

STATE OF WASHINGTON DEPARTMENT OF HEALTH Olympia, Washington 98504

RE: Bradford S. Weeks, MD Docket No.: 07-03-A-1080MD Document: Statement of Charges

Regarding your request for information about the above-named practitioner, certain information may have been withheld pursuant to Washington state laws. While those laws require that most records be disclosed on request, they also state that certain information should not be disclosed.

The following information has been withheld:

The identity of the complainant if the person is a consumer, health care provider, or employee, pursuant to RCW 43.70.075 (Identity of Whistleblower Protected) and/or the identity of a patient, pursuant to RCW 70.02.020 (Medical Records - Health Care Information Access and Disclosure)

If you have any questions or need additional information regarding the information that was withheld, please contact:

Customer Service Center P.O. Box 47865 Olympia, WA 98504-7865 Phone: (360) 236-4700 Fax: (360) 586-2171

You may appeal the decision to withhold any information by writing to the Deputy Secretary, Department of Health, P.O. Box 47890, Olympia, WA 98504-7890.

STATE OF WASHINGTON DEPARTMENT OF HEALTH MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of

BRADFORD S. WEEKS, MD Credential No. MD00030856 Docket No. 07-03-A-1080MD



STATEMENT OF CHARGES

Respondent

The Health Services Consultant, on designation by the Medical Quality Assurance Commission (Commission), makes the allegations below, which are supported by the evidence contained in program file numbers 2004-12-0036MD, 2005-03-0080MD, and 2005-07-0054MD. The patients referred to in this Statement of Charges are identified in the attached Confidential Schedule.

1: ALLEGED FACTS

1.1 Respondent was issued a credential to practice as a physician and surgeon by the state of Washington in May 1993. Respondent's credential is currently active.

Xyrem® (sodium oxybate) is a schedule III controlled substance. The 1.2 Federal Food and Drug Administration (FDA) approved Xyrem® for use in people who have narcolepsy who experience episodes of cataplexy, a condition characterized by a sudden loss of muscular control or weakness. Because of serious concerns and adverse events associated with the use of Xyrem®, including death, the FDA has worked with Orphan Medical Inc., the manufacturer, to establish a comprehensive risk-management program. As part of this program, the FDA requires that prescribers and patients will be able to obtain the medication from a single, centralized pharmacy. To obtain Xyrem®, the prescriber must contact the pharmacy, which will provide written materials to the prescriber explaining the risks and proper use of the medication. The prescriber must read the materials and return a form to the pharmacy. On the form, the prescriber must declare that he or she understands that Xyrem® is approved for the treatment of cataplexy in patients with narcolepsy, and that safety or efficacy has not been established for any other indication. The pharmacy then sends educational materials to the patient. Once the pharmacy receives documentation that the patient has read the materials, the pharmacy

sends the medication to the patient. The FDA also requires the prescriber to see the patient no less frequently than every three months and to report all serious adverse events to the manufacturer.

1.3 In 2004 and 2005, Respondent prescribed Xyrem® to Patient A, a 63-year old male. Patient A suffered from a number of conditions, including untreated severe obstructive sleep apnea, a severe psychiatric disorder, and alcohol abuse. Respondent's prescribing of Xyrem® to Patient A was below the standard of care and created a significant risk of harm to Patient A.

1.4 In 2003 and 2004, Respondent prescribed Xyrem® to Patient B, a 40-year old male. Patient B suffered from alcoholism, obesity, insomnia, and excessive daytime sleepiness. Respondent prescribed Xyrem® to Patient B to ease the symptoms of alcohol withdrawal, reduce alcohol dependence, and blunt alcohol cravings. Respondent's prescribing of Xyrem® to Patient B was below the standard of care and created a significant risk of harm to Patient B.

1.5 In 2005, Respondent prescribed Xyrem® to Patient C, a 23-year old male. Patient C suffered from, among other things, chronic and severe insomnia, excessive daytime sleepiness, excessive compulsive disorder, and anxiety. Patient C resides in Utah. Respondent never actually saw or examined Patient C. All of the communication between Respondent and Patient C occurred via e-mail or telephone. Respondent's prescribing of Xyrem® to Patient C was below the standard of care and created a significant risk of harm to Patient C.

1.6 Patients D, E, F, and G all reside outside the state of Washington. Between 2003 and 2005, Respondent prescribed Xyrem® to Patients D, E, F, and G without seeing or physically examining these patients. Respondent's prescribing of Xyrem® to these patients was below the standard of care and created a significant risk of harm to Patients D, E, F, and G.

2: ALLEGED VIOLATIONS

2.1 Based on the facts in Section 1, Respondent has committed unprofessional conduct in violation of RCW 18.130.180(4), which provides in part:

RCW 18.130.180 Unprofessional conduct. The following conduct, acts, or conditions constitute unprofessional conduct for any license holder or applicant under the jurisdiction of this chapter:

(4) Incompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed. The use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed.

2.2 The above violation provides grounds for imposing sanctions under RCW 18.130.160.

3: NOTICE TO RESPONDENT

The charges in this document affect the public health, safety and welfare. The Health Services Consultant of the Commission directs that a notice be issued and served on Respondent as provided by law, giving Respondent the opportunity to defend against these charges. If Respondent fails to defend against these charges, Respondent shall be subject to discipline pursuant to RCW 18.130.180 and the imposition of sanctions under RCW 18.130.160.

DATED: . 2007.

STATE OF WASHINGTON DEPARTMENT OF HEALTH MEDICAL QUALITY ASSURANCE COMMISSION

HEALTH SERVICES CONSULTANT

SUSAN PIERINI, WSBA # 17714

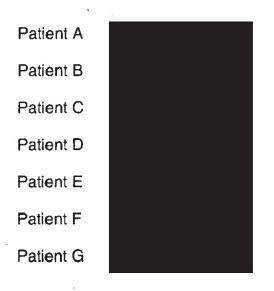
ASSISTANT ATTORNEY GENERAL

FOR INTERNAL USE ONLY:

PROGRAM NO. 2004-12-0036MD, 2005-03-0080MD, & 2005-07-0054MD

CONFIDENTIAL SCHEDULE

This information is confidential and is NOT to be released without the consent of the individual or individuals named herein. RCW 42.56.240(1)





STATE OF WASHINGTON DEPARTMENT OF HEALTH Olympia, Washington 98504

RE: Bradford S. Weeks Master No.: M2007-59091 Docket No.: 07-03-A-1080MD Document: Final Order

Regarding your request for information about the above-named practitioner, certain information may have been withheld pursuant to Washington state laws. While those laws require that most records be disclosed on request, they also state that certain information should not be disclosed.

The following information has been withheld: NONE

If you have any questions or need additional information regarding the information that was withheld, please contact:

Customer Service Center P.O. Box 47865 Olympia, WA 98504-7865 Phone: (360) 236-4700 Fax: (360) 586-2171

You may appeal the decision to withhold any information by writing to the Deputy Secretary, Department of Health, P.O. Box 47890, Olympia, WA 98504-7890.

STATE OF WASHINGTON DEPARTMENT OF HEALTH MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of

BRADFORD S. WEEKS

Credential No. MD00030856

Docket No. 07-03-A-1080MD

STIPULATED FINDINGS OF FACT, CONCLUSIONS OF LAW AND AGREED ORDER

Respondent

The Medical Quality Assurance Commission (Commission), through Michael L. Farrell, Department of Health Staff Attorney, and Respondent, represented by counsel, Kenneth S. Kagan, stipulate and agree to the following:

1. PROCEDURAL STIPULATIONS

1.1 On June 20, 2007, the Commission issued a Statement of Charges against Respondent.

1.2 In the Statement of Charges, the Commission alleges that Respondent violated RCW 18.130.180(4).

1.3 Respondent understands that the State is prepared to proceed to a hearing on the allegations in the Statement of Charges.

1.4 Respondent understands that if the allegations are proven at a hearing, the Commission has the authority to impose sanctions pursuant to RCW 18.130.160.

1.5 Respondent has the right to defend against the allegations in the Statement of Charges by presenting evidence at a hearing.

1.6 Respondent waives the opportunity for a hearing on the Statement of Charges provided that the Commission accepts this Stipulated Findings of Fact, Conclusions of Law and Agreed Order. (Agreed Order)

1.7 The parties agree to resolve this matter by means of this Agreed Order.

1.8 Respondent understands that this Agreed Order is not binding unless and until it is signed and accepted by the Commission.

1.9 If the Commission accepts this Agreed Order, it is subject to the federal reporting requirements pursuant to Section 1128E of the Social Security Act and 45 CFR Part 61, RCW 18.130.110 and any other applicable interstate/national reporting

PAGE 1 OF 7



requirements. It is a public document and will be available on the Department of Health web site.

1.10 If the Commission rejects this Agreed Order, Respondent waives any objection to the participation at hearing of any Commission members who heard the Agreed Order presentation.

2. FINDINGS OF FACT

Without agreeing to any specific allegation, Respondent acknowledges that the evidence is sufficient to justify one or more of the following Findings of Fact:

2.1 Respondent was issued a credential to practice as a physician and surgeon by the state of Washington in May 1993. Respondent's credential is currently active.

2.2 Xyrem® (sodium oxybate) is a schedule III controlled substance. The Federal Food and Drug Administration (FDA) approved Xyrem® for use in people who have narcolepsy who experience episodes of cataplexy, a condition characterized by a sudden loss of muscular control or weakness. Because of serious concerns and adverse events associated with the use of Xyrem®, including death, the FDA has worked with Orphan Medical Inc., the manufacturer, to establish a comprehensive risk-management program. As part of this program, the FDA requires that prescribers and patients will be able to obtain the medication from a single, centralized pharmacy. To obtain Xyrem®, the prescriber must contact the pharmacy, which will provide written materials to the prescriber explaining the risks and proper use of the medication. The prescriber must read the materials and return a form to the pharmacy. On the form, the prescriber must declare that he or she understands that Xyrem® is approved for the treatment of cataplexy in patients with narcolepsy, and that safety or efficacy has not been established for any other indication. The pharmacy then sends educational materials to the patient. Once the pharmacy receives documentation that the patient has read the materials, the pharmacy sends the medication to the patient. The FDA also requires the prescriber to see the patient no less frequently than every three months and to report all serious adverse events to the manufacturer.

2.3 In 2004 and 2005, Respondent prescribed Xyrem® to Patient A, a 63-year old male. Patient A suffered from a number of conditions, including untreated severe obstructive sleep apnea, a severe psychiatric disorder, and alcohol abuse. Respondent's

PAGE 2 OF 7

prescribing of Xyrem® to Patient A was below the standard of care and created a significant risk of harm to Patient A.

2.4 In 2003 and 2004, Respondent prescribed Xyrem® to Patient B, a 40-year old male. Patient B suffered from alcoholism, obesity, insomnia, and excessive daytime sleepiness. Respondent prescribed Xyrem® to Patient B to ease the symptoms of alcohol withdrawal, reduce alcohol dependence, and blunt alcohol cravings. Respondent's prescribing of Xyrem® to Patient B was below the standard of care and created a significant risk of harm to Patient B.

2.5 In 2005, Respondent prescribed Xyrem® to Patient C, a 23-year old male. Patient C suffered from, among other things, chronic and severe insomnia, excessive daytime sleepiness, excessive compulsive disorder, and anxiety. Patient C resides in Utah. Respondent never actually saw or examined Patient C. All of the communication between Respondent and Patient C occurred via e-mail or telephone. Respondent's prescribing of Xyrem® to Patient C was below the standard of care and created a significant risk of harm to Patient C.

2.6 Patients D, E, F, and G all reside outside the state of Washington. Between 2003 and 2005, Respondent prescribed Xyrem® to Patients D, E, F, and G without seeing or physically examining these patients. Respondent's prescribing of Xyrem® to these patients was below the standard of care and created a significant risk of harm to Patients D, E, F, and G.

3. CONCLUSIONS OF LAW

The State and Respondent agree to the entry of the following Conclusions of Law:

3.1 The Commission has jurisdiction over Respondent and over the subject matter of this proceeding.

3.2 Respondent has committed unprofessional conduct in violation of RCW 18.130.180(4) and accepts personal responsibility for his actions.

3.3 The above violations provide grounds for imposing sanctions under RCW 18.130.160.

- 11
- 11

4. AGREED ORDER

Based on the Findings of Fact and Conclusions of Law, Respondent agrees to entry of the following Agreed Order:

4.1 Respondent's license is placed on PROBATION for a period of five (5) years. During the period of probation, Respondent will comply with the following terms and conditions.

4.2 Respondent is prohibited from prescribing or administering Xyrem®.

4.3 Prior to treating or prescribing medication to a patient, Respondent will physically examine and take a history of the patient adequate to establish a diagnoses and to identify underlying conditions and contra-indications to the medication recommended.

4.4 Respondent will attend a two-day ethics course recommended by the Commission Medical Consultant. Respondent will complete the course within six months of the effective date of this Agreed Order unless otherwise allowed in writing by the Commission Medical Consultant. Respondent will provide the course instructors with a copy of this Agreed Order prior to the course. Respondent will sign all necessary waivers to allow the Department staff to communicate with the course instructors as needed. Respondent will submit proof of the satisfactory completion of the course to the Commission. If the course requires Respondent to complete a written report, Respondent will assure that the Commission receives a copy of Respondent's written report. If the course instructors inform the Commission that Respondent did not satisfactorily complete the course, the Commission may require Respondent to re-take the course.

4.5 Respondent shall pay a fine to the Commission in the amount of five thousand dollars (\$5,000.00) which must be received by the Commission within ninety (90) days of the effective date of this Agreed Order. The fine shall be paid by certified or cashier's check or money order, made payable to the Department of Health and mailed to the Department of Health, Medical Quality Assurance Commission, at P.O. Box 1099, Olympia, Washington 98507-1099.

4.6 Respondent will obey all federal, state and local laws and all administrative rules governing the practice of the profession in Washington.

4.7 In order to monitor compliance with the Order Respondent agrees that a representative of the Commission may make announced semi-annual visits to Respondent's practice to inspect office and medical records, and to interview Respondent's employees.

4.8 Respondent will appear before the Commission twelve months from the date this Agreed Order is signed by the Commission, or as soon thereafter as the Commission's schedule permits, and present proof that he is complying with this Order. After the first appearance, Respondent will continue to make compliance appearances every twelve months unless otherwise instructed in writing by the Commission or its representative, until the Commission releases Respondent from the terms and conditions of this Order.

4.9 Respondent is responsible for all costs of complying with this Agreed Order.

4.10 The Commission's jurisdiction over Respondent under this Agreed Order shall continue until Respondent files a written petition for termination of the terms and conditions of this Agreed Order. Respondent may file such a petition no sooner than three years after the effective date of this Agreed Order. When and if Respondent so petitions the Commission, a date shall be arranged to have Respondent appear personally before the Commission and present evidence he is capable of practicing medicine with reasonable skill and safety without the terms and conditions of this Agreed Order. Termination of the terms and conditions of this Agreed Order shall be by written order of the Commission. The Commission has sole discretion whether to grant or deny Respondent's petition for termination of the terms and conditions of this Agreed Order.

4.11 Respondent shall inform the Program and the Adjudicative Service Unit, in writing, of changes in Respondent's residential and/or business address within thirty (30) days of the change.

4.12 The effective date of this Agreed Order is the date the Adjudicative Service Unit places the signed Agreed Order into the U.S. mail. If required, Respondent shall not submit any fees or compliance documents until after the effective date of this Agreed Order.

5. FAILURE TO COMPLY

Protection of the public requires practice under the terms and conditions imposed in this order. Failure to comply with the terms and conditions of this order may result in suspension of the credential after a show cause hearing. If Respondent fails to comply with the terms and conditions of this order, the Commission may hold a hearing to require Respondent to show cause why the credential should not be suspended. Alternatively, the Commission may bring additional charges of unprofessional conduct under RCW 18.130.180(9). In either case, Respondent will be afforded notice and an opportunity for a hearing on the issue of non-compliance.

6. ACCEPTANCE

I, Bradford S. Weeks, MD, Respondent, have read, understand and agree to this Agreed Order. This Agreed Order may be presented to the Commission without my appearance. I understand that I will receive a signed copy if the Commission accepts this Agreed Order.

BRADFORD S. WEEKS, MD RESPONDENT

DATE

KENNETH S. KAGAN, WSBA# ¹ ATTORNEY FOR RESPONDENT

7. ORDER

The Commission accepts and enters this Stipulated Findings of Fact, Conclusions of Law and Agreed Order.

DATED: 08

STATE OF WASHINGTON DEPARTMENT OF HEALTH MEDICAL QUALITY ASSURANCE COMMISSION

PANEL CHAIR

PRESENTED BY:

he

MICHAEL L. FARRELL WSBA# 16022 DEPARTMENT OF HEALTH STAFF ATTORNEY

vary 28,2008 DATE

FOR INTERNAL USE ONLY:

PROGRAM NO. 2004-12-0036MD, 2005-03-0080MD, & 2005-07-0054MD

STIPULATED FINDINGS OF FACT, CONCLUSIONS OF LAW AND AGREED ORDER DOCKET NO. 07-03-A-1080MD



STATE OF WASHINGTON DEPARTMENT OF HEALTH Olympia, Washington 98504

RE: Bradford S. Weeks, MD Master Case No.: M2011-839 Document: Statement of Charges

Regarding your request for information about the above-named practitioner; attached is a true and correct copy of the document on file with the State of Washington, Department of Health, Adjudicative Clerk Office. These records are considered Certified by the Department of Health.

Certain information may have been withheld pursuant to Washington state laws. While those laws require that most records be disclosed on request, they also state that certain information should not be disclosed.

The following information has been withheld:

The identity of the complainant if the person is a consumer, health care provider, or employee, pursuant to RCW 43.70.075 (Identity of Whistleblower Protected) and/or the identity of a patient, pursuant to RCW 70.02.020 (Medical Records - Health Care Information Access and Disclosure)

If you have any questions or need additional information regarding the information that was withheld, please contact:

Customer Service Center P.O. Box 47865 Olympia, WA 98504-7865 Phone: (360) 236-4700 Fax: (360) 586-2171

You may appeal the decision to withhold any information by writing to the Privacy Officer, Department of Health, P.O. Box 47890, Olympia, WA 98504-7890.