### STATE OF FLORIDA BOARD OF MEDICINE

DEPARTMENT OF HEALTH,

Petitioner,

FILED DATE - JUN 1 8 2014
Department of Health

Final Order No. DOH-14-0947-

Deputy Agency Clerk

vs.

DOH CASE NO.: 2012-05273 LICENSE NO.: ME0077300

HAROLD EDWARD SMITH, M.D.,

Respondent.

#### FINAL ORDER

THIS CAUSE came before the BOARD OF MEDICINE (Board) on June 6, 2014, in Tampa, Florida, for the purpose of considering Respondent's offer to voluntarily relinquish his license to practice medicine in the State of Florida. (Attached hereto as Exhibit A.) Said written offer of relinquishment specifically provides that Respondent agrees never again to apply for licensure as a physician in the State of Florida.

Upon consideration of the written offer of voluntary relinquishment, the charges, and the other documents of record, and being otherwise fully advised in the premises,

IT IS HEREBY ORDERED that Respondent's Voluntary
Relinquishment of his license to practice medicine in the State
of Florida is hereby ACCEPTED, and shall constitute discipline
upon Respondent's license.

This Final Order shall take effect upon being filed with the Clerk of the Department of Health.

DONE AND ORDERED this 17th day of 12ne.

BOARD OF MEDICINE

Allison M. Dudley, J.D., Executive Director For Nabil El Sanadi, M.D., Chair

### CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been provided by U.S. Mail to HAROLD EDWARD SMITH, M.D., 4001 SW 13<sup>th</sup> Street, Gainesville, Florida 32608; and 501 N. Orlando Avenue, Suite 313-247, Winter Park, Florida 32789; to Juan A. Ruiz, Esquire, Rissman, Barrett, et al., 201 East Pine Street, 15<sup>th</sup> Floor, Post Office Box 4940, Orlando, Florida 32802-4940; and by interoffice delivery to Doug Sunshine, Department of Health, 4052 Bald Cypress Way, Bin #C-65, Tallahassee, Florida 32399-3253 this day of

**Deputy Agency Clerk** 

# FILED DEPARTMENT OF HEALTH DEPUTY CLERK

# STATE OF FLORIDA DEPARTMENT OF HEALTH

CLERK: Bridget Coates

DEPARTMENT OF HEALTH, Petitioner, MAY 05 2014

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DOH Case No. 2012-05273

Harold	Edward Smith,	M.D.,					
Respondent.							

#### **VOLUNTARY RELINOUISHMENT OF LICENSE**

Respondent, Harold Edward Smith, M.D., license No. ME 77300, hereby voluntarily relinquishes Respondent's license to practice medicine in the State of Florida and states as follows:

- 1. Respondent's purpose in executing this Voluntary Relinquishment is to avoid further administrative action with respect to this cause. Respondent understands that acceptance by the Board of Medicine (hereinafter the Board) of this Voluntary Relinquishment shall be construed as disciplinary action against Respondent's license pursuant to Section 456.072(1)(f), Florida Statutes. As with any disciplinary action, this relinquishment will be reported to the National Practitioner's Data Bank as disciplinary action. Licensing authorities in other states may impose discipline in their jurisdiction based on discipline taken in Florida.
- 2. Respondent agrees to never reapply for licensure as a Medical Doctor in the State of Florida.
- 3. Respondent agrees to voluntarily cease practicing medicine immediately upon executing this Voluntary Relinquishment. Respondent further agrees to refrain from

the practice of Medicine until such time as this Voluntary Relinquishment is presented to the Board and the Board issues a written final order in this matter.

- 4. In order to expedite consideration and resolution of this action by the Board in a public meeting, Respondent, being fully advised of the consequences of so doing, hereby waives the statutory privilege of confidentiality of Section 456.073(10), Florida Statutes, regarding the complaint, the investigative report of the Department of Health, and all other information obtained pursuant to the Department's investigation in the above-styled action. By signing this waiver, Respondent understands that the record and complaint become public record and remain public record and that information is immediately accessible to the public. Section 456.073(10) Florida Statutes.
- 5. Upon the Board's acceptance of this Voluntary Relinquishment, Respondent agrees to waive all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this Voluntary Relinquishment and of the Final Order of the Board incorporating this Voluntary Relinquishment.
- 6. Petitioner and Respondent hereby agree that upon the Board's acceptance of this Voluntary Relinquishment, each party shall bear its own attorney's fees and costs related to the prosecution or defense of this matter.
- 7. Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent in connection with the Board's consideration of this Voluntary Relinquishment. Respondent agrees that consideration of this Voluntary Relinquishment and other related materials by the Board shall not prejudice or preclude the

Board, or any of its members, from further participation, consideration, or resolution of these
proceedings if the terms of this Voluntary Relinquishment are not accepted by the Board.
DATED this 3rd day of May, 2014.
Harold E. Smith, M.D.
STATE OF Florida COUNTY OF Plackage
Before me, personally appeared Harriel Smith, whose identity is known to me or
who produced Florida Novecs 1. Conse (type of identification) and who, under
oath, acknowledges that his signature appears above.
Sworn to and subscribed before me this day of
Andrea Maria Perodi NOTARY PUBLIC STATE OF FLORIDA Commir FF019129 Expires 5/19/2017  NOTARY PUBLIC

My Commission Expires:  $\cos l \cot L \omega / \gamma$ 

DEPARTMENT OF HEALTH
DEPUTY CLERK

# STATE OF FLORIDA DEPARTMENT OF HEALTH

CLERK: Orgen Studies

DATE: APR 2 8 2014

DEPARTMENT OF HEALTH,

PETITIONER,

NO:	2012-05	5273
	NO:	NO: 2012-05

HAROLD EDWARD SMITH, M.D.,

RESPONDENT.

### AMENDED ADMINISTRATIVE COMPLAINT

The Petitioner, Department of Health ("Department"), by and through the undersigned counsel, files this Amended Administrative Complaint before the Board of Medicine ("Board") against the Respondent, Harold Edward Smith, M.D., and in support thereof alleges:

- 1. The Petitioner is the state department charged with regulating the practice of medicine pursuant to Section 20.43, Florida Statutes and Chapters 456 and 458, Florida Statutes.
- 2. At all times material to this Complaint, the Respondent was a licensed physician within the State of Florida, having been issued license number ME 77300.

- 3. The Respondent's address of record is 501 North Orlando Avenue, Suite 313-247, Winter Park, Florida 32789.
- 4. The Respondent is not board certified in any boards recognized by the Board of Medicine.
- 5. At all times relevant to this Amended Administrative Complaint, the Respondent was employed at an inpatient mental health hospital (hospital).
- 6. On or about December 11, 2010, A.T., a 51 year-old woman was voluntarily admitted to the hospital for frequent and severe panic attacks, crying for hours and thoughts of cutting her wrists. A.T. also complained of feeling overwhelmed by chronic pain.
- 7. Patient A.T. had a history of mental illness and for which she had been previously hospitalized several times. In addition, A.T. had chronic pain syndrome.
- 8. When A.T. was admitted, she was taking several medications, including Klonopin 1 mg, taken twice a day.
- 9. Klonopin is the trade name for the drug clonazepam, which is prescribed to treat anxiety. According to Section 893.03(4), Florida Statutes, clonazepam is a Schedule IV controlled substance that has a low

potential for abuse relative to the substances in Schedule III and has a currently accepted medical use in treatment in the United States. Abuse of clonazepam may lead to limited physical or psychological dependence relative to the substances in Schedule III.

- 10. From on or about December 11, 2010, through on or about December 22, 2010, A.T. continued to complain of pain and appeared depressed and withdrawn.
- 11. From on or about December 11, 2010, through on or about December 22, 2010, A.T. appeared to exhibit medication seeking behavior.
- 12. The standard of care for a patient with complicated symptoms such as a mood disorder, chronic pain syndrome and medication seeking behaviors would have been to consult with a specialist in internal medicine or pain management.
- 13. The Respondent did not consult with an internist, a pain management specialist, or a prior treating physician.
- 14. On or about December 13, 2010, the Respondent prescribed Percocet 5/325 and continued the patient's Klonopin 1 mg, taken twice daily.

- 15. Percocet is the brand name of a drug which consists of a combination of oxycodone and acetaminophen. According to Section 893.03(2), Florida Statutes, oxycodone is a Schedule II controlled substance that has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States. Abuse of oxycodone may lead to severe psychological or physical dependence.
- 16. On or about December 14, 2010, the Respondent discontinued the patient's Percocet 5/325. The Respondent started the patient on OxyContin 20 mg to be taken twice daily, and increased her Klonopin 1 mg to three pills a day.
- 17. OxyContin is the trade name for an extended release formulation of oxycodone, an opioid prescribed to treat pain. According to Section 893.03(2), Florida Statutes, oxycodone is a Schedule II controlled substance that has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States. Abuse of oxycodone may lead to severe psychological or physical dependence.

- 18. OxyContin and Klonopin are central nervous system depressants and can have a synergistic effect when prescribed together.
- 19. On or about December 16, 2010, the Respondent increased the patient's OxyContin 20 mg to three times a day, and maintained her Klonopin 1 mg, three times daily.
- 20. On or about December 19, 2010, hospital staff reported that A.T. appeared sedated.
- 21. When A.T. began to appear sedated, the standard of care was to withhold the OxyContin and Klonopin, obtain a toxicology report to check the level of drugs in the patient's blood, and then closely observe the patient. Respiratory support should have been provided as needed.
- 22. The Respondent failed to meet the standard of care by continuing to increase A.T.'s OxyContin and Klonopin despite the patient's appearance of sedation due to medication.
- 23. The Respondent failed to order a toxicology report on the patient, failed to have the patient closely monitored, or provide respiratory support.

- 24. On or about December 20, 2010, the Respondent increased the patient's OxyContin 20 mg, three pills a day, to OxyContin 30 mg taken three times a day and continued A.T.'s Klonopin as previously ordered.
- 25. On or about December 21, 2010, the Respondent noted that the patient was overly sedated and was not participating in treatment.
- 26. On or about December 21, 2010, the Respondent decreased A.T.'s OxyContin to 20 mg to be taken twice a day and reduced her Klonopin to half a milligram mg taken three times a day.
- 27. The prevailing professional standard of care required Respondent to conduct a complete history and physical examination of the patient prior to prescribing oxycodone and clonazepam. The standard of care required Respondent to obtain a consultation from a pain management specialist, internal medicine specialist, or prior treating physician to address the patient's complaints of pain. Additionally, the standard of care required Respondent to discontinue or appropriately adjust the patient's medication after the patient appeared sedated, and order appropriate laboratory testing.
- 28. The Respondent failed to meet the prevailing professional standard of care regarding the treatment of patient A.T. by; failing to

conduct a complete history and physical examination, failing to obtain an appropriate consultation, failing to discontinue or appropriately adjust the patient's medication, failing to order appropriate testing after the patient was noted as sedated, and failing to provide respiratory support as needed.

29. On or about December 22, 2010, A.T. was found on the floor after reportedly falling. Hospital staff put A.T. back into bed and checked on her periodically. Later that morning, she died after being found unresponsive.

## **COUNT ONE (Standard of Care)**

- 30. The Petitioner realleges and incorporates paragraphs one (1) through twenty-nine (29) as if fully set forth in this count.
- 31. Section 458.331(1)(t), Florida Statutes (2010), subjects a licensee to discipline for committing medical malpractice as defined in Section 456.50, Florida Statutes. Section 456.50(1)(g), Florida Statutes (2010), states medical malpractice means the failure to practice medicine in accordance with the level of care, skill, and treatment recognized in general law related to health care licensure.

- 32. The Respondent fell below the standard of care in one or more of the following ways when:
  - a. The Respondent failed to conduct a complete history and physical examination of the patient.
  - b. The Respondent increased the patient's OxyContin despite the patient's apparent sedation.
  - c. The Respondent increased the patient's Klonopin despite the patient's apparent sedation.
  - d. The Respondent failed to discontinue or appropriately adjust the patient's OxyContin and Klonopin, and order appropriate testing after the patient was noted as sedated.
  - e. The Respondent failed to consult with a specialist in internal medicine, a specialist in pain management, or the patient's previous treating physician.
  - f. The Respondent prescribed OxyContin at escalating doses over the course of the patient's hospitalization.
- 33. Based on the foregoing, the Respondent violated Section 458.331(1)(t), Florida Statutes, (2010), by committing medical malpractice and is subject to disciplinary action by the Board of Medicine.

## **COUNT TWO (Inappropriate Prescribing)**

- 34. The Petitioner realleges and incorporates paragraphs one (1) through twenty-nine (29) as if fully set forth in this count.
- 35. Section 458.331(1)(q), Florida Statutes (2010), subjects a licensee to discipline for prescribing, dispensing, administering, mixing, or otherwise preparing a legend drug, including any controlled substance, other than in the course of the physician's professional practice. For the purposes of this paragraph, it shall be legally presumed that prescribing, dispensing, administering, mixing, or otherwise preparing legend drugs, including all controlled substances, inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the physician's professional practice, without regard to his or her intent.
- 36. The Respondent prescribed a controlled substances other than in the course of his professional practice by prescribing a legend drug inappropriately or in excessive or inappropriate quantities in one or more of the following ways:
  - a. The Respondent inappropriately prescribed OxyContin to the patient at escalating doses.

- b. The Respondent inappropriately prescribed OxyContin and Klonopin to the patient after she was noted as sedated.
- 37. Based on the foregoing, the Respondent violated Section 458.331(1)(q), Florida Statutes (2010), by prescribing excessively and inappropriately and is subject to disciplinary action by the Board of Medicine.

WHEREFORE, the Petitioner respectfully requests that the Board enter an order imposing one or more of the following penalties: permanent revocation or suspension of the Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

[signature appears on the following page]

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SIGNED	this	241	day o	f <u> </u>	pri		2014.

John H. Armstrong, MD, FACS, Surgeon General & Secretary

André Ourso

Assistant General Counsel Florida Bar No. 91570 Florida Department of Health Office of the General Counsel 4052 Bald Cypress Way, Bin C-65 Tallahassee, Florida 32399-3265

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Email: Andre.Ourso@flhealth.gov

PCP: June 21, 2013

PCP Members: Dr. Avila, Dr. Averoff, Mr. Dyches

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### **NOTICE OF RIGHTS**

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

# NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition any other discipline imposed.