MODEL EXPERT OPINION #6

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Date

Investigator/Medical Consultant (requesting review)
Medical Board of California
Street
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Re: Ada B. Smith, M.D.
Case: 10-2008-XXXXXX
Patient:

MATERIALS REVIEWED:

1. Senior Investigator's report.
2. Memorandum dated 4-1-08 from District Medical Consultant.
3. Department of Justice Bureau of Narcotic Enforcement Controlled Substance Utilization Review and Evaluation System (CURES) report of controlled substances prescribed by subject physician Smith from 2002 through 2007.
4. Anonymous source complaint dated 12-30-06 and subsequently identified as R. Roberts, the office manager for subject physician Smith.
5. Medical records on Glen Iris from the office of Dr. Smith.
6. Medical records on Bob Cone from the office of Dr. Smith.
7. Medical records on Lilly Kamp from the office of Dr. Smith.
8. Curriculum vitae from Dr. Smith.
9. Two audio cassette tapes from the physician interview of Dr. Smith by the District Medical Consultant and Senior Investigator on 1-5-08.
10. Business & Professions Code Section 2190.5
11. Business & Professions Code Section 2241.5
12. Health & Safety Code Section 11159.2
13. Health & Safety Code Section 124961 (Pain Patient's Bill of Rights)
14. Guidelines for Prescribing Controlled Substances for Pain (2003)

SUMMARY OF CASES:

The Medical Board of California received a letter dated 12-30-06 from an anonymous source who turned out to be the office manager for Dr. Smith. It was alleged Dr. Smith was negligent in treatment of many patients coming into her office on a monthly basis for triplicate medications and that no routine assessments or treatment plans were ever established for pain management or diagnostic testing. It was further alleged that pharmacies frequently phoned the office expressing concerns over the excessive amounts of opiate medications being prescribed by Dr. Smith to various patients. A CURES printout was obtained revealing large quantities of narcotic and other scheduled substances being prescribed over a period of years to a number of patients. Three of those patients' medical records were secured for further review with a subsequent physician interview of Dr. Smith regarding care rendered to those patients.

Patient #1: Glen Iris

- **Summary of Case:**

  Patient Iris was first seen on 1-3-03 and last seen on 11-8-07. There are over 50 office visits and a total of 24 pages in the certified copy of records. The patient routinely received prescriptions for 5 mg. Percocet starting at 200 tablets a month and then increasing to 400 tablets a month in June of 2003 and then to 600 tablets a month by July of 2006. The patient was being treated for cervical spine disease. Review of the medical records reveals at a typical visit there was one and sometimes two lines of a brief handwritten note. No physical examinations are recorded in the chart record except for the initial history and physical. No informed consents are found in the chart record. No treatment plans are noted. There is mention of a referral to a pain clinic but that never occurred according to the physician interview. There was reference to obtaining a diagnostic study of the C spine but there is no documentation in the medical records of any x-rays, CT or MRI scan of the cervical spine being obtained. The physician interview confirms that no diagnostic studies were performed.

- **Medical Issue:**

1. **Did Dr. Smith comply with the standard of care for prescribing controlled substances to patient Glen Iris who had chronic cervical neck pain?**

- **Standard of Care:**

The Medical Board of California Action Report in October of 2003 provided guidelines for prescribing controlled substances for chronic pain conditions. Those guidelines are fully consistent with the standard of care in the community as outlined below:

⇛ **Medical History and Physical Examination**

The standard of care requires a medical history and physical exam which includes an assessment of the patient's pain, including physical and psychological status and function; substance abuse history; history of prior pain treatments and assessment of any other underlying or co-existing conditions. Finally, it should include documentation of recognized medical indications for the use of controlled substances such as opiates for pain control.

- **Analysis:**

A history and physical was documented and although it fails to mention the previous substance abuse history it is otherwise thorough and complete and details prior pain treatment and management of co-morbid conditions.

- **Conclusion:**

There was no departure from the standard of care in performing an initial history and physical examination although it would have been of value to note the past history of substance abuse in that medical record.

⇛ **Treatment Plan and Objectives**

The standard of care requires the medical records contain stated objectives that may include relief of pain or improved physical or psychological function or ability to perform certain tasks or activities of daily living. This should also include any plans for further diagnostic evaluations and treatments, such as rehabilitation program.

- **Analysis:**

  Dr. Smith failed to repeatedly record a treatment plan or describe in subsequent notes the objectives of treatment over a period of five years.

- **Conclusion:**

  There were repeated simple departures from the standard of care in Dr. Smith's failure to develop and record a treatment plan or to ever pursue any further diagnostic evaluations or treatment for this patient such as rehab. Attempts to obtain previous treatments records or any previous diagnostic studies are not demonstrated.

⇛ **Informed Consent**

The standard of care requires the medical records document that the physician discussed risks and benefits of the use of controlled substances along with other treatment modalities. An actual written consent is not required but is recommended.

- **Analysis:**

  Dr. Smith alleges that in fact he did discuss with patient Iris the risks and benefits of use of opiate medications. However, there are no written consent forms in the chart record.

- **Conclusion:**

  There was no departure from the standard of care for failure to obtain an informed consent on a written basis since this is neither required by the Medical Board guidelines for prescribing controlled substances and the standard of care in the community varies with most obtaining written consent forms but some only obtaining verbal consent. It would have been of extreme value for Dr. Smith to have recorded the verbal discussions as documentation in the medical record.

⇛ **Periodic Preview**

The standard of care requires the medical records reflect that the physician is periodically reviewing the course of pain treatment for the patient and making appropriate modifications in treatment based on the patient's progress or lack of progress.

■ **Analysis:**

Review of the 26 pages of medical records on patient Iris fails to demonstrate that Dr. Smith ever performed a periodic review on the patient's pain treatment despite the fact that the amount of Percocet dosing doubled and doubled again over five years.

■ **Conclusion:**

There were multiple simple departures from the standard of care over a number of years for failure to perform periodic reviews of the patient's pain, treatment and status, especially in the face of doubling and further substantially increasing Percocet dosing.

⇛ **Consultation**

The standard of care requires the physician consider obtaining additional evaluations and consultations, especially with complex pain problems. Special attention should be given to patients who are at risk for misusing their medications or have a history of drug addiction/substance abuse. The above patients require extra care and monitoring along with documentation and consultation with an addiction medicine specialist and pain management specialist.

■ **Analysis:**

Although Dr. Smith alleges that she attempted to get a pain management consultation one never occurred. Dr. Smith claims that this was due to the patient's lack of compliance and that she urged the patient to seek out pain consultation. Medical records and the physician interview documented at least two attempts to obtain consultation.

- **Conclusion:**

  There was no departure from the standard of care for failure to obtain a consultation in this patient since there is a notation in the medical record on two occasions that such attempts were made.

⇛ **Maintenance of Medical Records**

The standard of care requires the physician must maintain accurate and complete records, demonstrating a history and exam along with evaluations and consultations, treatment plans and objectives, informed consent, medications prescribed and periodic review documentation.

- **Analysis:**

  The medical records for visits are typically one or two lines in length and are fundamentally illegible and primarily record a renewed prescription for Percocet with the doctor's initials.

- **Conclusion:**

  There were multiple simple departures from the standard of care in the maintenance of medical records which are nearly illegible and quite cursory and failed to document standard guidelines in the use of controlled substances for patients with chronic pain conditions.

♦ **Overall Conclusion:**

Taken all together the management of patient Glen Iris's chronic pain conditions with opiate medications represents an extreme departure from the standard of care as outlined above.

Patient #2: Bob Cone

♦ **Summary of Case:**

This was a 52 year-old male first seen on 4-16-02 and last seen on 5-13-08. There are a total of 34 clinic visits in that time frame. The patient was essentially seen for low back pain

radiating into the legs, with a past history of a lumbar laminectomy. On the initial history and physical by Dr. Smith she concluded that the patient might have arachnoiditis and she began prescribing four tablets of Tylenol #4 a day. The patient then requested Doridan with Tylenol #4 which was prescribed. Dr. Smith also maintained dosing of Tylenol #4 along with prescriptions for 4 mg Dilaudid at 4-5 tablets a day. In addition, 10 mg Valium was prescribed to the patient at 100 tablets a month. By 2004 the patient was on 300 tablets of 10 mg. Methadone a day along with Tylenol #4's, the Valium and some Dilaudid. There is no evidence that any diagnostic studies or referrals for consultation were made for this patient. The patient had a history of heroin addiction.

♦ **Medical Issue:**

1. **Did Dr. Smith comply with the standard of care for prescribing controlled substances to patient Bob Cone?**

■ **Standard of Care:**

The Medical Board of California Action Report in October of 2003 provided guidelines for prescribing controlled substances for chronic pain conditions. Those guidelines are fully consistent with the standard of care in the community as outlined below:

⇛ **Medical History and Physical Examination**

The standard of care requires a medical history and physical exam which includes an assessment of the patient's pain, including physical and psychological status and function; substance abuse history; history of prior pain treatments and assessment of any other underlying or co-existing conditions. Finally, it should include documentation of recognized medical indications for the use of controlled substances, such as opiates for pain control.

■ **Analysis:**

Dr. Smith did record a history and physical examination with a past history of substance abuse noted for this patient. There was a limited assessment of other underlying and co-existing conditions and no reference to prior treatments or treating physicians.

- **Conclusion:**

There was a simple departure from the standard of care for failing to fully document a comprehensive history and physical examination which should have included previous treatments and treating physicians and details regarding co-existing conditions including the history of heroin addiction and past management.

⇛ **Treatment plan and Objectives**

The standard of care requires the medical record contain stated objectives that may include relief of pain or improved physical or psychological function or abilities to perform certain tasks or activities of daily living. This should also include plans for further diagnostic evaluations and treatments.

- **Analysis:**

Nowhere in review of the six years of medical records was a treatment plan ever outlined or objectives stated. Dr. Smith stated in the physician interview that he was just helping the patient live day by day.

- **Conclusion:**

There were repeated simple departures from the standard of care for failure to document a treatment plan or objectives of treatment, over a period of greater than six years.

⇛ **Informed consent**

The standard of care requires the medical records document that the physician discussed risks and benefits of the use of controlled substances along with other treatment modalities. An actual written consent is not required but is recommended. However, in a patient with a past history of opiate addiction it is incumbent of the physician to document and/or record consent discussions including risks and benefits of opioid treatment.

- **Analysis:**

Dr. Smith alleges that he gave verbal consent to this patient and all of his patients. Dr. Smith acknowledged that he never had any written contracts or written consents

placed in the chart records.

- **Conclusion:**

In this instance there was a simple departure from the standard of care when Dr. Smith failed to document into the chart record that he had verbal discussions with this patient regarding the chronic use of opiates. This was of particular importance because this patient was a known addict and the potential for misuse and abuse of opiates was high.

⇛ **Period Review**

The standard of care requires the medical record reflect the physician is periodically reviewing the course of pain treatment for the patient and making appropriate modifications of treatment based on the patient's progress or lack of progress.

- **Analysis:**

Over more than six years Dr. Smith never recorded that he performed any periodic reviews, nor is there any evidence of assessment regarding the patient's progress towards improvement or resolution of pain. Dr. Smith acknowledged that he was simply trying to have the patient get by on a day by day basis and the patient reported that he was doing well with treatment.

- **Conclusion:**

There are repeated simple departures from the standard of care for failure to record progress or lack of progress in treatment of this patient's chronic pain condition.

⇛ **Consultation**

The standard of care requires the physician consider obtaining additional evaluations and consultations, especially with complex pain problems. Special attention should be given to patients who are at risk for misusing their medications or having a history of drug addiction/substance abuse. The above patients require extra care in monitoring along with documentation and consultation with an addiction medicine specialist and pain management specialist.

- **Analysis:**

When patient Cone came into the office asking for Doridan with Tylenol #4 (known on the street as doors and fours) it was highly suggestive that this was a drug seeking abusing behavior since the medication is known to reproduce sensations of IV heroin use among addicts. Given that this patient was a self-admitted addict it was incumbent upon Dr. Smith to seek out consultations with a pain management specialist and an addiction medicine specialist. There is no evidence that any attempt was made to do so for this patient who clearly needed a very rigid system of care along with routine drug screening. This patient most likely would have benefitted from being placed on long term maintenance Methadone rather than use of various short term opiates prescribed for him.

- **Conclusion:**

There were repeated simple departures from the standard of care on the part of Dr. Smith in failure to provide consultations to an addictionologist and chronic pain management specialist to assist in the management of this patient.

⇛ **Maintenance of Medical Records**

The standard of care requires the physician must maintain accurate and complete records demonstrating a history and exam along with evaluations and consultations, treatment plans and objectives, informed consent, medications prescribed and periodic review documentation.

- **Analysis:**

The medical records maintained for this patient were clearly substandard. The records were mostly illegible and it was necessary that the pages be retyped from the illegible handwritten notes for my review. If another physician needed to suddenly take over the care of this patient the medical records that were written were of zero utility in this very complex patient case.

- **Conclusion:**

Dr. Smith's medical records on patient Cone clearly demonstrates her failure to exercise want of even scant care and represents an extreme departure from the standard of care.

♦ **Overall Conclusion:**

The overall management of this patient's chronic pain condition with opiate medications clearly failed to follow the guidelines set forth by the Medical Board of California in October of 2003 and are also each in the standard of care at least since October 2003. Dr. Smith failed to follow the standards of practice for treatment of a self admitted addict with chronic pain and inappropriately treated with short-acting opiate medications and failed to assess the patient's response to treatment. Taken all together Dr. Smith's management of this patient represents an extreme departure from the standard of care.

<u>Patient #3: Lilly Kamp</u>

♦ **Summary of Case:**

Patient Kamp was a 32 year-old female who suffered from a personality disorder and profound somatization disorder. The patient also suffered from diagnoses of bipolar disorder and anxiety disorders. She was diagnosed with chronic fibromyalgia syndrome and taking long-term Vicodin and Valium for that condition. Dr. Smith first saw the patient on 8-11-03 with a final visit on 9-27-08. There are 18 entries in the clinic record. The record reveals that periodically the patient was homeless and there were intermittent exacerbations of her psychiatric conditions leading to a few hospital admissions by other treating physicians. The patient was primarily maintained on Oxycontin and Fentanyl. There are over 12 occasions where the patient allegedly either threw out her medication, had it stolen, it was lost, or fell into a sink or a toilet. The dosing of Oxycontin and the Fentanyl patch increased every few years for reasons that are not clear from the minimal recordings and the patient's progress notes.

♦ **Medical Issue:**

1. **Did Dr. Smith comply with the standard of care for prescribing controlled substances to patient Lilly Kamp?**

■ **Standard of Care:**

The Medical Board of California Action Report in October of 2003 provided guidelines for prescribing controlled substances for chronic pain conditions. Those guidelines are fully consistent with the standard of care in the community as outlined below:

⇛ **Medical History and Physical Examination**

The standard of care requires a medical history and physical exam which includes an assessment of the patient's pain, including physical and psychological status and function; substance abuse history; history of prior pain treatments and assessment of any other underlying and co-existing conditions. Finally, it should include documentation of recognized medical indications for the use of controlled substances such as opiates for pain control.

■ **Analysis:**

Although Dr. Smith performed a history and physical on this patient, she failed to note the previous psychiatric history and did not attempt to request previous treatment records. The indications for the use of opiates and management of fibromyalgia are not noted nor are previous treatments that were given to the patient recorded.

■ **Conclusion:**

There was a simple departure from the standard of care when Dr. Smith failed to perform an adequate history and physical examination which excluded pertinent portions of the patient's mental health history, previous treatments and diagnostic workups.

⇛ **Treatment Plan and Objectives**

The standard of care requires the medical records contain stated objectives that may include relief of pain or improved physical or psychological function and ability to perform certain tasks or activities of daily living. This should also include any plans for further diagnostic evaluations and treatments, such as a rehabilitation program.

■ **Analysis:**

Although this patient was diagnosed with fibromyalgia there was never any objective documentation regarding the diagnosis or objectives for treatment. There is no mention in the chart record of other treatments that had previously been tried or were being planned. There was no reference to physical therapy, exercise programs or other medical treatment options. There is no documentation if opiate medications were clearly benefitting the patient's fibromyalgia/chronic pain complaints.

- **Conclusion:**

Given that patients with chronic fibromyalgia do not clearly benefit from chronic opiate use, the ongoing prescribing of opiates without setting objectives or a treatment plan represents an extreme departure from the standard of care.

⇛ **Informed Consent**

The standard of care requires the medical record should document that the physician discussed risks and benefits of the use of controlled substances along with other treatment modalities. An actual written consent is not required but is recommended.

- **Analysis:**

Dr. Smith alleges that he did provide a verbal consent to the patient, although there is no documentation in the medical record to substantiate that consent.

- **Conclusion:**

There was a simple departure from the standard of care when Dr. Smith failed to record anywhere in the medical record that he had verbal discussions with the patient regarding the use of long term opiates. This was of critical importance in a patient who clearly suffered from multiple psychological/mental health conditions and had behaviors suggestive of addictive behaviors (more than a dozen occasions where medication was lost, stolen or inaccessible).

⇛ **Periodic Review**

The standard of care requires the medical record reflect that the physician is periodically reviewing the course of pain treatment for the patient and making appropriate modifications in treatment based on the patient's progress or lack of progress.

- **Analysis:**

Review of the medical records fails to demonstrate that Dr. Smith performed periodic assessments of this patient's fibromyalgia. There is no evidence that modification to the plan was based on the patient's progress or lack of progress. Dr. Smith acknowledged in the physician interview that there were many occasions when she simply renewed

prescriptions for the patient over a period of years without any history or exam being obtained.

- **Conclusion:**

There was an extreme departure from the standard of care when Dr. Smith, over a period of five years failed to do periodic reassessments of the patient's fibromyalgia and chronic pain condition and failed to take written histories and physical examinations and to consider ongoing treatment and plans.

⇛ **Consultation**

The standard of care requires the physician consider obtaining additional evaluations and consultations, especially with complex pain problems. Special attention should be given to patients who are at risk for misusing the medications or have a history of drug addiction/substance abuse, or co-morbid serious mental health conditions. Such patients require extra care and monitoring along with documentation and consultation with an addiction medicine specialist, psychiatrist and/or pain management specialist.

- **Analysis:**

There was a failure on Dr. Smith's part to obtain any pain management specialist consultations or addition medicine specialist consultations. Dr. Smith never initiated or requested consults with psychiatrists despite the patient's numerous co-morbid psychiatric conditions. However, the patient was admitted to a psychiatric hospital on at least a few occasions and did have some psychiatric assessment at those times. Nonetheless, there was no coordination of her pain management opiate prescribing with her co-morbid psychiatric conditions.

- **Conclusion:**

There were repeated simple departures from the standard of care over a number of years for failure to obtain consultations from psychiatrists, and pain management specialists in this patient case.

⇛ **Maintenance of Medical Records**

The standard of care requires the physician must maintain accurate and complete records, demonstrating a history and exam along with evaluations and consultations, treatment plans and objectives, informed consent, medications prescribed and periodic review documentation.

■ **Analysis:**

Medical records maintained on this patient are mostly illegible. Dr. Smith read her notations into the record during her physician interview and this demonstrates that there was a failure to document periodic review, informed consent, treatment plans or objectives or any consultations.

■ **Conclusion:**

There was an extreme departure from the standard of care in failure to maintain adequate medical records demonstrating want of even scant care.

♦ **Overall Conclusion:**

Given all of the above, there was an extreme departure from the standard of care on the part of Dr. Smith in the management of this patient's chronic pain condition (fibromyalgia). The extreme departures persisted over a period of many years without evidence of improvement on the part of Dr. Smith.

(Signature) *Carol Nerves, M.D.* (Date) 1/5/09
CAROL B. NERVES, M.D.