## DEPARTMENT OF PUBLIC HEALTH

- 1) <u>Heading of the Part:</u> Compassionate Use of Medical Cannabis Patient Registry
- 2) <u>Code Citation:</u> 77 Ill. Adm. Code 946
- 3) Section Numbers: Adopted Actions: 946.10 Amendment 946.25 New Section 946.30 Amendment 946.35 New Section 946.60 Amendment 946.200 Amendment 946.201 Amendment 946.205 Amendment 946.210 Amendment 946.220 Amendment 946.240 Amendment 946.290 Amendment 946.300 Amendment 946.310 Amendment 946.315 New Section 946.500 Amendment
- 4) <u>Statutory Authority:</u> Compassionate Use of Medical Cannabis Pilot Program Act [410 ILCS 130]
- 5) <u>Effective Date of Amendments:</u>
- 6) <u>Does this rulemaking contain an automatic repeal date</u>? No
- 7) <u>Does this rulemaking contain incorporations by reference</u>? No
- 8) <u>A copy of the adopted amendments, including any material incorporated by reference, is</u> on file in the agency's principal office and is available for public inspection.
- 9) <u>Notice of Proposed Amendments Published in Illinois Register:</u> 40 Ill. Reg. 10751; August 12, 2016
- 10) <u>Has JCAR issued a State of Objection to these amendments</u>? No

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# 11) <u>Difference(s) between proposal and final version</u>: The following changes were made a result of comments received during the first notice or public comment period:

- Delete reference to the physician written certification in Section 946.205
- Specify waiver recommendations for increasing the adequate supply of medical cannabis does not constitute a prescription for medical cannabis in Section 946.315
- Revise the definition of "reasonable amount" in Section 946.10 to ensure correct a contradiction identified in the definition which was included in the first notice

The following changes were made in response to comments and suggestions of JCAR:

- The fee structure was revised in Section 946.210(a), (b), and (c) to accommodate a one-, two-, and three-year registry card
- Section 946.290 was clarified to address the renewal process for the registry identification fee structure.
- The ability to extend a registry identification for one- or two-years to accommodate the total three-year period for which a patient application is valid was specified in Section 946.290(d)

At Second Notice, various typographical, grammatical, and form changes were made in response to the comments from JCAR.

- 12) <u>Have all the changes agreed upon by the agency and JCAR been made as indicated in the agreements issued by JCAR?</u> Yes
- 13) Will this rulemaking replace an emergency rule currently in effect? Yes
- 14) <u>Are there any amendments pending on this Part?</u> No
- 15) <u>Summary and Purpose of Rulemaking:</u> This rulemaking implements P.A. 99-0519, effective June 30, 2016, to set forth the requirements for qualifying patients to participate in the Department's Compassionate Use of Medical Cannabis Patient Registry Program. The amendments provide for additional debilitating conditions; add an eligibility category for persons diagnosed with a terminal illness; make changes in the physician written certification; change fees to correspond with the lengthened time frame for a valid registry identification card; add requirements for increasing the adequate supply of medical cannabis and make other changes.
- 16) <u>Information and questions regarding these adopted amendments shall be directed to:</u>

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#### NOTICE OF ADOPTED AMENDMENTS

Elizabeth Paton Assistant General Counsel Division of Legal Services Illinois Department of Public Health 535 W. Jefferson St., 5<sup>th</sup> floor Springfield, Illinois 62761

217/782-2043 e-mail: <u>dph.rules@illinois.gov</u>

The full text of the adopted amendments begin on the next page:

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## TITLE 77: PUBLIC HEALTH CHAPTER I: DEPARTMENT OF PUBLIC HEALTH SUBCHAPTER u: MISCELLANEOUS PROGRAMS AND SERVICES

# PART 946 COMPASSIONATE USE OF MEDICAL CANNABIS PATIENT REGISTRY

#### SUBPART A: GENERAL PROVISIONS

## Section

- 946.10 Definitions
- 946.15 Referenced Materials
- 946.20 Debilitating Medical Conditions
- <u>946.25</u> <u>Terminal Illness</u>
  - 946.30 Addition of Debilitating Medical Conditions
- 946.35 Medical Cannabis Advisory Committee
- 946.40 Limitations and Penalties
- 946.50 Notifications to the Department
- 946.60 Confidentiality
- 946.70 Applicability to the Smoke Free Illinois Act

## SUBPART B: QUALIFYING PATIENTS AND DESIGNATED CAREGIVERS

Section

946.200	Application for Registry Identification Card for Qualifying Patients and
	Designated Caregivers
946.201	Application for Registry Identification Card for Qualifying Patients under 18
	Years of Age
946.205	Deadlines for Submission of Application for Registry Identification Card
946.210	Fees
946.220	Fingerprint-Based Criminal History Records Check
946.230	General Provisions
946.240	Persons Receiving Medical Care at U.S. Department of Veterans Affairs Facilities
946.250	Disposal of Medical Cannabis by Qualifying Patients
946.260	Responsibilities of Designated Caregivers
946.270	Revocation of a Registry Identification Card
946.275	Suspension of a Registry Identification Card
946.280	Medical Cannabis Obtained from a Medical Cannabis Dispensing Organization
046 000	

946.290 Renewal of Registry Identification Cards

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# SUBPART C: PHYSICIAN REQUIREMENTS

Section	
946.300	Qualifications of the Certifying Physician
946.310	Physician Written Certification
<u>946.315</u>	Waiver for Increasing the Adequate Supply of Medical Cannabis
946.320	Records Maintained by the Physician and Department

## SUBPART D: CANNABIS-INFUSED PRODUCTS

Section	
946.400	Manufacture of Cannabis-Infused Products
946.410	Sale and Distribution of Cannabis-Infused Products
946.420	Preparation
946.430	Health Hazards

# SUBPART E: ENFORCEMENT

Section 946.500 Circuit Court Review

AUTHORITY: Implementing and authorized by the Compassionate Use of Medical Cannabis Pilot Program Act [410 ILCS 130].

SOURCE: Adopted at 38 III. Reg. 17367, effective July 29, 2014; emergency amendment at 39 III. Reg. 444, effective December 22, 2014, for a maximum of 150 days; amended at 39 III. Reg. 7712, effective May 15, 2015; emergency amendment at 40 III. Reg. 10992, effective August 1, 2016, for a maximum of 150 days; emergency amendment to emergency rule at 40 III. Reg. 13732, effective September 16, 2016, for the remainder of the 150 days; amended at 40 III. Reg. , effective

## SUBPART A: GENERAL PROVISIONS

## Section 946.10 Definitions

"Act" means the Compassionate Use of Medical Cannabis Pilot Program Act [410 ILCS 130].

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"Adequate supply" means 2.5 ounces of usable cannabis during a period of 14 days and that is derived solely from an intrastate source. (Section 10(a)(1) of the Act)

"Administer" or "Administration" means the direct introduction of medical cannabis into the body of a person, whether by inhalation, ingestion, or any other means.

"Bona-fide physician-patient relationship" means a relationship in which the physician has ongoing responsibility for the assessment, care and treatment of a patient's debilitating medical condition, or a symptom of the patient's debilitating medical condition, for which the physician has certified to the Department that the qualifying patient would receive therapeutic or palliative benefit from the medical use of cannabis.

"Cannabis" means marihuana, hashish and other substances which are identified as including any parts of the plant Cannabis sativa and including any and all derivatives or subspecies, such as Indica, of all strains of cannabis, whether growing or not; the seeds thereof, the resin extracted from any part of such plant; and any compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or resin, including tetrahydrocannabinol (THC) and all other cannabinol derivatives, including its naturally occurring or synthetically produced ingredients, whether produced directly or indirectly by extraction, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis; but shall not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil or cake, or the sterilized seed of such plant which is incapable of germination. (Section 3(a) of the Cannabis Control Act)

"Caregiver" or "designated caregiver" means a person who is designated by a qualifying patient as the person authorized, on the qualifying patient's behalf, to possess, obtain from a certified medical cannabis dispensary, dispense and assist in the administration of medical cannabis.

"Cultivation center" means a facility operated by an organization or business that is registered by the Department of Agriculture to perform necessary activities to provide only registered medical cannabis dispensing organizations with usable medical cannabis. (Section 10(e) of the Act)

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"DD214" means a certified DD214 Certificate of Release or Discharge from Active Duty Member Copy 4 or State Director of Veteran Affairs Copy 6; a certified DD214 Report of Separation from Active Duty Copy 2; or equivalent certified document indicating character of service and dates of service. A DD214 can be certified by the State Department of Veterans' Affairs, county veteran's officials, and the federal Department of Veterans Affairs.

## "DEA Registration Certificate" means a certificate to prescribe controlled substances issued by the U.S. Department of Justice's Drug Enforcement Administration.

"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, agitation of Alzheimer's disease, cachexia/wasting syndrome, muscular dystrophy, severe fibromyalgia, spinal cord disease, including but not limited to arachnoiditis, Tarlov cysts, hydromyelia, syringomyelia, Rheumatoid arthritis (RA), fibrous dysplasia, spinal cord injury, traumatic brain injury (TBI) and post-concussion syndrome, Multiple Sclerosis, Arnold-Chiari malformation and Syringomelia, Spinocerebellar Ataxia (SCA), Parkinson's disease, Tourette's syndrome, Myoclonus, Dystonia, Reflex Sympathetic Dystrophy, RSD (Complex Regional Pain Syndromes Type I), Causalgia, CRPS (Complex Regional Pain Syndromes Type II), Neurofibromatosis, Chronic Inflammatory Demyelinating Polyneuropathy, Sjogren's syndrome, Lupus, Interstitial Cystitis, Myasthenia Gravis, Hydrocephalus, nail-patella syndrome, residual limb pain, seizures (including those characteristic of epilepsy); and post-traumatic stress disorder (PTSD) or the treatment of these conditions; or any other debilitating medical condition that is added pursuant to the statute or by the Department by rule as provided in Section 946.30. (Section 10(h) of the Act)

"Department" means the Illinois Department of Public Health.

"Director" means the Director of the Illinois Department of Public Health or his or her designee.

"Dispensing organization district" or "District" means one of the 43 geographically dispersed areas identified in the Act and by the Department of Financial and Professional Regulation where one or more dispensing organizations may be located.

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"Evidence-based medical research" means documentation of published, peerreviewed best evidence on research related to the use of medical cannabis, which includes up-to-date information from relevant, valid research about the effects of medical cannabis on different forms of diseases and conditions, its use in health care, the potential for harm from exposure, and other relevant medical information.

"Excluded offense" means: a violent crime defined in Section 3 of the Rights of Crime Victims and Witnesses Act or a substantially similar offense that was classified as a felony in the jurisdiction where the person was convicted; or a violation of a state or federal controlled substance law, the Cannabis Control Act, or the Methamphetamine and Community Protection Act, that was classified as a felony in the jurisdiction where the person was convicted, except that the Department may waive this restriction if the person demonstrates to the Department's satisfaction that his or her conviction was for the possession, cultivation, transfer, or delivery of a reasonable amount of cannabis intended for medical use.

This exception does not apply if the conviction was under state law and involved a violation of an existing medical cannabis law. (Section 10(1-5)10(1) of the Act)

"Fingerprint-based criminal history records check" means a fingerprint-based criminal history records check conducted by the Illinois State Police in accordance with the Uniform Conviction Information Act (UCIA).

"Health care facility" means any and all facilities and agencies licensed by the Hlinois Department of Public Health, including, but not limited to, those registered under the Hospital Licensing Act, Nursing Home Care Act, Ambulatory Surgical Treatment Center Act, Alternative Health Care Delivery Act, Hospice Program Licensing Act, Specialized Mental Health Rehabilitation Act of 2013 and any nursing facility operated by the Illinois Department of Veterans' Affairs.

"ISP" means the Illinois State Police.

"Livescan" means an inkless electronic system designed to capture an individual's fingerprint images and demographic data in a digitized format that can be transmitted to ISP for processing. The data is forwarded to the ISP Bureau of

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Identification (BOI) over a virtual private network (VPN) and then processed by ISP's Automated Fingerprint Identification System (AFIS). Once received at the BOI for processing, the inquiry may be forwarded electronically to the Federal Bureau of Investigation (FBI) for processing.

"Livescan vendor" means an entity licensed by the Department of Financial and Professional Regulation to provide commercial fingerprinting services under the Private Detective, Private Alarm, Private Security, Fingerprint Vendor, and Locksmith Act of 2004.

"Medical cannabis" means cannabis and its constituent cannabinoids, such as tetrahydrocannabinol (THC) and cannabidiol (CBD), used as an herbal remedy or therapy to treat disease or alleviate symptoms. Medical cannabis can be administered in a variety of ways, including, but not limited to: vaporizing or smoking dried buds; using concentrates; administering tinctures or tonics; applying topicals such as ointments or balms; or consuming medical cannabis-infused food products.

"Medical cannabis container" means a sealed, traceable, food compliant, tamper resistant, tamper evident container or package used for the purpose of containment of medical cannabis. (Section 10(n) of the Act)

"Medical cannabis dispensing organization" or "Dispensing organization" means a facility operated by an organization or business that is registered by the Department of Financial and Professional Regulation to acquire medical cannabis from a registered cultivation center for the purpose of dispensing medical cannabis, paraphernalia, or related supplies and educational materials to registered qualifying patients. (Section 10(0) of the Act)

"Medical cannabis-infused product" means food, oils, ointments, sodas or teas, capsules or other products containing usable cannabis that are not smoked. (Section 10(q) of the Act)

"Petitioner" means an applicant who seeks to add debilitating medical conditions to those listed in Section 10(h) of the Act as allowed under Section 946.30.

"Private residence" means the part of a structure used as a dwelling, including, without limitation: a private home, townhouse, condominium, apartment, mobile home, vacation home, cabin or cottage. For the purposes of this definition, a hotel, motel, inn, resort, lodge, bed and breakfast or other similar public

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accommodation, hospital, nursing home or assisted living facility shall not be considered a private residence.

"Promptly" means as soon as reasonably practicable, but not later than five days.

"Public place" means any place where an individual could reasonably be expected to be observed by others, including all parts of buildings owned in whole or in part or leased by the State or a unit of local government. A "public place" does not include health care facilities, as defined in this Part, or private residences unless the private residence is used to provide child care, foster care or other similar social service care on the premises.

"Qualifying patient" means a person who has been diagnosed by a physician as having a debilitating medical condition. (Section 10(t) of the Act)

"Quorum" means a majority of the appointed members of the advisory committee being present in person or participating through video conference or by telephonic means.

"Reasonable amount" means less than 2,000 grams of cannabis for any conviction that occurred in the past 10 years or any amount of cannabis if the felony in the jurisdiction where the conviction occurred has been reclassified as a misdemeanor or petty offense since the time of the conviction.

"Registered qualifying patient" means a qualifying patient who has been approved by the Department and has been issued a registry identification card.

"Registry identification card" or "medical cannabis patient registry card" means a document issued by the Department that identifies a person as a current registered qualifying patient or registered designated caregiver. (Section 10(v) of the Act)

"Resident" means a person who maintains a legal place of residence in the State of Illinois.

"Reviewing physician" means a physician currently licensed under the Medical Practice Act of 1987 or who possesses a current, active medical license issued by another state, who has conducted a review of the medical records from other physician treating a qualifying patient who is under 18 years of age for the purpose of <u>confirming the diagnosis of debilitating medical conditions as defined</u>

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in the Actattesting that the qualifying patient is likely to receive therapeutic or palliative benefit from the medical use of cannabis to treat or alleviate the qualifying patient's debilitating medical condition.

"Spinal cord injury" means damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity.

"Terminal illness" means a debilitating condition or other illness for which the qualifying patient has received a diagnosis for a life expectancy of six months or less.

"Tincture" means cannabis flowered tops and leaves that are soaked in liquid, usually an alcohol solution, transferring the THC and other cannabanoids to the liquid. The tincture may be added to foods and liquids, applied to the skin, or consumed directly by drinking a small quantity or placing a few drops under the tongue.

"Tetrahydrocannabinol" or "THC" means the primary active ingredient in cannabis.

"VA" means federal Department of Veterans Affairs.

"Veteran" means person who served in one of the five active-duty Armed Services or their respective Guard or Reserve units, and who was discharged or released from service under conditions other than dishonorable.

"VA hospital" means a health care facility operated by the federal Department of Veterans Affairs-Veterans Health Administration providing hospital and outpatient health care services to U.S. military service veterans.

"VA official hospital medical records" means records from the VA documenting medical conditions and dates of treatment in the VA healthcare system.

"Violent crime" means any felony in which force or threat of force was used against the victim, or any offense involving sexual exploitation, sexual conduct or sexual penetration, or a violation of Section 11-20.1, 11-20.1B, or 11-20.3 of the Criminal Code of 1961 or the Criminal Code of 2012, domestic battery, violation of an order of protection, stalking, or any misdemeanor which results in death or great bodily harm to the victim or any violation of Section 9-3 of the Criminal Code of 1961 or the Criminal Code of 2012, or Section 11-501 of the Illinois

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Vehicle Code, or a similar provision of a local ordinance, if the violation resulted in personal injury or death, and includes any action committed by a juvenile that would be a violent crime if committed by an adult. For the purposes of this definition, "personal injury" shall include any Type A injury as indicated on the traffic accident report completed by a law enforcement officer that requires immediate professional attention in either a doctor's office or medical facility. A Type A injury shall include severely bleeding wounds, distorted extremities, and injuries that require the injured party to be carried from the scene; or a substantially similar offense that was tried and convicted as a felony in the jurisdiction where the qualifying patient or designated caregiver was convicted. (Section 3(c) of the Rights of Crime Victims and Witnesses Act and Section 10(1)(1) of the Act)

"Waiver" means a waiver of an excluded offense granted by the Department solely based upon the results of a fingerprint-based criminal history records check *if the person demonstrates to the Department's satisfaction that his or her conviction was for the possession, cultivation, transfer, or delivery of a reasonable amount of cannabis intended for medical use.* (Section 10(1)(2) of the Act)

"Written certification" means a document dated and signed by a physician, stating that in the physician's professional opinion, the patient is likely to receive therapeutic or palliative benefit from the medical use of cannabis to treat or alleviate the patient's debilitating medical condition or symptoms associated with the debilitating medical condition; that the qualifying patient has a debilitating medical condition and specifying the debilitating medical condition the qualifying patient has; and that the physician is treating or managing treatment of the patient's debilitating condition.patient is under the physician's care for the debilitating medical condition. A written certification shall be made only in the course of a bona-fide physician-patient relationship, after the physician has completed an assessment of the qualifying patient's medical history, reviewed relevant records related to the patient's debilitating condition, and conducted a physical examination. (Section 10(y) of the Act)

(Source: Amended at 40 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

Section 946.25 Terminal Illness

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An individual who submits an application for a registry identification card as someone who is terminally ill as defined in Section 946.10 shall have all fees and fingerprinting requirements waived. (Section 60(c-10) of the Act)

- a) <u>A qualifying patient who has been diagnosed with a terminal illness shall register</u> with the Department on forms and in a manner prescribed by the Department.
- b) To qualify for a registry identification card, a qualifying patient with a diagnosis of terminal illness shall:
  - 1) Be a resident of the State of Illinois at the time of application and remain a resident during participation in the program.
  - 2) Meet the definition of terminal illness in Section 946.10.
  - 3) Have a signed, written attestation specifying that the qualifying patient has a terminal illness, on a form provided by the Department, submitted by a physician who meets the requirements set forth in the Act, along with an application for a registry identification card.
  - 4) Complete an application on a form provided by the Department and submit a copy of his or her Illinois driver's license, Temporary Visitor's Driver's License or state identification card. If the individual does not have an Illinois driver's license or state identification card, a color copy of a current passport will be accepted.
  - 5) Provide a current digital passport-sized photograph meeting the criteria specified in Section 946.200(b)(6).
- <u>A veteran or spouse of a veteran who is receiving care for a debilitating condition at a VA hospital, as specified in Section 946.240, shall sign a written attestation indicating they have been diagnosed with a terminal illness and shall submit one year of official VA hospital medical records from the VA using VA Form 10-5345 and provide a copy of his or her DD214 indicating character and dates of service.</u>
- <u>d)</u> <u>A qualifying patient under the age of 18 diagnosed with a terminal illness will not be required to obtain a written certification from a reviewing physician.</u>

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- e) <u>A patient with a terminal illness may specify a designated caregiver. A qualifying patient under age 18 may have two designated caregivers as described in Section 946.201(c).</u>
- <u>A qualifying patient shall not possess a school bus permit or a Commercial</u> Driver's License. (Section 30 of the Act). Persons who possess such licenses should revoke them prior to submitting an application for a medical cannabis registry identification card.
- g) <u>Applications submitted by an applicant diagnosed with a terminal illness *shall be approved or denied within 14* business days, not including State holidays, *of the submission of their* complete *application*. (Section 60(c-10) of the Act) The time period for approval or denial will not include the time necessary for the Secretary of State verification process to be completed or the printing, mailing and receipt of the registry identification card by the patient.</u>
- h) Persons whose diagnosis is no longer terminal after a period of six months and their designated caregiver, may submit an application for a registry identification card in accordance with Section 946.200 or Section 946.201 and pay all applicable fees specified in Section 946.210.

(Source: Added at 40 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

# Section 946.30 Addition of Debilitating Medical Conditions

Residents may petition the Department to add debilitating medical conditions to those listed in Section 10(h) of the Act and Section 946.20. The Department will accept petitions <u>annuallytwice</u> annually. The <u>annual petitionopen</u> period for accepting petitions will be for a one-month period from January 1 through January 31 and again from July 1 through July 31 each year. Petitions received outside of the open periods specified in this Section will not be reviewed and will be returned to the resident submitting the petition.

a) During the open period, the Department will accept petitions from any resident requesting the addition of a new debilitating medical condition or disease to the list of approved debilitating medical conditions for which the use of cannabis has been shown to have a therapeutic or palliative effect. The Department shall provide public notice 30 days before the open period for accepting petitions, which shall describe the time period for submission, the required format of the submission, and the submission address, which is set forth in Section 946.205. (Section 45(b) of the Act)

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The Department will convene a Medical Cannabis Advisory Board (Advisory Board) composed of 16 members, including:

- 1) One medical cannabis patient advocate or designated caregiver;
- 2) One parent or designated caregiver of a person under age 18 who is a qualified medical cannabis patient;
- 3) Two registered nurses or nurse practitioners;
- 4) Three registered qualifying patients, including one veteran; and
- 5) Nine healthcare practitioners with current professional licensure in their field. The Advisory Board shall be composed of healthcare practitioners representing the following areas. At least one appointed healthcare practitioner shall have direct experience related to the health care needs of veterans and at least one individual shall have pediatric experience:
  - A) Neurology;
  - B) Pain management;
  - C) Medical oncology;
  - D) Psychiatry or mental health;
  - E) Infectious disease;
  - F) Family medicine;
  - G) General primary care;
  - H) Medical ethics;
  - I) Pharmacy;
  - J) Pediatrics; or
  - K) Psychiatry or mental health for children or adolescents.

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- b) The Advisory Board shall review petitions and recommend to the Department additional debilitating conditions or diseases that would benefit from the medical use of cannabis.
- e) Members of the Advisory Board will be appointed by the Governor.
  - Members shall serve a term of four years or until a successor is appointed and qualified. If a vacancy occurs, the Governor will appoint a replacement to complete the original term created by the vacancy.
  - 2) Members shall select a chairperson.
  - 3) Members may serve multiple terms.
  - 4) Members shall not have an affiliation with, serve on the board of, or have a business relationship with a registered cultivation center or a registered medical cannabis dispensary.
  - 5) Members shall disclose any real or apparent conflicts of interest that may have a direct bearing of the subject matter, such as relationships with pharmaceutical companies, biomedical device manufacturers, or corporations whose products or services are related to the medical condition or disease to be reviewed.
  - 6) Members will not be paid but will be reimbursed for travel expenses incurred while fulfilling the responsibilities of the Advisory Board.
- d) The Advisory Board shall convene at least twice per year to:
  - 1) Review petitions received from residents of Illinois for the addition of debilitating medical conditions or diseases that would benefit from the medical use of cannabis.
  - 2) Conduct a public hearing to review the petitions received.
  - 3) Review conditions previously reviewed by the Advisory Board and accepted by the Department for the purposes of determining whether to recommend the revision of the list of debilitating medical conditions or to

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review new medical and scientific evidence pertaining to currently approved conditions.

- 4) Recommend the approval or denial of each petitioner's request by submitting a written report to the Department within 60 days after conducting the public hearing. The written report shall include a medical justification for the recommendation based upon the individual or collective expertise of the members of the advisory board. The medical justification shall delineate between the findings of fact made by the Advisory Board and the scientific conclusions of evidence-based medical research.
- e) During the open period, the Department will accept petitions from any resident requesting the addition of a new debilitating medical condition or disease to the list of approved debilitating medical conditions for which the use of cannabis has been shown to have a therapeutic or palliative effect. The Department will provide public notice 30 days before the open period for accepting petitions, describing the time period for submission, the required format of the submission, and the submission address, which is set forth in Section 946.205.
- b)f) <u>Each petition shall be limited to one proposed debilitating medical condition or</u> <u>disease</u>. (Section 45(c) of the Act)Each petition shall be limited to one proposed debilitating medical condition or disease.
- <u>c)g</u>) <u>A petitioner shall file one original petition in the format provided by the</u> <u>Department and in the manner specified by the Department. For a petition to be</u> <u>processed and reviewed, the following information shall be included:</u> (Section <u>45(d) of the Act)A petitioner shall file one original petition in the format provided</u> by the Department and two paper copies, along with a CD/DVD or flash drive containing the petition and all associated documents in electronic form, with the Department by certified U.S. mail. For a petition to be processed and submitted to the Advisory Board, the following information shall be included:
  - 1) The petition, prepared on forms provided by the Department.
  - <u>1)</u>2) <u>A specific description of the medical condition or disease that is the subject of the petition. A specific description of the medical condition or disease that is the subject of the petition.</u> The petitioner shall not submit broad categories, e.g., all mental illnesses. <u>Each petition shall be limited to a single condition or disease. Information about the proposed condition</u>

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or disease shall include: Each petition shall be limited to a single condition or disease. Information about the proposed condition or disease shall include:

- <u>A)</u> <u>The extent to which the condition or disease itself and/or the</u> <u>treatments cause severe suffering, such as severe and/or chronic</u> <u>pain, severe nausea and/or vomiting, or otherwise severely impair</u> <u>a person's ability to carry on with activities of daily living;</u>
- B) Information about why conventional medical therapies are not sufficient to alleviate the suffering caused by the disease or condition and its treatment;
- <u>C)</u> <u>The proposed benefits from the medical use of cannabis specific to</u> <u>the medical condition or disease;</u>
- <u>D)</u> <u>Evidence from the medical community and other experts</u> <u>supporting the use of medical cannabis to alleviate suffering</u> <u>caused by the condition or disease and/or treatment;</u>
- <u>E)</u> <u>Letters of support from physicians or other licensed health care</u> providers knowledgeable about the condition or disease, including, if feasible, a letter from a physician with whom the petitioner has a bona-fide physician-patient relationship;
- F) Any additional medical, testimonial or scientific documentation; and
- <u>G)</u> <u>An electronic copy of all materials submitted.</u>
- A) The extent to which the condition or disease itself and/or the treatments cause severe suffering, such as severe and/or chronic pain, severe nausea and/or vomiting, or otherwise severely impair a person's ability to carry on with activities of daily living;
- B) Information about why conventional medical therapies are not sufficient to alleviate the suffering caused by the disease or condition and its treatment;

- C) The proposed benefits from the medical use of cannabis specific to the medical condition or disease;
- D) Evidence from the medical community and other experts supporting the use of medical cannabis to alleviate suffering caused by the condition or disease and/or treatment;
- E) Letters of support from physicians or other licensed health care providers knowledgeable about the condition or disease, including, if feasible, a letter from a physician with whom the petitioner has a bona-fide physician-patient relationship;
- F) Any additional medical, testimonial or scientific documentation; and
- G) An electronic copy of all materials submitted.
- 2) Upon receipt of a petition, the Department shall determine whether the petition meets the standards for submission and, if so, will accept the petition for further review; or whether the petition does not meet the standards for submission and, if so, shall deny the petition without further review.
- 3) If the petition does not fulfill the standards for submission, the petition shall be considered deficient. The Department shall notify the petitioner, who may correct any deficiencies and resubmit the petition during the next open period.
- 3) Upon review of materials submitted pursuant to subsection (g)(2), the Department will determine whether:
  - A) The petition meets the standards for submission and, if so, will accept the petition for further review; or
  - B) The petition does not meet the standards for submission and, if so, will deny the petition without further review.
- 4) If the petition does not fulfill the standards for submission, the petition will be considered deficient. The Department will notify the petitioner,

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who may correct any deficiencies and resubmit the petition during the next open period.

- 5) If the petition is accepted, the Department will refer the petition documents to the Advisory Board for review.
- <u>d)</u>h) The petitioner may withdraw his or her petition by submitting a written statement to the Department indicating withdrawal. The petitioner may withdraw his or her petition by submitting a written statement to the Department indicating withdrawal.
- e) Upon review of accepted petitions, the Director will consult with Department staff to analyze the clinical and scientific merit of the petitions. This consultation will occur before the Director renders a final decision regarding the acceptance or denial of the proposed debilitating medical conditions or diseases. (Section 45(f) of the Act) The Department's analysis will be recorded in a format prescribed by the Department.
- <u>f)</u> <u>The Department will approve or deny a petition within 180 days after its</u> <u>submission.</u> (Section 45(a) of the Act)
- g) All petitions to add debilitating conditions submitted to the Department in January 2016 will be reviewed in accordance with the rules for the addition of debilitating medical conditions in effect at the time of the submission.
- i) The Advisory Board shall have a minimum of 30 days to review the petitions before convening a public hearing.
- The Advisory Board shall convene a public hearing to review all petitions accepted by the Department pursuant to Section f(4)(B) requesting the addition of medical conditions or diseases to the list of debilitating medical conditions that would benefit from the medical use of cannabis.
  - 1) The Department will provide a notice of public hearing setting forth the date, time and location of the hearing, a brief description of the petitions received, and information on the requirements for public comment or statement of intent to present technical evidence, as required by the Open Meetings Act. The Department will publish a notice of the hearing on its website to provide notice to the public.

- 2) Meetings of the Advisory Board shall be in accordance with the Open Meetings Act.
- 3) Any meeting consisting of a quorum of the Advisory Board members held for the purpose of evaluating, discussing or otherwise formulating specific opinions concerning the recommendation of a petition filed pursuant to this Part shall be declared a public hearing open to the public at all times, unless a portion of the hearing is closed to protect information made confidential by applicable State or federal laws.
- 4) A petitioner may request to close a portion of the hearing to protect the disclosure of confidential information. The request for closure of the hearing shall be submitted to the same address as the initial submission set forth in Section 946.205. The request must be received by the Department at least 48 hours prior to the hearing.
- Any individual or an association of individuals who wishes to present technical evidence at the hearing shall file a statement of intent, no later than 15 days prior to the date of the hearing. The statement of intent to present technical evidence shall include:
  - 1) Name of the person filing the statement;
  - 2) Indication of whether the person filing the statement supports or opposes the petition at issue;
  - 3) Name of each witness;
  - 4) Estimate of the length of the direct testimony of each witness;
  - 5) List of exhibits, if any, to be offered into evidence at the hearing; and
  - 6) Summary or outline of the anticipated direct testimony of each witness.
- I) Upon final determination, the Advisory Board shall provide the Director a written report of findings recommending either the approval or denial of the petitioner's request. The written report of findings shall include a medical justification for the recommendation based upon the individual or collective expertise of the Advisory Board membership. The medical justification shall delineate between the findings of fact made by the Advisory Board and scientific conclusions of evidence-based

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medical research. The written report of findings shall protect information by applicable State or federal laws (e.g., FOIA or HIPAA).

- m) Upon review of the Advisory Board's recommendations, the Director will render a final decision regarding the acceptance or denial of the proposed debilitating medical conditions or diseases.
- n) *The Department will approve or deny a petition within 180 days after its submission* during the biannual petition period. (Section 45 of the Act)

(Source: Amended at 40 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

# Section 946.35 Medical Cannabis Advisory Board

- a) The Department shall convene a Medical Cannabis Advisory Board (Advisory Board) composed of 16 members, including (Section 45(q) of the Act):
  - 1) *One medical cannabis patient advocate or designated caregiver;*
  - 2) <u>One parent or designated caregiver of a person under age 18 who is a qualified medical cannabis patient;</u>
  - 3) <u>Two registered nurses or nurse practitioners;</u>
  - <u>4)</u> <u>Three registered qualifying patients, including one veteran; and</u>
  - 5) Nine health care practitioners with current professional licensure in their field. The Advisory Board shall be composed of health care practitioners representing the following areas:
    - <u>A)</u> <u>Neurology;</u>
    - <u>B)</u> *Pain management;*
    - <u>C)</u> <u>Medical oncology;</u>
    - D) <u>Psychiatry or mental health;</u>
    - E) Infectious disease;
    - <u>F)</u> *Family medicine;*

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- <u>G)</u> <u>General primary care;</u>
- <u>H)</u> <u>Medical ethics;</u>
- <u>I)</u> <u>Pharmacy;</u>
- <u>J)</u> <u>Pediatrics; or</u>
- <u>K)</u> <u>Psychiatry or mental health for children or adolescents.</u>

<u>At least one appointed health care practitioner shall have direct</u> <u>experience related to the health care needs of veterans and at least one</u> <u>individual shall have pediatric experience.</u>

- b) <u>Members of the Advisory Board shall be appointed by the Governor.</u>
  - 1) Members shall serve a term of four years or until a successor is appointed and qualified. If a vacancy occurs, the Governor shall appoint a replacement to complete the original term created by the vacancy.
  - 2) *The Governor shall select a chairperson.*
  - 3) <u>Members may serve multiple terms.</u>
  - 4) <u>Members shall not have an affiliation with, serve on the board of, or have</u> <u>a business relationship with a registered cultivation center or a registered</u> <u>medical cannabis dispensary.</u>
  - 5) Members shall disclose any real or apparent conflicts of interest that may have a direct bearing of the subject matter, such as relationships with pharmaceutical companies, biomedical device manufacturers, or corporations whose products or services are related to the medical condition or disease to be reviewed.
  - 6) <u>Members shall not be paid but will be reimbursed for travel expenses</u> incurred while fulfilling the responsibilities of the Advisory Board.
- <u>c)</u> <u>*The Advisory Board shall convene at the call of the Chair to:*</u>

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- 1) *Examine debilitating conditions or diseases that would benefit from the medical use of cannabis, and;*
- 2) <u>Review any new medical and scientific evidence pertaining to currently</u> <u>approved debilitating conditions.</u>
- 3) *The Advisory Board shall issue an annual report of its activities each year.*

(Source: Added at 40 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

# Section 946.60 Confidentiality

- a) The following information received and records kept by the Department for purposes of administering this Part are subject to all applicable federal privacy laws, are confidential, are exempt from the Illinois Freedom of Information Act, and are not subject to disclosure to any individual or public or private entity, except as necessary for authorized employees of the Department to perform official duties of the Department pursuant to this Part:
  - 1) Applications or renewals, their contents and supporting information submitted by qualifying patients and designated caregivers, including information regarding designated caregivers and physicians;
  - 2) The individual names and other information identifying persons to whom the Department has issued registry identification cards; and
  - 3) All medical records provided to the Department in connection with an application for a registry identification card.
- b) Department hard drives or other data recording media that are no longer in use and that contain cardholder information will be destroyed.
- c) Data subject to this Section shall not be *combined or linked in any manner with any other list or database and shall not be used for any purpose not provided by* this Part or the Act. (Section 150(a) of the Act)
- d) Any dispensing information required to be kept under Section 135 or 150 of the Act or under this Part will identify cardholders by their registry identification numbers and not contain names or other personally identifying information.

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- e) The Department of Agriculture, the Department of Financial and Professional Regulation and the Illinois State Police may verify registry identification cards. Law enforcement personnel shall have access to the Department's on-line verification system to verify application date and application status of qualifying patients who have submitted an application for a registry identification card.
- f) This Section does not preclude the following notifications:
  - 1) Department employees may notify law enforcement if information submitted to the Department is suspected to be falsified or fraudulent.
  - 2) The Department may notify State or local law enforcement about alleged criminal violations of this Part.
  - 3) The Department will notify the Department of Financial and Professional Regulation if there is reasonable cause to believe that a physician has:
    - A) Issued a written certification without a bona-fide physician-patient relationship; or
    - B) Issued a written certification to a person who was not under the physician's care for the debilitating medical condition; or
    - C) Failed to abide by the acceptable and prevailing standard of care when evaluating a patient's medical condition.
- g) The Department will share, disclose, and forward patient information as required by Section 60(e) of the Act.

(Source: Amended at 40 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

SUBPART B: QUALIFYING PATIENTS AND DESIGNATED CAREGIVERS

# Section 946.200 Application for Registry Identification Card for Qualifying Patients and Designated Caregivers

a) A qualifying patient who has been issued a written certification who seeks to use medical cannabis for palliative or therapeutic benefit to treat or alleviate the symptoms associated with the patient's debilitating condition, and the qualifying

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patient's designated caregiver, when applicable, shall register with the Department on forms and in a manner prescribed by the Department.

- b) To qualify for a registry identification card, a qualifying patient shall:
  - 1) Be a resident of the State of Illinois, as defined in subsection (c), at the time of application and remain a resident during participation in the program;
  - 2) Have a qualifying medical condition for which the use of medical cannabis will provide help with treating or alleviating the pain, nausea and other symptoms associated with the condition or be diagnosed with a terminal illness;
  - 3) Have a signed, written certification for the use of medical cannabis meeting the requirements of this Part;
  - 4) Complete the fingerprint-based background check and not have been convicted of an offense specified under Section 65(b) of the Act<u>, unless</u> diagnosed with a terminal illness.
- c) Residency. For purposes of this Part, the qualifying patient and designated caregiver, if any, shall be a resident of the State of Illinois if the individual:
  - 1) Physically resides in the State of Illinois, or has taken verifiable actions to make Illinois his or her home indefinitely with no present intent to reside in another state.
  - 2) Provides proof of Illinois residency by submitting at least two of the following items with the application for a registry identification card. The address on the documentation provided shall match the address on the application. Persons; persons who are homeless shall only be required to submit a Notarized Homeless Status Certification (available at https://www.cyberdriveillinois.com/publications/pdf\_publications/ dsd\_a230.pdf):
    - A) Pay stub or electronic deposit receipt, issued less than 60 days prior to the application date, that shows evidence of the applicant's withholding for State income tax;

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- B) Valid voter registration card with an address in Illinois;
- C) Valid, unexpired Illinois <u>Driver's License</u>, <u>Illinois Temporary</u> <u>Visitor Driver's License</u>, <u>driver's license</u> or other State identification card issued by the Illinois Secretary of State in the name of the applicant in accordance with the Illinois Identification Card Act<u>or a current military identification card</u>;
- D) Bank statement (dated less than <u>9060</u> days prior to application)<u>or</u> credit card statement (dated less than 60 days prior to application);
- E) Deed/title, mortgage or rental/lease agreement; property tax bill;
- F) Insurance policy (<u>current coverage for automobile</u>, homeowner's, <u>health or medical</u>, or renter's);
- G) Medical claim or statement of benefits (from <u>a hospital or health</u> <u>clinic or</u> private insurance company or public (government) agency, dated less than <u>12 months90 days</u> prior to application) or <u>Social Security Disability Insurance Statement or Supplemental Security Income Benefits Statement;</u>
- <u>H</u>) Persons enrolled in the federal Social Security Disability Income (SSDI) or Supplemental Security Income (SSI) disability program may submit a "Benefit Verification Letter" from the Social Security Administration; showing the individual's name and address and the type of benefits received. The letter must be dated within the last year. A copy of the letter may be obtained on-line at https://www.ssa.gov/myaccount/ or by contacting the Social Security Administration. The annual cost of living increase letter mailed to recipients of social security benefits will not be accepted.
- <u>I)</u> Tuition invoice/official mail from college or university, dated less than the 12 months prior to application; or
- <u>J</u>) Utility bill, including, but not limited to, those for electric, water, refuse, telephone land-line, <u>cellular phone</u>, cable or gas, issued less than 60 days prior to application; <u>or</u>.
- <u>K)</u> <u>W-2 form from the most recent tax year.</u>

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- d) To apply for a registry identification card, a qualifying patient shall submit a completed application to the Department on the required forms, which shall include, at a minimum, the following items:
  - Written certification for the use of medical cannabis meeting the requirements of this Part issued by a physician who meets the requirements set forth in the Act and the Medical Practice Act of 1987 and dated less than 90 days prior to the application;
  - 2) Proof of Illinois residency of the qualifying patient, as specified in subsection (c);
  - 3) Proof of identity of the qualifying patient;
  - 4) Proof of the qualifying patient's age;
  - 5) Photograph of the qualifying patient and designated caregiver, if applicable, as follows:
    - A) Current digital passport-size <u>photographimage</u>, taken no more than 30 calendar days before the submission of the application;
    - B) Taken against a plain background or backdrop;
    - C) At least 2 inches by 2 inches in size;
    - D) In natural color; and
    - E) That provides an unobstructed front view of the full face. A fullfaced photograph must be taken without any obstruction of the applicant's facial features or any items covering any portion of the face. Prescription glasses and religious head coverings not covering any areas of the open face will be allowed. <u>Head</u> <u>coverings for persons diagnosed and undergoing treatment for cancer will be allowed.</u>
      - i) A qualifying patient or designated caregiver will not be required to submit to a photograph if sufficient justification is provided by the qualifying patient or caregiver to

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establish that a photograph would be in violation of or contradictory to the qualifying patient's or designated caregiver's religious convictions. If a qualifying patient or designated caregiver declares that the use of a photograph is against his/her religious convictions, the qualifying patient or designated caregiver will be given an affidavit to be completed. This affidavit contains designated areas for a detailed written explanation of the reasons why a photograph is against the qualifying patient's or designated caregiver's religious convictions, a place for the qualifying patient's or designated caregiver's signature and date, the designation of the religious sect or denomination involved, space for a minister or other religious leader to apply his/her signature attesting to the explanation the qualifying patient or designated caregiver has offered, along with the date and official title of the minister or religious leader.

- The <u>affidavit</u> Affidavit shall be submitted to the Department. The Director will appoint a committee of three Department employees to review each affidavit. The committee shall submit a recommendation to the Director for his or her final decision.
- iii) If the qualifying patient or designated caregiver meets all other application requirements of this Part, the Department will issue a non-photo temporary registry identification card, not to exceed 90 days in duration, to allow for medical cannabis use privileges during the determination
- iv) Upon approval by the Department, a valid registry identification card without a photograph will be issued and can be renewed. The card will be mailed to the qualifying patient's home address.
- 6) Designation of the medical cannabis dispensing organization where the qualifying patient will receive his or her medical cannabis. <u>Only one</u> medical cannabis dispensing organization may be selected at any time, however, the patient is able to submit a request to change the selected dispensary by notifying the Department. During 2014, and later if the Department so elects, a qualifying patient may designate the dispensing

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organization district in which he or she expects to obtain his or her medical cannabis.

- 7) Completion of the designated caregiver application if applicable.
- 8) Payment of the applicable application fee (see Section 946.210) by check or money order. If the qualifying patient or caregiver is applying on-line, the Department will accept credit card payments.

(Source: Amended at 40 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

# Section 946.201 Application for Registry Identification Card for Qualifying Patients under 18 Years of Age

- a) A qualifying patient under 18 years of age shall register with the Department on forms and in a manner prescribed by the Department. The designated caregiver shall complete the application for registry identification card for a qualifying patient under 18 years of age. Once the qualifying patient becomes 18 years of age, he or she must submit a full application for a registry identification card as specified in Section 946.200. Qualifying patients who become 18 years of age during the time period in which their registry identification card is valid may apply for a registry identification card either immediately or during the normal renewal period. Until that time, the registry identification card shall be subject to the conditions applicable to the registered qualifying patient under age 18.
- b) To qualify for a registry identification card, a qualifying patient under 18 years of age shall:
  - 1) Be a resident of the State of Illinois, as defined in subsection (c), at the time of application and remain a resident during participation in the program;
  - Be diagnosed with any debilitating medical condition listed in Section 946.310 for which medical cannabis may be used to treat or alleviate the pain, nausea or other symptoms associated with the condition<u>or have a</u> <u>diagnosis of terminal illness</u>.
- c) The application for a registry identification card for a qualifying patient under 18 years of age shall include the following:

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- 1) Two signed written certifications for the use of medical cannabis:
  - A) A signed written certification as specified in Section 946.310; and
  - B) A signed written certification from a reviewing physician indicating that a comprehensive review of the qualifying patient's medical records from other physicians treating the qualifying patient has been conducted;
- 2) Identify a designated caregiver (custodial parent or legal guardian) who shall complete an application for a caregiver registry identification card as specified in Section 946.200;
  - A) A qualifying patient under 18 years of age may identify two designated caregivers if both biological parents or two legal guardians have significant decision-making responsibilities over the qualifying patient; or
  - B) If only one biological parent or legal guardian has significant decision-making responsibilities for the qualifying patient under 18 years of age, then a second designated caregiver may be identified.
- 3) A completed, signed Medical Cannabis Custodial Parent and Legal Guardian Attestation form. This form can be downloaded from the Illinois Department of Public Health website at http://idph.state.il.us/; and
- 4) If applicable, provide proof of guardianship documentation.
- d) Residency. For purposes of this Part, the qualifying patient and custodial parent or legal guardian shall be residents of the State of Illinois.
- e) The designated caregiver shall provide proof of Illinois residency by submitting the following items with the application for a registry identification card. Persons who are homeless shall be required to submit only a Notarized Homeless Status Certification (available at https://www.cyberdriveillinois.com/publications/ pdf\_publications/dsd\_a230.pdf):
  - 1) A copy of the caregiver's unexpired Illinois <u>Driver's License or Illinois</u> <u>Temporary Visitor Driver's License</u>driver's license; or

- 2) A copy of the caregiver's unexpired Illinois identification card; or
- 3) A copy of the caregiver's unexpired U.S. passport.
- f) To apply for a registry identification card for a qualifying patient under 18 years old, the designated caregiver shall submit a completed application to the Department on the required forms, which shall include, at a minimum, the following items:
  - 1) A written certification for the use of medical cannabis meeting the requirements of this Part, issued by a physician who meets the requirements set forth in the Act and the Medical Practice Act of 1987, and dated less than 90 days prior to the application;
  - 2) A signed written certification from a reviewing physician indicating that a comprehensive review of the qualifying patient's medical records from other physicians treating the qualifying patient has been conducted. This physician shall meet the requirements set forth in the Medical Practice Act of 1987 or shall provide proof of a current, active medical license issued by another state.
  - 3) Proof of Illinois residency of the qualifying patient, as specified in subsection (c);
  - 4) Proof of identity of the qualifying patient (copy of the qualifying patient's birth certificate);
  - 5) Proof of the qualifying patient's age. A copy of the qualifying patient's birth certificate shall fulfill this requirement;
  - 6) Current digital passport-size photograph of the designated caregiver, as follows:
    - A) Taken no more than 30 calendar days before the submission of the application;
    - B) Taken against a plain background or backdrop;
    - C) At least 2 inches by 2 inches in size;

- D) In natural color; and
- E) That provides an unobstructed front view of the full face. A full-faced photograph must be taken without any obstruction of the applicant's facial features or any items covering any portion of the face. Prescription glasses and religious head coverings not covering any areas of the open face will be allowed.
  - A designated caregiver for a qualifying patient under 18 i) years old will not be required to submit a photograph if sufficient justification is provided by the caregiver to establish that a photograph would be in violation of or contradictory to the designated caregiver's religious convictions. If a designated caregiver declares that the use of a photograph is against his/her religious convictions, the designated caregiver will complete an affidavit on a form provided by the Department. The affidavit contains designated areas for a detailed written explanation of the reasons why a photograph is against the designated caregiver's religious convictions; a place for the designated caregiver's signature and date, the designation of the religious sect or denomination involved; space for a minister or other religious leader to apply his/her signature attesting to the explanation the designated caregiver has offered; and the date and official title of the minister or religious leader.
  - The affidavit shall be submitted to the Department. The Director will appoint a committee of three Department employees to review each affidavit. The committee shall submit a recommendation to the Director for his or her final decision.
  - iii) If the designated caregiver meets all other application requirements of this Part, the Department will issue a non-photo temporary registry identification card, not to exceed 90 days in duration, to allow for medical cannabis use privileges during the determination.

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- iv) Upon approval by the Department, a valid registry identification card without a photograph will be issued and can be renewed. The card will be mailed to the designated caregiver's home address.
- 7) Designation of the medical cannabis dispensing organization where the designated caregiver will obtain medical cannabis on behalf of the qualifying patient under 18 years of age.
- 8) Completion of the Medical Cannabis Parent and Legal Guardian Attestation form.
- 9) If applicable, submission of proof of guardianship documentation.
- 10) Payment of the applicable application fee (see Section 946.210) by check or money order. If the patient or caregiver is applying on-line, the Department will accept credit card payments.

(Source: Amended at 40 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

# Section 946.205 Deadlines for Submission of Application for Registry Identification Card

A qualifying patient who has been issued a physician written certification who seeks to use medical cannabis for palliative or therapeutic benefit for the patient's debilitating condition, and the qualifying patient's designated caregiver when applicable, shall register with the Department on forms and in a manner prescribed in this Part.

- a) <u>Applications</u>Beginning January 1, 2015, applications for registry identification cards will be accepted year round.
- b) Application Submission
  - 1) Applications for registry identification cards shall be submitted electronically through the Department's website (www.idph.state.il.us) or shall be sent via U.S. mail to the following address:

Division of Medical Cannabis Illinois Department of Public Health 535 West Jefferson Street Springfield, IL 62761-0001

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- 2) Applications for registry identification cards not submitted electronically or to the above address shall be considered deficient.
- c) The Department of Public Health shall send a notification to a registered qualifying patient or designated caregiver 90 days prior to the expiration date on the registry identification card. (Section 70 of the Act)
- d) To maintain a valid registry identification card, a registered qualifying patient and designated caregiver must annually resubmit, at least 45 days prior to the expiration date stated on the registry identification card, a completed renewal application (see Section 946.200), renewal fee (see Section 946.210) and accompanying documentation (see Section 946.200). (Section 70 of the Act)

(Source: Amended at 40 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

## Section 946.210 Fees

a) Except as set forth in subsection (b), the registration, renewal and replacement card fees are as specified in this subsection (a). All fees submitted to the Department shall be non-refundable. Annually, the Department may revise these fees:

1)		i <mark>fying</mark> Annual qualifying patient cation fee <u>valid for:</u>	<del>\$100</del>
	<u>A)</u>	One year	<u>\$100</u>
	<u>B)</u>	<u>Two years</u>	<u>\$200</u>
	<u>C)</u>	Three years	<u>\$250</u>
2)	<del>quali</del> appli	ifyingAnnual application fee for a fying patient under 18 years of age cation fee (includes <u>one</u> caregiver cation fee) valid for:	<del>\$100</del>
	<u>A)</u>	One year	<u>\$100</u>
	<u>B)</u>	Two years	<u>\$200</u>

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	<u>C)</u> <u>Three years</u>	<u>\$250</u>
3)	<u>Caregiver or second caregiver for a patient</u> <u>under 18 years of ageAnnual caregiver</u> application fee <u>valid for:</u>	<del>\$25</del>
	<u>A)</u> <u>One year</u>	<u>\$25</u>
	<u>B)</u> <u>Two years</u>	<u>\$50</u>
	<u>C)</u> <u>Three years</u>	<u>\$75</u>
4)	Replacement card fee	\$25
5)	Returned check fee	\$35

b) The Department may reduce registration and renewal card fees for a qualifying patient enrolled in the federal Social Security Disability Income (SSDI) or the Supplemental Security Income (SSI) disability programs, with submission of proof as described in subsection (b)(2), and for veterans with proof of service as described in subsection (b)(3).

Reduced Annual reduced qualifying patient application fee valid for:		<del>\$50</del>
<u>A)</u>	One year	<u>\$50</u>
<u>B)</u>	<u>Two years</u>	<u>\$100</u>
<u>C)</u>	Three years	<u>\$150</u>

1)

2) The applicant <u>enrolled in the federal Social Security Disability Income</u> (SSDI) or Supplemental Security Income (SSI) disability program shall <u>submit a "Benefit Verification Letter" from the Social Security</u> <u>Administration, showing the individual's name and address and the type of</u> <u>benefits received. The letter must be dated within the last year. A copy of</u> <u>the letter may be obtained on-line at https://www.ssa.gov/myaccount/ or</u> <u>by contacting the Social Security Administration. The annual cost of</u> <u>living increase letter mailed to recipients of social security benefits will</u>

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not be accepted shall submit a copy of a letter or other documentation from the Social Security Administration identifying the qualifying patient and showing the amount of monthly SSDI and SSI benefits to be received by the qualifying patient during the current year of application.

- 3) Veterans shall provide a copy of their DD214.
- c) Registered qualifying patients seeking to add a designated caregiver after a registry identification card has been issued shall submit a fee of \$50 for the designated caregiver application and an additional \$25 replacement card fee to print a new registry identification card for the registered qualifying patient. The designated caregiver registry card shall expire on the same day as the registered qualifying patient registry card expiration date.

(Source: Amended at 40 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

## Section 946.220 Fingerprint-Based Criminal History Records Check

No person convicted of an excluded offense shall be eligible to receive a registry identification <u>card.No person who has been convicted of a felony under the Illinois Controlled Substances Act,</u> <u>Cannabis Control Act, or Methamphetamine Control and Community Protection Act, or similar</u> <u>provisions in a local ordinance or other jurisdiction is eligible to receive a registry identification</u> <u>card. (Section 65(b) of the Act)</u>

- a) The Illinois State Police (ISP) will act as the Department's agent for purposes of receiving electronic fingerprints and conducting background checks of each qualifying patient and designated caregiver, if applicable, applying for a registry identification card.
  - 1) The ISP will conduct background checks for conviction information contained within ISP and Federal Bureau of Investigation (FBI) criminal history databases to the extent allowed by law.
  - 2) For verification of any statutorily imposed duty to conduct background checks pursuant to the Act, ISP will transmit the results of the background check to the Department.
  - 3) The electronic background checks will be submitted as outlined in the Illinois Uniform Conviction Information Act or ISP rules at 20 Ill. Adm. Code 1265.30 (Electronic Transmission of Fingerprints).

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- b) Each qualifying patient and designated caregiver, if applicable, applying for a registry identification card shall have his or her fingerprints collected electronically by a livescan vendor licensed by the Illinois Department of Financial and Professional Regulation, and transmitted to ISP for processing no more than 30 days prior to the date of application or renewal for a registry identification card. If the qualifying patient is under age 18 at the time of application, no fingerprint collection shall be necessary for the qualifying patient; however, the designated caregiver shall comply with the requirements of this Section.
  - 1) The qualifying patient or designated caregiver shall submit to the Department, with the registry card application or renewal, a copy of the livescan request form and the receipt provided by the livescan fingerprint vendor containing the Transaction Control Number (TCN) as proof that fingerprints have been collected.
  - 2) Registry card applications submitted, except those for persons with a diagnosis of terminal illness in accordance with Section 946.25, without a copy of the livescan request form and receipt will be considered incomplete and will not be processed until fingerprinting is completed.
  - 3) Any fees associated with the livescan fingerprint-based criminal history records check shall be the responsibility of the individual seeking a registry identification card and will be collected by the livescan vendor at the time of fingerprinting.
  - 4) If the fingerprints are rejected by ISP, the qualifying patient or designated caregiver shall have his or her fingerprints collected electronically by a licensed livescan vendor a second time.
  - 5) If equipment malfunction or other special circumstances make electronic transmission of fingerprint data impractical, the Department will allow use of paper fingerprint records.
  - <u>A qualifying patient who is unable to be fingerprinted due to an</u> amputation, deformed or missing fingers, or fingerprints which are worn or missing due to age or illness, may seek a waiver from the livescan process from the Department by explaining in writing why a fingerprint

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background check cannot be processed. If approved, the Department will provide a name-based background check form.

- A) The qualifying patient shall be responsible for all fees associated with the name-based background check.
- <u>B)</u> Disability or immobility shall not be accepted as a reason for waiving the fingerprint background check.
- c) The Department will obtain from ISP a State and federal criminal records check for each qualifying patient applying for a registry identification card and for each designated caregiver identified on a qualifying patient registry application.
- d) The Department will maintain the results of the criminal history records check for the time period associated with the registry identification card or the registered qualifying patient and designated caregiver, if any, and in accordance with the State Records Act, after which the documentation shall be destroyed.
- e) Denial of Application or Renewal
  - 1) The Department may deny an application or renewal for a qualifying patient or a designated caregiver who has been convicted of an excluded offense in accordance with this subsection (e).
    - A) Denial of a designated caregiver will not automatically result in the denial of a qualifying patient application.
    - B) The qualifying patient shall identify a new designated caregiver within 15 days after receiving notice of the denial of his or her designated caregiver application or shall indicate that a designated caregiver is not required.
    - C) The Department will not deny an application for a registry identification card based solely on the qualifying patient's or designated caregiver's conviction for an excluded offense for a violation of a State or federal controlled substance law that was classified as a felony if his or her conviction was for the possession, cultivation, transfer or delivery of a reasonable amount of cannabis intended for medical use and the termination of the last sentence was 10 or more years prior to application.

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#### 2) Exception

If the qualifying patient or designated caregiver has been convicted of any excluded offenses, the Department may approve a registry identification card pursuant to this Part *if the person demonstrates that his or her conviction was for the possession, cultivation, transfer, or delivery of a reasonable amount of cannabis intended for medical use.* (Section 10(1)(1-5)10(1)(2) of the Act) In determining whether to waive a conviction for excluded offenses, the Department will:

- A) Review the criminal records and the qualifying patient's medical history to determine whether the patient had been diagnosed with the debilitating medical condition at the time of the offense; and
- B) Determine whether the offense consisted of conduct for which, had it occurred on or after January 1, 2014, would likely have been protected by the Act and would likely not have resulted in a conviction.
- 3) Qualifying Patients Under 18 Years of Age
  - A) Denial of a designated caregiver (custodial parent or legal guardian) because of an excluded offense will not automatically result in the denial of an application for a qualifying patient under 18.
  - B) The custodial parent or legal guardian shall identify a new designated caregiver within 15 days after receiving notice of the denial of his or her designated caregiver application. The custodial parent or legal guardian shall execute an Authorization and Consent form designating a person over 21 years of age to act as the designated caregiver for the qualifying patient under 18.
- f) The Department will not waive convictions for violations of the medical cannabis laws of Illinois or any other State or jurisdiction.

(Source: Amended at 40 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

# Section 946.240 Persons Receiving Medical Care at U.S. Department of Veterans Affairs Facilities

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- a) A qualifying patient who is a veteran or spouse of a veteran who has received treatment at a VA hospital is deemed to have a bona-fide physician-patient relationship with a VA physician if the patient has been seen for his or her debilitating condition at the VA hospital in accordance with VA hospital protocols. (Section 60 of the Act)
- b) A veteran <u>or spouse of a veteran</u> receiving care for a debilitating condition at a VA hospital shall not be required to submit a written certification from a physician.
- c) A veteran <u>or spouse of a veteran</u> receiving care for a debilitating condition at a VA hospital shall register with the Department on the Registry Identification Card application (see Section 946.200) and shall comply with all other requirements specified in this Part.
- d) To qualify for a patient registry identification card, a qualifying patient who is a veteran <u>or spouse of a veteran</u> and receiving medical care and treatment at a VA hospital shall:
  - 1) Be a resident of the State of Illinois, as defined in Section 946.200(c), at the time of application and remain a resident during participation in the program;
  - 2) Have a qualifying medical condition<u>or be diagnosed with a terminal</u> <u>illness;</u>
  - Provide a copy of his or her official hospital medical records requested from the VA using VA Form 10-5345. The official hospital medical records shall indicate the diagnosis of a qualifying medical condition by a licensed physician;
  - 4) Provide a copy of his or her DD214 or equivalent certified document indicating character and dates of service, or if the spouse of a veteran, a copy of the veteran's documents as described;
  - 5) Complete the fingerprint-based background check and not have been convicted of an excluded offense; and
  - 6) Be at least 18 years of age.

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(Source: Amended at 40 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

#### Section 946.290 Renewal of Registry Identification Cards

- <u>a)</u> <u>Medical cannabis registry identification cards may be valid for up to three years.</u>
- b) If the qualifying patient or designated caregiver who applied for and received a registry identification card that was approved for a 12-month period before September 12, 2016 seeks to extend his or her registry identification card for up to three years from the original effective date, the patient or caregiver shall complete a renewal application no less than 45 days prior to the expiration date of the card. It is not necessary to provide proof of Illinois residency, obtain a physician certification or obtain a fingerprint background check. A fee is required in accordance with Section 946.210. The qualifying patient or designated caregiver may seek a renewal of the registry identification card for a period of one year or two years by paying the fee required by Section 946.210.
- c) <u>At the end of every three-year period, no No</u> less than 45 days prior to the expiration of a registry identification card, the qualifying patient and designated caregiver, if one is indicated, may apply for <u>a newrenewal of his or her</u> registry identification card as follows:
  - **<u>1</u>a**) Submit a completed renewal application for the qualifying patient and designated caregiver, if one is indicated, to the Department on the required forms and include:
    - <u>A</u>4) One clear photocopy of a U.S. or State government-issued photo ID, such as a driver's license, as proof of identity;
    - <u>B</u>2) Proof of Illinois residency by meeting the requirements specified in Section 946.200(c); and
    - C3) A signed and dated written physician's certification for the use of medical cannabis-meeting the requirements of this Part and dated not more than 90 days prior to the application renewal date. A qualifying patient who is a veteran or spouse of a veteran and receiving medical care for his or her qualifying medical condition at a VA hospital shall submit his or her official VA Medical Record instead of a written physician's certification;

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- 2b) Designate the medical cannabis dispensing organization where the qualifying patient will receive his or her medical cannabis; and
- <u>3</u>e) Pay the required application fee (see Section 946.210).
- d) If a qualified registered patient or designated caregiver who was issued a registry identification card for a period of one or two years after September 12, 2016 seeks to extend his or her registry identification card up to three years from the registry identification card's original effective date, he or she may complete a renewal application no less than 45 days before the expiration date. It is not necessary to provide proof of Illinois residency, obtain a physician certification or obtain a fingerprint background check. The qualifying patient or designated caregiver may seek a renewal of the registry identification card for a period of one year or two years by paying the fee required by Section 946.210.

(Source: Amended at 40 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

## SUBPART C: PHYSICIAN REQUIREMENTS

#### Section 946.300 Qualifications of the Certifying Physician

- a) A doctor of medicine or osteopathy who has a current, valid license under the Medical Practice Act of 1987 and has a current valid controlled substances license under Article III of the Illinois Controlled Substances Act <del>and DEA registration</del> may <u>issue a written certification forrecommend the use of medical cannabis to</u> a qualifying patient if the physician:
  - <u>HasIs in</u> a bona-fide physician-patient relationship with the qualifying patient. The bona-fide physician-patient relationship may not be limited to <u>issuing a written</u> certification for the patient to use medical cannabis or a consultation simply for that purpose.
  - 2) Complies with generally accepted standards of medical practice, the Medical Practice Act of 1987 and applicable State and federal rules specific to physician practice (e.g., HIPAA rules).
  - 3) Has responsibility for the ongoing care and treatment of the qualifying patient's debilitating condition, provided that the ongoing treatment and care shall not be limited to or for the primary purpose of certifying a

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debilitating medical condition or providing a consultation solely for that purpose.

- 4) Has completed an in-person full assessment of the patient's medical history and current medical condition, including a personal physical examination, not more than 90 days prior to making the certification for medical cannabis. The assessment of the qualifying patient's current medical condition shall include, but not be limited to, symptoms, signs and diagnostic testing related to the debilitating medical condition.
- 5) Certifies that the qualifying patient is under the physician's care, either for the qualifying patient's primary care or for his or her debilitating medical condition or symptoms of a debilitating medical condition.
- 6) Confirms that he or she completed an assessment for the qualifying patient's medical history, including reviewing medical records from other treating physicians from the previous 12 months.
- 7) Explains the potential risks and benefits of the medical use of cannabis to the qualifying patient.
- b) The physician shall not:
  - 1) Except as provided in subsection (c), *accept, solicit, or offer any form of remuneration from or to a qualifying patient, primary caregiver, cultivation center, or dispensing organization, including each principal officer, board member, agent, and employee;*
  - 2) Offer a discount or any other item of value to a qualifying patient who uses or agrees to use a particular primary caregiver or dispensing organization to obtain medical cannabis;
  - 3) Conduct a personal, in person, physical examination of a patient for purposes of diagnosing a debilitating medical condition at a location where medical cannabis is sold or distributed or at the address of a principal officer, agency, or employee or a medical cannabis organization;
  - 4) Hold a direct or indirect economic interest in a cultivation center or dispensing organization if he or she recommends the use of medical

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cannabis to qualified patients or is in a partnership with a physician who recommends medical cannabis;

- 5) Serve on the board of directors or as an employee of a cultivation center or dispensing organization;
- 6) *Refer qualifying patients to a cultivation center, a dispensing organization, or* an individual who seeks to become a designated caregiver;
- 7) *Advertise in a cultivation center or a dispensing organization.* (Section 35 of the Act)
- c) The physician may accept payment from a qualifying patient for the fee associated with the personal physical examination required prior to issuing the written certification for the qualifying patient. (Section 35 of the Act)

(Source: Amended at 40 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

#### Section 946.310 Physician Written Certification

- a) A certification <u>confirming the patient's debilitating medical condition</u>indicating that a qualifying patient is recommended for the use of medical cannabis shall be written on a form provided by the Department and shall include, at minimum, the following:
  - 1) The qualifying patient's name, date of birth, home address and primary telephone number;
  - The physician's name, address, telephone number, e-mail address, medical license number, indication of specialty or primary area of clinical practice, if any, and <u>active controlled substances license under the Illinois</u> <u>Controlled Substances ActDEA registration number</u>;
  - 3) The length of time the qualifying patient has been under the care of the physician;
  - 4) The qualifying patient's debilitating medical condition;

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# 5) Additional comments, if necessary, that would be useful in assessing the qualifying patient's application for use of medical cannabis;

- 5)6) A statement that the physician has confirmed a diagnosis of a debilitating medical condition; is treating or managing treatment of the patient's debilitating condition; has a bona-fide physician-patient relationship; has conducted an in-person physical examination; has conducted a review of the patient's medical history, including reviewing medical records from other treating physicians, if any, from the previous 12 months; and has explained the potential risks and benefits of the use of medical cannabis to the qualifying patient; and
- $\underline{6}$ )7) The physician's signature and date.
- b) The physician written certification does not constitute a prescription for medical cannabis.
- b) A patient may apply for a waiver where a physician provides a substantial medical basis in a signed, written statement asserting that, based on the patient's medical history, in the physician's professional judgment, 2.5 ounces is an insufficient adequate supply for a 14-day period to properly alleviate the patient's debilitating medical condition or symptoms associated with the debilitating medical condition. (Section 10(a)(2) of the Act)
  - 1) The waiver recommendation shall be on a Physician Waiver Recommendation form provided by the Department.
  - 2) The waiver shall describe in the physician's professional opinion why 2.5 ounces is an insufficient supply for a 14-day period.
  - 3) The waiver shall describe how the qualifying patient will benefit from an increased supply.
  - 4) The waiver shall include a statement by the physician indicating the amount of medical cannabis that would be a sufficient supply for the qualifying patient's debilitating medical condition and provide a recommendation for the length of time the waiver should be in effect.

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- 5) If the Department approves the waiver, the amount of medical cannabis recommended by the physician shall be noted on the registry identification card.
- c) Applications for qualifying patients under 18 years old shall require a written certification from a physician and a reviewing physician.

(Source: Amended at 40 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

#### Section 946.315 Waiver for Increasing the Adequate Supply of Medical Cannabis

A patient may apply for a waiver where a physician provides a substantial medical basis in a signed, written statement asserting that, based on the patient's medical history, in the physician's professional judgment, 2.5 ounces is an insufficient adequate supply for a 14-day period to properly alleviate the patient's debilitating medical condition or symptoms associated with the debilitating medical condition. (Section 10(a)(2) of the Act)

- a) The waiver recommendation shall be on a form provided by the Department. The waiver recommendation shall be completed by the physician who issued the physician certification for the registered qualifying patient.
- b) The waiver shall describe in the physician's professional opinion why 2.5 ounces is an insufficient adequate supply for a 14-day period.
- c) The waiver shall describe how the qualifying patient will benefit from an increased supply.
- <u>d)</u> The waiver shall include a statement by the physician indicating the amount of medical cannabis that would be a sufficient supply for the qualifying patient's debilitating medical condition.
- e) If the Department approves the waiver, the amount of medical cannabis recommended by the physician shall be noted on the registry identification card.
- <u>f)</u> The waiver recommendation does not constitute a prescription for medical cannabis.

(Source: Amended at 40 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

SUBPART E: ENFORCEMENT

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#### Section 946.500 Circuit Court Review

- a) Denial of an application or renewal is considered a final Department action, subject to judicial review. Jurisdiction and venue for judicial review are vested in the Circuit Court. (Section 65 of the Act)
- b) The suspension or revocation of a registration is a final Department action, subject to judicial review. Jurisdiction and venue for judicial review are vested in the Circuit Court. (Section 185 of the Act)
- c) The approval or denial of any petition pursuant to Section 946.30 is a final decision of the Department, subject to judicial review. Jurisdiction and venue are vested in the Circuit Court. (Section 45 of the Act)
- d) All final administrative decisions of the Department of Public Health are subject to direct judicial review under the provisions of the Administrative Review Law and the rules adopted under that Law. The term "administrative decision" is defined as in Section 3-101 of the Code of Civil Procedure. (Section 155 of the Act)
- e) If any final Department action is appealed in Circuit Court pursuant to this Section, the record on review shall include the following:
  - 1) The application or petition submitted;
  - 2) Any written documentation considered by the Department in making its final decision with respect to the application or petition. With respect to petitions for the addition of a medical condition or disease as referenced in Section 946.30, the record on review shall include:
    - Any written report made by the Medical Cannabis Advisory Board to the Department, to the extent that the report actually materially discusses the medical condition or disease proposed in the petition;
    - B) Any public minutes of an Advisory Board meeting at which the medical condition or disease proposed in the petition is materially discussed;

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- C) Any statement of intent to present technical evidence, as referenced in Section 946.30(k), to the extent that the technical evidence relates to the medical condition or disease proposed in the petition;
- 3) Any written correspondence between the Department and the person submitting the application or petition, provided that the correspondence either played a material role in the final decision rendered by the Department; made a material argument to the Department with respect to the application or petition; or would be helpful to the Circuit Court in reviewing the matter because the correspondence provides helpful procedural background.
- f) If the materials in the record on review contain any confidential information as defined in Section <u>946.60946.80</u>, either the information shall be redacted, as appropriate, or the entirety or portions of the record on review shall be filed under seal so as to retain the confidentiality of, without limitation, patient medical records or Departmental documents or data.

(Source: Amended at 40 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)