Michael L. Fanning
Special Assistant Montana Attorney General
Department of Labor and Industry
Office of Legal Services
301 South Park Avenue
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#### BEFORE THE BOARD OF MEDICAL EXAMINERS DEPARTMENT OF LABOR AND INDUSTRY STATE OF MONTANA

In the Matter of the Disciplinary Treatment of the License of

Docket No. CC-10-0352-MED

Complaint No. 2010-051-MED

Patricia Cole, M.D.,

NOTICE OF PROPOSED BOARD ACTION AND OPPORTUNITY FOR HEARING

License No. 11039.

TO:

Patricia Cole, M.D. c/o Mark H. Frisbie, J.D. 410 Central Ave. Ste. 301 Great Falls, MT 59401

#### PLEASE TAKE NOTICE THAT:

On April 23, 2010, the Screening Panel of the Board of Medical Examiners of the State of Montana (Screening Panel) met to review the complaint against Patricia Cole, M.D., in case number 2010-051-MED. The Screening Panel found reasonable cause to believe that Dr. Cole violated Title 37, Chapter 1 and Chapter 3 of Montana Code Annotated and Administrative Rules

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of Montana Title 8, and Chapter 32. Such violations justify disciplinary sanctions. The Board of Medical Examiners (Board) has such authority pursuant to Montana Code Annotated §\$37-1-307 and 37-1-316 and ARM Title 24, Chapter 156.

The Screening Panel has reason to believe Dr. Cole committed the following violations:

**37-1-316.** Unprofessional conduct. The following is unprofessional conduct for a licensee or license applicant governed by this chapter:

\* \* \*

(18) conduct that does not meet the generally accepted standards of practice.

The applicable standards of practice are supplemented in the Montana Medical Marijuana Act, codified at Mont. Code Ann. §50-46-102 *et seq*.

THEREFORE, pursuant to Montana Code Annotated §37-1-307, the Board proposes to impose against Dr. Cole one or more of the sanctions authorized under Montana Code Annotated §37-1-312.

#### REASONS FOR ACTION

There is reasonable cause to believe that the following assertions will be proven and will justify the imposition of sanctions.

#### FACTUAL ASSERTIONS

- 1. Patricia Cole, M.D., is licensed by the Montana Board of Medical Examiners to practice as a physician, holding Montana License number 11039.
  - 2. At its November 20, 2009, meeting, the Board of Medical Examiner's Screening

Panel considered a Board-generated complaint against Dr. Cole. The complaint was based on October 2009 press accounts that reported that Dr. Cole served as the physician at a medical marijuana conference that processed approximately 250 medical marijuana registry applicants over a single fifteen-hour day. In response to the allegations in that complaint, Dr. Cole stated that prior to the conference she devoted ten hours to reviewing patient histories and medical records that were available in virtually all of the cases. Additionally, Dr. Cole stated her patients over a fourteen and one-half hour day numbered 151. The Screening Panel announced that it was concerned *not* with her recommendation of medical marijuana, but with the medical standard of care due each patient. Consequently, the Screening Panel voted to randomly select twenty representative cases for peer review by an independent reviewer.

- 3. The Department's collection of the records for peer review was delayed because Dr. Cole did not maintain the patient's medical records. Those records were under the care and control of the medical marijuana caregiver that sponsored the October 2009 medical marijuana registration conference. The care provider resisted the Department's request for the medical records, but ultimately supplied twenty files which were tendered on February 1, 2010, for peer review.
- 4. An "independent quality of care peer review" was completed on March 11, 2010.

  The questions framed for the peer review were as follows:

The questions presented for the peer reviewer are whether the physician is practicing within the standard of care and whether the peer reviewer finds any violations of the Medical Practice Act. Has this physician met her statutory obligation, defined in §50-46-102[(11)], of completing a full assessment of the patient's medical history and current condition in the course of a bona fide

physician/patient relationship to confirm the patient has a debilitating medical condition and, after a risk/benefit consideration, determined that the patient is eligible for a marijuana registry card? Has this physician complied with the Montana Medical Practice Act and parallel regulation which require each physician's practice to comport with the "generally accepted standards of practice" and avoid any other act that "constitutes unprofessional conduct?" §37-1-316(18), 24.156.625(1)(v). And in the opinion of the peer reviewer, is this physician's practice regarding medical records consistent with the generally accepted standards of care?

- 5. The peer reviewer completed a study of the twenty patients' care based on a graduated scale with a zero indicating "no problem with documentation or quality of care."

  Documentation problems were assessed from D-1 to D-3 and quality of care problems were assessed from Q-1 to Q-4 with higher numbers indicating more serious deficiencies.
- 6. Of the twenty cases, the peer reviewer issued D-3 ratings in seventeen cases: "documentation falls below standard of care with significant omissions." Not all of the twenty appeared at the conference with records permitting a review.
- 7. Of the twenty cases, the peer reviewer issued Q-3 ratings in five cases: "an occurrence in medical/surgical care or process; significant or potentially significant impact on patient morbidity; opportunity for improvement."
- 8. The peer reviewer concluded that Dr. Cole breached her statutory obligation, defined in Mont. Code Ann. §50-46-102(11) of the Montana Medical Marijuana Act, through the following acts or omissions:
  - a. Dr. Cole did not document that she personally took a comprehensive past or present medical history at the time of the visits. There is minimal documentation of patient's symptoms on Dr. Cole's visit records. There is no documented physical examination performed on any patient.

- b. The patients that received signed certifications saw Dr. Cole only once on the same day of certification, and without more, this scenario may not represent a bona-fide doctor-patient relationship, as required for medical marijuana certification.
  - c. Dr. Cole failed to document a medical benefit/risk analysis on any patient.
- d. In five of the reviewed cases, treatment with medical marijuana could have posed a significant or potentially significant impact on patient morbidity.
- 9. The peer reviewer concluded that Dr. Cole breached her statutory obligation, defined in Mont. Code Ann. §37-1-316(18), to comport with "generally accepted standards of practice" through the following acts or omissions:
  - a. Dr. Cole's practice of seeing scores of new patients in one day is below the standard of care particularly given that physicians commonly afford new patients greater time than that allotted for established patients.
  - b. Dr. Cole breached the standard of care by failing to advise patients (or to document that advice) on a new medical marijuana regime regarding usage information including:
    - i) proper dosing; and
    - ii) potential dangerous side effects.
  - c. Dr. Cole breached the standard of care by failing to recommend a follow-up evaluation to assess the effectiveness of the treatment.
    - d. Dr. Cole breached the standard of care regarding her medical records by:
      - i) Maintaining in fourteen cases records release consent forms dated the day of the conference, raising questions concerning whether Dr. Cole was able to preview the records prior to the conference;
      - ii) Failing to keep in her control for a reasonable period medical records for the patients seen at the conference;
      - iii) Allowing the medical marijuana care provider to manage Dr. Cole's patients' records; and

- iv) Failing to maintain in ten of the cases a signed certification documenting the patient's debilitating medical condition despite the fact Dr. Cole concluded the patient was eligible to use medical marijuana.
- 10. Medical marijuana conferences similar to the one peer reviewed here have become commonplace across Montana and Dr. Cole's practice was representative of other physicians' practices in similar settings.
- 11. At the November 20, 2009, Screening Panel, Dr. Cole volunteered to cease seeing patients at medical marijuana conferences during the pendency of this matter. At the April 23, 2010, Dr. Cole reported that she had dissociated from the care provider who sponsored the clinic at issue in this case.
- 12. Dr. Cole's failure to comport with the standard of care amounts to sanctionable unprofessional conduct.
- 13. Based on a finding of reasonable cause to believe a violation has occurred, the Screening Panel at the April 23, 2010, meeting voted to initiate discipline through a contested case action.

#### ASSERTIONS OF LAW

The information contained in the fact assertions herein indicates that Patricia Cole, M.D. has committed unprofessional conduct.

**37-1-316. Unprofessional conduct.** The following is unprofessional conduct for a licensee or license applicant governed by this chapter:

\* \* \*

(18) conduct that does not meet the generally accepted standards of practice.

The applicable standards of practice are supplemented in the Montana Medical Marijuana Act, codified at Mont. Code Ann. §50-46-102 et seq.

#### UNIFORM PROFESSIONAL LICENSING AND REGULATION PROCEDURE

You are advised that the law provides:

### MCA 37-1-309. Notice -- request for hearing.

- (1) If a reasonable cause determination is made pursuant to 37-1-307 that a violation of this part has occurred, a notice must be prepared by department legal staff and served on the alleged violator. The notice may be served by certified mail to the current address on file with the board or by other means authorized by the Montana Rules of Civil Procedure. The notice may not allege a violation of a particular statute, rule, or standard unless the board or the board's screening panel, if one has been established, has made a written determination that there are reasonable grounds to believe that the particular statute, rule, or standard has been violated.
- (2) A licensee or license applicant shall give the board the licensee's or applicant's current address and any change of address within 30 days of the change.
- (3) The notice must state that the licensee or license applicant may request a hearing to contest the charge or charges. A request for a hearing must be in writing and received in the offices of the department within 20 days after the licensee's receipt of the notice. Failure to request a hearing constitutes a default on the charge or charges, and the board may enter a decision on the basis of the facts available to it.

# MCA 37-1-312. Sanctions -- stay --costs --stipulations.

- (1) Upon a decision that a licensee or license applicant has violated this part or is unable to practice with reasonable skill and safety due to a physical or mental condition or upon stipulation of the parties as provided in subsection (3), the board may issue an order providing for one or any combination of the following sanctions:
  - (a) revocation of the license:
  - (b) suspension of the license for a fixed or indefinite term;
  - (c) restriction or limitation of the practice;
- (d) satisfactory completion of a specific program of remedial education or treatment;
- (e) monitoring of the practice by a supervisor approved by the disciplining authority;
  - (f) censure or reprimand, either public or private;
  - (g) compliance with conditions of probation for a designated period of time;
- (h) payment of a fine not to exceed \$1,000 for each violation. Fines must be deposited in the state general fund.
  - (i) denial of a license application;
  - (j) refund of costs and fees billed to and collected from a consumer.

- (2) A sanction may be totally or partly stayed by the board. To determine which sanctions are appropriate, the board shall first consider the sanctions that are necessary to protect or compensate the public. Only after the determination has been made may the board consider and include in the order any requirements designed to rehabilitate the licensee or license applicant.
- (3) The licensee or license applicant may enter into a stipulated agreement resolving potential or pending charges that includes one or more of the sanctions in this section. The stipulation is an informal disposition for the purposes of 2-4-603.
- (4) A licensee shall surrender a suspended or revoked license to the board within 24 hours after receiving notification of the suspension or revocation by mailing it or delivering it personally to the board.

#### MCA 2-4-631(3). Licenses.

Whenever notice is required, no revocation, suspension, annulment, withdrawal, or amendment of any license is lawful unless the agency gave notice by mail to the licensee of facts or conduct which warrant the intended action. If the agency finds that public health, safety, or welfare imperatively requires emergency action and incorporates a finding to that effect in its order, summary suspension of a license may be ordered pending proceedings for revocation or other action. These proceedings shall be promptly instituted and determined.

#### STATEMENT OF RIGHTS

You are entitled to a hearing, promptly instituted and determined, as provided for by the Montana Administrative Procedure Act (§ 2-4-601, MCA, and following, including 2-4-631, MCA) and by §37-1-121(1), MCA. You have a right to be represented by an attorney at such hearing and during related proceedings. If you desire to have a hearing and to resist the proposed action taken under the jurisdiction of the Board, you must so advise Becky Carter, Compliance Unit Supervisor, Department of Labor and Industry, 301 South Park, P.O. Box 200513, Helena, Montana 59620-0513, in writing within **twenty** (20) days of your receipt of this notice.

#### POSSIBILITY OF DEFAULT

Failure to give notice or to advise the Board of your request for a hearing within the time

specified will result in the entry of a default order pursuant to § 37-1-309, MCA, and the Board may enter a decision on the basis of the facts available to it without additional prior notice to you.

DATED this day of May 2010.

Michael L. Fanning
Special Assistant Attorney General
Attorney for Department of Labor & Industry

#### CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of the foregoing *Notice of Proposed Board Hearing and Opportunity for Hearing* was sent by U.S. mail, postage prepaid, on

may 5, 2010 to the following:

Mark H. Frisbie, J.D. 410 Central Ave. Ste. 301 Great Falls, MT 59401

Department of Labor and Industry

Michael L. Fanning
Special Assistant Montana Attorney General
Department of Labor and Industry
Office of Legal Services
301 South Park Avenue
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Helena, MT 59620-0513

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#### BEFORE THE BOARD OF MEDICAL EXAMINERS DEPARTMENT OF LABOR AND INDUSTRY STATE OF MONTANA

In the Matter of the Disciplinary Treatment of the License of

Docket No. CC- 10-0352-MED

Patricia Cole, M.D.,

Complaint No. 2010-051-MED

License No. 11039.

Acknowledgment of Service

The undersigned is counsel for Respondent, Patricia Cole, M.D. By this document, the undersigned acknowledges service of the Notice of Proposed Board Action and Opportunity for Hearing filed in this matter and admits personal jurisdiction of the Board of Medical Examiners over Patricia Cole, M.D.

DATED this 6th day of May 2010.

Mark H. Frisbie, J.D. 410 Central Ave. Ste. 301 Great Falls, MT 59401 Michael L. Fanning
Special Assistant Montana Attorney General
Department of Labor and Industry
Office of Legal Services
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#### BEFORE THE BOARD OF MEDICAL EXAMINERS DEPARTMENT OF LABOR AND INDUSTRY STATE OF MONTANA

In the Matter of the Disciplinary Treatment of the License of

Patricia Cole, M.D.,

License No. 11039.

Docket No. CC-10-0352-MED Complaint No. 2010-051-MED

> STIPULATION FOR FINAL ORDER

The Department of Labor and Industry of the State of Montana (Department), through legal counsel, and Patricia Cole, M.D., through counsel, Mark H. Frisbie, J.D., (Licensee) stipulate and agree as follows:

- 1. **Montana Licensure.** Dr. Cole is licensed as a physician by the State of Montana Board of Medical Examiners, holding Montana license number 11039.
- 2. **Board's Duty.** The Montana Board of Medical Examiners has a statutory obligation to protect the public health, welfare and safety under Mont. Code Ann. §37-8-101.

- 3. Jurisdiction and Waiver of Contested Case Hearing Rights. Licensee admits the jurisdiction of the Board of Medical Examiners over the subject matter of this proceeding as well as personal jurisdiction over herself as a licensee. Licensee desires to avoid unnecessary expenditure of time and other valuable resources in resolving the issues in this action. Therefore, Licensee now specifically and affirmatively waives a contested case hearing and all rights to appeal under the Montana Administrative Procedure Act, and elects to resolve this matter on the terms and conditions set forth in this stipulation.
- 4. Voluntary Action. Licensee acknowledges that she has read and understands each term of this stipulation and the Notice of Proposed Board Action issued in this matter. Licensee understands that she has the right to the assistance of an attorney at every stage of this matter and has availed herself of that right. Licensee acknowledges that she enters into this stipulation voluntarily, and without reservation. Licensee acknowledges that no promise, other than those contained in this stipulation, and no threat has been made by the Department or by any member, officer, agent or representative of the Department to induce Licensee to enter into this stipulation.
- 5. **Department's Amended Contentions and Respondent's Admissions.**The Department's full contentions are set forth in the *Notice of Proposed Department Action* and are incorporated here by reference. For brevity, and not by way of limitation, those contentions are digested below.

Following a medical marijuana conference conducted in October 2009, at which Dr. Cole saw 151 patients over a fourteen and one-half hour day, the Board collected twenty patients' charts from the patients' medical marijuana care provider and submitted them for an independent peer review. That peer review found that Dr. Cole breached the standard of care in the following particulars:

- 1. Of the twenty cases, the peer reviewer issued D-3 ratings in seventeen cases: "documentation falls below standard of care with significant omissions."
- 2. Of the twenty cases, the peer reviewer issued Q-3 ratings in five cases: "an occurrence in medical/surgical care or process; significant or potentially significant impact on patient morbidity; opportunity for improvement."
- 3. The peer reviewer concluded that Dr. Cole breached her statutory obligation, defined in Mont. Code Ann. §50-46-102(11) of the Montana Medical Marijuana Act, through the following acts or omissions:
  - a. Dr. Cole did not document that she personally took a comprehensive past or present medical history at the time of the visits. There is minimal documentation of patient's symptoms on Dr. Cole's visit records. There is no documented physical examination performed on any patient.
  - c. Dr. Cole failed to document a medical marijuana benefit/risk analysis on any patient.
  - d. In five of the reviewed cases, the reviewer rendered an opinion that Dr. Cole's treatment with medical marijuana should receive a Q-3 rating: "An occurrence in medical/surgical care or process; significant or potentially significant impact on patient morbidity; opportunity for improvement."
- 4. The peer reviewer concluded that Dr. Cole breached her statutory obligation, defined in Mont. Code Ann. §37-1-316(18), to comport with "generally accepted standards of practice" through the following acts or omissions:
  - a. Dr. Cole's practice of seeing scores of new patients in one day is below the standard of care particularly given that

physicians commonly afford new patients greater time than that allotted for established patients.

- b. Dr. Cole breached the standard of care by failing to document that she advised each patient beginning or continuing a medical marijuana regimen about usage information including:
  - i) proper dosing; and
  - ii) potential dangerous side effects, interactions, operating machinery or motor vehicles, etc.
- c. Dr. Cole breached the standard of care by failing to recommend a timely follow-up evaluation to assess the effectiveness of the treatment: the patients that received signed certifications saw Dr. Cole only once on the same day of certification.
- d. Dr. Cole breached the standard of care regarding her medical records by:
  - i) Maintaining in fourteen cases records release consent forms dated the day of the conference, raising questions concerning whether Dr. Cole was able to preview the records prior to the conference;
  - ii) Failing to keep medical records in her control for a reasonable period for the patients seen at the conference;
  - iii) Allowing MCN to manage Dr. Cole's patients' records; and
  - iv) Despite the fact Dr. Cole concluded the patient was eligible to use medical marijuana in ten cases, she failed to assure that MCN maintained a signed certification documenting the patient's debilitating medical condition.

This conduct amounts to a violation of the standard of care provided in Mont.

Code Ann. §37-1-316(18) and the standards set forth in the Montana Medical Marijuana Act, Mont. Code Ann. 50-46-101 *et. seq.* 

Dr. Cole admits the allegations contained in the Department's *Notice of Proposed*Department Action and the facts digested above.

- 6. **Final Compromise and Settlement.** The Department and the Licensee agree that this stipulation shall be a final compromise and settlement of proposed discipline as a result of Licensee's conduct.
- 7. **Incorporation into Final Order.** The Department and the Licensee agree that this stipulation shall be incorporated and made a part of the final order issued by the Montana Board of Medical Examiners.
- 8. Public Documents and Reportability. The Department and the Licensee agree that this stipulation and the attached final order are public documents. Licensee understands that this disciplinary action will be reported to customary data banks as required by federal law, including (but not limited to) the Healthcare Integrity and Protection Data Bank (HIPDB), the National Practitioners Data Bank (NPDB) and the Federation of State Medical Boards (FSMB).
- 9. **Agreed Sanction and Costs.** In light of the foregoing, the parties agree that the proper disposition of these cases is to seek the Adjudication Panel's Final Order adopting the following terms.
  - a. Dr. Cole is fined \$4,000 of which \$2,000 is stayed for 12 months from the date of execution of the Final Order in this case. In the event, that Dr. Cole

abides by the Board's Final Order and commits no further violations within that 12-month period, the stayed portion of the fine will be deemed satisfied. Mont. Code Ann. §37-1-312(1)(h), -312(2). If Dr. Cole is alleged to have committed a violation within that 12-month period, the Board may initiate such action as may be appropriate on the new allegations as well as seek to revoke the stayed portion of the fine in this case. Such action may take place after the 12-month period, provided the violation is proven to have occurred within that period.

The fine must be paid by cashier's check or money order, payable to the Montana Board of Medical Examiners and is due within seven days of entry this order. The payment must be mailed or delivered to the Board office at:

Montana Board of Medical Examiners c/o LaVelle Potter 301 South Park Avenue P.O. Box 200513 Helena, Montana 59620-0513

- b. Dr. Cole is prohibited from issuing medical marijuana certifications outside of the ordinary course of her clinical practice and specifically is prohibited from serving as the consulting physician for third parties or care givers in mass conference-like settings akin to that which gave rise to this action. Mont. Code Ann. §37-1-312(1)(c).
- c. In issuing written certifications for medical marijuana use by qualifying patients, Dr. Cole must scrupulously adhere to all then applying medical standards of care, statutes and regulations governing medical marijuana, and governing case law including, but not limited to, the following:
  - i. Collect and maintain for each patient all pertinent past medical records;
  - ii. Take a comprehensive past and present medical history for each patient;
  - iii. Perform an appropriate physical examination;
  - iv. Maintain an ongoing, bona fide, physician-patient relationship including recommending follow-up at medically indicated intervals;
  - v. Conduct medical benefit/risk analysis for medical marijuana use;
  - vi. Provide appropriate consultation time for each new patient and appropriate consultation time for established patients;
  - vii. Counsel all patients on medical marijuana usage information

- including proper dosing and potential dangerous side effects; and viii. Identify the debilitating medical condition for which medical marijuana is recommended.
- d. Dr. Cole must thoroughly document each point required in paragraph 9(c)(i) through (viii) above.
- e. Dr. Cole must maintain in her possession and control for a reasonable period medical records for all patients for whom she issues a written certification for medical marijuana use.
- f. To assure compliance with the terms of the Final Order issued pursuant to this stipulation, Dr. Cole will be subject to a peer review at her expense, not to exceed \$1,500.00. This peer review will be completed according to the following terms.
  - i. For one year following entry of the Final Order in this case, Dr. Cole will maintain a log of each patient for who she has issued a written certification for medical marijuana use. Within thirty days of the one-year anniversary of entry of the Final Order in this case, Dr. Cole will present that complete log to the Board of Medical Examiner's compliance officer identified in paragraph 9(a) above.
  - ii. From that patient log, the compliance officer will select a random sample of no more than ten patients whose charts Dr. Cole will then promptly deliver to the compliance officer for submission for peer review. The peer reviewer will be named in the sole discretion of the Board of Medical Examiners from a peer reviewer that is a Montana licensed physician, or a peer reviewer from a state that recognizes medical use of marijuana, if available through the Board's review contractor. Dr. Cole will be solely responsible for the cost of the peer review; failure to pay that charge will be deemed a breach of this Final Order.
  - iii. Should the peer reviewer establish a breach of the terms of the Board's Final order, a breach of any applicable standard of care, other unprofessional conduct, or violation of any applicable law, the Board may move to initiate action on that violation(s). The Board may move to take action for failure to comply with any term of this Final Order, Mont. Code Ann. §37-1-316(8), and/or may move to take action on the new alleged violation. Additionally, the Board may seek to revoke the stayed portion of fine set forth in paragraph 9(a) above.

10. Inadmissibility. In the event the Board of Medical Examiners, in its discretion, does not approve this settlement, this stipulation is withdrawn and shall be of no evidentiary value and shall not be relied upon nor introduced in any disciplinary action by either party except that Licensee agrees that should the Board reject this stipulation, and if this case proceeds to hearing, Licensee will assert no claim that the Board of Medical Examiners was prejudiced by its review and discussion of this stipulation or of any records relating to this stipulation.

This agreement is subject to final approval by the Montana Board of Medical Examiners.

Michael L. Faming Department Counsel Montana Board of Medic			er -	Date Date	<u> </u>
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# BEFORE THE BOARD OF MEDICAL EXAMINERS DEPARTMENT OF LABOR AND INDUSTRY STATE OF MONTANA

#### BEFORE THE BOARD OF MEDICAL EXAMINERS DEPARTMENT OF LABOR AND INDUSTRY STATE OF MONTANA

In the Matter of the Disciplinary Treatment of the License of

Patricia Cole, M.D.,

License No. 11039.

Docket No. CC-10-0352-MED

Complaint No. 2010-051-MED

FINAL ORDER

Based upon the Stipulation between Licensee and the Department, and good cause appearing therefor,

IT IS HEREBY ORDERED that the parties' stipulation is approved, incorporated in, and made a part of, the Board's Final Order.

By a preponderance of the evidence,

## THE BOARD ENTERS THE FOLLOWING FINDINGS OF FACT:

Following a medical marijuana conference conducted in October 2009, at which Dr. Cole saw 151 patients over a fourteen and one-half hour day, the Board collected twenty patients' charts from the patients' medical marijuana care provider and submitted them for an independent peer review. That peer review found that Dr. Cole breached the standard of care in the following particulars:

- 1. Of the twenty cases, the peer reviewer issued D-3 ratings in seventeen cases: "documentation falls below standard of care with significant omissions."
- 2. Of the twenty cases, the peer reviewer issued Q-3 ratings in five cases: "an occurrence in medical/surgical care or process; significant or potentially significant impact on patient morbidity; opportunity for improvement."
- 3. The peer reviewer concluded that Dr. Cole breached her statutory obligation, defined in Mont. Code Ann. §50-46-102(11) of the Montana Medical Marijuana Act, through the following acts or omissions:
  - a. Dr. Cole did not document that she personally took a comprehensive past or present medical history at the time of the visits. There is minimal documentation of patient's symptoms on Dr. Cole's visit records. There is no documented physical examination performed on any patient.
  - b. Dr. Cole failed to document a medical marijuana benefit/risk analysis on any patient.
  - c. In five of the reviewed cases, the reviewer rendered an opinion that Dr. Cole's treatment with medical marijuana should receive a Q-3 rating: "An occurrence in medical/surgical care or process; significant or potentially significant impact on patient morbidity; opportunity for improvement."

- 4. The peer reviewer concluded that Dr. Cole breached her statutory obligation, defined in Mont. Code Ann. §37-1-316(18), to comport with "generally accepted standards of practice" through the following acts or omissions:
  - a. Dr. Cole's practice of seeing scores of new patients in one day is below the standard of care particularly given that physicians commonly afford new patients greater time than that allotted for established patients.
  - b. Dr. Cole breached the standard of care by failing to document that she advised each patient beginning or continuing a medical marijuana regimen about usage information including:
    - i) proper dosing; and
    - ii) potential dangerous side effects, interactions, operating machinery or motor vehicles, etc.
  - c. Dr. Cole breached the standard of care by failing to recommend a timely follow-up evaluation to assess the effectiveness of the treatment: the patients that received signed certifications saw Dr. Cole only once on the same day of certification.
  - d. Dr. Cole breached the standard of care regarding her medical records by:
    - i) Maintaining in fourteen cases records release consent forms dated the day of the conference, raising questions concerning whether Dr. Cole was able to preview the records prior to the conference;
    - ii) Failing to keep medical records in her control for a reasonable period for the patients seen at the conference;
    - iii) Allowing MCN to manage Dr. Cole's patients' records; and

iv) Despite the fact Dr. Cole concluded the patient was eligible to use medical marijuana in ten cases, she failed to assure that MCN maintained a signed certification documenting the patient's debilitating medical condition.

This conduct amounts to unprofessional conduct.

Based on these findings of fact,

IT IS FURTHER ORDERED that Patricia Cole, M.D. is adjudged to have violated Montana law under the jurisdiction of the Montana Board of Medical Examiners warranting sanctions under Mont. Code Ann. § 37-1-312. Specifically, the Board concludes that Patricia Cole, M.D. committed a sanctionable breach of Mont. Code Ann. § 37-1-316(18), "conduct that does not meet the generally accepted standards of practice."

As required by Mont. Code Ann. §37-1-312(2), the Board has first considered the sanctions that are necessary to protect and compensate the public. Having considered the concerns of the public, and the rehabilitation of the licensee,

#### THE BOARD ENTERS THE FOLLOWING ORDER:

1. Dr. Cole is fined \$4,000 of which \$2,000 is stayed for 12 months from the date of execution of the Final Order in this case. In the event, that Dr. Cole abides by the Board's Final Order and commits no further violations within that 12-month period, the stayed portion of the fine will be deemed satisfied. Mont. Code Ann. '37-1-312(1)(h), -312(2). If Dr. Cole is alleged to have committed a violation within that 12-month period, the Board may initiate such action as may be appropriate on the new allegations as well as seek to revoke the stayed portion of the fine in this

case. Such action may take place after the 12-month period, provided the violation is proven to have occurred within that period.

The fine must be paid by cashier=s check or money order, payable to the Montana Board of Medical Examiners and is due within seven days of entry this order. The payment must be mailed or delivered to the Board office at:

Montana Board of Medical Examiners c/o LaVelle Potter 301 South Park Avenue P.O. Box 200513 Helena, Montana 59620-0513

- 2. Dr. Cole is prohibited from issuing medical marijuana certifications outside of the ordinary course of her clinical practice and specifically is prohibited from serving as the consulting physician for third parties or care givers in mass conference-like settings akin to that which gave rise to this action.

  Mont. Code Ann. '37-1-312(1)(c).
- 3. In issuing written certifications for medical marijuana use by qualifying patients, Dr. Cole must scrupulously adhere to all then applying medical standards of care, statutes and regulations governing medical marijuana, and governing case law including, but not limited to, the following:
  - i. Collect and maintain for each patient all pertinent past medical records;
  - ii. Take a comprehensive past and present medical history for each patient;
  - iii. Perform an appropriate physical examination;
  - iv. Maintain an ongoing, bona fide, physician-patient relationship including recommending follow-up at medically indicated intervals;

- v. Conduct medical benefit/risk analysis for medical marijuana use;
- vi. Provide appropriate consultation time for each new patient and appropriate consultation time for established patients;
- vii. Counsel all patients on medical marijuana usage information including proper dosing and potential dangerous side effects; and
- viii. Identify the debilitating medical condition for which medical marijuana is recommended.
- 4. Dr. Cole must thoroughly document each point required in paragraph 3(i) through (viii) above.
- 5. Dr. Cole must maintain in her possession and control for a reasonable period medical records for all patients for whom she issues a written certification for medical marijuana use.
- 6. To assure compliance with the terms of the Final Order issued pursuant to this stipulation, Dr. Cole will be subject to a peer review at her expense, not to exceed \$1,500.00. This peer review will be completed according to the following terms.
  - i. For one year following entry of the Final Order in this case, Dr. Cole will maintain a log of each patient for who she has issued a written certification for medical marijuana use. Within thirty days of the one-year anniversary of entry of the Final Order in this case, Dr. Cole will present that complete log to the Board of Medical Examiner's compliance officer identified in paragraph 1 above.
  - ii. From that patient log, the compliance officer will select a random sample of no more than ten patients whose charts Dr. Cole will then promptly deliver to the compliance officer for submission for peer review. The peer reviewer will be named in the sole discretion of the Board of Medical Examiners from a peer reviewer that is a Montana licensed

physician, or a peer reviewer from a state that recognizes medical use of marijuana, if available through the Board's review contractor. Dr. Cole will be solely responsible for the cost of the peer review; failure to pay that charge will be deemed a breach of this Final Order.

iii. Should the peer reviewer establish a breach of the terms of the Board's Final Order, a breach of any applicable standard of care, other unprofessional conduct, or violation of any applicable law, the Board may move to initiate action on that violation(s). The Board may move to take action for failure to comply with any term of this Final Order, Mont. Code Ann. '37-1-316(8), and/or may move to take action on the new alleged violation. Additionally, the Board may seek to revoke the stayed portion of fine set forth in paragraph 1 above.

DATED this 27 th day of May 2010.



Chair, Adjudication Panel Board of Medical Examiners

# **CERTIFICATE OF SERVICE** I hereby certify that I served a true and accurate copy of the foregoing STIPULATION and FINAL ORDER by U.S. mail, postage prepaid, upon the Licensee at the following address as follows: Patricia Cole, M.D. c/o Mark H. Frisbie, J.D. 410 Central Ave. Ste. 301 Great Falls, MT 59401 DATED this 27 th day of May Department of Labor and Industry