

Issues for Physicians in Certifications of Medical Marijuana Patients

Bill Ryder, Esq.
Massachusetts Medical Society

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Topics

- Federal Law and the DEA
- Certifications vs. Prescriptions
- The Massachusetts Law
- The Massachusetts Regulations
- Areas for Thought

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MY COLLEAGUE'S VIEW

- “Although unbelievably challenging and difficult, it’s also very clear, Unfortunately what’s clear is that there’s confusion.”

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MMS Positions

- Longstanding position in support of responsible clinical trials of marijuana and rescheduling of the drug to allow for research.
- Oppose legislation legalizing marijuana for recreational use under any circumstances.
- The MMS was active in expressing our concerns about the insufficiency of clinical evidence supporting the safety of marijuana and the unsupported characterization of marijuana as a medical treatment for a wide variety of diseases and conditions. We opposed the referendum.
- After passage of the referendum, the MMS HOD passed a new policy which repealed our opposition to any enactment of medical marijuana regulations to allow the MMS to comment on pending regulations of the Department of Public Health and the Board of Registration in Medicine.
- MMS advocated for adoption of standards of practice for physicians engaged in certifying patients as qualifying for marijuana use, standards for treatment of children, specific diseases which may qualify and other provisions designed to responsibly implement the new law.

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Department of Justice Statement August 29, 2013

- Key Factors in determining whether to target a federal law marijuana violation
- No focus on the seriously ill individuals or their caregivers
- Whether the operation is demonstrably in compliance with a strong and effective state regulatory system.
- Preventing the distribution of marijuana to minors

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21 U.S.C. §§ 801 – 971 vs. Conant v. Walters

- Federal Law Prohibits writing a prescription for a schedule 1 drug , including marijuana
- The 2002 federal appeals court decision is best summarized as protecting a physician's first amendment right to discuss medical marijuana with their patients, but it does not create a right for physicians to help patients obtain cannabis for medical use. DEA action prompted this case. Certification vs. Prescribing is a result.

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MASSACHUSETTS LAW

- November 6, 2012 63% of Massachusetts voters approved a binding referendum question summarized on the ballot as:
- “Should the state eliminate criminal and civil penalties for the use of marijuana by qualifying patients who have been diagnosed with a debilitating medical condition?”

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Key Statutory Provisions

- No payer mandate to reimburse any person for the **expenses of the medical use** of marijuana.
- Nothing in this law requires any health care professional to authorize the use of medical marijuana for a patient.
- Nothing in this law requires any accommodation of any on-site medical use of marijuana in any place of employment, school bus or on school grounds, in any youth center, in any correctional facility, or of smoking medical marijuana in any public place.
- Nothing in this law requires the violation of federal law or purports to give immunity under federal law.

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Protection from State Prosecution

- A physician, and other health care professionals under a physician's supervision, shall not be penalized under Massachusetts law, in any manner, or denied any right or privilege, for:
- (a) Advising a qualifying patient about the risks and benefits of medical use of marijuana; or
- (b) Providing a qualifying patient with written certification, based upon a full assessment of the qualifying patient's medical history and condition, that the medical use of marijuana may benefit a particular qualifying patient.

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DPH REGULATIONS

- Regulations heard in the Spring of 2013 clarified and in some cases modified the provisions of the referendum.

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Qualifying Adult Patient

- a Massachusetts resident 18 years of age or older who has been diagnosed by a Massachusetts licensed certifying physician as having a debilitating medical condition.

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Debilitating Medical Condition

- means cancer, glaucoma, positive status for human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS), hepatitis C, amyotrophic lateral sclerosis (ALS), Crohn's disease, Parkinson's disease, and multiple sclerosis (MS), when such diseases are debilitating, and other debilitating conditions as determined in writing by a qualifying patient's certifying physician.

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Debilitating

- Debilitating means causing weakness, cachexia, wasting syndrome, intractable pain, or nausea, or impairing strength or ability, and progressing to such an extent that one or more of a patient's major life activities is substantially limited.

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Limiting Pediatric Access

- Those less than 18 years of age, require parent or guardian approval and certification by two physicians, one of whom must be a pediatrician or pediatric specialist. The regulation allows youth access for a life-limiting illness, likely to result in death within two years.
- The two physicians may override the life-limiting restriction if they document the benefits of medical use of marijuana outweigh the risks.

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Standards of Care

- A bona fide physician patient relationship is required
- The Board of Registration will maintain an active role in enforcing this standard.
- Certifying physicians should have an ongoing role in the care and treatment of the patient.

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Standards of Care

- • Development of a treatment plan with objectives;
- • Provision of informed consent, including discussion of side effects;
- • Periodic review of a treatment's efficacy.

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Bona Fide Physician-Patient Relationship

- in the usual course of professional practice,
- Includes: a clinical visit;
- documentation of complete medical history and current medical condition;
- informed consent on the potential benefits and risks of marijuana use,
- and requires that the MD has a role in the ongoing care and treatment of the patient.

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Certifying Physician (not really)

- a Massachusetts licensed physician (Medical Doctor or Doctor of Osteopathy) who certifies that in his or her professional opinion, the potential benefits of the medical use of marijuana would likely outweigh the health risks for a qualifying patient.
- Nothing in 105 CMR 725.000 shall be construed to limit the scope of practice of a nurse practitioner pursuant to M.G.L. c. 112, s. 80I.

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Nursing Board Pending Regulations

- Recognize NP's with prescribing privileges as being able to certify patients.

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What You Would Certify

- Written Certification means a form submitted to the Department by a Massachusetts licensed certifying physician, describing the qualifying patient's pertinent symptoms, specifying the patient's debilitating medical condition, and stating that in the physician's professional opinion the potential benefits of the medical use of marijuana would likely outweigh the health risks for the patient.

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Certification by a Registered Physician leads to Patient Registration by the DPH

- Registration Card means an identification card issued by the Department. A patient registration card verifies that a certifying physician has provided a written certification to the Department.
- Registered patients may be served by dispensaries or grow their own.
- Online system expected this Fall

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Certification of a Debilitating Medical Condition for a Qualifying Patient

- (A) As of July 1, 2014, certifiers must have completed a minimum of 2.0 Category 1 continuing professional development credits in the proper use of marijuana, including side effects, dosage, and contraindications, including with psychotropic drugs, as well as on substance abuse recognition, diagnosis, and treatment related to marijuana.
- (B) A certifying physician issuing a written certification shall comply with generally accepted standards of medical practice, including regulations of the Board of Registration in Medicine at 243 CMR 1.00, 2.00, and 3.00.
- (C) A certifying physician may not delegate to any other health care professional or any other person, authority to diagnose a patient as having a debilitating medical condition.
- (D) A certifying physician may issue a written certification only for a qualifying patient with whom the physician has a bona fide physician-patient relationship.
- (E) Before issuing a written certification, a certifying physician must utilize the Massachusetts Prescription Monitoring Program, unless otherwise specified by the Department, to review the qualifying patient's prescription history.

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Statutory Disease not Enough

- Disease must be active, not in remission.
- An initial written certification submitted before a clinical visit is prohibited. A renewal written certification may be submitted after a clinical visit or a telephonic consultation, however a clinical visit must occur no less than once per year.
- A certification must indicate the time period for which the certification is valid, and shall not be less than 15 calendar days or longer than one year.
- A certifying physician may determine and certify that a qualifying patient requires an amount of marijuana exceeding 10 ounces as a 60-day supply. This is not clearly protected federally.

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DPH REGISTRATION

- (B) To register as a certifying physician, a physician shall submit, in a form and manner determined by the Department, the physician's:
 - (1) Full name and business address;
 - (2) License number issued by the Massachusetts Board of Registration in Medicine;
 - (3) Massachusetts Controlled Substances Registration number; and
 - (4) Any other information required by the Department.

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Registration Requirements of Certifying Physicians

- (A) at least one established place of practice in Massachusetts and shall hold:
 - (1) An active full license, with no prescribing restriction, to practice medicine in Massachusetts; and
 - (2) A Massachusetts Controlled Substances Registration from the Department.

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Grounds for Revocation

- (1) The physician's license to practice medicine in Massachusetts is suspended, revoked, or restricted with regard to prescribing, or the physician has voluntarily agreed not to practice medicine in Massachusetts;
- (2) (3) **The physician has fraudulently issued a written certification of a debilitating medical condition;**
- (4) The physician has certified a qualifying patient for a debilitating medical condition on or **after July 1, 2014**, without appropriate completion of continuing professional development credits pursuant to 105 CMR 725.010(A); or
- (5) The physician surrenders his or her registration.
- (D) After registering, a certifying physician is responsible for notifying the Department, in a form and manner determined by the Department, within five business days after any changes to the physician's information.

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Prohibited Certifying Physician Behavior

- Any exchange of value or financial relationship with a marijuana dispensary or affiliated person
- A discount or any other thing of value to a qualifying patient based on the patient's agreement or decision to use a particular personal caregiver or RMD;
- Examining or counseling a patient, or issuing a written certification, at a RMD;
- Directly or indirectly benefit from a patient obtaining a written certification, which shall not prohibit the physician from charging an appropriate fee for the clinical visit.
- A certifying physician shall not issue a written certification for himself or herself or for his or her immediate family members.
- A written certification shall be issued in a form and manner determined by the Department.

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Patient Education by Dispensaries

- Physicians don't prescribe marijuana they certify a patient may benefit from it based on a diagnosis of a debilitating disease or condition.
- Without prescriptions patients work out treatment modalities with the dispensary that sells them the marijuana.
- Contrast this with prescriptions and pharmacies

MMS Area of Concern

- Individual physicians and Certification Centers have certified 1000 or more patients each already
- “You can’t have a clinic that just gives out one substance. I can’t open an oxycodone or a Percocet clinic. That is not medicine, then you are an access point for a specific substance.”

Standards of Care

- A bona fide physician patient relationship is required
- The Board of Registration will maintain an active role in enforcing this standard.
- Certifying physicians should have an ongoing role in the care and treatment of the patient.

indicia of the lack of good faith in prescribing guidelines

- There are several factors the Board looks at including the following:
- 1. Failure to follow at least minimum professional procedure;
- 2. **The physician permitting the patient to name the drug he desires**
- 3. General remarks of the physician indicating his or her experience with nontherapeutic uses of the drug and of drug enforcement actions and procedures;
- 4. Failure to schedule appropriate additional appointments for return visits and other factors indicating a lack of interest in follow-up care; and
- 5. Conversations and other circumstances that demonstrate that the physician knew that the drugs were not to be used for a therapeutic or medical purpose.

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New Oversight by the DPH

- While disciplinary processes and implications for the Board of Medicine are well established, the mechanism by which the DPH would conduct such a process is unclear, as are the implications for physicians regarding the national practitioner databank, physician licensing here and in other states and credentialing for participation in insurance and public payment systems should the DPH revoke a registration.

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PMP Review

- Registered Physicians are required to participate in the PMP
- The DPH has records of both patient certification and physician look up of PMP records on that patient
- What is a physician to do based on the PMP records? What is the standard of care?

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RMD's vs. Treatment Centers

- A RMD must operate on a non-profit basis for the benefit of registered qualifying patients.
- No executive, member, or any entity owned or controlled by such executive or member, may directly or indirectly control more than three RMDs.
- A RMD must make vaporizers available for sale to registered qualifying patients.
- A RMD may not have more than two locations in Massachusetts at which marijuana is cultivated, MIPs are prepared, and marijuana is dispensed.
- A RMD must have a program to provide reduced cost or free marijuana to patients with documented verified financial hardship.

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The “Professional” who Determines your patient’s medicine and dosage

- (1) Be at least 21 years old; and
- (2) Have not been convicted of a felony drug offense in the Commonwealth, or a like violation of the laws of another state, the United States or a military, territorial, or Indian tribal authority.

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Patient Education (not your job!)

- A RMD shall provide educational materials about marijuana to registered qualifying patients and their personal caregivers. Such materials shall be made available for inspection by the Department upon request. The educational material must include at least the following:
 - (1) A warning that marijuana has not been analyzed or approved by FDA, that there is limited information on side effects, that there may be health risks associated with using marijuana, and that it should be kept away from children;
 - (2) A warning that when under the influence of marijuana, driving is prohibited and machinery should not be operated;
 - (3) Information to assist in the selection of marijuana, describing the potential differing effects of various strains of marijuana, as well as various forms and routes of administration;
 - (4) Materials offered to registered qualifying patients and their personal caregivers to enable them to track the strains used and their associated effects;

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More Requirements

- (5) Information describing proper dosage and titration for different routes of administration. Emphasis shall be on using the smallest amount possible to achieve the desired effect. The impact of potency must also be explained;
- (6) A discussion of tolerance, dependence, and withdrawal;
- (7) Facts regarding substance abuse signs and symptoms, as well as referral information for substance abuse treatment programs;
- (8) A statement that registered qualifying patients may not distribute marijuana to any other individual, and that they must return unused, excess, or contaminated product to the RMD from which they purchased the product, for disposal; and
- (9) Any other information required by the Department

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Physician Options

- For a registered qualifying patient certified for less than 60 days, the amount of marijuana dispensed, shall be no more than the appropriate proportion of a 60-day supply. However, possession isn't legal after the period.
- For a registered qualifying patient certified for 60 days or longer, the amount of marijuana dispensed shall be no more than a 60-day supply in each 60-day period
- For a registered qualifying patient whose certifying physician has determined that he or she requires a 60-day supply in excess of 10 ounces, the amount of marijuana dispensed shall be adjusted accordingly.

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Insurance Claims

- If a patient presents for lower back pain seeking certification for marijuana why isn't that a billable patient visit in the ordinary course of practice?
- Is a different fee for a new patient visit ok for a Medicare patient seeking marijuana certification?
- Is it permissible to bill a medicaid patient if the visit is to assess a specific symptom?

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Malpractice Coverage

- Physicians are recommended to contact their insurer to determine if they would be covered for defense and judgment costs on issues associated with marijuana certifications.
- Self-insured hospital systems may have prohibitions on certifications based on federal concerns.
- Physicians may not practice medicine without coverage.

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Employer and Group Issues

- Registering physicians are encouraged to discuss their plans with their groups and employers before an issue arises.
- Medicare and Medicaid provider agreements require certification of compliance with all federal and state laws, regulations, and rules applicable to the Provider's participation in MassHealth

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MassHealth Provider Agreement

- The Provider agrees:
- A.to furnish only those services and goods that qualify as medically necessary under MassHealth regulations;
- and to furnish services and/or goods that conform to the professionally recognized standards of health care within the Commonwealth.....
- B. to comply with all federal and state laws, regulations, and rules applicable to the Provider's participation in MassHealth, now existing or adopted during the term of this Provider Contract.

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Discrimination

- Physicians facing accusations of discrimination for not participating in the program should be secure in the specific protection for non-participating physicians in the law and in the general standard of care for physicians which requires them not to participate in clinical evaluations and treatments which are beyond or inconsistent with their skills, knowledge and training.

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CONTACT INFO

- Bill Ryder
- Regulatory and Legislative Counsel
- Massachusetts Medical Society
- wryder@mms.org
- 781-434-7219
- <http://www.massmed.org/Advocacy/Key-Issues/Medical-Marijuana/Medical-Marijuana/#.U6F4omdOUdU>

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DPH Website

<http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/medical-marijuana/>

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