

December 19, 2016

>> HB 4014 Clinical Guidelines Work Group

Guidelines for Attending Physicians When
Recommending the Medical Use of Marijuana

Oregon
Health
Authority
PUBLIC HEALTH DIVISION

Acknowledgments

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Executive summary

House Bill 4014, passed during the 2015 legislative session, directed the Oregon Health Authority (OHA) to convene a work group to develop, at a minimum, “guidelines for attending physicians to follow when recommending the medical use of marijuana for the purpose of mitigating the symptoms or effects of a debilitating medical condition.”¹

The work group consisted of allopathic physicians (MDs), osteopathic physicians (DOs) and a patient advocate. It developed guidelines on the principal that physicians who recommend the medical use of marijuana to a patient engage in the practice of medicine and do so within the context of a bona fide physician-patient relationship. The physician who recommends the medical use of marijuana to a patient is obligated to provide that patient with an appropriate level of medical care. At a minimum this level of care consists of a thorough patient evaluation, treatment and follow-up plan, with documentation in the patient’s medical record. Patient evaluation includes obtaining a comprehensive medical history and performing a complete physical examination appropriate to the patient’s debilitating medical condition and medical history. The physician should develop and document a written treatment plan including documentation of informed consent and a discussion of risks and benefits.

It is important to note that the work group strongly opposes the smoking of marijuana, noting that there are several other means of ingesting marijuana that obtain a therapeutic effect and pose less risk to patient health.

These guidelines advise physicians to consider contraindications and precautions related to the concurrent use of marijuana and opioids. Physicians are referred to Oregon’s Opioid Prescribing Guidelines.

The work group also addressed treatment of pediatric patients and provided guidance on obtaining consent when treating minor patients or patients who lack decision-making capacity. Additionally, the work group advised that physicians complete continuing medical education related to medical marijuana before they begin recommending it to patients.

The work group’s report neither encourages nor discourages a physician to recommend the medical use of marijuana. Its purpose is to provide guidance to physicians on evaluating and developing a treatment plan and follow-up for a patient diagnosed with one of the qualifying medical conditions for the medical use of marijuana.

¹ *Oregon Laws 2016, Chapter 24, Section 72*

Work group overview

The work group created by House Bill 4014 “shall include at least one attending physician who has diagnosed an individual as having a debilitating medical condition and at least one individual for whom the medical use of marijuana has been recommended for the purpose of mitigating the symptoms or effects of a debilitating medical condition.” The work group must contain at least one physician who has diagnosed a patient having one of the debilitating medical conditions defined and listed in ORS 475B.410 and one patient who has been diagnosed with a debilitating medical condition and for whom the medical use of marijuana has been recommended. OHA convened a nine-member work group including allopathic and osteopathic physicians from various medical specialties and backgrounds, a physician retired from medical practice, and an individual diagnosed with a debilitating medical condition who has had a physician recommendation to use medical marijuana. The work group members contributed their time, expertise, advice and authorship to the report.

Work group members:

Patrick Bergin, MD; cardiology, Heart Associates of Oregon

Kathleen Cordes, MD; family practice, Wild Rose Medical Clinic; Compassion Center

Lee Dorfman, DO; anesthesiology, Anesthesia Associates Northwest

Ralph Eccles, DO; family practice, Assistant Professor of Family Medicine, Oregon Health & Science University

James Lace, MD; pediatrics, Childhood Health Associates Pediatric Clinic

Catherine Livingston, MD, MPH; Associate Medical Director, Health Evidence Review Commission, Oregon Health Authority

Ben Mackaness; patient advocate; former member Advisory Committee for Medical Marijuana

Colin Roberts, MD; pediatric neurology, Associate Professor of Neurology and Pediatrics, Oregon Health & Science University

Ex-officio members:

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Introduction and background

In 1998 voters in Oregon passed Oregon Ballot Measure 67, allowing for the limited cultivation, possession and use of marijuana for medical purposes. The successful ballot measure became known as the Oregon Medical Marijuana Act (“the Act”) and was codified into Oregon Revised Statutes.² The Act finds that:

1. Patients and doctors have found marijuana to be an effective treatment for suffering caused by debilitating medical conditions that must be treated like other medicines;
2. That Oregonians suffering from debilitating medical conditions should be allowed to use marijuana without fear of civil or criminal penalties when a doctor advises that using marijuana may provide a medical benefit and when other reasonable restrictions are met regarding that use;
3. The Act is intended to allow Oregonians with debilitating medical conditions who may benefit from the medical use of marijuana to be able to freely discuss with doctors the possible risks and benefits associated with the medical use of marijuana and to have the benefit of professional medical advice; and
4. The Act is intended to protect patients and doctors from criminal and civil penalties and are not intended to change current civil and criminal laws governing the use of marijuana for nonmedical purposes.³

The Oregon Medical Marijuana Program (OMMP), housed within the Public Health Division of the Oregon Health Authority, administers the Act by overseeing the registration and regulation of medical marijuana patients, designated caregivers, growers, grow sites, dispensaries and medical marijuana processing sites.

Under this legal and administrative framework OHA registers and issues a registry identification card to an individual medical marijuana patient if the individual provides certain required information in an application submitted to the OMMP.⁴ In order to be registered as a cardholder the applicant must provide written documentation from the applicant’s attending physician “stating that the attending physician has diagnosed the applicant as having a debilitating medical condition and that the medical use of marijuana may mitigate the symptoms or effects of

² ORS 475B.400 to 475B.525

³ ORS 475B.400

⁴ ORS 475B.415

the applicant’s debilitating medical condition.”^{5,6} For the purposes of the Act an “attending physician” is defined as “a physician licensed under ORS chapter 677 who has primary responsibility for the care and treatment of a person diagnosed with a debilitating medical condition.”⁷ Only an allopathic or osteopathic physician (MD or DO) with an active license to practice in Oregon may provide the written documentation needed for a patient to be registered with OHA. For the purposes of patient registration and protection from civil and criminal liability, the attending physician is limited to recommending the medical use of marijuana for a patient who has been diagnosed with a statutorily enumerated debilitating medical condition. Those conditions include:

- Cancer
- Glaucoma
- A degenerative or pervasive neurological condition positive status for human immunodeficiency virus or acquired immune deficiency syndrome
- A side effect related to the treatment of those medical conditions

A physician also may recommend medical marijuana for a medical condition or treatment for a medical condition that produces:

- Cachexia
- Severe pain
- Severe nausea, seizures or persistent muscle spasms
- Post-traumatic stress disorder⁸

⁵ *Id.*

⁶ *This written documentation is defined in administrative rule OAR 333-008-0010 as an “attending physician statement” or “APS” which means the form, prescribed by the Authority and signed by an attending physician, states the individual has been diagnosed with a debilitating medical condition and that the medical use of marijuana may mitigate the symptoms or effects of the individual’s debilitating medical condition. The term prescription is not used within the context of the Act due to issues with how that term is defined under federal law and how the term relates to a physician’s DEA registration certificate.*

⁷ ORS 475B.410(1)

⁸ ORS 475B.410(6)

For information on the clinical evidence for treating conditions and symptoms with cannabinoids, please see Senate Bill 844 Task Force Report and a recent JAMA systemic review and meta-analysis on cannabinoids for medical use.^{9,10}

Approximately 68,032 patients are registered with the OMMP and 1,723 physicians have recommended the medical use of marijuana for those patients.^{11,12} Of the total physicians who have recommend marijuana for patient applications, 1,702 physicians currently recommend marijuana for one to 449 patients and account for 27 percent of patient applications; 21 physicians recommend marijuana for 450 or more patients each and account for 73 percent of patient applications.

Severe pain is the most common qualifying condition diagnosed and documented by physicians for medical marijuana patients. Approximately 89 percent of patients list severe pain as a qualifying debilitating medical condition. However, physicians may recommend medical marijuana for more than one debilitating condition and patients may list more than one qualifying condition as part of their registration application. Table 1 provides a breakdown of patients by condition. Counts are not cumulative or mutually exclusive. For example, a patient may have written documentation for the medical use of marijuana from their physician that lists both severe pain and cancer as qualifying conditions.

At this writing 289 minor patients (under 18 years of age) are registered with the OMMP. Most of those minor patients report severe pain and/or seizures as qualifying conditions.¹³ [Tables 2 and 3]

⁹ Senate Bill 844 Task Force Report: Researching the medical and public health properties of Cannabis, February 2016. Retrieved from: <https://public.health.oregon.gov/DiseasesConditions/ChronicDisease/MedicalMarijuanaProgram/Documents/sb844taskforce/SB844Report.pdf>

¹⁰ Whiting PF, Wolff RF, Deshpande S, et al. Cannabinoids for Medical Use: A Systemic Review and Meta-analysis JAMA 2015; 313(24):2456-2473. doi:10.1001/jama.2015.6358.

¹¹ As of October 5, 2016. Oregon Medical Marijuana Program Statistical Snapshot October, 2016. Retrieved from: <https://public.health.oregon.gov/DiseasesConditions/ChronicDisease/MedicalMarijuanaProgram/Documents/OMMP-Statistic-Snapshot-10-2016.pdf>.

¹² There are approximately 13,293 physicians (M.D. and D.O.) with full and active Oregon Medical Board licensure. There are approximately 21,187 full and limited licensees; which may include inactive, emeritus, administrative, postgraduate, fellow, military/public health and locum tenens status. License Totals Report (November 2, 2016). Retrieved from: <http://www.oregon.gov/omb/board/Pages/Licensee-Statistics.aspx>.

¹³ Oregon Medical Marijuana Program Statistical Snapshot October, 2016. Lists of conditions are not cumulative or mutually exclusive. Multiple conditions may be provided with a physician's documentation.

Table 1 Patients by Condition (n=68,032)¹⁴

| Condition | Count of Reporting Patients | Percentage of Reporting Patients |
|--------------|-----------------------------|----------------------------------|
| Severe Pain | 60,411 | 88.8% |
| Spasms | 19,438 | 28.6% |
| Nausea | 8,881 | 13.1% |
| Cancer | 4,418 | 6.5% |
| Seizures | 1,756 | 2.6% |
| Cachexia | 983 | 1.4% |
| HIV/AIDS | 647 | 1.0% |
| Glaucoma | 977 | 1.4% |
| PTSD | 5,276 | 7.8% |
| Neurological | 638 | 0.9% |

Table 2 Minor Patients by Age Range (n=289)

| Minor Patient Age Range | Count |
|-------------------------|------------|
| 0 – 10 | 110 |
| 11 – 15 | 98 |
| 16 – 17 | 81 |
| Total | 289 |

Table 3 Minor Patients by Condition (n=289)

| Condition | Count of Reporting Minor Patients ² | Percentage of Reporting Minor Patients |
|------------------------|--|--|
| Severe Pain | 118 | 40.8% |
| Spasms | 54 | 18.6% |
| Nausea | 47 | 16.2% |
| Cancer | 25 | 8.6% |
| Seizures | 123 | 42.5% |
| Cachexia | 9 | 3.1% |
| Neurological | 34 | 11.7% |
| PTSD | 21 | 7.2% |
| Glaucoma, HIV/ AIDS | 0 | 0.0% |

¹⁴ Oregon Medical Marijuana Program Statistical Snapshot October, 2016. Retrieved from: <https://public.health.oregon.gov/DiseasesConditions/ChronicDisease/MedicalMarijuanaProgram/Documents/OMMP-Statistic-Snapshot-10-2016.pdf>.

Medical marijuana recommendation guidelines for physicians

The guidelines developed by this work group provide recommendations to physicians on the appropriate care of a patient diagnosed with one or more debilitating conditions for which the physician is recommending the medical use of marijuana. Nothing in these guidelines change or override a physician's obligation to comply with applicable state laws relating to medical marijuana or the practice of medicine. A recommendation by a physician for the medical use of marijuana constitutes the practice of medicine and the physician must establish a bona-fide physician-patient relationship prior to recommending the medical use of marijuana to a patient.^{15,16}

Patient evaluation

The physician should obtain and evaluate the patient's health history and perform a physical examination before recommending marijuana for a debilitating medical condition. The initial physical examination should be done in person; use of telemedicine is not approved.

- a. The patient's health history should include:
 - i. Current and past treatments (including use of marijuana) for the debilitating condition;
 - ii. Comorbidities;
 - iii. Any history of substance (including alcohol) misuse or abuse (including treatment for chemical dependence);
 - iv. Review of the patient's medications including indication(s), date, type, dosage, and quantity prescribed, and the potential contra-indications; and
 - v. Check of the Prescription Drug Monitoring Program (PDMP) database for the patient's receipt of controlled substances.
- b. The health care provider should complete an initial physical examination appropriate to the patient's debilitating medical condition and medical history.

¹⁵ See *Oregon Medical Board Statements of Philosophy for information related to the establishment of a physician-patient relationship*. Retrieved from: <http://www.oregon.gov/omb/board/philosophy/Pages/Physician-Patient-Relationship.aspx>.

¹⁶ See also *Colorado Medical Board: Laws, Rules and Policies; 40-28 Policy Regarding Recommendations for Marijuana as a Therapeutic Option*. Issued November 19, 2015. Retrieved from: https://www.colorado.gov/pacific/dora/Medical_Laws#Policies.

Treatment plan, including informed consent

The physician should document a written treatment plan that includes:

- a. An assessment of any relative or absolute contraindications to medical marijuana;
- b. Review of other attempts to treat the debilitating medical condition that do not involve the medical use of marijuana;
- c. Advice about other options for treating the debilitating medical condition;
- d. Determination that the patient may benefit from treatment of the debilitating medical condition with medical use of marijuana;
- e. Determine patient's past experience with marijuana, and whether or not the patient deemed it beneficial.
- f. Advice about the potential risks of the medical use of marijuana to include:
 - i. The variability of the concentration of cannabinoids (e.g. THC, CBD) in medical marijuana;
 - ii. Adverse effects;
 - iii. Use of marijuana during pregnancy or breast feeding; and
 - iv. The need to safeguard all usable marijuana and marijuana items from children and pets or domestic animals.
- g. Additional diagnostic evaluations or other planned treatments;
- h. A specific duration for the medical marijuana authorization for a period no longer than 12 months; and
- i. A specific ongoing treatment plan as medically appropriate.

Ongoing treatment

The physician should conduct ongoing medical evaluation and treatment at least annually, and more frequently as medically appropriate to review the course of patient's treatment. It should include:

- a. Any change in the overall medical condition;
- b. Any change in physical and psychosocial function; and
- c. Any new information about the patient's terminal or debilitating medical condition.

- d. The evaluation also should assess the patient’s response to the therapy, including maintenance or improvement in their condition and documentation of adverse events, focusing on maintaining or improving the patient’s functional status.

Maintenance of health records

The physician should maintain the patient’s health record. It should be accessible and readily available for review, and include:

- a. The evaluation, including history and physical, diagnosis, treatment plan, material risk notification¹⁷, and therapeutic objectives (as outlined in sections 1-3 above);
- b. Documentation of the presence of one or more recognized terminal or debilitating medical conditions identified in ORS 475B.410(6);
- c. Results of ongoing treatment; and
- d. The physician’s instructions to the patient.
- e. Section 1, Section 2, and Section 3 should be documented in the patient’s record.

Special considerations for pediatric patients; obtaining consent when treating minor patients or patients without decision making capacity

In addition to the above recommendations, physicians should be aware of additional considerations related to recommending marijuana for pediatric patients.

If the patient is under the age of 18 years or the patient is without decision-making capacity, the physician should:

- a. Ensure that the patient’s parent, guardian, or health care surrogate participates in the treatment and agrees to the medical use of marijuana;
- b. Consult with other health care providers involved in the patient’s treatment, especially the patient’s primary care provider, as medically indicated and as agreed to by the patient’s parent, guardian, or surrogate, before authorization or reauthorization of the medical use of marijuana;
- c. Discuss with the parent or patient surrogate the risks and possible effects of cannabinoids, specifically THC, on the minor patient’s developing brain; and

¹⁷ A material risk notice (MRN) is a written record documenting the provider-patient discussion on long-term controlled substance therapy for intractable pain. An example MRN when prescribing opioids for chronic pain can be found here <https://www.oregon.gov/omb/OMBForms1/material-risk-notice.pdf>.

- d. Include a follow-up discussion with the minor's parent or patient surrogate to ensure the parent or patient surrogate continues to participate in the treatment.

Continuing education

A physician who recommends the medical use of marijuana should complete a minimum of three hours of category 1 continuing medical education related to medical marijuana. Ideally, this should be before the physician begins making recommendations for the medical use of marijuana to patients. Such a program should explain the proper use of marijuana, including the endo-cannabinoid system, pharmacology and effects of marijuana (e.g., distinction between cannabidiol [CBD] and tetrahydrocannabinol [THC]; methods of administration; and potential side effects or risks). Physicians who recommend marijuana should closely follow the emerging evidence on the use of marijuana for therapeutic purposes and adopt consistent best practices.

Physicians recommending marijuana for minors also should be keenly aware and up-to-date on the peer-reviewed literature regarding the effects of THC on children and young adults' developing brains.

Financial prohibitions

A physician who recommends the medical use of marijuana shall not:

- a. Accept, solicit, or offer any form of pecuniary remuneration from or to a primary caregiver, distributor, or any other provider of medical marijuana;
- b. Offer a discount or any other thing of value to a patient who uses or agrees to use a particular primary caregiver, distributor, or other provider of medical marijuana to procure medical marijuana;
- c. Examine a patient for purposes of diagnosing a debilitating medical condition at a location where medical marijuana is sold or distributed;
- d. Hold an economic interest in an enterprise that provides or distributes medical marijuana.

Recommending marijuana and the concurrent use of opioids

Current data are limited on the interactions between opioids and marijuana. As with all pain treatment, clinicians should focus on improving their patient's quality of life and ability to function, and on ensuring patient safety, when they consider marijuana use by patients who are also using opioids. Clinicians should assess for contraindications and precautions to the concurrent use of marijuana and opioids.

For additional information on opioid prescribing including prescribing opioids in patients who use marijuana, see [Oregon's Opioid Prescribing Guidelines: Recommendations for the Safe Use of Opioid Medications](http://public.health.oregon.gov/PreventionWellness/SubstanceUse/Opioids/Documents/taskforce/oregon-opioid-prescribing-guidelines.pdf), at <http://public.health.oregon.gov/PreventionWellness/SubstanceUse/Opioids/Documents/taskforce/oregon-opioid-prescribing-guidelines.pdf>.

Mechanism of delivery and dosing

Aside from certain FDA-approved synthetic forms of cannabinoids, there is a lack of clinical evidence on the effective method of delivery and dose response of the medical use of marijuana. The work group recommends that physicians focus on maintaining or improving a patient's ability to function when considering method of delivery, product type and amount of marijuana consumed.

Because of harms associated with inhaling any kind of smoke, the work group strongly opposes of patients smoking marijuana. Physicians should advise patients to consume the lowest possible amount of marijuana to achieve discussed treatment goals. Physicians and patients also should be aware of legal limitations in the amount of THC that is allowed in certain medical marijuana items sold at retail.¹⁸ There is no limit in the amount of cannabidiol (CBD) that a medical marijuana product may contain; however, the work group advises physicians to be aware of the type of product and amount of cannabinoids the patient is consuming to achieve the desired treatment goals.

¹⁸ OAR 333-007-0220, Table 2 Medical Cannabis Concentration and Serving Limits. Retrieved from: <https://public.health.oregon.gov/DiseasesConditions/ChronicDisease/MedicalMarijuanaProgram/documents/rules/333-007-0220-table-2.pdf>.



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