New York State Board for Professional Medical Conduct
433 River Street, Suite 303 • Troy, New York 12180-2299 • (518) 402-0863

Public

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Katherine A. Hawkins, M.D., J.D.
Executive Secretary

April 21, 2011

CERTIFIED MAIL-RECEIPT REQUESTED

David N. Smith, M.D.
200 Canal View Boulevard
Suite 102
Rochester, NY 14623

Re: License #128352

Dear Dr. Smith:

Enclosed is a copy of the New York State Board for Professional Medical Conduct (BPMC) Order No. 11-96. This Interim Order for Limitation of Medical Practice is effective April 28, 2011.

Sincerely,

REDACTED

Katherine A. Hawkins, M.D., J.D.
Executive Secretary
Board for Professional Medical Conduct

cc: Richard Tubiolo, Esq.
Hirsch & Tubiolo, P.C.
1000 Reynolds Arcade Building
16 East Main Street
Rochester, NY 14614

NEW YORK STATE DEPARTMENT OF HEALTH
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

IN THE MATTER
OF
DAVID SMITH, M.D.

ORDER FOR
LIMITATION OF
MEDICAL PRACTICE

BPMC No. 11-96

Upon the application and agreement of DAVID SMITH, M.D. for an Order by which DAVID SMITH, M.D. agrees to limit his practice of medicine pending the final disposition of the present Department of Health, Office of Professional Medical Conduct investigation of certain aspects of the medical practice of DAVID SMITH, M.D., which application and agreement is made a part hereof, it is agreed to and

ORDERED, that the application and agreement and the provisions thereof are hereby adopted and so ORDERED, and it is further

ORDERED, that this order shall be effective upon issuance by the Board, which may be accomplished by mailing, by first class mail, a copy of the Consent Order to the attorney of DAVID SMITH, M.D., or upon transmission via facsimile to that attorney, whichever is earliest.

SO ORDERED.

DATED: 4/21/11

REDACTED

KENDRICK A. SEARS, M.D.
Chair
State Board for Professional
Medical Conduct

NEW YORK STATE DEPARTMENT OF HEALTH
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

IN THE MATTER

OF

DAVID SMITH, M.D.

APPLICATION FOR AGREEMENT TO LIMIT MEDICAL PRACTICE/ ORDER OF THE BOARD

STATE OF NEW YORK)
ss.:
COUNTY OF MONROE)

DAVID SMITH, M.D., states:

1. That on or about September 17, 1976, I was licensed to practice as a physician in the State of New York, having been issued License No. 128352 by the New York State Education Department.

2. My current address is 200 Canal View Boulevard, Suite 102, Rochester, New York 14623, and I will advise the Director of the Office of Professional Medical Conduct of any change of my address.

3. I understand that the New York State Board for Professional Medical Conduct is investigating certain aspects of my medical practice to determine if I may have engaged in professional misconduct.

4. I voluntarily make this Application to the State Board for Professional Medical Conduct (the Board) and request that it be granted.

5. I hereby agree to the following :

> I will limit my practice of medicine as set forth in Exhibit A, pending the final disposition of the currently open Department of Health, Office of Professional Medical Conduct investigation. I further agree to abide by such final disposition, without hereby waiving any rights to appeal to which I might otherwise be entitled.

For the purpose of this agreement, "final disposition" shall mean the latest of any of the following: disposition by administrative warning, administrative closure, consent agreement, license surrender, determination of a Hearing Committee of the State Board for Professional Medical Conduct, of the Administrative Review Board of the State Board for Professional Medical Conduct, or any judicial appeal by Licensee of a determination of a Hearing Committee of the State Board for Professional Medical Conduct or the Administrative Review Board of the State Board for Professional Medical Conduct.

6. I hereby stipulate that any failure by me to comply with the above condition imposed by this Order shall constitute misconduct as defined by New York State Education Law §6530(29).

7. I agree not to exercise my hospital privileges at any hospital at which I maintain privileges. I agree not to seek additional privileges at any hospital during the pendency of this agreement.

8. I agree that this agreement may be made public, including notice to the National Practitioners' Data Bank, Federation of State Medical Boards, and posting on the NYS Department of Health's website.

9. I understand that the Department of Health, Office of Professional Medical Conduct shall notify each hospital or facility at which I presently hold privileges, or at which I will be practicing medicine, that I have agreed to limit my practice of medicine as set forth in Exhibit A during the pendency of this agreement.

10. I understand that, in the event that this Application is not granted by the Board, nothing contained herein shall be binding upon me or construed to be an admission of any act of misconduct alleged or charged against me. This Application shall not be used against me in any way in any professional misconduct disciplinary proceeding.

11. I agree that, in the event the Board grants my Application, as set forth herein, an order of the Chairperson of the Board shall be issued in accordance with same. I agree that such order shall be effective upon issuance by the Board, which may be accomplished by mailing, by first class mail, a copy of the Order to my attorney, or upon transmission via facsimile to my attorney, whichever is earliest.

12. I am making this Application of my own free will and accord and not under duress, compulsion or restraint of any kind or manner. In consideration of the value to me of the acceptance by the Board of this Application, I knowingly waive any right I may have to contest the Order for which I hereby apply, whether administratively or judicially, and ask that the Application be granted.

DATED: 4/2/11

REDACTED

DAVID SMITH, M.D.
LICENSEE

The undersigned agree to the attached application of the Licensee based on the terms and conditions thereof.

DATE: 4-2-11

REDACTED

RICHARD TUBIOLO, ESQ.
Hirsch & Tubiolo, P.C.
Attorneys for David Smith, M.D.

DATE: 4/4/11

REDACTED

CINDY M. FASCIA
Associate Counsel
Bureau of Professional
Medical Conduct

DATE: 4/20/11

REDACTED

KEITH SERVIS
Director
Office of Professional
Medical Conduct

EXHIBIT A

1. My practice of medicine shall be limited as follows:

I will not initiate or continue treatment with Tysabri infusion for any patient, whether a new or established patient, without first obtaining consultation with and a written second opinion concurring with said treatment from a Board certified neurologist experienced in the treatment of patients with multiple sclerosis (MS). Said neurologist shall not be a personal friend, family member or employee.

I will not initiate or continue prescribing to and/or treating any patient with the medication Mycophenolate (Cellcept or Myfortic), whether said patient is a new or established patient, without first obtaining consultation with and a written second opinion concurring with said treatment from a Board certified neurologist experienced in the treatment of patients with multiple sclerosis (MS). Said neurologist shall not be a personal friend, family member or employee.

RST 4/2/11 4/2/11 CMP 4/4/11

Within 30 days of the effective date of this Order, I shall transfer the care of all patients who have been receiving Tysabri infusion and/or Mycophenolate (Cellcept or Myfortic) to the care of another physician experienced in the treatment of patients with multiple sclerosis (MS). Within ten days of the transfer of care of said patients, I shall provide to the Director of the Office Of Professional Medical Conduct or his designee a written list of the names of all said patients whose care was transferred, and the name and office address of each physician to whom care of each patient was transferred.

2. During the pendency of this Agreement, I shall submit in writing on a monthly basis to the Director of OPMC or his designee a list of all patients treated by me and the medications which each patient is receiving or prescribed. Said information shall be sent to OPMC within five days of the last day of the month during which the patients were treated.

3. During the pendency of this Agreement, if any patient whom I have treated is:

   a) transferred or transported by ambulance or by private vehicle or by any other means from my office to a hospital on the date of receiving Tysabri infusion or due to complications from or side effects of Tysabri infusion;

   b) presents at an Urgent Care or Emergency Department, and/or is admitted to a hospital, within 72 hours of receiving a Tysabri infusion, for any condition which may reasonably be deemed to be related to Tysabri or its side effects;

   c) expires from any condition which may reasonably be deemed to be related to Tysabri or its side effects;

I shall report or cause to be reported said event, including the patient's name, the date on which the patient was last seen or treated in my office, the name of facility to which the patient was transferred or to which the patient subsequently presented or was admitted. I shall report or cause to be reported said information in writing to the Director of OPMC or his

designee within 48 hours of the occurrence of said event, or within 48 hours of the date when I became aware of said event, whichever is earlier. Said reporting shall be in addition to any reporting requirements pursuant to any other statute or regulation.

PRACTICE MONITOR

4. Within thirty days of this Order's effective date, Respondent shall practice medicine only when monitored by a licensed physician, board certified in an appropriate specialty, ("practice monitor") proposed by Respondent and subject to the written approval of the Director of OPMC. Any medical practice in violation of this term shall constitute the unauthorized practice of medicine.

   a. Respondent shall make available to the monitor any and all records or access to the practice requested by the monitor, including on-site observation. The practice monitor shall visit Respondent's medical practice at each and every location, on a random unannounced basis at least monthly and shall examine a selection (no fewer than 20) of records maintained by Respondent, including patient records, prescribing information and office records. The review will determine whether the Respondent's medical practice is conducted in accordance with the generally accepted standards of professional medical care. Any perceived deviation of accepted standards of medical care or refusal to cooperate with the monitor shall be reported within 24 hours to OPMC.

   b. Respondent shall be solely responsible for all expenses associated with monitoring, including fees, if any, to the monitoring physician.

   c. Respondent shall cause the practice monitor to report quarterly, in writing, to the Director of OPMC.

   d. Respondent shall maintain medical malpractice insurance coverage with limits no less than $2 million per occurrence and $6 million per policy year, in accordance with Section 230(18)(b) of the Public Health Law. Proof of coverage shall be submitted to the Director of OPMC prior to Respondent's practice after the effective date of this Order.

5. Respondent shall maintain a log of all drugs prescribed, administered or dispensed (hereafter "prescribed"), in a form acceptable to OPMC. This log shall include each patient's name, the drug(s) prescribed to the patient, the date each drug was prescribed, and the name, strength, dosage and quantity for each drug prescribed. The log shall be maintained separately from the medical records referred to in paragraph 6 below, and shall be forwarded to OPMC monthly for review. Respondent shall produce the prescribing log for review by OPMC upon the request of the Director or his designee.

6. Respondent shall maintain complete and legible medical records that accurately reflect the evaluation and treatment of patients, including but not limited to any individual for whom Respondent prescribes or has prescribed any drug, and contain all information required by State rules and regulations concerning controlled substances. Respondent shall produce any medical record for review by OPMC upon the request of the Director or his designee.