

University of Washington/Harborview Medical Center Adopt Medical Marijuana Policy

by Jennifer Brzana, Pharm.D.

The University of Washington/Harborview Medical Centers have developed a medical marijuana policy designed to assist health care providers in practicing within the boundaries of the law. This policy, entitled: "University of Washington Policy for Physician Authorization of Medical Marijuana," was written in response to the passing of a medical marijuana initiative by Washington State voters. Initiative 692 became law in December of 1998 and provides protection to certain qualifying citizens of Washington State from criminal prosecution under state law for the possession and use of a limited amount of marijuana. It is important to keep in mind that Washington's initiative does not legalize or decriminalize marijuana, which remains federally classified as a schedule I substance, a category reserved for substances with a high abuse potential and no accepted medical use. For clarification, marijuana is composed of unpurified plant material, containing upwards of 400 different substances and 66 different cannabinoids. THC, marijuana's most active cannabinoid, is currently available by prescription as the schedule III drug, dronabinol (Marinol[®]).

Consistent with the provisions of Initiative 692, the UWMC/HMC medical marijuana policy reaffirms that no health care provider is required to authorize the use of marijuana for any patient. Evidence supporting the use of marijuana in the treatment of disease symptoms is poorly defined and difficult to evaluate because few randomized, placebo-controlled trials are available. Most of the evidence for safety and efficacy consists of case reports and personal testimonies. The Institute of Medicine's 1999 report "Marijuana and Medicine: Assessing the Science Base" concluded that the use of smoked marijuana in chronic illnesses is not recommended because of the long-term harm caused by smoking. In terminal illnesses this harm is of little consequence, but to date neither marijuana nor THC have proven to be safer or more effective than the gold standard of treatment for any disease state. This report can be found on the Institute of Medicine's web page at <http://www.iom.edu>.

Patient eligibility requirements

Currently under Initiative 692, illnesses that qualify for medical marijuana include cancer, acquired immune deficiency syndrome, multiple sclerosis, spasticity disorders, epilepsy or other seizure disorders, Chron's disease, hepatitis C, intractable pain, and glaucoma. Accepted indications are subject to change as doctors and patients can petition the Washington State medical quality assurance board to add additional terminal or debilitating conditions to those originally included in Initiative 692.

Patients who satisfy the approved diagnostic criteria must be residents of Washington State and have their diagnoses confirmed in Washington State. Eligibility is extended to minor patients less than 18 years of age but acquisition, possession, dosing

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As a provision of Initiative 692, the caregiver of an incapacitated patient is exempt from prosecution for possessing and administering medically-authorized marijuana to a patient as long as the caregiver is designated in writing by the patient and is only responsible for one patient at a time.

An up-to-date list of accepted medical indications for marijuana authorization can be obtained by contacting the Washington State Medical Quality Assurance Commission at (360) 236-4792.

THC (dronabinol; Marinol[®]), marijuana's most active cannabinoid, is available on the UWMC/HMC Drug Formulary as 2.5, 5, and 10mg capsules. The usual adult doses are:

- **Appetite Stimulant**
2.5mg po BID before lunch and supper.
- **Antiemetic**
5mg/m² 1-3h before chemotherapy, then q 2-4h after chemotherapy for a total of 4–6 doses daily.

Physicians should warn patients about the risk of impairment of cognitive abilities and coordination and warn patients not to engage in potentially dangerous activities while using medical marijuana.

and frequency of administration must be the responsibility of a parent or legal guardian. Marijuana must be used in private; use in public facilities, including hospitals, is classified as a misdemeanor, and can be subject to legal action regardless of physician authorization. Initiative 692 also extends legal protection to caregivers of incapacitated patients, exempting them from prosecution for possessing and administering marijuana to the patient. However, to guarantee protection, the primary caregiver of an adult patient must be designated in writing as such by the patient.

The Institute of Medicine recommends that once an appropriate candidate for medical marijuana has been identified, the following criteria be applied before short-term (less than 6 months) authorization is granted:

- As appropriate, other approved medications have been tried and their failure documented in the patient's medical chart.
- The use of rapid onset cannabinoid drugs is expected to provide relief.
- Treatment is monitored in a manner that allows for assessment of effectiveness.

Provider responsibility and protection

Initiative 692 protects physicians from state-level penalties for counseling appropriate patients about the risks and possible benefits of medical marijuana. This counseling is required by state law and the UWMC/HMC policy and procedure requires documentation of it. Counseling should emphasize the following:

- There is limited scientific data examining its use in any disease state.
- There is little information regarding the long- and short-term complications of marijuana use, including: impairment of coordination and cognition, respiratory damage, and dependency issues. Long-term use has been associated with a withdrawal syndrome although it is less acute than withdrawal from ethanol or benzodiazepines, presumably due to the much longer half-life of marijuana. Marijuana may also exacerbate psychiatric illnesses. Chronic use has also been associated with an increased risk of cancer and lung damage. Smoking marijuana exposes a patient to 50% higher levels of precarcinogens and levels of tar that are three times higher than those associated with tobacco smoking.
- Marijuana is a schedule I substance and manufacturing is not overseen by the Food and Drug Administration; impurities and contaminants may be contained in the product and the effect of these cannot be predicted or evaluated. *Klebsiella*, *Enterobacter*, *Streptococcus*, and *Bacillus* species have all been cultured from marijuana tobacco; *Salmonella* and fungal infections, including *Aspergillus* infections, have also been linked to its use. Smoking marijuana has been associated with an increased risk of developing bacterial pneumonia in HIV-infected individuals.
- The potency of marijuana cannot be predicted and is based on growing conditions, genetics of the plant, and harvesting procedures. The concentration of THC has been shown to vary from 0.3–15%; a 1g cigarette may deliver anywhere from 3–150mg of THC.
- It is unknown whether marijuana interferes with the metabolism of any prescription drugs. However, components are metabolized through the cytochrome P450 system and marijuana is highly protein bound, increasing the likelihood of clinically significant drug interactions. It is known that THC and another significant cannab-

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The UWMC/HMC Medical Marijuana Policy requires that authorization be renewed every 6 months and that the following be placed in an authorized patient's chart:

1. **Copy of valid Washington State driver's license or identification card.**
2. **Copy of completed UWMC/HMC forms:**
 - a. **"Physician Authorization for Medical Marijuana"**
 - b. **"Consent to Assume Risks for Medical Marijuana."**

For more information, a CME Program titled "Cannabis Therapy: Science, Medicine and the Law," is scheduled for June 3, 2000. Registration information can be obtained by calling (206) 543-1050.

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References

inoid, cannabidiol, inhibit the activity of mixed function oxidase enzymes, but the clinical significance of this is unknown. The metabolism of other drugs may be affected differently based on the sequence of drug exposure. Secondary to marijuana's effect on slowing gastric emptying time, ethanol taken prior to marijuana is known to peak at a much higher level than the same dose taken afterwards.

- It is unknown whether marijuana has harmful effects in any of the disease states for which its use has been advocated; for example, it could have damaging effects on the immune system. Although the clinical significance remains unknown, cannabinoids appear to suppress antibody formation, cytokine production, and leukocyte migration.

Marijuana remains a schedule I controlled substance under both federal and state laws; by definition it is illegal to issue a prescription for it. Initiative 692 does not give health care providers the authority to write prescriptions for marijuana, and doing so could result in felony charges. One can predict that many patients seeking authorization to use medical marijuana may simultaneously seek assistance from health care providers in obtaining this substance. Initiative 692 does not allow a prescriber to aid in the procurement of marijuana, which includes directing a patient to an underground buyers' club, such as the Green Cross. Initiative 692 does not extend legal protection to buyers' clubs. Assisting a patient in obtaining marijuana can result in criminal prosecution under federal law and the loss of a physician's DEA registration.

Procedure to authorize medical marijuana use

In accordance with the UWMC/HMC medical marijuana policy, once an appropriate patient has been identified and the health care provider feels marijuana therapy would provide benefits that possibly outweigh the risks involved, two forms must be completed. The policy and these forms can be found online in the institutions' Administrative Policies and Operational Procedures Manual at <http://hermia.mcis.washington.edu>. Use your Iris password and choose "UWMC APOP;" from here you can use the search engine to locate the policy. The "Physician Authorization for Medical Marijuana" form must be signed and dated by the physician. This, along with a valid Washington State driver's license or identification card provides the patient with the documentation of medical authorization required by law, and copies of both must be placed in the patient's chart. Authorization must be renewed every six months. The second form, "Consent To Assume Risks For Medical Marijuana" must also be completed and kept in the patient's chart to document patient counseling and informed consent, and to release the Medical Centers from any liability for harm to the patient secondary to their use of marijuana.

Although medical evidence is lacking and risks are possible and largely unknown, Initiative 692 cites humanitarian compassion as the motivation to allow the decision to use marijuana in terminal or debilitating illness to be one between a patient and his or her doctor. Marijuana has not been legalized, nor has it been proven to be as safe and effective as currently available treatments. However, if the decision to authorize is made, following the guidelines outlined in the University of Washington Policy for Physician Authorization of Medical Marijuana will assure that a UWMC/HMC health care provider is practicing in accordance with state law.

1. Voith EA, Schwartz RH, Medicinal applications of delta-9-tetrahydro-cannabinol and marijuana. *Ann Intern Med* 1997;126(10):791-8.
2. Hubbard JR, Franco SE, Onaivi ES. Marijuana: Medical Implications. *Am Fam Physician* 1999;60(9):2583-8.
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Pharmacy & Therapeutics Committee Actions

| Formulary Additions | Dosage Form(s), Strength(s), & Cost | Therapeutic Classification | Use | Usual Adult Starting Dose* |
|---|--|--|-------------------------------|----------------------------|
| Calcium citrate (Citracal) | Capsule: 315mg calcium + 200IU vitamin D-\$0.07 | Mineral | Calcium supplementation | Individualized |
| Fluoride (Prevident) | Gel: 1.8% (51g)-\$7.36 | Trace element | Prevention of dental caries | Refer to product labeling |
| Magnesium plus protein (generic) | Tablet: 133mg magnesium-\$0.04 | Mineral | Magnesium supplementation | Individualized |
| Potassium chloride (K-Dur) | Tablet: 10mEq-\$0.11 | Electrolyte | Potassium replacement | Individualized |
| Rapacuronium (Raplon) | Injection: 20mg/mL (5mL-\$11.08; 10mL-\$19.32) | Non-depolarizing neuromuscular blocker | Adjunct to general anesthesia | 1.5mg/kg |
| Other Formulary Actions | | | | |
| Automatic Therapeutic Interchange Automatic therapeutic interchange has been authorized for the following products commonly ordered by Seattle Cancer Care Alliance prescribers: | Product | UWMC Formulary Substitution | | |
| | famotidine (Pepcid) | ranitidine (Zantac) 150mg | | |
| | lidocaine ointment (generic) 2..5% (35g) | lidocaine ointment (generic) 5% (37.5g) | | |
| | miconazole nitrate powder (generic) 2% | nystatin 100,000U/g powder (generic) 15g | | |
| | ophthalmic lubricant ointment (Lacri-Lube 3.5g) | ophthalmic lubricant ointment (Lacri-Lube 0.7g); ophthalmic lubricant ointment (Hypotears 3.5g) | | |
| | pancrelipase [amylase 30,000U + lipase 8,000U + protease 30,000U] (Ku-Zyme HP) | pancrelipase [amylase 30,000U + lipase 8,000U + protease 30,000U] (Cotazym) | | |
| | sunscreen lotion (generic) SPF 15 | sunscreen lotion (generic) SPF 30 | | |

* Refer to product labeling for full prescribing information.

Milo Gibaldi Honored at World Congress as “Millennial Pharmaceutical Scientist”

Dr. Milo Gibaldi, Dean Emeritus of the UW School of Pharmacy and author of the *Drug Therapy Topics Supplement*, was honored at the Millennial World Congress of Pharmaceutical Sciences in San Francisco on April 16 for contributions that have led to significant advances in the field during the past century. Dr. Gibaldi is widely recognized for his excellence in pharmacy research, education, and publishing, and is the author of a new book: *Gibaldi’s Drug Therapy 2000*.

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