted for why those results had only "just become available."

82. On June 1, 2015, a formal letter discharging Patient B from Dr. Smith's practice was sent regular and certified mail to the patient.

83. On June 16, 2015, Patient B came to the office for a "final refill" of his medications.

84. Patient B's CURES reports obtained by complainant as part of the investigation, documented the controlled substances prescribed by Dr. Smith and the other physicians treating Patient B before Dr. Smith. When Patient B first saw Dr. Smith, he was on day 11 of his 14 day supply of Soma, a benzodiazepine muscle relaxer, but Dr. Smith gave him a 30 day prescription. There was no documentation in the chart that Dr. Smith was aware of this overlap. Neither Dr. Smith nor Dr. Helms offered an explanation for the Soma overlap. The other medications Patient B was receiving from other providers was consistent with what was documented in Dr. Smith's records.

Evaluation of Dr. Smith's Care and Treatment of Patient B

GROSS NEGLIGENCE ALLEGATIONS

Combination of Medications

85. Dr. Geula opined that Dr. Smith was grossly negligent in his care and treatment of Patient B when he prescribed a combination of high dose opioids and Soma to him. He opined that this combination of drugs is dangerous for risks of over-sedation and respiratory issues and was especially dangerous in a patient with a history of substance abuse. Dr. Geula did not believe there was any indication for Soma as there was no documentation of muscle spasms or documentation the patient

would benefit from Soma. He also noted the patient's request for early refills raised additional concerns about prescribing this combination.

Dr. Helm opined that Dr. Smith documented that the medications were working, so there would be no reason to wean them. Patient B was getting good pain relief. It was reasonable keep the patient on the opioids and Soma until there could be some determination made about whether he would have spinal surgery. His morphine equivalent dosage was above 90, but not significantly high that he would qualify for the FDA study Dr. Helm previously referenced. The documentation of his pain complaints was synonymous with describing spasm, so Soma was appropriate and was documented as being prescribed for his spasm.

Dr. Helm's opinions, which were supported by Dr. Smith's documentation, that there was spasm, is accepted, but his opinions that this combination of medications met the standard of care is not. Complainant established by clear and convincing evidence that Dr. Smith was grossly negligent in his care and treatment of Patient B when he prescribed a combination of high dose opioids and Soma to him.

Failure to Modify Controlled Substance Regimen

86. Dr. Geula opined that Dr. Smith was grossly negligent in his care and treatment of Patient B for failing to adequately modify his controlled substance regimen. Patient B had a history of substance abuse and "several red flags" which required additional attention be given to his treatment. Although his MS Contin dosage was increased after his rib fractures, it was never reduced nor was it closely monitored when he remained on such a high level. Dr. Geula was critical that Dr. Smith did not refer Patient B for consults with other providers, that Patient B's medications were not changed but instead routinely refilled, that an insufficient number of UDS's

were ordered, and there was no follow-up on those ordered or any documentation of a discussion regarding the inconsistent results obtained.

Dr. Helm opined that the types and amounts of medications prescribed were within the standard of care. The records documented the pain relief Patient B received from the medications prescribed and other modalities offered, such as an epidural injection. He found no violations from the standard of care.

It is not enough to simply document that a treatment is not recommended; the physician must actually follow through on those recommendations. Here Dr. Smith merely charted his philosophy but then did not follow it and he and his physician assistants continued to prescribe high dose opioids to Patient B, with no end in sight. Contrary to his philosophy, he prescribed those high dose opioids despite Patient B's use of medical marijuana. Dr. Geula's opinions were more persuasive than Dr. Helm's. Complainant established by clear and convincing evidence that Dr. Smith was grossly negligent in his care and treatment of Patient B for failing to adequately modify his controlled substance regimen.

Failure to Review CURES Reports

87. Dr. Geula opined that Dr. Smith was grossly negligent in his care and treatment of Patient B for failing to review his CURES reports. Patient B had an extensive history of substance abuse, sought early refills, and had inconsistent UDS, which should have been red flags. Reviewing CURES was required to properly monitor this patient.

Dr. Helm simply testified that he had "seen CURES" for Patient B that Dr. Smith "did and it corroborated" what was prescribed.

Patient B was on multiple medications, many of which were not prescribed by Dr. Smith. Given the patient's decades long history of drug abuse, it was imperative that Dr. Smith review CURES and document doing so. Dr. Geula's opinion that CURES should have been ordered at every visit, seemed excessive, but his opinions that CURES should have been ordered more frequently was more persuasive than Dr. Helm's to the contrary. Further, the only CURES reports offered at hearing were the ones complainant obtained as part of the investigation, Dr. Smith offered none at hearing. Complainant established by clear and convincing evidence that Dr. Smith was grossly negligent in his care and treatment of Patient B for failing to review his CURES reports.

Failure to Obtain More Frequent UDS

88. Dr. Geula opined that Dr. Smith was grossly negligent in his care and treatment of Patient B for failing to obtain more frequent urine drug screens. As with his opinions regarding obtaining CURES reports, Dr. Geula opined that given this patient's substance abuse history and requests for early refills, Dr. Smith should have ordered more frequent UDS testing, followed up at the visits to determine why testing ordered had not been done, and been aware of the inconsistent results of the tests he ordered.

Dr. Helm testified that lost or buried reports are something that can happen in medical practices, and "happens very often." There were also times where Dr. Smith, as noted above, was not getting lab results back that had been ordered. Dr. Helm did not see any violation from the standard of care.

Patient B was on multiple medications, many of which were not prescribed by Dr. Smith. Given the patient's decades long history of drug abuse, it was imperative

that Dr. Smith order more frequent UDS testing and follow-up on UDS tests ordered. The issues Dr. Smith had with the labs did not absolve him of his duty to follow up on labs ordered and chart having done so. Dr. Geula's opinions are accepted over those of Dr. Helm's to the contrary. Complainant established by clear and convincing evidence that Dr. Smith was grossly negligent in his care and treatment of Patient B for failing to obtain more frequent urine drug screens.

Failure to Maintain Timely Medical Records

89. Dr. Geula opined that Dr. Smith was grossly negligent in his care and treatment of Patient B for failing to adequately maintain timely medical records. As with Patient A, the basis for his opinion was that the records were "electronically signed" on December 11, 2017, the date they were printed for the investigator.

For the reasons noted above about locking and printing records, that opinion is rejected. Complainant did not establish by clear and convincing evidence that Dr. Smith failed to adequately maintain timely medical records for Patient B.

Repeated Negligent Acts Allegations

Failure to Obtain Consultations

90. Dr. Geula opined that Dr. Smith was negligent in his care and treatment of Patient B for failing to obtain adequate consultations for complex pain issues. Given the patient's complaints, Dr. Geula believed Dr. Smith should have ordered psychological consults, neurological consults, and physical therapy. Dr. Geula was not aware that Dr. Smith submitted approval for Patient B's TENS Unit and could not recall that Patient B brought his hospital records to the visit following his bike accident.

Dr. Helm noted the various therapies documented in the record and that the patient had been referred to Dr. Smith for pain management. He found no deviation from the standard of care.

Dr. Helm's opinions, which were supported by the records, were more persuasive than Dr. Geula's to the contrary. Complainant failed to establish by clear and convincing that Dr. Smith was negligent in his care and treatment of Patient B for failing to obtain adequate consultations.

Failure to Document Detailed Physical Examinations

91. Dr. Geula opined that Dr. Smith was negligent in his care and treatment of Patient B for failing to adequately document a detailed physical examination of all areas of Patient B's pain complaints. Dr. Geula noted that often at visits there were missing physical examinations or only portions of the physical exam documented.

Dr. Helm opined that the physical examinations documented in the records were sufficient and met the standard of care. There was no need to perform a complete physical examination at follow-up appointments where the same pain complaints were being addressed.

Many of the entries were cut-and-paste, physical examinations were cursory and there was no documentation of examining areas of the body where there were pain complaints. Dr. Geula's opinions were persuasive and supported by the records. Complainant established by clear and convincing evidence that Dr. Smith was negligent in his care and treatment of Patient B for failing to adequately document a detailed physical examination of all areas of his pain complaints.

Failure to Document Treatment Objectives

92. Dr. Geula opined that Dr. Smith was negligent in his care and treatment of Patient B for failing to adequately document treatment objectives of continued opioid therapy. Dr. Geula opined that the physician should document the objectives of therapy the physician is trying to achieve and those objectives were not sufficiently addressed in Dr. Smith's records.

Dr. Helm saw no departures from the standard of care.

Dr. Smith's records adequately documented his treatment objectives. Complainant failed to establish by clear and convincing evidence that Dr. Smith was negligent in his care and treatment of Patient B for failing to adequately document treatment objectives of continued opioid therapy.

Dr. Smith's Care and Treatment of Patient C

93. Patient C, a 50-year-old female, had her new patient consultation with Dr. Smith on August 26, 2014. She complained of low back pain, left lower extremity pain associated with numbness and weakness, and chronic left foot pain. Her pain began in 2006 following a work injury. Prior treatment included an epidural, biofeedback/ relaxation training, massage, bedrest, psychotherapy, steroid injections, physical therapy, and two surgeries for her plantar fasciitis. She was currently taking 30 mg of morphine sulfate immediate release every four hours, 15 mg of morphine sulfate immediate release (MSIR) every eight hours, and one to two 50 mg tablets of Amitriptyline[28] at bedtime. She smoked half a pack of cigarettes per day. Dr. Smith

[28] Amitriptyline is a tricyclic antidepressant with sedative effects.

took a pain management history where she described her low back and foot pain that radiated down her left lower extremity. She described the pain as "pulsing, throbbing, aching, penetrating, shooting, tight, numb, caring, pricking, cold, sharp, gnawing, pinching, cramping, pulling, hot, tingling, stinging, intense, unbearable." She described the severity as being 10 out of 10. She had weakness and tingling in her left lower extremity, which was aggravated by activity. Patient C also complained of constipation.

Dr. Smith performed a physical examination and assessed Patient C with degeneration of lumbar disc(s), lumbar radiculitis/radiculopathy, plantar fasciitis, and long-term use meds nec. Dr. Smith started MS Contin, extended-release, 15 mg every 12 hours, started MSIR capsule 30 mg every 4 to 6 hours as needed for pain with a maximum of six per day.

Patient C reported that she underwent a worker's compensation Agreed Medical Evaluation (AME),[29] where that physician had her undergo a lumbar MRI and recommended against surgical intervention. Another physician prescribed medications and attempted various interventional therapies. Prior lumbar epidural injections had not been effective. She was "currently receiving high-dose oral systemic opioid therapy, receiving a total daily dose of 225 mg of morphine." She had tried various neuropathic pain medications without success. Dr. Smith reviewed her current medications with Patient C, who reported having been on sustained-release and immediate release medications, "but this has been inadvertently changed since [her

[29] An Agreed Medical Evaluation is a type of medical evaluation performed in worker's compensation cases.

treating physician] has been unable to take care of her." Dr. Smith recommended obtaining a copy of her AME and her 2012 lumbar spine MRI scans. Dr. Smith charted:

> Patient understands I do not recommend chronic oral systemic opioid therapy nor high-dose oral systemic opioid therapy. Patient's constipation is most likely due to her oral systemic opioids. Therefore, patient may be a good candidate for an implantable therapy. The implantable therapies would be a more appropriate long-term therapeutic modality when compared to chronic oral systemic opioid therapy. For now, I will continue her opioid therapy, but change her to a sustained release MS Contin and immediate release MSIR. I recommend slowly titrating and increasing her sustained release medications while reducing her immediate release medication.

Dr. Smith documented that Patient C was interested in implantable therapies and he gave her literature about them to review. Patient C reported she was familiar with intrathecal drug delivery therapy. Dr. Smith recommended she "continue her disability status as per her primary treating physician." Patient C signed a medication management agreement like the ones Patients A and B signed, and UDS screening was ordered. A "Bowel Regimen" document, like the ones in Patient A's and Patient B's chart, was also in Patient C's chart.

Dr. Smith prescribed 15 mg of MS Contin twice a day for 30 days, and 30 mg of MSIR every 4 to 6 hours as needed for pain, with a maximum of six per day for 30 days. Patient C's follow-up was: "office visit one month medication management with urine tox screen. Please obtain agreed medical evaluation from patient or work comp

carrier. This will identify future medical care. Her lumbar spine MRI scan results we'll [*sic*] most likely also be there." There was no documentation that Dr. Smith reviewed CURES or ordered a UDS at this visit.

94. Patient C was next seen on September 23, 2014, by a physician assistant. She reported "a significant increase in her chronic low back and both legs for no apparent reason, which makes it difficult for her to walk." She was currently receiving no pain relief without her medication. The physician assistant documented that Patient C was currently taking MS Contin 15 mg twice a day, MSIR 30 mg every 4 to 6 hours for pain maximum six per day, MSIR 30 mg capsules orally every four hours, MSIR 50 mg tablet orally every eight hours, and Amitriptyline. Although it was documented that the medication list was reviewed and reconciled with the patient, no explanation for the two morphine sulfate prescriptions Patient C was taking that Dr. Smith had not prescribed was documented. Much of the chart note appears to be cut-and-paste from the initial chart entries.

Patient C brought her AME and MRI scan report for review. Her MRI showed mild bilateral mid-line level facet degenerative joint disease with a slight L4-5 anterolisthesis and degenerative disc disease. The physician assistant explained to Patient C that she would review the information with Dr. Smith to see if any further interventional procedures were recommended. Given the patient's recent flareups of low back, buttocks and leg pain making it difficult for her to walk, a new lumbar spine scan may be needed. In the meantime, Patient C agreed to continue conservative treatment and follow-up with her primary care provider regarding her elevated blood pressure (155/92) at today's visit. The physician assistant refilled Patient C's MS Contin and MSIR and reviewed with her "Dr. Smith's medication management philosophy to use medications as a bridge to more appropriate therapies," noting that Dr. Smith

does not recommend continued high-dose oral systemic opioid therapy for Patient C's condition. Patient C declined neuropathic pain medication because of its previous ineffectiveness and since she was "adequately functioning and tolerating her current medications without difficulty," no change was made to her prescriptions. "A slow titration of increasing her sustained-release medication while reducing her immediate release medication will begin as her pain allows." A random UDS was performed and the dipstick results were positive for opiates, TCA,[30] which was inconsistent with the medication list she verified at the visit.[31]

95. Patient C was next seen on October 21, 2014, by a physician assistant. She reported a significant increase in her chronic left buttock pain, leg cramping, and burning pain which made it difficult for her to walk and care for her grandson. She was currently receiving no relief without her medications. A very minimal physical examination was documented and it was again noted that a new lumbar spine MRI may be needed. The physician assistant also documented: "We again requested the medical exam report from [worker's compensation physician] regarding her future medical care to review with Dr. Smith. In the meantime, the patient agrees to continue conservative treatment with her primary treater." Patient C's medications were refilled, and the results of her UDS were reviewed which were consistent with her medication

[30] TCA is the acronym for tricyclic antidepressants and TCA testing is done to confirm the presence of antidepressants.

[31] Dr. Geula testified the UDS results could be consistent with the medications the patient was taking.

list. Patient C again declined neuropathic pain medication and no change to her medications was made. There was no documentation of reviewing CURES.

96. An October 30, 2014, telephone note documented that the worker's compensation pharmacist wished to speak with Dr. Smith, but the time the pharmacist was available conflicted with another patient's scheduled appointment time. An October 31, 2014, telephone note documented the conversation with the pharmacist where her questions regarding Patient C's medication management were answered.

97. On November 26, 2014, Dr. Smith saw Patient C who reported increased pain in her left buttock. She was receiving 75 percent relief with her medications. The severity of her pain was "10/10 average." Much of the notes for this visit appear to be copied from prior visits. The treatment plan included an MRI of the lumbar spine and refilling her two morphine prescriptions. No UDS was ordered and no CURES report was documented as being reviewed. A December 9, 2014, addendum documented that the December 7, 2011, AME report was reviewed and showed a need for spine evaluation as part of the patient's future medical care, so Dr. Smith recommended obtaining a new lumbar spine MRI.

98. Patient C was a no-show for her December 22, 2014, appointment.

99. At Patient C's December 29, 2014, visit, the physician assistant documented that she reported increased pain in her left buttock and leg pain. She was receiving 75 percent pain relief. Her appetite has been adversely affected because of the severity of her pain. The need for new MRI scan was noted and in the meantime Patient C would continue with her current medication regimen. No change was made but it was again documented that a "slow titration of increasing her sustained-release medication while reducing her immediate release medication would begin as her pain

allows." Patient C agreed to follow up with her primary care physician regarding her elevated blood pressure (155/93) at today's visit. There was no documentation of a UDS being ordered, a CURES report being reviewed, or explanation of the missed appointment.

100. Patient C's next appointment was January 26, 2015, with a physician assistant. She reported increased pain in her left buttock and posterior thigh since the last office visit. She was receiving 75 percent relief with her current treatment. Her sleep and mood were adversely affected due to the severity of her pain. Many of the entries appear to be copied from prior entries. The results of Patient C's January 20, 2015, lumbar spine MRI scan were reviewed with her. The MRI scan report showed a grade 1 L4-5 anterolisthesis and degenerative disc disease resulting in moderate to severe central stenosis as well as moderate bilateral foraminal narrowing along with L5-S1 degenerative disc disease and facet degenerative joint disease with mild central stenosis. The physician assistant would review the results with Dr. Smith to determine an interventional pain management plan for the patient's chronic low back, buttock and left posterior thigh pain which made it difficult for her to walk. In the meantime, Patient C agreed to continue her conservative treatment with her primary treater. Her medications were refilled with no changes and again it was documented that a "slow titration of increasing her sustained-release medication while reducing her immediate release medication will begin as her pain allows." Patient C would follow up with her primary care physician regarding her elevated blood pressure (148/98) obtained on this visit. No UDS was ordered and there was no documentation of CURES being reviewed.

101. At her next visit on February 25, 2015, the physician assistant documented that Patient C felt no change in her chronic left buttock and posterior

thigh pain since her last visit and continued to receive 75 percent pain relief with her current treatment. Again, much of the information in the note appeared to be copied over from prior visits. The Assessment section stated: "After extensive review of the patient's records and recent lumbar spine MRI scan report by Dr. Smith, he recommends obtaining psychological clearance in preparation for a spine cord stimulator trial to determine her candidacy for an implant to provide long-term neuropathic pain relief of her chronic low back, buttock, and left posterior thigh pain that makes it difficult for her to walk." Patient C was given educational materials regarding this therapy and would discuss it further with Dr. Smith at her next visit. In the meantime, she agreed to continue conservative treatment with her primary treater. Her medications were refilled with no changes and again the chart referenced slowly titrating Patient C's sustained release and immediate release medications when her pain allowed. A neuropathic agent can be added if needed, but there was no documentation that this treatment had been offered and refused in the past. The patient agreed to follow up with her primary care physician regarding her elevated blood pressure (145/104) obtained at the visit. No UDs was ordered and no review of CURES was charted.

102. Patient C's April 3, 2015, visit was with Dr. Smith. She reported no change in her pain and continued to receive 75 percent pain relief. Patient C was interested in pursuing percutaneous spinal cord stimulation therapy to treat her low back and left lower extremity symptoms that will enable her to significantly reduce or eliminate her oral analgesic pain medications. Again, much of the entries appear to be copied over from prior visits. Dr. Smith noted that due to Patient C's failed conservative treatments, he believed she was a good candidate for percutaneous spinal cord stimulation therapy. He recommended obtaining psychological clearance for that therapy. In the meantime, she wished to continue with her conservative treatment and he refilled her

medications with no changes. Patient C was advised to follow up with her primary care physician regarding her elevated blood pressure (152/86) obtained at today's visit. No UDS was ordered and Dr. Smith did not document reviewing a CURES report.

103. An April 8, 2015, telephone note documented that the pharmacy could only fill 90 of the 180 morphine sulfate immediate release tablets prescribed because they were out of stock. The pharmacy would have more in stock next week and could fill the remaining 90 pills then, but would need a new prescription. In a follow-up call, the patient advised was able to get her complete prescription and did not need any medication at this time.

104. Patient C was next seen on April 30, 2015 by a physician assistant. She reported no change in her chronic left buttock and posterior thigh pain. She again reported 75 percent pain relief with her current treatment. She reported increased pain in her groin, but otherwise no changes in her condition. Again, much of the note appeared to be copied from previous entries, for example she was again to follow up with her primary care physician for her elevated blood pressure today, but there was no entry in the chart of her blood pressure reading, and again there would be a slow titration her medications, but, as with all other similar entries, there was no such titration and her medications were refilled with no changes. No UDS was ordered and no review of CURES was charted.

105. At Patient C's May 29, 2015, visit with a physician assistant, she reported a new pain in her buttock bilaterally that felt like a muscle ache, but there was no tingling or burning down her legs with this intermittent pain and she was taking Advil for it. Patient C was told to see her primary care physician to discuss this new pain. Patient C requested a back brace due to the location of her pain and MRI results. She continued to wait for approval from her insurance company for a psychological

evaluation in order to proceed with implant therapy. Patient C was receiving 50 percent relief with her current treatment plan and the physician assistant believed a back brace would help her chronic pain. Again, much of the note appears copied over from prior notes. The patient's medications were refilled with no changes and the office would "see if patient is covered for a back brace." No UDS was ordered and no CURES report review was documented.

106. Patient C was next seen on June 26, 2015, by a physician assistant. She reported experiencing nausea and headaches on one occasion and was not sure if it was related to her medications. She reported getting good pain relief from her current medication combination and did not want to change it. She was advised that if it happened again to stop taking her medication and they would "trial other medications." Patient C was receiving 75 percent pain relief with her current treatment and was still waiting insurance approval for a psychological evaluation. Patient C was again requesting a back brace and the physician assistant recommended she be fitted with a supportive back brace to be intermittently worn during periods of increased physical activity. Again, much of the note appears copied from prior entries. The patient's medications were refilled with no changes. No UDS was ordered and no review of a CURES report was documented.

107. At Patient C's August 12, 2015, visit with the physician assistant, she reported no recurrence of her headache and improvement in her back pain since receiving her back brace. She was receiving 75 percent pain relief with her current treatment. Much of the entries in the note were copied over from prior entries, including documentation once again of the titration plan, but her medications were refilled with no changes. No UDS was ordered and no review of a CURES report was documented.

108. At her September 9, 2015, visit with a physician assistant, Patient C reported continued improvement in her back pain and increases in her activity because of her back brace. She was receiving 50 percent pain relief with her current treatment. She recently underwent a tooth extraction and reported just finishing a course of amoxicillin and Ibuprofen. "Due to some issues with her psyche clearance. . . . A new psychiatrist is being contacted." Patient C was also advised about DNA testing[32] for her chronic pain and was given information about that testing. Much of the note appears copied from prior entries. Patient's medications were refilled with no changes, a UDS was ordered as was follow up in one month with DNA testing, but there was no documentation of reviewing CURES.

109. Patient C's next visit on October 15, 2015, was with Dr. Smith. Much of his chart entries are from prior visits, with many being repeats from the August 9, 2015, chart notes making the October 15, 2015, entries somewhat confusing because what Dr. Smith listed under History of Present Illness, were the findings that had been listed under the August 12, 2015, History of Present Illness section. Patient C reported that the Ibuprofen she had taken her for her tooth extraction also helped alleviate her back pain. Dr. Smith did not document following up on the UDS that had been ordered at the prior visit and no CURES review was charted.

Dr. Smith recommended Patient C continue trying to obtain a psychological evaluation in order to be cleared for implant therapy. In the meantime, Patient C would continue with her current medications. Dr. Smith refilled her medications with no changes and started her on Ibuprofen 800 mg to be taken twice a day. He wrote: "I

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[32] Dr. Smith explained that at this time, DNA testing was being used for pain management patients, but has since fallen out of favor.

recommend temporarily continuing MS Contin 15 mg [twice a day], MSIR 30 mg maximum six per day, and trialing Ibuprofen 800 mg [twice a day] for nociceptive[33] pain." He again noted that he did not recommend chronic oral systemic opioid therapy for her condition and that a more appropriate therapeutic modality would include percutaneous spinal cord stimulation therapy. Dr. Smith also noted that Patient C was receiving high-dose oral systemic opioid therapy and he did not recommend chronic high-dose oral systemic opioid therapy for her condition. No UDS was ordered and no CURES review was charted.

110. Patient C was next seen by Dr. Smith on November 12, 2015. The current medication list now contained Lisinopril, a high blood pressure medication but there was no documentation of when Patient C began taking that medication. She complained "of her usual and familiar low back and left lower extremity pain." Patient C denied any analgesic effect from her opioid therapy and reported no change in her activities of daily living. Dr. Smith noted that she showed no diversionary nor aberrant behavior, but he did not document ordering or reviewing a UDS, or following up on the one previously ordered, nor did he document reviewing a CURES report, so it was unclear how he reached that conclusion. Again, much of the note appears to be copied from prior entries. He was still awaiting a psychological evaluation in order to proceed with percutaneous spinal cord stimulation therapy. Dr. Smith refilled Patient C's medications, including the Ibuprofen, with no changes and did not recommend any opioid increases. He again recommended DNA testing to help guide medication management. He also charted that he recommended temporarily continuing the 15

[33] Nociceptive pain is a type of pain caused by injury, physical pressure, or inflammation.

mg of MS Contin and continuing the MSIR and Ibuprofen, but did not chart what "temporarily" meant. He ordered a UDS but did not document reviewing CURES.

111. Patient C was seen by a physician assistant on December 16, 2015. She reported no change in her condition and had "not been able to schedule her psychological clearance, which has been frustrating." She continued to receive 50 to 75 percent pain relief with her current treatment. Much of the chart entries appear copied from prior entries. There was no documentation of following up on the UDS ordered at the prior visit. Patient C's medications were refilled with no changes as she "showed no aberrant or diversionary behavior." Again, given the failure to follow up on the UDS previously ordered and not documenting a CURES review, it was unclear how this conclusion was reached. A random UDS was performed at the visit and the dipstick results were positive for opiates and oxycodone "which was inconsistent with the medication list" that was verified with Patient C.[34] The specimen would be sent out for further testing. There was no documentation of discussing the inconsistent UDS results, no repeat UDS was ordered, and no CURES was reviewed.

112. At the January 18, 2016, visit with a physician assistant, Patient C reported no change in her pain and 50 to 75 percent pain relief with her current treatment. She had been "started on a water pill to help improve her blood pressure." Her medications were refilled with no changes. She showed no "aberrant or diversionary behaviors," but as there was no documentation of the inconsistent UDS

[34] Dr. Geula testified that the UDS results could be consistent with the medications the patient was taking.

results being discussed, no UDS ordered, and no documentation of reviewing CURES, the basis of that conclusion was unclear.

113. Dr. Smith saw Patient C on February 12, 2016. She reported no change and 75 percent relief with her current treatment. The results of her DNA testing showed that she was "a low risk for opioid abuse, but unfortunately her pain perception could not be defined." Her ability and inability to metabolize various medications was noted. Dr. Smith refilled her medications with no changes. He did not document discussing her inconsistent UDS results, following up on the UDS ordered on December 16, 2015, and did not document reviewing CURES.

114. A physician assistant next saw Patient C on March 10, 2016. She continued to report her condition as previously documented. She was taking a weight loss supplement to help lose weight and had received a letter from Social Security that she will no longer be receiving disability. She would be following up with her primary care physician to appeal her disability status. Her medications were refilled with no changes but it was noted her Ibuprofen may be reduced in the future, but it never was. She was noted to have no aberrant or diversionary behavior, but, again, the basis for that finding was unclear. The physician assistant ordered a UDS but there was no documentation of reviewing a CURES report.

115. Patient C was seen by a physician assistant on April 7, 2016. She continued to receive 50 percent pain relief with her current treatment. The chart noted: "Her normal UDS results were discussed today," presumably referring to the UDS ordered at the last visit. Again, much of the chart notes appeared copied from prior entries. Patient C's medications are refilled with no changes. No UDS was ordered and no CURES was reviewed.

116. An April 12, 2016, telephone note documented the patient's call to the office because the pharmacy would not accept the prescription because the physician assistant who wrote it was not licensed. The patient was instructed to come to the office to get a new prescription.[35]

117. Patient C was next seen on May 6, 2016, by a physician assistant. She reported no change in her pain and continued to receive 50 percent pain relief with her current treatment. Much of the note appears copied from other chart notes. Her medications were refilled with no changes. There was no documentation of a UDS being ordered or a CURES report being reviewed.

118. Patient C was a no-show for her June 3, 2016, appointment.

119. Patient C was seen by a physician assistant on June 7, 2016. She reported an increase in her chronic low back and left lower extremity pain "for no apparent reason" and admitted to having increased stress from appealing her disability benefits after they were discontinued because "they decided she can return to work despite no improvements in her chronic pain." She was receiving 25 percent pain relief with her current treatment. Dr. Smith's office was still attempting to have Patient C undergo a psychological evaluation but were having difficulty finding an approved provider in her medical plan. Patient C's medications were refilled with no changes and a UDS dipstick was positive for opiates which was consistent with her medication list. The urine specimen was sent out for a complete UDS. There was no documentation of reviewing CURES.

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[35] No explanation regarding this note was offered at hearing and complainant did not allege that Dr. Smith employed unlicensed physician assistants.

120. Patient C treated with the physician assistant on July 5, 2016. She reported chronic left buttock and leg pain "for no apparent reason" and increased stress because of her disability appeal. She was receiving 50 percent pain relief with her current treatment. She was advised to follow up with her primary treating physician regarding her disability status appeal.[36] Again much of Patient C's chart note appears to be copied from prior visits. Dr. Smith's office was still awaiting approval for a psychological evaluation and Patient C was advised to follow-up. Her medications were refilled with no changes. No UDS was ordered and no CURES report was reviewed.

121. A July 8, 2016, telephone note documented that the worker's compensation adjuster advised that Dr. Smith is the primary treating physician and the "only name on the account and has been for a long period of time." Dr. Smith's office was able to find a psychologist on the patient's plan so the adjuster was going to get the authorization for the psychological evaluation extended and Patient C was referred to the psychologist. The "Action Taken" portion of the note stated: "Please follow up on this and let me know if there is anything I need to do differently as a primary treater." The next section of the note provided information about how Dr. Smith was to chart his records and what information he was to provide because he was the primary treating physician. Despite that notation, Dr. Smith's notes for Patient C did not change because the records for the following visits were in the same format as all prior records.

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[36] Dr. Geula was critical of this entry because he opined that Dr. Smith was Patient C's primary treating physician.

122. On August 3, 2016, Patient C seen by a physician assistant. She reported an increase in her chronic left buttock and leg pain "for no apparent reason" and was receiving 25 percent pain relief with her current treatment. Much of the entries appear to be copied from prior entries. Her medications were refilled with no changes. No UDS was ordered and no documentation of reviewing CURES was charted.

123. An August 26, 2016, telephone note documented authorization for a psychological evaluation and the documentation the psychologist requested to perform that evaluation.

124. Patient C was a no-show for her August 31, 2016, visit.

125. Patient C was next seen on September 14, 2016, by a physician assistant. She reported a continued increase in her chronic left buttock and leg pain "for no apparent reason." She was receiving 50 percent relief with her current treatment. Much of the entries appear copied from prior chart entries. Patient C was given the contact information for the approved psychologist and agreed to schedule an appointment. The patient's "condition has not changed while under our care, so her disability status will be continued. Patient will need to be seen by Dr. Smith to determine a change in her disability status, as primary treater, if needed." Patient C's medications were refilled with no changes. A UDS was ordered and the dipstick results were positive for opiates which was consistent with her medications. The specimen was sent to the lab for further evaluation.

126. An October 10, 2016, telephone note documented Patient C called advising that she was unable to "get through to [psychologist's] office" and was requesting an authorization be faxed, which was done.

127. Patient C was next seen on October 13, 2016, by a physician assistant. She reported an increase in her chronic left buttock and leg pain "for no apparent reason" and was receiving 25 percent pain relief with her current treatment. She had been unable to set up her psychological appointment because the phone number Dr. Smith's office gave her was a fax number. Dr. Smith's worker's compensation specialist was asked to help facilitate this evaluation. Given her condition, obtaining a new lumbar spine MRI was recommended to evaluate her worsening symptoms which may require surgical intervention. Patient C's UDS results were reviewed which were consistent with her medication list. Her medications were refilled with no changes.

128. An October 25, 2016, telephone note documented that Patient C was "short #40 tabs of her morphine" and wanted to know if she could "come pick up a script for the remaining quantity?" Dr. Smith's office was to call the pharmacy "to confirm they shorted her." No action was taken because the patient never called back regarding this message.

129. On November 10, 2016, Patient C was seen by a physician assistant. She reported a continued increase in her chronic left buttock and leg pain "for no apparent reason" and reported 25 to 50 percent pain relief with her current treatment plan. Patient C advised that she does not want to proceed with the spinal cord stimulator trial for her chronic neuropathic pain and instead wants to continue oral medication and await authorization for a lumbar MRI in order to have injection therapy. Although authorization for psychological evaluation was obtained, Patient C advised that she no longer wanted to have the spinal cord stimulator trial. "She states her reasons are the long psych eval, and after talking with her mother about the procedure, she does not want to have the implant. I reiterated that Spinal [*sic*] cord stimulation therapy may allow us to significantly reduce and/or eliminate daily oral analgesic requirements."

Patient C's medications were refilled with no changes. Again, the entries appear cut-and-pasted from other entries. There was no UDS ordered and no CURES reviewed.

130. A November 21, 2016, telephone note documented that the MRI request was denied because Patient C "doesn't meet guidelines and is deemed as not medically necessary."

131. Patient C was next seen on December 8, 2016, by a physician assistant. She continued to report an increase in her chronic left buttock and leg pain "for no apparent reason" and was now using a cane to walk. She reported her pain level as "8/10." Her pain was not well relieved with current oral medications and she wanted to try interventional injection therapy which required a new lumbar spine MRI which had been denied on November 21, 2016. She was currently receiving 25 percent pain relief with her treatment, "primarily due to the colder weather this past month." She reiterated her decision not to proceed with a spinal cord stimulator trial, wanted to continue taking oral medications, and wished to appeal the denial of the request for a lumbar MRI. Many of the entries were copied from prior entries. A lumbar MRI was still recommended and the plan was to appeal its denial. Patient C's medications were refilled with no changes. No UDS was ordered and no CURES report was documented as having been reviewed.

132. A January 3, 2017, telephone note documented that Patient C had missed the deadline to file an appeal of the denial of the request for a lumbar spine MRI. A review of the denial had been upheld. Dr. Smith's office was advised they could try and resubmit a new request if there had been changes in Patient C's condition, and they would review the chart notes to see if they could meet that criteria.

133. Patient C had a missed appointment on January 5, 2017.

134. Patient C's next visit was on January 18, 2017, with a physician assistant. Much of the chart entry appears copied from prior entries. Her pain was not well relieved with her current oral medications and she wanted to try interventional injection therapy which required a new lumbar MRI that had been denied. She continued to receive 25 percent pain relief with her current therapy. It was again noted that she did not want to proceed with spinal cord stimulator therapy. Patient C wanted to continue with her current medication management regimen and the physician assistant "explained to the patient that the current research does not support long-term use of oral opioid therapy for chronic pain and her MSIR was reduced from #180 to#160, which almost likely continued [*sic*] to be decreased by her insurance. She verbalized her frustration of understanding." Patient C's medications were refilled with no changes other than the decrease to 160 MSIR because of her insurance, not because Dr. Smith had decided to reduce them.

135. At Patient C's next visit on February 7, 2017, with the physician assistant, she reported an increase in her chronic left buttock and leg burning/pins and needles pain that was starting to involve the right lateral calf region. She was using a cane to walk and her pain was not well relieved with her current oral medication treatment plan. She continued to receive 50 percent pain relief with her current treatment plan "primarily due to the cold rainy weather this past month." She again stated she did not want to undergo spinal cord stimulator therapy and wished to continue with her oral medications per her AME report which documented the need for chronic oral medications. On physical examination there were new findings of limited trunk range of motion in all directions with increased stiffness and discomfort near the end of range of motion and altered sensation along the L4-5 and L5-S1 dermatome of her left lower extremity. Much of the entries are copied from prior entries. Her medications were refilled and her MSIR was increased back to 180 because she had difficulty

managing her pain with the decrease "so her quantity was adjusted back to #180." Patient C was encouraged to decrease her medications in the future and consider detox off[37] her oral opioid regimen to other non-opioid options, but she "was hesitant to consider this because she will still have pain and her AME evaluation recommended continued medication management for chronic pain." No UDS was ordered and no review of CURES was documented. The plan was that the patient would meet next month with Dr. Smith to discuss treatment options.

136. Despite the prior entry that at her next visit she was to follow-up with Dr. Smith to discuss treatment options, on March 7, 2017, Patient C met, instead, with a physician assistant. She continued to report increased left buttock and leg burning pain, which was not well relieved with her current oral medications and she wished to try interventional injection therapy, but that was not a treatment option because the request for a lumbar MRI had been denied. She was only receiving 50 percent pain relief with her current treatment plan. Patient C reported a new pain on the left side of her neck that radiated to her left shoulder and had an appointment with her primary care provider for an evaluation. She still did not want to proceed with spinal cord stimulator therapy. Her medications were refilled with no changes, and the results of her UDS were reviewed which are consistent with her medication list. The physician

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[37] Dr. Geula opined that this entry regarding detox was significant because Patient C's chart repeatedly documented that there was "no aberrant or diversionary behavior" and yet detox was being recommended. Patient C's refusal to consider detox or decreasing her opioids was concerning to Dr. Geula because there might now be an addiction issue on top of her pain issue, but that was not documented as being addressed in these visits.

assistant charted that Patient C reported difficulty managing her pain with the decrease in her MSIR 180 to 160 so her quantity was continued at 180. Patient C was again encouraged to decrease her medications in the future and "consider detox off her oral opioid regimen so other non-opioid options can be tried," but she "was hesitant to consider this because she will still have pain and her AME evaluation recommended continued medication management for chronic pain." She was to follow-up with Dr. Smith in one month to discuss treatment options. No UDS was ordered and there was no documentation of reviewing CURES.

137. On April 4, 2017, Patient C was seen by Dr. Smith. He documented that she "reports today complaining of her usual in [*sic*] familiar left shoulder pain, low back pain, left lower extremity pain, and left leg pain." However, the left shoulder pain had only been reported by Patient C at the prior visit so it was neither "usual" nor "familiar." She was experiencing 50 percent analgesic effect from her medications. Much of the chart notes appear copied from prior entries. All of the patient's medications were refilled with no changes despite Dr. Smith documenting, "Patient understands I do not recommend chronic oral systemic opioid therapy for condition nor do I recommend chronic high-dose oral systemic opioid therapy for her condition. She understands 90 morphine milligram equivalence is considered high-dose oral daily opioid therapy. She understands opioid weaning will be necessary in her future to a maximum dose of 50 morphine milligram equivalence per day." Her medications "may be decreased in the future," and she was again encouraged to "consider detox off her oral opioid regimen, so other non-opioid options could be tried." Again, she was hesitant to consider this because she would still have pain and her AME evaluation recommended continued medication management or her chronic pain. Her disability status remained unchanged. Dr. Smith did not order a UDS or document reviewing CURES.

138. On May 2, 2017, Patient C was seen by the physician assistant. She was "complaining of usual in [*sic*] familiar left shoulder pain, left low back and lower extremity pain, and left foot pain." Her pain was "8-9/10" and she received 50 percent pain relief from her medications. Her primary care provider had ordered left shoulder x-rays and the results were pending. Much of the chart entries appear to be copied from prior entries. Her medications were refilled with no changes. The necessity of morphine weaning was discussed. She was again encouraged to detox and try non-opioid therapy which she was hesitant to consider because she would still have her pain and her AME evaluation recommended continued medication management for her chronic pain. No UDS was ordered and no CURES were reviewed.

139. Patient C was next seen by a physician assistant on June 7, 2017. She still complained of left shoulder, left low back, lower extremity, and left foot pain. She was receiving 50 percent relief from her medications. She reported recently starting chiropractic care for her left shoulder. Much of the chart entries are copied from prior entries. Her medications were refilled with no changes although it was documented that "Dr. Smith doesn't recommend chronic oral systemic opioid therapy for her condition nor her current high-dose systemic oral opioid therapy for her condition." Patient C understood that opioid weaning would be necessary "in her future," and detox and non-opioid therapy were recommended. A UDS dipstick performed was positive for opiates, and oxycodone which was inconsistent with the medication list that was verified today. The UDS would be sent out for further evaluation. The patient would follow-up in one month for medication management and to review the UDS results. There was no documentation of reviewing CURES or of a conversation with Patient C regarding her inconsistent dipstick results.

140. A July 6, 2017, telephone note documented a call from Patient C advising that when she dropped off her prescription at the pharmacy last month, they had only filled half of it. She was still missing her 30 mg of morphine. She has "been leaving messages but no one has called her back." Dr. Smith's office contacted the pharmacy which advised that Patient C had picked up the medication yesterday. Dr. Smith's office called the patient to verify and the patient called back stating that she had called the office last week and left a message telling the front desk that she got her medication. Of note: if that were true, it was unclear why Patient C had called the morning of July 6, 2017, to report an unfilled prescription and no explanation for this was offered at hearing.

141. On July 17, 2017, Patient C was seen by the physician assistant. She complained of left shoulder, left low back, lower extremity and left foot pain. She advised that her left shoulder worker's compensation case was closed. She reported new pain and limited range of motion in her right shoulder. She was receiving 50 percent relief from her current medications. She denied "diversionary and aberrant behavior." The physician assistant documented reviewing Patient C's UDS results, "which were consistent with her medication list." These notes contradicted the prior inconsistent UDS dipstick results and there was no documentation of a discussion regarding those inconsistent results. Patient C's medications were refilled with no changes despite the notation that Dr. Smith does not recommend chronic oral systemic opioid therapy or chronic high-dose systemic oral opioid therapy for Patient C's condition and she understood the need to wean her opioid dosage "in her future." She was again encouraged to detox from opioids which she was again "hesitant to consider." No UDS was ordered and no CURES was reviewed.

142. A September 19, 2017, telephone note from another of Patient C's treating physicians documented that the physician was calling regarding the patient's care and had questions about her opioid management. That physician suggested that Dr. Smith start the patient on cognitive behavioral therapy and aqua therapy "in an effort to reduce her oral opioid intake" and Dr. Smith "agreed with the suggestion set forth." That physician would be "sending an official letter" to Dr. Smith's office.

143. On August 14, 2017, Patient C was seen by the physician assistant and had the same complaints of left shoulder, left low back, lower extremity, and left foot pain. She reported "some new pain and limited range of motion of her right shoulder" that was being treated by her primary care physician who prescribed physical therapy that was scheduled to begin next week. Patient C reported 50 percent relief with her current medications. Much of the chart entries appear to be copied from prior entries. The discussion of recommended non-opioid therapies was charted. The patient's medications were refilled with no changes, despite the notation that Dr. Smith did not recommend that therapy, Patient C was encouraged to detox and would have to wean her opioids "in her future." Again, the patient was hesitant to consider detox. No UDS was ordered and a review of CURES was not charted.

144. An August 22, 2017, telephone note documented a message left with Patient C's worker's compensation adjuster advising that "Dr. Smith is no longer accepting primary treating responsibilities, that [his office] would be notating and closing the patient's account, and requesting that the adjuster would ensure the patient is being transitioned to another primary treating physician." When Dr. Smith's office received no return call, despite leaving two messages, they contacted Patient C's worker's compensation attorney to advise the patient needed to transition to another

primary treating physician. Dr. Smith's office would provide Patient C a list of providers.

145. Despite that telephone note, Patient C was seen on September 11, 2017, by the physician assistant for medication management and there was nothing different about this visit charted. She reported the same pain complaints and that her current medications gave her 50 percent relief. Much of the chart entries appear to be copied from prior entries. The patient's "previous UDS results were consistent with her medication," but it was unclear what results this note referred as none had been ordered at the prior visit. Again, it was noted that Dr. Smith did not recommend chronic oral systemic opioid therapy or her current high-dose systemic oral opioid therapy for her condition. "Patient also understands opioid weaning will be necessary to a maximum dose of 50 morphine milligram equivalence per day. Since the patient's medications were approved and modified by her insurance to help facilitate a move in this direction, I explained to the patient that her MS Contin 15 mg will be decreased from [twice a day to once a day] and her MSIR 30 mg will be decreased from [a maximum of six per day to a maximum of four per day]." Her Ibuprofen would be continued but "may be decreased in the future if her asymptomatic hypertension continues to persist." Patient C was again encouraged to consider detox from opioids, and use non-opioid options, but was "hesitant to consider" it. Patient C would continue her care with her primary care provider for her chronic shoulder pain and her asymptomatic elevated blood pressure (142/90) obtained today. Patient C was informed that Dr. Smith was no longer providing primary treating physician services, and that the worker's compensation adjuster had been notified of that fact but had not returned Dr. Smith's office's call. Patient C advised that her attorney had informed her of this and she was working with them to transition her care to a new primary treating physician. Patient C was informed that "[s]econdary treating services can be

continued by [Dr. Smith's] office when her care is transitioned." The follow-up was the patient would have a new primary treating physician for continued care and she would return in one month for final medication management if needed. No UDS was ordered and there was no documentation of reviewing CURES.

146. Patient C was seen by the physician assistant on October 11, 2017. She continued to complain of left shoulder pain, left low back lower extremity pain that was increasing, and left foot pain. She received 50 percent relief from her current medication. She had been trying to reduce her medication use as pain allowed and had difficulty obtaining her medication from her pharmacy. Much of the note appears copied from other notes. Her medications were refilled with no changes from the decrease that had been prescribed at the prior visit. It was again documented that Dr. Smith did not agree with this therapy for her condition, that she was encouraged to detox, that her morphine would need to be weaned, that her Ibuprofen "may be decreased in the future," and that she was hesitant to consider detox. Of note, she was never weaned nor was her Ibuprofen decreased. She was instructed to go to the emergency room if her "withdrawal symptoms became too intense," but those "withdrawal symptoms" were not charted. She was continuing to transition to a new primary treating physician, but had been unsuccessful in her attempts to do so. Patient C would continue trying to find a new primary treating physician and would follow-up with Dr. Smith's office in one month for final medical management if needed.

147. A November 6, 2017, telephone note documented Patient C's call to the office to ask about the registered letter she received. The patient advised "she forgot the copy at her last appointment, but will bring it in the next time she is in the office." An addendum dated April 13, 2018, states: "Patient never did end up bringing a copy of the registered letter that she received, nor was she able to provide our office with

any details about what the letter was in regard to. The letter she received did not come from our office. Since the patient did not provide our office with any details about the contents of the letter, our office was unfortunately unable to assist her any further."

148. Patient C was a no-show for a November 30, 2017, medication management appointment and no further visits were documented.

149. Patient C's CURES reports obtained by complainant as part of the investigation documented that during the time she was treating with Dr. Smith, the only controlled substances she was prescribed were from Dr. Smith's office. Dr. Smith produced copies of CURES reports that he testified had been scanned into the patient's file but did not print out when his office produced copies of the records to the investigator.

150. Unlike Patient A and Patient B, no lab reports of UDS results for Patient C were introduced at hearing.

Evaluation of Dr. Smith's Care and Treatment of Patient C

GROSS NEGLIGENCE ALLEGATIONS

Failure to Modify Controlled Substance Regimen

151. Dr. Geula opined that Dr. Smith was grossly negligent in his care and treatment of Patient C for failing to adequately modify her controlled substance regimen. Dr. Geula opined that the patient's dosages continued throughout her treatment with no changes, despite documentation that she was receiving no benefit from them, no CURES were documented as being reviewed, and the physical examinations performed at the visits were cursory. Of note, Dr. Geula's testimony that

there were no changes to the patient's medication regimen was inaccurate, given the reductions noted towards the end of her treatment.

Dr. Helm testified that it is extremely difficult to get care for patients, like Patient C, who are in the worker's compensation system. There are limitations on the care that can be provided and it can only be given to the body parts identified by the worker's compensation carrier. Dr. Helm cited to an article written by the CDC after issuing its 2016 morphine equivalent guidelines, cautioning physicians not to misconstrue the guidelines and wean patients from their medications.

It is not enough for a physician to simply document that he has told the patient what he does not recommend; the physician must actually follow through on those recommendations. Here Dr. Smith merely charted his philosophy but then did not follow it and continued to prescribe high dose opioids to Patient C, with no end in sight. Dr. Smith claimed that he discharged Patient C when she declined his recommendation for a spinal cord stimulator because her mother did not want her to have the procedure, but that was not the case. The records showed she remained his patient for one more year and had numerous visits where she continued to receive opioids after she declined the spinal cord stimulator therapy. Dr. Geula's opinions were more persuasive than Dr. Helm's. Complainant established by clear and convincing evidence that Dr. Smith was grossly negligent in his care and treatment of Patient A for failing to adequately modify her controlled substance regimen.

Failure to Review CURES Reports

152. Dr. Geula opined that Dr. Smith was grossly negligent in his care and treatment of Patient C for failing to review her CURES report. The standard of care at this time required pain management physicians to review CURES reports, especially

given the inconsistent UDS results. Dr. Geula was questioned about the CURES reports Dr. Smith produced at hearing which his office obtained while treating Patient C, but which had not been printed out when the records were produced to the investigator. Dr. Geula opined that while "three was better than none," he would have wanted to see more reviewed because Patient C was on high doses of opioids with minimal benefits. If Dr. Smith had only treated Patient C for 18 months and gotten three CURES, he would revise his opinion from an extreme departure to a simple departure from the standard of care, but here Patient C was seen for over three years, which meant only one CURES per year was obtained, which was not enough and was an extreme departure.

Dr. Helm opined that even current legislation does not require CURES obtained at every visit and the three CURES ordered here was sufficient.

Given the many medications identified in the records that Dr. Smith and his staff were not prescribing, and the inconsistent UDS, it was imperative Dr. Smith review CURES at the visits so he could confirm the medications Patient C was reporting and to ensure there were no other medications she was taking that she was not reporting. Although Dr, Smith obtained three CURES, this was insufficient given the length of time he treated Patient C. Complainant established by clear and convincing evidence that Dr. Smith was grossly negligent in his care and treatment of Patient C for failing to review her CURES report.

Failure to Maintain Timely Medical Records

153. Dr. Geula opined that Dr. Smith was grossly negligent in his care and treatment of Patient C for failing to adequately maintain timely medical records. His opinion was again based upon the fact that several of the records were dated

December 11, 2017, the date they were printed for the investigator. For the reasons stated above regarding locking and printing, that opinion is rejected. Complainant did not establish by clear and convincing evidence that Dr. Smith failed to adequately maintain timely medical records for Patient C.

REPEATED NEGLIGENT ACTS ALLEGATIONS

Failure to Obtain Adequate Consultations

154. Dr. Geula opined that Dr. Smith was negligent in his care and treatment of Patient C for failing to obtain adequate consultations for complex pain issues. Dr. Smith continued to prescribe high-dose opioid medications but did not refer the patient to any other providers or for any other therapies despite her numerous pain complaints which were detailed as not improving with her medications.

Dr. Helm opined that the records documented the therapies being attempted, the outside consultations and treatment Patient C was receiving, as well as previous therapies and consultations that did not resolve her pain complaints. Dr. Smith was the pain management consultant and worker's compensation limited his options.

Dr. Helm's opinions, which were supported by the records, were more persuasive than Dr. Geula's to the contrary. Complainant failed to establish by clear and convincing that Dr. Smith was negligent in his care and treatment of Patient C for failing to obtain adequate consultations.

Failure to Document Detailed Physical Examinations

155. Dr. Geula opined that Dr. Smith was negligent in his care and treatment of Patient C for failing to adequately document a detailed physical examination of

all areas of patient C's pain complaints. The physical examinations in the records were cursory and were inadequate given her pain complaints.

Dr. Helm opined that the physical examinations documented in the records were sufficient and met the standard of care. There was no need to perform a complete physical examination at follow-up appointments where the same pain complaints are being addressed.

Many of the entries were cut-and-paste, physical examinations were cursory and there was no documentation of examining areas of the body where there were pain complaints. Dr. Geula's opinions were persuasive and supported by the records. Complainant established by clear and convincing evidence that Dr. Smith was negligent in his care and treatment of Patient C for failing to adequately document a detailed physical examination of all areas of her pain complaints.

Failure to Adequately Document Treatment Objectives

156. Dr. Geula opined that Dr. Smith was negligent in his care and treatment of Patient C for failing to adequately document treatment objectives of continued opioid therapy. Dr. Geula opined that the records should document the reason medications are being prescribed and the plan for treatment, which was not done.

Dr. Helm opined that a review of the records showed that the objectives were clearly documented and the modalities for treating the pain were provided. There were discussions regarding therapies previously tried, notes regarding therapies being considered, and the therapies worker's compensation denied. Dr. Helm opined that the notes clearly documented the whole process of caring for this patient and the decisions being made. There was no violation of the standard of care.

Dr. Helm's opinions were more persuasive and supported by the records. Complainant failed to establish by clear and convincing evidence that Dr. Smith was negligent in his care and treatment of Patient C for failing to adequately document treatment objectives of continued opioid therapy.

Evaluation of Medical Practice Act Violations

157. Complainant alleged that Dr. Smith's actions as set forth above violated the Medical Practice Act. For those causes for discipline that were sustained by clear and convincing evidence, complainant established that Dr. Smith violated the Medical Practice Act.

Closing Arguments

158. Complainant argued that based upon Dr. Smith's numerous violations, his failure to take responsibility, and the credibility of both experts, Dr. Smith's license should be revoked, the revocation should be stayed and he should be placed on five years' probation with standard terms and conditions. Complainant also requested that the following optional terms and conditions be ordered: the full PACE course, a prescribing practices course, an Ethics course, a record-keeping course, a prohibition from solo practice, a practice monitor, and a billing monitor.

159. Dr. Smith argued that complainant's expert was inexperienced, that the practice of pain management has evolved since Dr. Smith saw these patients, the evidence did not sustain most of the allegations, and that once Dr. Smith found out about medication management violations, he discharged the patients. Dr. Smith asserted that the experts were simply "quibbling" over the number of CURES reports to review and whether enough of a physical examination was documented. At most, he believed a public reprimand should be issued.

LEGAL CONCLUSIONS

Purpose of Physician Discipline

1. The purpose of a disciplinary action is not to punish, but to protect the public, and the inquiry must be limited to the effect of the physician actions upon the quality of his service to his patients. (*Watson v. Superior Court* (2009) 176 Cal.App.4th 1407, 1416.) It is far more desirable to impose discipline before a licensee harms any patient than after harm has occurred. (*Griffiths v. Superior Court* (2002) 96 Cal.App.4th 757, 772.)

The Burden and Standard of Proof

2. Complainant bears the burden of proof of establishing that the charges in the accusation are true. (*Martin v. State Personnel Board* (1972) 26 Cal.App.3d 573, 582.)

3. The standard of proof in an administrative action seeking to suspend or revoke a physician and surgeon's certificate is "clear and convincing evidence." (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.)

4. Clear and convincing evidence requires a finding of high probability, or evidence so clear as to leave no substantial doubt; sufficiently strong evidence to command the unhesitating assent of every reasonable mind. (*Katie V. v. Superior Court* (2005) 130 Cal.App.4th 586, 594.) The requirement to prove by clear and convincing evidence is a "heavy burden, far in excess of the preponderance sufficient in most civil litigation. [Citation.]" (*Christian Research Institute v. Alnor* (2007) 148 Cal.App.4th 71, 84.) "The burden of proof by clear and convincing evidence 'requires a finding of high probability. The evidence must be so clear as to leave no substantial doubt. It must be

sufficiently strong to command the unhesitating assent of every reasonable mind.' [Citation.]" (*Ibid.*)

5. In a disciplinary proceeding, the burden is on respondent to produce positive evidence of rehabilitation. (*Epstein v. California Horse Racing Board* (1963) 222 Cal.App.2d 831, 842-843.)

Applicable Code Section

6. Business and Professions Code section 2227 authorizes the board to discipline a licensee.

7. Business and Professions Code section 2234, provides in part:

> The board shall take action against any licensee who is charged with unprofessional conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not limited to, the following:
>
> (a) Violating or attempting to violate, directly or indirectly, assisting in or abetting the violation of, or conspiring to violate any provision of this chapter.
>
> (b) Gross negligence.
>
> (c) Repeated negligent acts. To be repeated, there must be two or more negligent acts or omissions. An initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care shall constitute repeated negligent acts.

(1) An initial negligent diagnosis followed by an act or omission medically appropriate for that negligent diagnosis of the patient shall constitute a single negligent act.

(2) When the standard of care requires a change in the diagnosis, act, or omission that constitutes the negligent act described in paragraph (1), including, but not limited to, a reevaluation of the diagnosis or a change in treatment, and the licensee's conduct departs form the applicable standard of care, each departure constitutes a separate and distinct breach of the standard of care.

Standard of Care

8. The standard of care requires that physicians exercise in diagnosis and treatment that reasonable degree of skill, knowledge and care ordinarily possessed and exercised by members of the medical profession under similar circumstances. The standard of care is a matter peculiarly within the knowledge of experts; it presents the basic issue in a malpractice action and can only be proved by their testimony, unless the conduct required by the particular circumstances is within the common knowledge of the layman. (*Williamson v. Prida* (1999) 75 Cal.App.4th 1417, 1424.)

9. The community standard of care is peculiarly within the knowledge of experts; it presents a basic issue and can only be proved by expert testimony, unless the conduct required under the particular circumstances is within the common knowledge of the layman. (*Flowers v. Torrance Memorial Hospital Medical Center* (1994) 8 Cal. 4th 992, 1001.)

10. The standard of care must be provided through expert testimony. (*Sinz, supra,* 33 Cal.2d at p. 753; See also *Alef v. Alta Bates Hospital* (1992) 5 Cal.App.4th 208, 215-219.) "The party offering the expert must demonstrate that the expert's knowledge of the subject is sufficient, and the determinative issue in each case is whether the witness has sufficient skill or experience in the field so his testimony would be likely to assist" the trier of fact. (*Id.* at p. 219.) The expert's qualifications must establish that he or she has "the education, training, experience, or knowledge necessary to testify to the standards to be upheld in the practice" of the profession on which he or she is opining. (*Cooper v. Board of Medical Examiners* (1975) 49 Cal.App.3d 931, 947.)

Simple and Gross Negligence

11. A physician is not necessarily negligent due to every "untoward result which may occur." (*Norden v. Hartman* (1955) 134 Cal.App.2d 333, 337.) A physician is negligent only where the error in judgment or lack of success is due to failure to perform any of the duties required of reputable members of the medical profession practicing under similar circumstances. (See *Black v. Caruso* (1960) 187 Cal.App.2d 195, 200-202.)

12. While a lack of ordinary care defines negligent conduct, gross negligence is defined by an error or omission that is egregious and flagrant. "Gross negligence has been said to mean the want of even scant care or an extreme departure from the ordinary standard of conduct." (*Van Meter v. Bent Construction Co.* (1946) 46 Cal.2d 588, 594; *City of Santa Barbara v. Superior Court* (2007) 41 Cal.4th 747, 753-754.)

13. So far as the phrase has any accepted meaning, "gross negligence" is "merely an extreme departure from the ordinary standard of care." (*Franz v. Board of Medical Quality Assurance* (1982) 31 Cal. 3d 124.)

Repeated Negligent Acts

14. A repeated negligent act involves two or more negligent acts or omissions. No pattern of negligence is required; repeated negligent acts means two or more acts of negligence. (*Zabetian v. Medical Board of California* (2000) 80 Cal.App.4th 462, 468.)

Causes for Discipline Established

GROSS NEGLIGENCE ESTABLISHED

15. Dr. Smith committed gross negligence in violation of Business and Professions Code section 2234, subdivision (b), in his care and treatment of Patient A when he prescribed a combination of high-dose opioids and Soma to her, failed to modify her controlled substance regimen, failed to review CURES, and failed to obtain more frequent UDS.

16. Dr. Smith committed gross negligence in violation of Business and Professions Code section 2234, subdivision (b), in his care and treatment of Patient B when he prescribed a combination of high-dose opioids and Soma to him, failed to modify his controlled substance regimen, failed to review CURES, and failed to obtain more frequent UDS.

17. Dr. Smith committed gross negligence in violation of Business and Professions Code section 2234, subdivision (b), in his care and treatment of Patient C

when he when he failed to modify her controlled substance regimen, and failed to review CURES.

REPEATED NEGLIGENCE ESTABLISHED

18. Dr. Smith committed repeated negligence in violation of Business and Professions Code section 2234, subdivision (c), in his care and treatment of Patient A when he failed to adequately document a detailed physical examination at many of her visits.

19. Dr. Smith committed repeated negligence in violation of Business and Professions Code section 2234, subdivision (c), in his care and treatment of Patient B when he failed to adequately document a detailed physical examination at many of his visits.

20. Dr. Smith committed repeated negligence in violation of Business and Professions Code section 2234, subdivision (c), in his care and treatment of Patient C when he failed to adequately document a detailed physical examination at many of her visits.

21. Dr. Smith violated the Medical Practice Act in violation of Business and Professions Code section 2234, subdivision (a), when he was grossly and repeatedly negligent in his care and treatment of Patients A, B and C, as found above in Legal Conclusion Nos. 15 through 20.

Causes for Discipline Not Established

GROSS NEGLIGENCE NOT ESTABLISHED

22. Dr. Smith did not fail to maintain timely medical records in violation of Business and Professions Code section 2234, subdivision (b), in his care and treatment of Patient A.

23. Dr. Smith did not fail to maintain timely medical records in violation of Business and Professions Code section 2234, subdivision (b), in his care and treatment of Patient B.

24. Dr. Smith did not fail to maintain timely medical records in violation of Business and Professions Code section 2234, subdivision (b), in his care and treatment of Patient C.

REPEATED NEGLIGENCE NOT ESTABLISHED

25. Dr. Smith was not repeatedly negligent in violation of Business and Professions Code section 2234, subdivision (c), in his care and treatment of Patient A. Dr. Smith did not fail to obtain adequate consultations and he did not fail to adequately document treatment objectives of continued opioid therapy.

26. Dr. Smith was not repeatedly negligent in violation of Business and Professions Code section 2234, subdivision (c), in his care and treatment of Patient B. Dr. Smith did not fail to obtain adequate consultations and he did not fail to adequately document treatment objectives of continued opioid therapy.

27. Dr. Smith was not repeatedly negligent in violation of Business and Professions Code section 2234, subdivision (c), in his care and treatment of Patient C.

Dr. Smith did not fail to obtain adequate consultations and he did not fail to adequately document treatment objectives of continued opioid therapy.

28. Dr. Smith did not violate the Medical Practice Act in violation of Business and Professions Code section 2234, subdivision (a), because he was not grossly or repeatedly negligent in his care and treatment of Patients A, B and C, as found above in Legal Conclusion Nos. 22 through 27.

The Board's Disciplinary Guidelines

29. With causes for discipline having been found, the degree of discipline to impose must now be determined. In this regard, the board's Manual of Model Disciplinary Orders and Disciplinary Guidelines (12th Edition 2016) states that they are intended to be used in the physician disciplinary process and "are not binding standards." Further,

> The Board expects that, absent mitigating or other appropriate circumstances such as early acceptance of responsibility, demonstrated willingness to undertake Board-ordered rehabilitation, the age of the case, and evidentiary problems, Administrative Law Judges hearing cases on behalf of the Board and proposed settlements submitted to the Board will follow the guidelines, including those imposing suspensions. Any proposed decision or settlement that departs from the disciplinary guidelines shall identify the departures and the facts supporting the departure.

30. California Code of Regulations, title 16, section 1360.1, sets forth the factors to be considered in determining discipline. As stated:

> When considering the suspension or revocation of a license, certificate or permit on the ground that a person holding a license, certificate or permit under the Medical Practice Act has been convicted of a crime, the division, in evaluating the rehabilitation of such person and his or her eligibility for a license, certificate or permit shall consider the following criteria:
>
> (a) The nature and severity of the act(s) or offense(s).
>
> (b) The total criminal record.
>
> (c) The time that has elapsed since commission of the act(s) or offense(s).
>
> (d) Whether the licensee, certificate or permit holder has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed against such person.
>
> (e) If applicable, evidence of expungement proceedings pursuant to Section 1203.4 of the Penal Code.
>
> (f) Evidence, if any, of rehabilitation submitted by the licensee, certificate or permit holder.

Evaluation of Discipline

31. Dr. Smith treated Patient A from 2013 to 2015, which was five to seven years ago; Patient B from 2014 to 2015, which was five to six years ago; and Patient C from 2014 until 2017, which was three to six years ago. There was no evidence of any violations after 2017. However, Dr. Smith treated these three patients, in toto, on a monthly basis, for four years. His failure to follow his own repeatedly documented note that he "does not recommend" the very treatment he continuously prescribed was concerning. Although the CDC issued new morphine equivalent guidelines in 2016, one year after Dr. Smith stopped treating Patients A and B, and shortly before he stopped treating Patient C, there were still issues with the care he rendered to these three patients. While no evidence contradicted Dr. Smith's testimony of changes to his practice after those CDC guidelines were issued, those changes were insufficient to redress the violations established here.

It is true that pain management is an evolving practice, but the somewhat lackadaisical approach reflected in these three patients' records and demonstrated during Dr. Smith's testimony was concerning. The patients' records suggested an environment where too little attention was being paid. Dr. Smith's testimony putting the onus on medical assistants to bring things to his attention and to labs for failing to report results, did little to allay those concerns. Dr. Smith and his physician assistants repeatedly documented that Dr. Smith "did not recommend" the high-dose opioid therapy they continued to prescribe, making those entries meaningless. Numerous inconsistencies in the records were not addressed, UDS ordered were not reviewed or followed up upon, and the patients violated their medication management agreements several times without consequence. On balance, weighing Dr. Smith's extensive background, training, and experience in pain management against the facts

established here, as well as how remote in time those events occurred, and Dr. Smith's credible, uncontroverted, testimony about the changes he has made to his practice, it is not necessary to order more than three years of probation.

Complainant's request that no solo practice be ordered is not necessary to ensure public protection. Dr. Smith is an extremely experienced pain management physician who was one of the pain management pioneers in San Diego County. He has successfully operated a pain management practice in San Diego for decades. Imposing a term and condition of no solo practice would be unduly punitive. The purpose of discipline is not to punish, but to protect the public by eliminating practitioners who are dishonest, immoral, disreputable or incompetent. (*Fahmy v. Medical Board of California* (1995) 38 Cal.App.4th 810, 817.) Dr. Smith is none of those things. Ordering he attend PACE so that his pain management skills can be evaluated and having a practice monitor oversee him and review his charts will sufficiently protect the public.

There is no basis to impose the board's standard term and condition that Dr. Smith be prohibited from supervising physician assistants while on probation. His practice employs physician assistants who routinely provide care to patients. Imposing this term would result in those physician assistants being terminated from employment. There were no causes for discipline alleged or facts established that Dr. Smith failed to supervise his physician assistants. There is no basis to order that term and doing so would be unduly punitive. Moreover, currently our nation is in the throes of a deadly pandemic. Medical providers are desperately needed and severe economic hardships are facing millions of people. Putting the physician assistants who Dr. Smith employs out of work would create hardships for them, likely cause undue patient harm as less pain patients could receive treatment, and is unwarranted because complainant did not allege a failure to supervise.

There is no basis to order a record keeping course. The only record keeping cause for discipline alleged was that the charts were not timely signed. As found above, that cause was not established. Complainant's argument that Dr. Smith's testimony about "locking" the records demonstrated that his record keeping system was flawed and he should use a different system, lacked foundation and was unpersuasive. There was no evidence that Dr. Smith did not keep accurate and adequate records. The issue presented here was that he failed to follow up on the information charted in his records. Ordering a record keeping course on these facts would be unduly punitive.

Similarly, there is no basis to order an Ethics course. Absolutely no evidence was introduced, or even remotely suggested, that Dr. Smith was dishonest or exhibited any type of conduct requiring he attend an Ethics course. Ordering such a course on the facts presented here would be unduly punitive. There was also no evidence that Dr. Smith improperly billed for his services, so ordering a billing monitor would also be unduly punitive.

Dr. Smith is clearly a very experienced pain management physician who now routinely reviews CURES and is making a better effort to stay on top of patients' care. He testified about the changes he has made in his practice. Dr. Smith's testimony demonstrated his vast pain management experience and training. He presented as a caring physician, but the medical records of these three patients were troubling. His failure to follow up on what was charted in these patients' records, repeatedly ordering what he "did not recommend," coupled with his testimony placing responsibility on others, makes the discipline ordered below necessary to ensure public protection.

ORDER

Certificate No. G 7047 issued to respondent, Kevin Sanford Smith, M.D., is revoked. However, the revocation is stayed, and respondent is placed on probation for three years upon the following terms and conditions:

1. Prescribing Practices Course

Within 60 calendar days of the effective date of this Decision, respondent shall enroll in a course in prescribing practices approved in advance by the Board or its designee. Respondent shall provide the approved course provider with any information and documents that the approved course provider may deem pertinent. Respondent shall participate in and successfully complete the classroom component of the course not later than six (6) months after respondent's initial enrollment. Respondent shall successfully complete any other component of the course within one (1) year of enrollment. The prescribing practices course shall be at respondent's expense and shall be in addition to the Continuing Medical Education (CME) requirements for renewal of licensure.

A prescribing practices course taken after the acts that gave rise to the charges in the Accusation, but prior to the effective date of the Decision may, in the sole discretion of the Board or its designee, be accepted towards the fulfillment of this condition if the course would have been approved by the Board or its designee had the course been taken after the effective date of this Decision.

Respondent shall submit a certification of successful completion to the Board or its designee not later than 15 calendar days after successfully completing the course,

or not later than 15 calendar days after the effective date of the Decision, whichever is later.

2. Clinical Competence Assessment Program

Within 60 calendar days of the effective date of this Decision, respondent shall enroll in a clinical competence assessment program approved in advance by the Board or its designee. Respondent shall successfully complete the program not later than six (6) months after respondent's initial enrollment unless the Board or its designee agrees in writing to an extension of that time.

The program shall consist of a comprehensive assessment of respondent's physical and mental health and the six general domains of clinical competence as defined by the Accreditation Council on Graduate Medical Education and American Board of Medical Specialties pertaining to respondent's current or intended area of practice. The program shall take into account data obtained from the pre-assessment, self-report forms and interview, and the Decision(s), Accusation(s), and any other information that the Board or its designee deems relevant. The program shall require respondent's on-site participation for a minimum of 3 and no more than 5 days as determined by the program for the assessment and clinical education evaluation. Respondent shall pay all expenses associated with the clinical competence assessment program.

At the end of the evaluation, the program will submit a report to the Board or its designee which unequivocally states whether the respondent has demonstrated the ability to practice safely and independently. Based on respondent's performance on the clinical competence assessment, the program will advise the Board or its designee of its recommendation(s) for the scope and length of any additional educational or

clinical training, evaluation or treatment for any medical condition or psychological condition, or anything else affecting respondent's practice of medicine. Respondent shall comply with the program's recommendations.

Determination as to whether respondent successfully completed the clinical competence assessment program is solely within the program's jurisdiction.

If respondent fails to enroll, participate in, or successfully complete the clinical competence assessment program within the designated time period, respondent shall receive a notification from the Board or its designee to cease the practice of medicine within three (3) calendar days after being so notified. The respondent shall not resume the practice of medicine until enrollment or participation in the outstanding portions of the clinical competence assessment program have been completed. If the respondent did not successfully complete the clinical competence assessment program, the respondent shall not resume the practice of medicine until a final decision has been rendered on the first amended accusation and/or a petition to revoke probation. The cessation of practice shall not apply to the reduction of the probationary time period.

3. Monitoring - Practice

Within 30 calendar days of the effective date of this Decision, respondent shall submit to the Board or its designee for prior approval as a practice monitor(s), the name and qualifications of one or more licensed physicians and surgeons whose licenses are valid and in good standing, and who are preferably American Board of Medical Specialties (ABMS) certified. A monitor shall have no prior or current business or personal relationship with respondent, or other relationship that could reasonably be expected to compromise the ability of the monitor to render fair and unbiased

reports to the Board, including but not limited to any form of bartering, shall be in respondent's field of practice, and must agree to serve as respondent's monitor. Respondent shall pay all monitoring costs.

The Board or its designee shall provide the approved monitor with copies of the Decision(s) and Accusation(s), and a proposed monitoring plan. Within 15 calendar days of receipt of the Decision(s), Accusation(s), and proposed monitoring plan, the monitor shall submit a signed statement that the monitor has read the Decision(s) and Accusation(s), fully understands the role of a monitor, and agrees or disagrees with the proposed monitoring plan. If the monitor disagrees with the proposed monitoring plan, the monitor shall submit a revised monitoring plan with the signed statement for approval by the Board or its designee.

Within 60 calendar days of the effective date of this Decision, and continuing throughout probation, respondent's practice shall be monitored by the approved monitor. Respondent shall make all records available for immediate inspection and copying on the premises by the monitor at all times during business hours and shall retain the records for the entire term of probation.

If respondent fails to obtain approval of a monitor within 60 calendar days of the effective date of this Decision, respondent shall receive a notification from the Board or its designee to cease the practice of medicine within three (3) calendar days after being so notified. Respondent shall cease the practice of medicine until a monitor is approved to provide monitoring responsibility.

The monitor(s) shall submit a quarterly written report to the Board or its designee which includes an evaluation of respondent's performance, indicating whether respondent's practices are within the standards of practice of medicine, and

whether respondent is practicing medicine safely. It shall be the sole responsibility of respondent to ensure that the monitor submits the quarterly written reports to the Board or its designee within 10 calendar days after the end of the preceding quarter.

If the monitor resigns or is no longer available, respondent shall, within 5 calendar days of such resignation or unavailability, submit to the Board or its designee, for prior approval, the name and qualifications of a replacement monitor who will be assuming that responsibility within 15 calendar days. If respondent fails to obtain approval of a replacement monitor within 60 calendar days of the resignation or unavailability of the monitor, respondent shall receive a notification from the Board or its designee to cease the practice of medicine within three (3) calendar days. After being so notified Respondent shall cease the practice of medicine until a replacement monitor is approved and assumes monitoring responsibility.

In lieu of a monitor, respondent may participate in a professional enhancement program approved in advance by the Board or its designee, that includes, at minimum, quarterly chart review, semi-annual practice assessment, and semi-annual review of professional growth and education. Respondent shall participate in the professional enhancement program at respondent's expense during the term of probation.

4. Notification

Within seven (7) days of the effective date of this Decision, the respondent shall provide a true copy of this Decision and First Amended Accusation to the Chief of Staff or the Chief Executive Officer at every hospital where privileges or membership are extended to respondent, at any other facility where respondent engages in the practice of medicine, including all physician and locum tenens registries or other similar agencies, and to the Chief Executive Officer at every insurance carrier which

extends malpractice insurance coverage to respondent. Respondent shall submit proof of compliance to the Board or its designee within 15 calendar days.

This condition shall apply to any change(s) in hospitals, other facilities or insurance carrier.

5. Obey All Laws

Respondent shall obey all federal, state and local laws, all rules governing the practice of medicine in California and remain in full compliance with any court ordered criminal probation, payments, and other orders.

6. Quarterly Declarations

Respondent shall submit quarterly declarations under penalty of perjury on forms provided by the Board, stating whether there has been compliance with all the conditions of probation.

Respondent shall submit quarterly declarations not later than 10 calendar days after the end of the preceding quarter.

7. General Probation Requirements

Compliance with Probation Unit

Respondent shall comply with the Board's probation unit.

Address Changes

Respondent shall, at all times, keep the Board informed of respondent's business and residence addresses, email address (if available), and telephone number. Changes of such addresses shall be immediately communicated in writing to the Board

or its designee. Under no circumstances shall a post office box serve as an address of record, except as allowed by Business and Professions Code section 2021, subdivision (b).

Place of Practice

Respondent shall not engage in the practice of medicine in respondent's or patient's place of residence, unless the patient resides in a skilled nursing facility or other similar licensed facility.

License Renewal

Respondent shall maintain a current and renewed California physician's and surgeon's license.

Travel or Residence Outside California

Respondent shall immediately inform the Board or its designee, in writing, of travel to any areas outside the jurisdiction of California which lasts, or is contemplated to last, more than thirty (30) calendar days.

In the event respondent should leave the State of California to reside or to practice respondent shall notify the Board or its designee in writing 30 calendar days prior to the dates of departure and return.

8. Interview with the Board or its Designee

Respondent shall be available in person upon request for interviews either at respondent's place of business or at the probation unit office, with or without prior notice throughout the term of probation.

9. Non-practice While on Probation

Respondent shall notify the Board or its designee in writing within 15 calendar days of any periods of non-practice lasting more than 30 calendar days and within 15 calendar days of respondent's return to practice. Non-practice is defined as any period of time respondent is not practicing medicine as defined in Business and Professions Code sections 2051 and 2052 for at least 40 hours in a calendar month in direct patient care, clinical activity or teaching, or other activity as approved by the Board. If respondent resides in California and is considered to be in non-practice, respondent shall comply with all terms and conditions of probation. All time spent in an intensive training program which has been approved by the Board or its designee shall not be considered non-practice and does not relieve respondent from complying with all the terms and conditions of probation. Practicing medicine in another state of the United States or Federal jurisdiction while on probation with the medical licensing authority of that state or jurisdiction shall not be considered non-practice. A Board-ordered suspension of practice shall not be considered as a period of non-practice.

In the event respondent's period of non-practice while on probation exceeds 18 calendar months, respondent shall successfully complete the Federation of State Medical Board's Special Purpose Examination, or, at the Board's discretion, a clinical competence assessment program that meets the criteria of Condition 18 of the current version of the Board's "Manual of Model Disciplinary Orders and Disciplinary Guidelines" prior to resuming the practice of medicine.

Respondent's period of non-practice while on probation shall not exceed two (2) years.

Periods of non-practice will not apply to the reduction of the probationary term.

Periods of non-practice for a respondent residing outside of California, will relieve respondent of the responsibility to comply with the probationary terms and conditions with the exception of this condition and the following terms and conditions of probation: Obey All Laws; General Probation Requirements; Quarterly Declarations; Abstain from the Use of Alcohol and/or Controlled Substances; and Biological Fluid Testing.

10. Completion of Probation

Respondent shall comply with all financial obligations (e.g., restitution, probation costs) not later than 120 calendar days prior to the completion of probation. Upon successful completion of probation, respondent's certificate shall be fully restored.

11. Violation of Probation

Failure to fully comply with any term or condition of probation is a violation of probation. If respondent violates probation in any respect, the Board, after giving respondent notice and the opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If an Accusation, or Petition to Revoke Probation, or an Interim Suspension Order is filed against respondent during probation, the Board shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.

12. License Surrender

Following the effective date of this Decision, if respondent ceases practicing due to retirement or health reasons or is otherwise unable to satisfy the terms and conditions of probation, respondent may request to surrender his or her license. The Board reserves the right to evaluate respondent's request and to exercise its discretion

in determining whether or not to grant the request, or to take any other action deemed appropriate and reasonable under the circumstances. Upon formal acceptance of the surrender, respondent shall within 15 calendar days deliver respondent's wallet and wall certificate to the Board or its designee and respondent shall no longer practice medicine. Respondent will no longer be subject to the terms and conditions of probation. If respondent re-applies for a medical license, the application shall be treated as a petition for reinstatement of a revoked certificate.

13. Probation Monitoring Costs

Respondent shall pay the costs associated with probation monitoring each and every year of probation, as designated by the Board, which may be adjusted on an annual basis. Such costs shall be payable to the Medical Board of California and delivered to the Board or its designee no later than January 31 of each calendar year.

DATE: October 22, 2020

DocuSigned by:
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MARY AGNES MATYSZEWSKI
Administrative Law Judge
Office of Administrative Hearings

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Attorneys for Complainant

BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **KEVIN SANFORD SMITH, M.D.** 7525 Linda Vista Road, Suite C San Diego, CA 92111-5344 Physician's and Surgeon's Certificate No. G 70647, Respondent.	Case No. 800-2016-025316 **A C C U S A T I O N**

PARTIES

1. Kimberly Kirchmeyer (Complainant) brings this Accusation solely in her official capacity as the Executive Director of the Medical Board of California, Department of Consumer Affairs (Board).

2. On or about January 14, 1991, the Medical Board issued Physician's and Surgeon's Certificate No. G 70647 to Kevin Sanford Smith, M.D. (Respondent). The Physician's and Surgeon's Certificate was in full force and effect at all times relevant to the charges brought herein and will expire on June 30, 2020, unless renewed.

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JURISDICTION

3. This Accusation is brought before the Board, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

4. Section 2227 of the Code states:

> (a) A licensee whose matter has been heard by an administrative law judge of the Medical Quality Hearing Panel as designated in Section 11371 of the Government Code, or whose default has been entered, and who is found guilty, or who has entered into a stipulation for disciplinary action with the board, may, in accordance with the provisions of this chapter:
>
> (1) Have his or her license revoked upon order of the board.
>
> (2) Have his or her right to practice suspended for a period not to exceed one year upon order of the board.
>
> (3) Be placed on probation and be required to pay the costs of probation monitoring upon order of the board.
>
> (4) Be publicly reprimanded by the board. The public reprimand may include a requirement that the licensee complete relevant educational courses approved by the board.
>
> (5) Have any other action taken in relation to discipline as part of an order of probation, as the board or an administrative law judge may deem proper.
>
> (b) Any matter heard pursuant to subdivision (a), except for warning letters, medical review or advisory conferences, professional competency examinations, continuing education activities, and cost reimbursement associated therewith that are agreed to with the board and successfully completed by the licensee, or other matters made confidential or privileged by existing law, is deemed public, and shall be made available to the public by the board pursuant to Section 803.1.

5. Section 2234 of the Code, states, in pertinent part:

> The board shall take action against any licensee who is charged with unprofessional conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not limited to, the following:
>
> (a) Violating or attempting to violate, directly or indirectly, assisting in or abetting the violation of, or conspiring to violate any provision of this chapter.
>
> (b) Gross negligence.
>
> (c) Repeated negligent acts. To be repeated, there must be two or more negligent acts or omissions. An initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care shall constitute repeated negligent acts.

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(1) An initial negligent diagnosis followed by an act or omission medically appropriate for that negligent diagnosis of the patient shall constitute a single negligent act.

(2) When the standard of care requires a change in the diagnosis, act, or omission that constitutes the negligent act described in paragraph (1), including, but not limited to, a reevaluation of the diagnosis or a change in treatment, and the licensee's conduct departs from the applicable standard of care, each departure constitutes a separate and distinct breach of the standard of care.

6. Section 2228.1 of the Code states, in pertinent part:

(a) On and after July 1, 2019, except as otherwise provided in subdivision (c), the board shall require a licensee to provide a separate disclosure that includes the licensee's probation status, the length of the probation, the probation end date, all practice restrictions placed on the licensee by the board, the board's telephone number, and an explanation of how the patient can find further information on the licensee's probation on the licensee's profile page on the board's online license information Internet Web site, to a patient or the patient's guardian or health care surrogate before the patient's first visit following the probationary order while the licensee is on probation pursuant to a probationary order made on and after July 1, 2019, in any of the following circumstances:

(1) A final adjudication by the board following an administrative hearing or admitted findings or prima facie showing in a stipulated settlement establishing any of the following:

(D) Inappropriate prescribing resulting in harm to patients and a probationary period of five years or more.

(2) An accusation or statement of issues alleged that the licensee committed any of the acts described in subparagraphs (A) to (D), inclusive, of paragraph (1), and a stipulated settlement based upon a nolo contendre or other similar compromise that does not include any prima facie showing or admission of guilt or fact but does include an express acknowledgment that the disclosure requirements of this section would serve to protect the public interest.

(b) A licensee required to provide a disclosure pursuant to subdivision (a) shall obtain from the patient, or the patient's guardian or health care surrogate, a separate, signed copy of that disclosure.

(d) On and after July 1, 2019, the board shall provide the following information, with respect to licensees on probation and licensees practicing under probationary licenses, in plain view on the licensee's profile page on the board's online license information Internet Web site.

(1) For probation imposed pursuant to a stipulated settlement, the causes alleged in the operative accusation along with a designation identifying those causes

by which the licensee has expressly admitted guilt and a statement that acceptance of the settlement is not an admission of guilt.

(2) For probation imposed by an adjudicated decision of the board, the causes for probation stated in the final probationary order.

(3) For a licensee granted a probationary license, the causes by which the probationary license was imposed.

(4) The length of the probation and end date.

(5) All practice restrictions placed on the license by the board.

FIRST CAUSE FOR DISCIPLINE

(Gross Negligence)

7. Respondent has subjected his Physician's and Surgeon's Certificate No. G 70647 to disciplinary action under sections 2227 and 2234, as defined by 2234, subdivision (b), of the Code, in that he committed gross negligence in his care and treatment of patients A, B, and C,[1] as more particularly alleged hereinafter:

Patient A

8. On or about October 10, 2013,[2] patient A, a then 59-year old female, presented for pain management for chronic pain in her face, lower back and knees. Respondent performed a physical examination of patient A and assessed her with, among other things, osteoarthritis, knee pain, degeneration disc disease, and spinal stenosis. Records for this visit indicate patient A reported a history of chronic opioid dependence but wished to be weaned off opioids. Records for this visit indicate patient A signed a Pain Management Program Participation Agreement and

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[1] Patients' true names are not used in the instant Accusation to maintain patient confidentiality. The patients' identities are known to Respondent or will be disclosed to Respondent upon receipt of a duly issued request for discovery and in accordance with Government Code section 11507.6.

[2] Any medical care or treatment rendered by Respondent more than seven years prior to the filing of the instant Accusation is described for informational purposes only and not pleaded as a basis for disciplinary action.

Consent form and indicated her current medications included, among other things, OxyContin[3] (40 mg, three times per day); oxycodone[4] (30 mg, six times per day as needed); Soma[5] (350 mg), Dilaudid[6] (4 mg), Klonopin[7] (two times per day) and Xanax[8] (as needed). Patient A also reported using medicinal marijuana. Records for this visit indicate Respondent issued prescriptions to patient A for 60 tablets of MS Contin[9] (60 mg, two times per day), 180 tablets of oxycodone (30 mg, every 6 hours as needed), and 90 tablets of Soma (350 mg, three times per day). Respondent did not request a urine sample from patient A for a urine drug screen (UDS) at this visit.

9. Beginning from on or about November 4, 2013 through on or about July 29, 2015, patient A presented for monthly office visits for medication refills. During these visits, patient A

[3] OxyContin is a brand name for oxycodone, a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b), and a dangerous drug pursuant to Business and Professions Code section 4022. When properly prescribed and indicated, it is used for the treatment of moderate to moderately severe pain. The Drug Enforcement Administration (DEA) has identified opioids, such as Oxycodone, as a drug of abuse. (Drugs of Abuse, DEA Resource Guide (2015 Edition), at p. 43.)

[4] Oxycodone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b), and a dangerous drug pursuant to Business and Professions Code section 4022. When properly prescribed and indicated, it is used for the treatment of moderate to moderately severe pain. The Drug Enforcement Administration (DEA) has identified opioids, such as Oxycodone, as a drug of abuse. (Drugs of Abuse, DEA Resource Guide (2015 Edition), at p. 43.)

[5] Soma is a brand name for Carisoprodol, a Schedule IV controlled substance pursuant to 21 C.F.R. § 1308.14, and a dangerous drug pursuant to Business and Professions Code section 4022. When properly prescribed and indicated, it is used as a muscle relaxant. According to the DEA, Office of Diversion Control, published comment on Carisoprodol, dated March 2014, "[c]arisoprodol abuse has escalated in the last decade in the United States...According to Diversion Drug Trends, published by the Drug Enforcement Administration (DEA) on the trends in diversion of controlled and non-controlled pharmaceuticals, carisoprodol continues to be one of the most commonly diverted drugs."

[6] Dilaudid is a brand name for hydromorphone, a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b), and a dangerous drug pursuant to Business and Professions Code section 4022.

[7] Klonopin is a brand name for clonazepam, a Schedule IV controlled substance pursuant to Health and Safety Code section 11057, subdivision (d), and a dangerous drug pursuant to Business and Professions Code section 4022. It is an anti-anxiety medication in the benzodiazepine family.

[8] Xanax is a brand name for alprazolam, a Schedule IV controlled substance pursuant to Health and Safety Code section 11057, subdivision (d), and a dangerous drug pursuant to Business and Professions Code section 4022. Alprazolam is a short-acting benzodiazepine. When properly prescribed and indicated, it is commonly used to relieve anxiety.

[9] MS Contin is a brand name for morphine, a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b), and a dangerous drug pursuant to Business and Professions Code section 4022.

was seen either by Respondent or a physician assistant under Respondent's supervision. Records for these visits indicate patient A's medications were refilled on a monthly basis without any change in dosage or frequency.

10. Beginning from on or about October 10, 2013 through on or about August 7, 2015, the California Controlled Substance Utilization Review and Evaluation System (CURES) database[10] lists regular monthly prescriptions for MS Contin, oxycodone, and Soma, as having been issued by either Respondent or a physician assistant under Respondent's supervision and filled to patient A.

11. Throughout the course of Respondent's care and treatment of patient A, Respondent failed to review the CURES database for controlled substance prescriptions listed for patient A.

12. Beginning from on or about October 10, 2013 through on or about August 7, 2015, Respondent's records for patient A indicate approximately five urine drug screens were requested and obtained, on dates including, but not limited to, December 2, 2013, March 20, 2014, April 17, 2014, January 15, 2015, and July 1, 2015. Results for these urine drugs screens revealed numerous inconsistent[11] results, including, but not limited to, positive results for marijuana and benzodiazepines and negative results for opiates and morphine. However, Respondent's records for patient A do not document any discussion with patient A regarding these inconsistencies, nor do they reflect any change in medications prescribed to patient A.

13. Beginning from on or about October 10, 2013 through on or about August 7, 2015, Respondent's records for patient A indicate patient A reported experiencing various adverse effects, including but not limited to, severe abdominal pain, nausea, vomiting, headaches, irritable

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[10] The Controlled Substance Utilization Review and Evaluation System (CURES) is a program operated by the California Department of Justice (DOJ) to assist health care practitioners in their efforts to ensure appropriate prescribing of controlled substances, and law enforcement and regulatory agencies in their efforts to control diversion and abuse of controlled substances. (Health & Saf. Code, § 11165.) California law requires dispensing pharmacies to report to the DOJ the dispensing of Schedule II, III, and IV controlled substances as soon as reasonably possible after the prescriptions are filled. (Health & Saf. Code, § 11165, subd. (d).) It is important to note that the history of controlled substances dispensed to a specific patient based on the data contained in CURES is available to a health care practitioner who is treating that patient. (Health & Saf. Code, § 11165.1, subd. (a).)

[11] Urine Drug Screen results are considered "inconsistent" when either prescribed medications are not detected (negative) or non-prescribed medications are detected (positive).

bowel syndrome and fecal impaction. However, Respondent's records for patient A do not document any discussion with patient A to address these side effects nor do they reflect any change in medications prescribed to patient A.

14. On multiple occasions throughout the course of Respondent's care and treatment of patient A, Respondent's records for patient A contained content that failed to adequately or accurately describe observations, discussions, or conduct occurring on the date indicated, but rather was generated by default by the medical record keeping system or was copied forward from prior visit notes.

15. Throughout the course of Respondent's care and treatment of patient A, records for patient A indicate review and approval of numerous visit notes was not conducted by Respondent until several months after each visit.

16. Respondent committed gross negligence in his care and treatment of patient A, including, but not limited to:

(a) Prescribing a combination of high dose opioids and Soma to patient A;

(b) Failing to adequately modify patient A's controlled substance regimen;

(c) Failing to review patient A's CURES report;

(d) Failing to obtain more frequent urine drug screens; and

(e) Failing to adequately maintain timely medical records for patient A.

Patient B

17. On or about July 8, 2014, patient B, a then 50-year old male, presented for pain management for chronic pain due in his lower back and neck. Respondent performed a physical examination of patient B and assessed him with, among other things, lower back pain and degeneration of lumbar discs. Records for this visit indicate patient B reported a history of drug addiction and occasional use of marijuana for pain relief. Records for this visit indicate patient B signed a Pain Management Program Participation Agreement and Consent form and indicated his

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current medications included, among other things, Percocet[12] (10/325, four times per day) and Soma (350 mg, three times per day). Records for this visit indicate Respondent issued prescriptions to patient B for 60 tablets of MS Contin (15 mg, two times per day), 180 tablets of Percocet (10/325, up to six times per day as needed), and 90 tablets of Soma (350 mg, three times per day). Respondent requested patient B provide a urine sample for a UDS.

18. Beginning from on or about August 5, 2014 through on or about May 29, 2015, patient B presented for monthly office visits for medication refills. During these visits, patient B was seen either by Respondent or a physician assistant under Respondent's supervision. Records for these visits indicate patient B's medications were refilled on a monthly basis with minimal changes.

19. On or about October 28, 2014, patient B reportedly tripped and fell on his back causing him to experience increased pain. Records for this visit indicate Respondent's physician assistant began issuing Naproxen[13] to patient B in addition to his other pain medications, which then continued for the remainder of his care.

20. On or about December 19, 2014, patient B reportedly fell off his bike and fractured his ribs. Records for this visit indicate Respondent's physician assistant increased patient B's prescription for MS Contin from 15 mg two times per day, to 15 mg three times per day, which then continued for the remainder of his care.

21. On or about January 20, 2015, patient B presented for medication refills. Records for this visit indicate Respondent's physician assistant issued a prescription to patient B for Amitriptyline without documenting any rationale for this prescription, which also continued for the remainder of his care.

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[12] Percocet is a brand name for oxycodone and acetaminophen combination (10 mg oxycodone, 325 mg acetaminophen). Oxycodone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b), and a dangerous drug pursuant to Business and Professions Code section 4022.

[13] Naproxen is a nonsteroidal anti-inflammatory drug (NSAID) commonly used to treat fevers and pain. It is considered a dangerous drug pursuant to Business and Professions Code section 4022.

22. On or about February 17, 2015, patient B presented for medication refills. Records for this visit indicate patient B requested to switch his prescription for Percocet for oxycodone. Records for this visit indicate Respondent's physician assistant issued a refill for patient B's previous medications and replaced patient B's Percocet prescription with 180 tablets of oxycodone (10 mg, every 6 hours as needed).

23. On or about April 21, 2015, patient B presented for medication refills. Records for this visit indicate patient B requested to switch back from oxycodone to Percocet. Records for this visit indicate Respondent's physician assistant issued a refill for patient B's previous medications and replaced patient B's oxycodone prescription with a prescription for Percocet, which continued for the remainder of his care.

24. Beginning from on or about July 8, 2014 through on or about June 17, 2015, the CURES database lists recurring monthly prescriptions for MS Contin, Percocet, oxycodone, and Soma, as having been issued by either Respondent or a physician assistant under Respondent's supervision and filled to patient B.

25. Throughout the course of Respondent's care and treatment of patient B, Respondent failed to review the CURES database for controlled substance prescriptions listed for patient B.

26. Beginning from on or about July 8, 2014 through on or about June 17, 2015, Respondent's records for patient B indicate approximately three urine drug screens were requested and obtained, on dates including, but not limited to, July 8, 2014, April 21, 2015, and May 19, 2015. Results for these urine drug screens revealed numerous inconsistent results, including, but not limited to, positive results for marijuana on all three tests, and negative results for oxycodone on April 21, 2015. However, Respondent's records for patient B do not document any discussion with patient B regarding these inconsistencies until May 29, 2015, when patient B was discharged as a patient.

27. Beginning from on or about July 8, 2014 through on or about June 17, 2015, Respondent's records for patient B indicate patient B reported a history of substance abuse, continued use of marijuana, and past use of methamphetamine, most recently within 18 months. Records also indicate patient B reportedly smelled of alcohol and displayed slurred speech during

an office visit on May 19, 2015. However, Respondent's records for patient B do not document any increase in UDS testing or any change in medications prescribed to patient B.

28. On multiple occasions throughout the course of Respondent's care and treatment of patient B, Respondent's records for patient B contained content that failed to adequately or accurately describe observations, discussions, or conduct occurring on the date indicated, but rather was generated by default by the medical record keeping system or was copied forward from prior visit notes.

29. Throughout the course of Respondent's care and treatment of patient B, records for patient B indicate review and approval of numerous visit notes was not conducted by Respondent until several months after each visit.

30. Respondent committed gross negligence in his care and treatment of patient B, including, but not limited to:

(a) Prescribing a combination of high dose opioids and Soma to patient B;

(b) Failing to adequately modify patient B's controlled substance regimen;

(c) Failing to review patient B's CURES report;

(d) Failing to obtain more frequent urine drug screens; and

(e) Failing to adequately maintain timely medical records for patient B.

Patient C

31. On or about August 26, 2014, patient C, a then 50-year old female, presented for pain management for chronic back pain, chronic pain in her left foot, and numbness in her lower left extremities. Respondent performed a physical examination of patient C and assessed her with, among other things, degeneration of lumbar discs and plantar fasciitis. Records for this visit indicate patient C signed a Pain Management Program Participation Agreement and Consent form and indicated her current medications included, among other things, morphine sulfate (15 mg, four times per day), morphine sulfate IR (MSIR)[14] (30 mg, six times per day) and Amitriptyline

[14] MSIR (Morphine Sulfate Immediate Release) is the immediate release version of morphine. Morphine is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b), and a dangerous drug pursuant to Business and Professions Code section 4022.

(50 mg). Records for this visit indicate Respondent issued prescriptions to patient C for 60 tablets of MS Contin Extended Release (15 mg, two per day) and 180 capsules of MSIR (30 mg, every 4 to 6 hours as needed, maximum six per day). Respondent did not request a urine sample from patient C for a UDS at this visit.

32. Beginning from on or about September 23, 2014 through on or about October 11, 2017, patient C presented for monthly office visits for medication refills. During these visits, patient C was seen either by Respondent or a physician assistant under Respondent's supervision. Records for these visits indicate patient C's medications were refilled on a monthly basis without any change in dosage or frequency, except on two occasions.

33. On or about January 18, 2017, patient C presented for medication refills. Records for this visit indicate Respondent's physician assistant issued a prescription to patient C for 160 capsules of MSIR (30 mg) and encouraged patient C to lower her opioid regimen. However, at patient C's next visit, her prescription for MSIR returned to 180 capsules (30 mg).

34. On or about September 11, 2017, patient C presented for medication refills. Records for this visit indicate Respondent's physician assistant issued a prescription to patient C for 120 capsules of MSIR (30 mg) and 35 tablets of MS Contin (15 mg). This reduced prescription was again issued on or about October 11, 2017 to patient C, her final visit with Respondent and his physician assistants.

35. Beginning from on or about August 31, 2014 through on or about October 11, 2017, the CURES database lists recurring monthly prescriptions for morphine (MS Contin 15 mg and MSIR 30 mg) as having been issued by either Respondent or a physician assistant under Respondent's supervision and filled to patient C.

36. Throughout the course of Respondent's care and treatment of patient C, Respondent failed to review the CURES database for controlled substance prescriptions listed for patient C.

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37. Throughout Respondent's care and treatment of patient C, Respondent's prescribing regimen for patient C maintained patient C at a daily morphine equivalent dose (MED)[15] of 210 mg of morphine per day.

38. On multiple occasions throughout the course of Respondent's care and treatment of patient C, Respondent's records for patient C contained content that failed to adequately or accurately describe observations, discussions, or conduct occurring on the date indicated, but rather was generated by default by the medical record keeping system or was copied forward from prior visit notes.

39. Throughout the course of Respondent's care and treatment of patient C, records for patient C indicate review and approval of numerous visit notes was not conducted by Respondent until several months after each visit.

40. Respondent committed gross negligence in his care and treatment of patient C, including, but not limited to:

(a) Failing to adequately modify patient C's controlled substance regimen;

(b) Failing to review patient C's CURES report; and

(c) Failing to adequately maintain timely medical records for patient C.

SECOND CAUSE FOR DISCIPLINE

(Repeated Negligent Acts)

41. Respondent has further subjected his Physician's and Surgeon's Certificate No. G 70647 to disciplinary action under sections 2227 and 2234, as defined by section 2234, subdivision (c), of the Code, in that he committed repeated negligent acts in his care and treatment of patients A, B, and C, as more particularly alleged hereinafter:

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[15] Morphine Equivalent Dose (MED), also commonly referred to as Morphine Milligram Equivalent (MME), is used to equate different opioids into one standard value, based on morphine and its potency, referred to as MED or MME. MED/MME calculations permit all opioids to be converted to an equivalent of one medication, for ease of comparison and risk evaluations. In general, the standard of practice is to limit a patient's opioid dose to less than 50 MED/MME in most patients receiving opioid treatment for chronic pain, and to exceed 90 MED/MME in only the most unusual circumstances.

42. Respondent committed negligence in his care and treatment of patient A, including, but not limited to:

(a) Paragraphs 8 through 16, above, are hereby incorporated by reference and realleged as if fully set forth herein;

(b) Failing to obtain adequate consultations for complex pain issues;

(c) Failing to adequately document a detailed physical examination of all areas of patient A's pain complaints; and

(d) Failing to adequately document treatment objectives of continued opioid therapy.

43. Respondent committed negligence in his care and treatment of patient B, including, but not limited to:

(a) Paragraphs 17 through 30, above, are hereby incorporated by reference and realleged as if fully set forth herein;

(b) Failing to obtain adequate consultations for complex pain issues;

(c) Failing to adequately document a detailed physical examination of all areas of patient B's pain complaints; and

(d) Failing to adequately document treatment objectives of continued opioid therapy.

44. Respondent committed negligence in his care and treatment of patient C, including, but not limited to:

(a) Paragraphs 31 through 40, above, are hereby incorporated by reference and realleged as if fully set forth herein;

(b) Failing to obtain adequate consultations for complex pain issues;

(c) Failing to adequately document a detailed physical examination of all areas of patient C's pain complaints; and

(d) Failing to adequately document treatment objectives of continued opioid therapy.

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THIRD CAUSE FOR DISCIPLINE

(Violations of Provisions of the Medical Practice Act)

45. Respondent has further subjected his Physician's and Surgeon's Certificate No. G 70647 to disciplinary action under sections 2227 and 2234, as defined by section 2234, subdivision (a), of the Code in that he violated or attempted to violate, directly or indirectly, any provision of the Medical Practice Act as more particularly alleged in paragraphs 7 to 44, above, which are hereby incorporated by reference and realleged as if fully set forth herein.

DISCIPLINARY CONSIDERATIONS

46. To determine the degree of discipline, if any, to be imposed on Respondent Kevin Sanford Smith, M.D., Complainant alleges that on or about July 25, 2013, in a prior investigation of Kevin Sanford Smith, M.D., by the Medical Board of California in Case No. 10-2011-213184, Respondent's license was publicly reprimanded for repeated negligent acts, in violation of section 2234, subdivision (c), of the Code. That decision is now final and is incorporated by reference as if fully set forth herein.

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PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Medical Board of California issue a decision:

1. Revoking or suspending Physician's and Surgeon's Certificate No. G 70647, issued to Respondent Kevin Sanford Smith, M.D.;

2. Revoking, suspending or denying approval of Respondent Kevin Sanford Smith, M.D.'s authority to supervise physician assistants and advanced practice nurses;

3. Ordering Respondent Kevin Sanford Smith, M.D., if placed on probation, to pay the Board the costs of probation monitoring;

4. Ordering Respondent Kevin Sanford Smith, M.D., if placed on probation, to disclose the disciplinary order to patients pursuant to section 2228.1 of the Code; and

5. Taking such other and further action as deemed necessary and proper.

DATED: August 15, 2019

KIMBERLY KIRCHMEYER
Executive Director
Medical Board of California
Department of Consumer Affairs
State of California
Complainant

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