

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED RULES

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

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AUTHORITY: Implementing and authorized by Compassionate Use of Medical Cannabis Pilot Program Act, P.A. 98-0122.

SOURCE: Adopted at 38 Ill. Reg. _____, effective _____.

SUBPART A: GENERAL PROVISIONS

Section 946.10 Definitions

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

"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 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

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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 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 of the Act)

"DD214" means a certified DD214 Certificate of Separation from Release from Active Duty Member Copy 4 or State Director of Veteran's 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 Veteran's 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

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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 Syringomyelia, 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, or the treatment of these conditions; or any other debilitating medical condition that is added by the Department by rule as provided in Section 946.30. (Section 10 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.

"Evidence-based Medical Research" means documentation of published, peer-reviewed 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*

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violation of a state or federal controlled substance law that was classified as a felony in the jurisdiction where the person was convicted, except that the registering Department may waive this restriction if the person demonstrates to the registering Department's satisfaction that his or her conviction was for the possession, cultivation, transfer, or delivery of a reasonable amount 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 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 Illinois 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.

"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 the State central repository (Illinois State Police) for processing. The data is forwarded to the Illinois State Police (ISP), Bureau of Identification (BOI) over a Virtual Private Network (VPN) and then processed by the 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 infused food

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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 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 education materials to registered qualifying patients. (Section 10 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 of the Act)

"Petitioner" means an applicant who seeks to add debilitating medical conditions to those listed in subsection (h) of Section 10 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 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 local unit of 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 of the Act)

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"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.

"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 of the Act)

"Tincture" means cannabis flowered tops and leaves that are soaked in liquid, usually an alcohol solution, transferring the THC and other cannaboids 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, Veteran's Health Administration, providing hospital and outpatient health care services to U.S. military service veterans.

"VA Official Hospital Medical Records" means records from the U.S. Department of Veterans Affairs documenting medical condition(s) 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

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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 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 paragraph, "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 of the Rights of Crime Victims and Witnesses Act and Section 10 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 registering 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 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 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 of the Act)

Section 946.15 Referenced Materials

- a) The following federal statutes are referenced in this Part:
 - 1) Federal Food, Drug, and Cosmetic Act (21 USCA 301)

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- 2) Federal Fair Packaging and Labeling Act (15 USCA 1451)
- b) The following Illinois statutes are referenced in this Part:
- 1) Compassionate Use of Medical Cannabis Pilot Program Act [410 ILCS 130]
 - 2) Administrative Review Law (Article III of the Code of Civil Procedure) [735 ILCS 5/Art. III]
 - 3) Cannabis Control Act [720 ILCS 550]
 - 4) Methamphetamine Control and Community Protection Act [720 ILCS 646]
 - 5) Open Meetings Act [5 ILCS 120]
 - 6) Medical Practice Act of 1987 [225 ILCS 60]
 - 7) Controlled Substances Act [720 ILCS 570]
 - 8) Food, Drug and Cosmetic Act [410 ILCS 620]
 - 9) Food Handling Regulation Enforcement Act [410 ILCS 625]
 - 10) Uniform Conviction Information Act [20 ILCS 2635]
 - 11) Private Detective, Private Alarm, Private Security, Fingerprint Vendor, and Locksmith Act of 2004 [225 ILCS 447]
 - 12) Vehicle Code [625 ILCS 5]
 - 13) Criminal Code of 2012 [720 ILCS 5]
 - 14) Smoke Free Illinois Act [410 ILCS 82]
 - 15) Identification Card Act [15 ILCS 335]
 - 16) Freedom of Information Act [5 ILCS 140]

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- 17) Rights of Crime Victims and Witnesses Act [725 ILCS 120]
 - 18) Code of Civil Procedure [735 ILCS 5]
 - 19) State Records Act [5 ILCS 160]
- c) The following State administrative rules are referenced in this Part:
- 1) The Illinois Food, Drug and Cosmetic Act (77 Ill. Adm. Code 720)
 - 2) Manufacturing, Processing, Packing or Holding of Food Code (77 Ill. Adm. Code 730)
 - 3) Food Service Sanitation Code (77 Ill. Adm. Code 750)
 - 4) Electronic Transmission of Fingerprints (20 Ill. Adm. Code 1265)

Section 946.20 Debilitating Medical Conditions

A qualifying patient shall be eligible to apply for a Medical Cannabis Registry Identification Card if diagnosed as having one or more of the following debilitating medical conditions: *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 Syringomyelia, 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, or the treatment of these conditions; or any other debilitating medical condition that is added by the Department by rule as provided in Section 946.30. (Section 10 of the Act)*

Section 946.30 Addition of Debilitating Medical Conditions

Residents may petition the Department to add debilitating medical conditions to those listed in subsection (h) of Section 10 of the Act and Section 946.20. The Department will accept petitions twice annually. The open period for accepting petitions will be for a one-month period from

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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) The Department will convene a Medical Cannabis Advisory Board (advisory board) composed of 15 members, including:
 - 1) One medical cannabis patient advocate or designated caregiver;
 - 2) Two nurses or nurse practitioners who work with medical cannabis patients;
 - 3) Three registered qualifying patients, including one veteran; and
 - 4) Nine healthcare practitioners with current professional licensure in their field. There shall be one healthcare practitioner with expertise in and representing each of the following areas and at least two of the appointed healthcare practitioners shall have direct experience with the health care needs of veterans:
 - 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; and
 - I) Pharmacy.
- b) The Medical Cannabis Advisory Board shall review petitions and recommend to the Department additional debilitating conditions or diseases that would benefit

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from the medical use of cannabis.

- c) Members of the Medical Cannabis Advisory Board will be appointed by the Governor.
 - 1) Members shall serve a term of four years, 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 Medical Cannabis 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 review new medical and scientific evidence pertaining to currently approved conditions.

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- 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.
- f) Each petition shall be limited to one proposed debilitating medical condition or disease.
- g) A petitioner shall file one original petition in the format provided 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 shall be prepared on forms provided by the Department.
 - 2) A specific description of the medical condition or disease that is the subject of the petition. The petitioner shall not submit broad categories, e.g., all mental illnesses. Each petition shall be limited to a single condition or disease. Information about the proposed condition or disease shall include:
 - 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

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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.
- 3) Upon review of materials submitted pursuant to subsection (3), 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 requirements for submission, the petition will be considered deficient. The Department will notify the petitioner, 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 Medical Cannabis Advisory Board for review.
- h) The petitioner may withdraw his or her petition by submitting a written statement to the Department indicating withdrawal.
 - i) The Medical Cannabis Advisory Board shall have a minimum of 30 days to

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review the petitions before convening a public hearing.

- j) The Medical Cannabis 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 notice of the hearing on its website to provide notice to the public.
 - 2) Meetings of the Medical Cannabis Advisory Board shall be in accordance with the Open Meetings Act.
 - 3) Any meeting consisting of a quorum of the Medical Cannabis 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.
- k) Any individual or an association of individuals who wish 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;

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- 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.
- l) Upon final determination, the Medical Cannabis 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 medical research. The written report of findings shall protect information by applicable State or federal laws.
 - m) Upon review of the Medical Cannabis 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)*

Section 946.40 Limitations and Penalties

- a) Any person engaging in the following conduct may be charged with civil, criminal, or other penalties for:
 - 1) *Undertaking any task under the influence of cannabis, when doing so would constitute negligence, professional malpractice, or professional misconduct;*
 - 2) *Possessing cannabis:*
 - A) *in a school bus;*
 - B) *on the grounds of any preschool or primary or secondary school;*
 - C) *in any correctional facility;*

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- D) *in a vehicle under Section 11-502.1 of the Illinois Vehicle Code;*
 - E) *in a vehicle not open to the public unless the medical cannabis is in a reasonably secured, sealed, tamper-evident container and reasonably inaccessible while the vehicle is moving; or*
 - F) *in a private residence that is used at any time to provide licensed child care or other similar social service care on the premises;*
- 3) *Using cannabis:*
- A) *in a school bus;*
 - B) *on the grounds of any preschool or primary or secondary school;*
 - C) *in any correctional facility;*
 - D) *in any motor vehicle;*
 - E) *in a private residence that is used at any time to provide licensed child care or other similar social service care on the premises;*
 - F) *in any public place. "Public place" as used in this subsection means any place where an individual could reasonably be expected to be observed by others. A "public place" includes all parts of buildings owned in whole or in part, or leased, by the State or a local unit of government. A "public place" does not include a private residence unless the private residence is used to provide licensed child care, foster care, or other similar social service care on the premises. For purposes of this subsection, a "public place" does not include a health care facility. For purposes of this Section, a "health care facility" includes, but is not limited to, hospitals, nursing homes, hospice care centers, and long-term care facilities;*
 - G) *knowingly in close physical proximity to anyone under the age of 18 years of age;*
- 4) *Smoking medical cannabis in any public place where an individual could reasonably be expected to be observed by others, in a health care facility,*

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or any other place where smoking is prohibited under the Smoke Free Illinois Act;

- 5) *Operating, navigating, or being in actual physical control of any motor vehicle, aircraft, or motorboat while using or under the influence of cannabis in violation of Sections 11-501 and 11-502.1 of the Illinois Vehicle Code;*
 - 6) *Using or possessing cannabis if that person does not have a debilitating medical condition and is not a registered qualifying patient or caregiver;*
 - 7) *Allowing any person who is not allowed to use cannabis under the Act to use cannabis that a cardholder is allowed to possess under the Act;*
 - 8) *Transferring cannabis to any person contrary to the provisions of the Act;*
 - 9) *The use of medical cannabis by an active duty law enforcement officer, correctional officer, correctional probation officer, or firefighter; or*
 - 10) *The use of medical cannabis by a person who has a school bus permit or a Commercial Driver's License.*
- b) *Nothing in the Act shall be construed to prevent the arrest or prosecution of a registered qualifying patient for reckless driving or driving under the influence of cannabis where probable cause exists.*
 - c) *Notwithstanding any other criminal penalties related to the unlawful possession of cannabis, knowingly making a misrepresentation to a law enforcement official of any fact or circumstance relating to the medical use of cannabis to avoid arrest or prosecution is a petty offense punishable by a fine of up to \$1,000, which shall be in addition to any other penalties that may apply for making a false statement or for the use of cannabis other than use undertaken under the Act.*
 - d) *Notwithstanding any other criminal penalties related to the unlawful possession of cannabis, any person who makes a misrepresentation of a medical condition to a physician or fraudulently provides material misinformation to a physician in order to obtain a written certification is guilty of a petty offense punishable by a fine of up to \$1,000.*

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- e) *Any cardholder or registered caregiver who sells cannabis shall have his or her registry identification card revoked and is subject to other penalties for the unauthorized sale of cannabis.*
- f) *Any registered qualifying patient who commits a violation of Section 11-502.1 of the Illinois Vehicle Code or refuses a properly requested test related to operating a motor vehicle while under the influence of cannabis shall have his or her registry identification card revoked.*
- g) *No registered qualifying patient or designated caregiver shall knowingly obtain, seek to obtain, or possess, individually or collectively, an amount of usable cannabis from a registered medical cannabis dispensing organization that would cause him or her to exceed the authorized adequate supply under subsection (a) of Section 10 of the Act.*
- h) *Nothing in the Act shall prevent a private business from restricting or prohibiting the medical use of cannabis on its property.*
- i) *Nothing in the Act shall prevent a university, college, or other institution of post-secondary education from restricting or prohibiting the use of medical cannabis on its property. (Section 30 of the Act)*
- j) Individuals who fail to comply with any of the following notification requirements (see Section 75(a) of the Act) shall be subject to a civil monetary penalty, pursuant to Section 75(d) of the Act. The civil monetary penalty, which may be assessed for each instance of non-compliance, is not to exceed \$150 per instance:
 - 1) *A registered qualifying patient shall notify the Department of Public Health of any change in his or her name or address, or if the registered qualifying patient ceases to have his or her debilitating medical condition, within 10 days of the change or death.*
 - 2) *A registered designated caregiver shall notify the Department of Public Health of any change in his or her name or address, or if the designated caregiver becomes aware the registered qualifying patient passed away, within 10 days of the change or death.*

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- 3) *Before a registered qualifying patient changes his or her designated caregiver, the qualifying patient must notify the Department of Public Health.*
- 4) *If a cardholder loses his or her registry identification card, he or she shall notify the Department within 10 days of becoming aware the card has been lost. (Section 75(a) of the Act)*
- k) *Any person, including an employee or official of the Department of Public Health, Department of Financial and Professional Regulation, or Department of Agriculture or another State agency or local government, is guilty of a Class B misdemeanor with a \$1,000 fine, for breaching the confidentiality of information obtained under the Act (Section 145(c) of the Act).*
- l) Any cardholder found to be in violation of the Act or this Part may have his or her registration suspended or revoked, pursuant to Section 185(a) of the Act.
- m) *The Department of Public Health may with reasonable cause refer a physician, who has certified a debilitating medical condition of a patient, to the Illinois Department of Financial and Professional Regulation for potential violations of Section 35 of the Act. (Section 35(c) of the Act)*

Section 946.50 Notifications to the Department

- a) The registered qualifying patient and designated caregiver shall notify the Department of any changes in application information within 10 days after the change occurs. After a registry identification card is issued, information changes shall be made by notifying the Department. Forms for this purpose will also be available on the Department's website <http://www.idph.state.il.us/HealthWellness/MedicalCannabis/index.htm>.
- b) Registered qualifying patients shall notify the Department:
 - 1) Of changes in the patient's name or address;
 - 2) If the patient ceases to have the debilitating medical condition. If the qualifying patient is deceased, the designated caregiver, if any, or a legal representative of the patient shall notify the Department;
 - 3) Of a change in the designated caregiver;

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- 4) Of a change in the selected dispensary organization;
 - 5) If the registry identification card is lost or stolen; and
 - 6) Upon conviction of any excluded offenses as specified in Section 25(b) of the Act and this Part.
- c) *If a registered qualifying patient ceases to be a registered qualifying patient or changes his or her registered designated caregiver, the registered qualifying patient shall immediately notify the Department promptly via telephone and the Department of Public Health shall promptly notify the designated caregiver. The registered designated caregiver's registry identification card shall immediately become void and all protections under the Act as to that qualifying patient shall expire 15 days after notification by the Department. (Section 75(c) of the Act)*
- d) *A cardholder who fails to make a notification to the Department of Public Health that is required by this Part is subject to a civil infraction, punishable by a penalty of no more than \$150. (Section 75(d) of the Act)*

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 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.

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- 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 of the Act)
- d) Any dispensing information required to be kept under Section 135 or Section 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.
- 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.

Section 946.70 Applicability to the Smoke Free Illinois Act

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The Act does not permit any persons to engage in, and does not prevent the imposition of any civil, criminal or other penalties for engaging in, smoking *medical cannabis in any public place where an individual could reasonably be expected to be observed by others, in a health care facility, or any other place where smoking is prohibited under the Smoke Free Illinois Act.* (Section 30(a)(4) of the Act)

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 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 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;
 - 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 excluded offense as specified under Section 25(b) of the Act; and
 - 5) Be least 18 years of age.
- 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.

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- 2) Provides proof of Illinois residency by submitting at least two of the following items with the application for a registry identification card:
 - A) Pay stub or electronic deposit receipt issued less than 60 days prior to the application date, which shows evidence of the applicant's withholding for State income tax;
 - B) Valid voter registration card with an address in Illinois;
 - C) A valid, unexpired Illinois driver's license 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;
 - D) Notarized Homeless status certification (available at https://www.cyberdriveillinois.com/publications/pdf_publications/dsd_a230.pdf) ;
 - E) Bank Statement (dated less than 60 days prior to application);
 - F) Deed/Title, Mortgage, or Rental/Lease agreement;
 - G) Insurance Policy (homeowner's or renter's);
 - H) Medical Claim or Statement of Benefits (from private insurance company or public (government) agency, dated less than 90 days prior to application) or Social Security Disability Insurance Statement; Supplemental Security Income Benefits Statement;
 - I) Tuition invoice/official mail from college or university, dated less than the 12 months prior to application; or
 - J) Utility bill including, but not limited to, those for electric, water, refuse, telephone land-line, cable or gas, issued less than 60 days prior to application.
- 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:

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- 1) Written certification for the use of medical cannabis meeting the requirements of this Part, which has been 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 by the Department in this Section;
- 3) Proof of identity of the qualifying patient as specified by the Department in this Section;
- 4) Proof of the qualifying patient's age as specified by the Department in this Section;
- 5) Photograph of the qualifying patient and designated caregiver, if applicable, as follows:
 - A) Current digital passport-size image, 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 may be allowed.
 - 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 establish that a photograph would be in violation of or contradictory to the qualifying patient or designated caregiver's religious convictions. If a qualifying patient or designated caregiver declares that the use of a photograph

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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.

- ii) 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 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 period.
 - iv) Upon approval by the Department, a valid registry identification card without a photograph will be issued and 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. During 2014, and later if the Department so elects, a qualifying patient may designate the dispensing 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 by check or money order.

Section 946.205 Deadlines for Submission of Application for Registry Identification Card

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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 by the Department in this Part.

- a) During 2014, qualifying patients whose last name begins with the letters A through L, and their designated caregivers, if applicable, regardless of the caregiver's last name, shall submit an application for a registry identification card from September 1, 2014 through October 31, 2014.
- b) During 2014, qualifying patients whose last name begins with the letters M through Z, and their designated caregivers, if applicable, regardless of the caregiver's last name, shall submit an application for a registry identification card from November 1, 2014 through December 31, 2014.
- c) Beginning January 1, 2015, applications for registry identification cards will be accepted year round.
- d) Applications for registry identification cards 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

Applications for registry identification cards not submitted to the above address shall be considered deficient.

- e) *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, renewal fee and accompanying documentation as described in this Part. (Section 70 of the Act)*
- f) *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)*

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Section 946.210 Fees

- a) Except as set forth in subsection (b), the registration, renewal and replacement card fees are as follows:
 - 1) Annual qualifying patient application fee \$100
 - 2) Annual caregiver application fee \$25
 - 3) Replacement card fee \$25
 - 4) 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).
 - 1) Annual reduced qualifying patient application fee \$50
 - 2) The applicant 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 Social Security and Supplemental Security Income disability benefits to be received by the qualifying patient during the current year of application.
 - 3) Veterans shall provide a copy of their DD214.

Section 946.220 Fingerprint-Based Criminal History Records Check

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

- a) The Illinois State Police 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.

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- 1) The Illinois State Police will conduct background checks for conviction information contained within the Illinois State Police and Federal Bureau of Investigation 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, the Illinois State Police 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 Section 1265.30 of Electronic Transmission of Fingerprints.
- 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 Professional and Financial Regulation, and transmitted to the Illinois State Police for processing no more than 30 days prior to the date of application or renewal for a registry identification card.
- 1) The qualifying patient or designated caregiver shall submit a copy of the livescan request form and receipt provided from the livescan fingerprint vendor containing the Transaction Control Number (TCN) with the registry card application or renewal to the Department as proof that fingerprints have been collected.
 - 2) Registry card applications submitted 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 the Illinois State Police, 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

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transmission of fingerprint data impractical, the Department will allow use of paper fingerprint records.

- c) The Department will obtain, from the Illinois State Police, 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) 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 and subsection (e).
 - 1) Denial of a designated caregiver will not automatically result in the denial of a qualifying patient application.
 - 2) 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.
 - 3) The Department will not deny an application for a registry identification card based solely on the qualifying patient 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.
- f) 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 of the Act) In determining whether to waive a conviction for excluded offenses, the Department will:
 - 1) Review the criminal records and the qualifying patient's medical history to

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determine whether the patient had been diagnosed with the debilitating medical condition at the time of the offense; and

- 2) 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.
- g) The Department will not waive convictions for violations of the medical cannabis laws of Illinois or any other State or jurisdiction.

Section 946.230 General Provisions

- a) A registry identification card shall not be transferable.
- b) A registry identification card issued under this Section is the property of the State of Illinois and shall be surrendered upon demand of the Director.
- c) The qualifying patient and the designated caregiver, if applicable, shall sign and date the application for a registry identification card.
- d) The Department will require each applicant for a registry identification card to include a signed statement that specifies that the applicant attests that all information submitted as part of the application is true and accurate to the best of the applicant's knowledge and, at minimum, certifies that the applicant has actual notice that, notwithstanding any State law:
 - 1) Cannabis is a prohibited Schedule I controlled substance under federal law;
 - 2) Participation in the program is permitted only to the extent provided by the strict requirements of the Act and this Part;
 - 3) Any activity not sanctioned by the Act or this Part may be in violation of state law;
 - 4) Growing, distributing, or possessing cannabis in any capacity, except through a federally approved research program, is a violation of federal law;
 - 5) Use of medical cannabis may affect an individual's ability to receive

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federal or state licensure in other areas;

- 6) Use of medical cannabis, in tandem with other conduct, may be in violation of State or federal law;
- 7) Participation in the program does not authorize any person to violate federal or state law and, other than as specified in 410 ILCS 130/25, does not provide any immunity from or affirmative defense to arrest or prosecution under federal or State law; and
- 8) Applicants shall indemnify, hold harmless, and defend the State of Illinois for any and all civil or criminal penalties resulting from participation in the program.

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

- a) *A qualifying patient who is 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 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 receiving care for a debilitating condition at a VA hospital shall register with the Department on forms and in a manner prescribed by the Department 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 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;
 - 3) Provide a copy of his or her U.S. Department of Veterans Affairs official hospital medical records requested from the U.S. Department of Veterans

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Affairs using VA Form 10-5345;

- 4) Provide a copy of his or her DD214 or equivalent certified document indicating character and dates of service;
- 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.

Section 946.250 Disposal of Medical Cannabis by Qualifying Patients

- a) A qualifying patient or designated caregiver who is no longer registered with the Department or eligible for a registry identification card shall, within 10 calendar days after he or she ceases to be registered or eligible, return any unused medical cannabis in his or her possession to the law enforcement agency having local jurisdiction for destruction.
- b) A qualifying patient or designated caregiver whose registration has been revoked by the Department shall, within 10 days after receiving notice of the revocation, return any unused medical cannabis in his or her possession to the law enforcement agency having local jurisdiction for destruction.
- c) A qualifying patient or designated caregiver who is no longer registered with the Department shall not transfer, share, give, sell, or deliver any unused medical cannabis in his or her possession to any other person, regardless of whether the person is participating in the Compassionate Use of Medical Cannabis Pilot Program.
- d) A qualifying patient or designated caregiver shall not dispose of medical cannabis in any manner other than permitted under this Part.
- e) Disposal of medical cannabis pursuant to this Part or in compliance with this Section shall not constitute a violation of the Criminal Code of 1961.

Section 946.260 Responsibilities of Designated Caregivers

- a) A designated caregiver shall not receive payment or other compensation for services provided as a designated caregiver other than reimbursement for reasonable expenses incurred in the provision of services as a designated

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caregiver. In the case of an employee of a hospice provider, nursing facility, medical facility, or a visiting nurse, personal care attendant, or home health aide serving as a designated caregiver, the individual shall not receive payment or compensation above or beyond his or her regular wages.

- b) A designated caregiver is responsible for notifying the Department within 10 business days after any change to the information that his or her registered qualifying patient was previously required to submit to the Department, or after the designated caregiver discovers that his or her registry identification card has been lost or stolen.
- c) A designated caregiver shall carry his or her registry identification card at all times while in possession of medical cannabis.
- d) A designated caregiver may:
 - 1) Transport a registered qualifying patient to and from a licensed medical cannabis dispensary;
 - 2) Obtain and transport an adequate supply of medical cannabis from a licensed medical cannabis dispensary on behalf of a registered qualifying patient;
 - 3) Prepare medical cannabis for consumption by a registered qualifying patient; and
 - 4) Administer medical cannabis to a registered qualifying patient.
- e) A designated caregiver shall not:
 - 1) Consume, by any means, medical cannabis that has been dispensed on behalf of a registered qualifying patient;
 - 2) Sell, provide, or otherwise divert medical cannabis that has been dispensed to a registered qualifying patient; or
 - 3) Grow or cultivate medical cannabis on behalf of a registered qualifying patient.
- f) The designated caregiver shall notify the Department promptly by phone and in

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writing within 10 calendar days following the death of the designated caregiver's registered qualifying patient.

Section 946.270 Revocation of a Registry Identification Card

- a) The Department will revoke a registry identification card for any of the following reasons:
 - 1) Submission of misleading, incorrect, false, or fraudulent information in the application or renewal application;
 - 2) Violation or violations of the Act or this Part;
 - 3) Fraudulent use of the registry identification card;
 - 4) Selling, distributing, transferring in any manner, or giving medical cannabis to any unauthorized person;
 - 5) Tampering with, falsifying, altering, modifying, or duplicating a registry identification card;
 - 6) Failure to notify the Department within 10 business days after becoming aware that the registry identification card has been lost, stolen or destroyed;
 - 7) Failure to notify the Department within 10 business days after a change in the information provided in the application for a registry identification card; or
 - 8) Conviction of an excluded offense following the issuance of a registry identification card.

- b) In addition, each of the following shall be grounds for the revocation of a registry identification card issued to a registered qualifying patient or designated caregiver:
 - 1) The registered qualifying patient is no longer a resident of Illinois;
 - 2) The registered qualifying patient purchases more medical cannabis than allowable under the Act or this Part from a registered medical cannabis

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organization.

- 3) The qualifying patient is convicted of a felony drug offense in Illinois or of a like violation of the laws of another State, the United States or a military, territorial, or Indian tribal authority; or
 - 4) The registered qualifying patient is deceased.
- c) A registry identification card issued to a designated caregiver is void:
- 1) When the registered qualifying patient or designated caregiver has notified the Department that the individual registered as the designated caregiver is no longer the designated caregiver for that patient;
 - 2) When the registered qualifying patient for whom the designated caregiver serves is no longer registered with the Department;
 - 3) Ten days after the death of the registered qualifying patient, to allow for appropriate disposal of medical cannabis in accordance with this Part.
- d) The Department shall notify the Office of Secretary of State of the revocation.
- e) A void registry identification card is inactive and invalid.

Section 946.280 Medical Cannabis Obtained from a Medical Cannabis Dispensing Organization

A registered qualifying patient or designated caregiver shall obtain medical cannabis only from the medical cannabis dispensing organization designated on his or her registry identification application and shall not:

- a) Grow or cultivate medical cannabis;
- b) Purchase medical cannabis from non-authorized sources; or
- c) Obtain medical cannabis from other registered qualifying patients or designated caregivers.

Section 946.290 Renewal of Registry Identification Cards

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No 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 renewal of his or her registry identification card as follows:

- 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:
 - 1) One clear photocopy of a US or State government-issued photo ID, such as a driver's license, as proof of identity;
 - 2) Proof of Illinois residency by meeting the requirements specified in Section 946.200(c); and
 - 3) 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 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;
- b) Designate the medical cannabis dispensing organization where the qualifying patient will receive his or her medical cannabis, and
- c) Pay the required application fee.

SUBPART C: PHYSICIAN REQUIREMENTS

Section 946.300 Qualifications of the Certifying Physician

- a) A doctor of medicine or osteopathy who is licensed under the Medical Practice Act of 1987 and is in good standing to practice medicine and who has a controlled substances license under Article III of the Illinois Controlled Substances Act and DEA registration may recommend the use of medical cannabis to a qualifying patient if the physician:
 - 1) Is in a bona-fide physician-patient relationship with the qualifying patient. The bona-fide physician-patient relationship may not be limited to a certification for the patient to use medical cannabis or a consultation

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simply for that purpose.

- 2) Complies with generally accepted standards of medical practice, the Medical Practice Act of 1987 and applicable 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 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.
 - 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) *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; (Section 35 of the Act)*
 - 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; (Section 35 of Act);*

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- 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; (Section 35 of the Act)*
 - 4) *Hold a direct or indirect economic interest in a cultivation center or dispensing organization if he or she recommends the use of medical cannabis to qualified patients or is in a partnership with a physician who recommends medical cannabis; (Section 35 of the Act)*
 - 5) *Serve on the board of directors or as an employee of a cultivation center or dispensing organization; (Section 35 of the Act)*
 - 6) *Refer qualifying patients to a cultivation center, a dispensing organization, or an individual who seeks to become a designated caregiver; (Section 35 of the Act)*
 - 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)*

Section 946.310 Physician Written Certification

- a) A certification 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;
 - 2) 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 DEA registration number;
 - 3) The length of time the qualifying patient has been under the care of the physician;

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- 4) The qualifying patient's debilitating medical condition;
 - 5) Comments that would be useful in assessing the qualifying patient's application for use of medical cannabis;
 - 6) A statement that the physician has confirmed a diagnosis of a debilitating medical 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 from the previous 12 months; and has explained the potential risks and benefits of the use of medical cannabis to the qualifying patient; and
 - 7) The physician's signature and date.
- 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 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.
 - 5) If the Department approves the waiver, the amount of medical cannabis recommended by the physician shall be noted on the registry identification card.

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Section 946.320 Records Maintained by the Physician and Department

A physician certifying the use of medical cannabis by a qualifying patient shall establish a medical record for the qualifying patient with regard to his or her medical condition and his or her continued treatment for the condition or conditions under the physician's care. *The physician shall maintain a record-keeping system for all patients for whom the physician has recommended the use of medical cannabis. These records shall be accessible to and subject to review by the Departments of Public Health and Financial and Professional Regulation upon request.* These records do not need to be maintained separately from the established records the physician maintains on the patient during the course of the ongoing bona fide physician-patient relationship. (Section 35 of the Act)

- a) In addition to records required to be maintained pursuant to the Medical Practice Act of 1987 and all applicable rules, the records shall accurately reflect the evaluation and treatment of the qualifying patient, and shall include the following as applicable:
 - 1) The patient's name and the date or dates of visits and treatment;
 - 2) The patient's medical history and updated health history;
 - 3) Documented results of a full assessment of the patient's medical history, including review of medical records from other treating physicians from the previous 12 months;
 - 4) A description of the patient's current medical condition;
 - 5) Documented results of the physician's physical examination of the patient;
 - 6) A treatment plan;
 - 7) Informed consent document or documents;
 - 8) Diagnosis and treatment rendered;
 - 9) A list of the drugs prescribed, administered and dispensed, and the quantity of the drugs;
 - 10) Radiographs and diagnostic tests;

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- 11) Patient financial and billing records;
 - 12) The name of the physician or assistive personnel providing services; and
 - 13) Laboratory results.
- b) The records for each qualifying patient for whom the physician has certified medical cannabis shall be kept for a minimum of three years after the physician last sees the patient.
 - c) The Department will maintain a confidential record of each certifying physician for the purpose of monitoring compliance with the Act. This confidential record will not be subject to requests under the Freedom of Information Act.

SUBPART D: CANNABIS-INFUSED PRODUCTS

Section 946.400 Manufacture of Cannabis-Infused Products

- a) The Department will conduct a pre-operational inspection at all registered cultivation centers to determine whether the facilities, methods, practices and controls used in the manufacture, processing, or holding of cannabis-infused products conform to or are operated or administered in conformity with good manufacturing practices to ensure that food products for human consumption are safe and have been prepared, packed and held under sanitary conditions.
 - 1) Registered cultivation centers shall allow the Department to inspect the premises and all utensils, fixtures, furniture, machinery and devices used for preparing cannabis-infused products.
 - 2) The Department will conduct pre-operational inspections of registered cultivation centers with regard to the manufacture and preparation of cannabis-infused products under the authority of the Illinois Food, Drug and Cosmetic Act and the Food Handling Regulation Enforcement Act and the Food Service Sanitation Code.
- b) *A cultivation center that prepares cannabis-infused products for sale or distribution at a dispensing organization shall be under the operational supervision of a certified food service sanitation manager.* (Section 80(a)(6) of the Act) Management responsibilities and supervision shall be in accordance with Sections 730.8000 and 730.8040 of the Manufacturing, Processing, Packing or

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Holding of Food Code.

- c) *All items shall be individually wrapped or packaged at the original point of preparation. Smaller like items such as hard candies or cookies may be packaged into larger quantities in a single wrapped package. The packaging of the medical cannabis-infused product shall conform to the labeling requirements of the Illinois Food, Drug and Cosmetic Act and shall include the following information in English on each product offered for sale or distribution:*
- 1) *The name and address of the registered cultivation center where the item was manufactured;*
 - 2) *The common or usual name of the item;*
 - 3) *All ingredients of the item, including any colors, artificial flavors, and preservatives, listed in descending order by predominance of weight shown with common or usual names;*
 - 4) *The following phrase: This product was produced in a medical cannabis cultivation center, not subject to public health inspection, that may also process common food allergens.”*
 - 5) *Allergen labeling as specified in the Federal Food, Drug and Cosmetic Act, Federal Fair Packaging and Labeling Act, and the Illinois Food, Drug and Cosmetic Act;*
 - 6) *The pre-mixed total weight (in ounces and grams) of usable cannabis in the food product;*
 - 7) *A warning that the item is a medical cannabis-infused product and not a food must be distinctly and clearly legible on the front of the package;*
 - 8) *A clearly legible warning emphasizing that the product contains medical cannabis and is intended for consumption by registered qualifying patients only; and*
 - 9) *Date of manufacture and “use by” date. (Section 80(a) of the Act)*
 - 10) *Signage may be translated into additional languages as needed.*
- d) The Department may institute additional labeling requirements for cannabis-

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infused products including, but not limited to, measures of potency.

Section 946.410 Sale and Distribution of Cannabis-Infused Products

Neither the Department of Public Health nor the Department of Agriculture nor the health department of a unit of local government may regulate the service of medical cannabis-infused food products by a registered cultivation center or registered dispensing organizations provided certain conditions are met. (Section 80 of the Act)

- a) *No cannabis infused products requiring refrigeration or hot-holding or considered potentially hazardous food (Section 4 of the Food Handling Regulation Enforcement Act) shall be manufactured at a cultivation center for sale or distribution at a dispensing organization due to the potential for food-borne illness (Section 80(a) of the Act).*
- b) *Baked products infused with medical cannabis (such as brownies, bars, cookies, cakes, breads, pastries), tinctures, and other non-refrigerated items are acceptable for sale at dispensing organizations. (Section 80(a) of the Act) The products are allowable for sale only at dispensing organizations registered with the Department of Financial and Professional Regulation.*
- c) *All cannabis-infused products offered for sale at registered dispensing organizations shall be labeled in accordance with Section 946.400.*

Section 946.420 Preparation

Cannabis-infused products for sale and distribution at a dispensing organization must be prepared by an approved staff member of a registered cultivation center. A cultivation center that prepares cannabis-infused products for sale or distribution at a dispensing organization shall be under the operational supervision of a certified food service sanitation manager. (Section 80(a) of the Act)

Section 946.430 Health Hazards

- a) *The Department of Public Health may at all times enter every building, room, basement, enclosure, or premises occupied or used or suspected of being occupied or used for the production, preparation, manufacture for sale, storage, sale, distribution or transportation of medical cannabis-infused products, to inspect the premises and all utensils, fixtures, furniture, and machinery used for the preparation of those products. (Section 80(b) of the Act)*

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- b) If a local health department *has a reasonable belief that a cultivation center's cannabis-infused product poses a public health hazard, it may refer the cultivation center to the Department of Public Health for inspection.* (Section 80(c) of the Act)
- c) Upon inspection of a cultivation center based on a referral that a cannabis- infused product poses a public health hazard, *the Department may without administrative procedure to bond, bring an action for immediate injunctive relief to require that action be taken as a court may deem necessary to meet the hazard posed by the cultivation center.* (Section 80(c) of the Act)

SUBPART E: ENFORCEMENT

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

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petitions for the addition of a medical condition or disease as referenced in Section 946.30, the record on review shall include:

- A) 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 a Medical Cannabis Advisory Board meeting where the medical condition or disease proposed in the petition is materially discussed;
 - 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 946.80, 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.

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- 1) Heading of the Part: Compassionate Use of Medical Cannabis Patient Registry
- 2) Code Citation: 77 Ill. Adm. Code 946
- 3)

<u>Section Numbers:</u>	<u>Proposed Action:</u>
946.10	New
946.20	New
946.20	New
946.30	New
946.40	New
946.50	New
946.60	New
946.70	New
946.200	New
946.205	New
946.210	New
946.220	New
946.230	New
946.240	New
946.250	New
946.260	New
946.270	New
946.280	New
946.290	New
946.300	New
946.310	New
946.320	New
946.330	New
946.400	New
946.410	New
946.420	New
946.430	New
946.440	New
946.500	New
- 4) Statutory Authority: Implementing and authorized by the Compassionate Use of Medical Cannabis Pilot Program Act, P.A. 98-0122.
- 5) A Complete Description of the Subjects and Issues Involved: This rulemaking sets forth

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the requirements for implementation of the Department's Compassionate Use of Medical Cannabis Patient Registry Program which is designed to ensure access to medical cannabis to qualifying patients with specific debilitating medical conditions who apply for and are approved for a registry identification card.

- 6) Published studies or reports, and sources of underlying data, used to compose this rulemaking: None
- 7) Will this proposed rule replace an emergency rule currently in effect? No
- 8) Does this rulemaking contain an automatic repeal date? No
- 9) Does this proposed rule contain incorporations by reference? No
- 10) Are there any other proposed rulemakings pending on this Part? No
- 11) Statement of Statewide Policy Objectives: This rulemaking does not create or expand any state mandates on units of local government.
- 12) Time, Place, and Manner in which interested persons may comment on this proposed rulemaking:

Written or e-mail comments may be submitted within 45 days after this issue of the Illinois Register to:

Susan Meister
Division of Legal Services
Illinois Department of Public Health
535 West Jefferson, Fifth Floor
Springfield, Illinois 62761

217-782-2043
E-mail: dph.rules@illinois.gov

- 13) Initial Regulatory Flexibility Analysis:
 - A) Types of small businesses, small municipalities and not for profit corporations affected: A doctor of medicine or osteopathy who is licensed under the Medical Practice Act of 1987 and is in good standing to practice medicine and who has a controlled substances license under Article III of the Illinois Controlled

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Substances Act

- B) Reporting, bookkeeping or other procedures required for compliance: A physician recommending the use of medical cannabis to a qualifying patient shall establish a medical record for the qualifying patient with regard to his or her medical condition and his or her continued treatment for the condition or conditions under the physician's care. The physician shall maintain a record-keeping system for all patients for whom the physician has recommended the use of medical cannabis. These records shall be accessible to and subject to review by the Departments of Public Health and Financial and Professional Regulation upon request.
 - C) Types of Professional skills necessary for compliance: Understanding of HIPAA requirements, general recordkeeping and records retention.
- 14) Regulatory Agenda on which this rulemaking was summarized: This rulemaking was not included on either of the two most recent Regulatory Agendas because the need for the rulemaking was not apparent when the Regulatory Agendas were prepared.

The full text of the Proposed Rules begins on the next page: