AN ACT CREATING A PRESCRIPTION DRUG REGISTRY; PROVIDING DEFINITIONS; ESTABLISHING PRESCRIPTION DRUG REPORTING REQUIREMENTS; PROVIDING FOR THE USE OF PRESCRIPTION DRUG REGISTRY INFORMATION; PROVIDING FOR FEES TO FUND THE PROGRAM; ALLOWING SANCTIONS AND PENALTIES; PROVIDING FOR IMMUNITY; PROVIDING RULEMAKING AUTHORITY; AMENDING SECTION 37-7-101, MCA; AND PROVIDING AN EFFECTIVE DATE AND A TERMINATION DATE.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

Section 1. Short title. [Sections 1 and 3 through 15] may be cited as the "Montana Patient Safety Act".

Section 2. Section 37-7-101, MCA, is amended to read:

"37-7-101. Definitions. As used in this chapter, the following definitions apply:

(1) (a) "Administer" means the direct application of a drug to the body of a patient by injection, inhalation, ingestion, or any other means.

(b) The term does not include immunization by injection for children under 18 years of age.

(2) "Board" means the board of pharmacy provided for in 2-15-1733.

(3) "Cancer drug" means a prescription drug used to treat:

(a) cancer or its side effects; or

(b) the side effects of a prescription drug used to treat cancer or its side effects.

(4) "Chemical" means medicinal or industrial substances, whether simple, compound, or obtained through the process of the science and art of chemistry, whether of organic or inorganic origin.

(5) "Clinical pharmacist practitioner" means a licensed pharmacist in good standing who meets the requirements specified in 37-7-306.

(6) "Collaborative pharmacy practice" means the practice of pharmacy by a pharmacist who has agreed to work in conjunction with one or more prescribers, on a voluntary basis and under protocol, and who may perform certain patient care functions under certain specified conditions or limitations authorized by the

prescriber.

(7) "Collaborative pharmacy practice agreement" means a written and signed agreement between one or more pharmacists and one or more prescribers that provides for collaborative pharmacy practice for the purpose of drug therapy management of patients.

(8) "Commercial purposes" means the ordinary purposes of trade, agriculture, industry, and commerce, exclusive of the practices of medicine and pharmacy.

(9) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device based on:

(a) a practitioner's prescription drug order;

(b) a professional practice relationship between a practitioner, pharmacist, and patient;

(c) research, instruction, or chemical analysis, but not for sale or dispensing; or

(d) the preparation of drugs or devices based on routine, regularly observed prescribing patterns.

(10) "Confidential patient information" means privileged information accessed by, maintained by, or transmitted to a pharmacist in patient records or that is communicated to the patient as part of patient counseling.

(11) "Controlled substance" means a substance designated in Schedules II through V of Title 50, chapter 32, part 2.

~~(11)~~(12) "Department" means the department of labor and industry provided for in Title 2, chapter 15, part 17.

~~(12)~~(13) "Device" has the same meaning as defined in 37-2-101.

~~(13)~~(14) "Dispense" or "dispensing" means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for administration to or use by a patient.

~~(14)~~(15) "Distribute" means the delivery of a drug or device by means other than administering or dispensing.

~~(15)~~(16) "Drug" means a substance:

(a) recognized as a drug in any official compendium or supplement;

(b) intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(c) other than food, intended to affect the structure or function of the body of humans or animals; and

(d) intended for use as a component of a substance specified in subsection ~~(15)(a), (15)(b), or (15)(c)~~ (16)(a), (16)(b), or (16)(c).

~~(16)~~(17) "Drug utilization review" means an evaluation of a prescription drug order and patient records for duplication of therapy, interactions, proper utilization, and optimum therapeutic outcomes. The term includes but is not limited to the following evaluations:

(a) known allergies;

(b) rational therapy contraindications;

(c) reasonable dose and route administration;

(d) reasonable directions for use;

(e) drug-drug interactions;

(f) drug-food interactions;

(g) drug-disease interactions; and

(h) adverse drug reactions.

~~(17)~~(18) "Equivalent drug product" means a drug product that has the same established name, active ingredient or ingredients, strength or concentration, dosage form, and route of administration and meets the same standards as another drug product as determined by any official compendium or supplement. Equivalent drug products may differ in shape, scoring, configuration, packaging, excipients, and expiration time.

~~(18)~~(19) "Health care facility" has the meaning provided in 50-5-101.

~~(19)~~(20) (a) "Health clinic" means a facility in which advice, counseling, diagnosis, treatment, surgery, care, or services relating to preserving or maintaining health are provided on an outpatient basis for a period of less than 24 consecutive hours to a person not residing at or confined to the facility.

(b) The term includes an outpatient center for primary care and an outpatient center for surgical services, as those terms are defined in 50-5-101, and a local public health agency as defined in 50-1-101.

(c) The term does not include a facility that provides routine health screenings, health education, or immunizations.

~~(20)~~(21) "Hospital" has the meaning provided in 50-5-101.

~~(21)~~(22) "Intern" means:

(a) a person who is licensed by the state to engage in the practice of pharmacy while under the personal supervision of a preceptor and who is satisfactorily progressing toward meeting the requirements for licensure

as a pharmacist;

(b) a graduate of an accredited college of pharmacy who is licensed by the state for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;

(c) a qualified applicant awaiting examination for licensure; or

(d) a person participating in a residency or fellowship program.

~~(22)~~(23) "Long-term care facility" has the meaning provided in 50-5-101.

~~(23)~~(24) (a) "Manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis.

(b) Manufacturing includes:

(i) any packaging or repackaging;

(ii) labeling or relabeling;

(iii) promoting or marketing; and

(iv) preparing and promoting commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons.

~~(24)~~(25) "Medicine" means a remedial agent that has the property of curing, preventing, treating, or mitigating diseases or which is used for this purpose.

~~(25)~~(26) "Participant" means a physician's office, pharmacy, hospital, or health clinic that has elected to voluntarily participate in the cancer drug repository program provided for in 37-7-1403 and that accepts donated cancer drugs or devices under rules adopted by the board.

~~(26)~~(27) "Patient counseling" means the communication by the pharmacist of information, as defined by the rules of the board, to the patient or caregiver in order to ensure the proper use of drugs or devices.

~~(27)~~(28) "Person" includes an individual, partnership, corporation, association, or other legal entity.

~~(28)~~(29) "Pharmaceutical care" means the provision of drug therapy and other patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of disease process.

~~(29)~~(30) "Pharmacist" means a person licensed by the state to engage in the practice of pharmacy and who may affix to the person's name the term "R.Ph.".

~~(30)~~(31) "Pharmacy" means an established location, either physical or electronic, registered by the board

where drugs or devices are dispensed with pharmaceutical care or where pharmaceutical care is provided.

~~(31)~~(32) "Pharmacy technician" means an individual who assists a pharmacist in the practice of pharmacy.

~~(32)~~(33) "Poison" means a substance that, when introduced into the system, either directly or by absorption, produces violent, morbid, or fatal changes or that destroys living tissue with which it comes in contact.

~~(33)~~(34) "Practice of pharmacy" means:

(a) interpreting, evaluating, and implementing prescriber orders;

(b) administering drugs and devices pursuant to a collaborative practice agreement and compounding, labeling, dispensing, and distributing drugs and devices, including patient counseling;

(c) properly and safely procuring, storing, distributing, and disposing of drugs and devices and maintaining proper records;

(d) monitoring drug therapy and use;

(e) initiating or modifying drug therapy in accordance with collaborative pharmacy practice agreements established and approved by health care facilities or voluntary agreements with prescribers;

(f) participating in quality assurance and performance improvement activities;

(g) providing information on drugs, dietary supplements, and devices to patients, the public, and other health care providers; and

(h) participating in scientific or clinical research as an investigator or in collaboration with other investigators.

~~(34)~~(35) "Practice telepharmacy" means to provide pharmaceutical care through the use of information technology to patients at a distance.

~~(35)~~(36) "Preceptor" means an individual who is registered by the board and participates in the instructional training of a pharmacy intern.

~~(36)~~(37) "Prescriber" has the same meaning as provided in 37-7-502.

~~(37)~~(38) "Prescription drug" means any drug that is required by federal law or regulation to be dispensed only by a prescription subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 353.

~~(38)~~(39) "Prescription drug order" means an order from a prescriber for a drug or device that is communicated directly or indirectly by the prescriber to the furnisher by means of a signed order, by electronic transmission, in person, or by telephone. The order must include the name and address of the prescriber, the

prescriber's license classification, the name and address of the patient, the name, strength, and quantity of the drug, drugs, or device prescribed, the directions for use, and the date of its issue. These stipulations apply to written, oral, electronically transmitted, and telephoned prescriptions and orders derived from collaborative pharmacy practice.

~~(39)~~(40) "Provisional community pharmacy" means a pharmacy that has been approved by the board, including but not limited to federally qualified health centers, as defined in 42 CFR 405.2401, where prescription drugs are dispensed to appropriately screened, qualified patients.

~~(40)~~(41) "Qualified patient" means a person who is uninsured, indigent, or has insufficient funds to obtain needed prescription drugs or cancer drugs.

(42) "Registry" means the prescription drug registry provided for in [section 3].

~~(41)~~(43) "Utilization plan" means a plan under which a pharmacist may use the services of a pharmacy technician in the practice of pharmacy to perform tasks that:

(a) do not require the exercise of the pharmacist's independent professional judgment; and

(b) are verified by the pharmacist.

~~(42)~~(44) "Wholesale" means a sale for the purpose of resale."

Section 3. Prescription drug registry -- purpose. (1) The board shall establish and maintain a prescription drug registry for the purpose of improving patient safety by:

(a) making a list of controlled substances prescribed to a patient available to the patient or to the patient's health care provider; and

(b) allowing authorized staff of the board who have signed appropriate confidentiality agreements to review the registry for possible misuse and diversion of controlled substances.

(2) The board shall electronically collect information on prescription drug orders involving controlled substances pursuant to [section 4] and shall disseminate information as provided in [sections 5 through 7].

Section 4. Prescription drug registry -- reporting requirements. (1) Except as provided in subsection (2), each entity licensed by the board as a certified pharmacy or as an out-of-state mail order pharmacy that dispenses drugs to patients in Montana shall provide prescription drug order information for controlled substances to the registry by:

(a) electronically transmitting the information in a format established by the board unless the board has granted a waiver allowing the information to be submitted in a nonelectronic manner; and

(b) submitting the information in accordance with time limits set by the board unless the board grants an extension because:

(i) the pharmacy has suffered a mechanical or electronic failure or cannot meet the deadline for other reasons beyond its control; or

(ii) the board is unable to receive electronic submissions.

(2) This section does not apply to:

(a) a prescriber who dispenses or administers drugs to the prescriber's patients; or

(b) a prescription drug order for a controlled substance dispensed to a person who is hospitalized.

Section 5. Prescription drug registry review. The board may review the information in the registry for possible misuse and diversion of controlled substances prescribed and dispensed to a patient. The board may provide information about possible misuse or diversion to prescribers and dispensers as allowed by rule.

Section 6. Confidentiality. Patient information that is collected, recorded, transmitted, and stored for the registry is protected and may not be disclosed except as allowed in [section 7]. The board shall adopt rules to protect the confidentiality of the registry and to ensure that only authorized individuals have access to the registry.

Section 7. Providing prescription drug registry information. (1) Registry information is health care information as defined in 50-16-504 and is confidential. Except as provided in [section 5], the board is authorized to provide data from the registry, upon request, only to the following:

(a) a person authorized to prescribe or dispense prescription drugs if the person certifies that the information is needed to provide medical or pharmaceutical treatment to a patient who is the subject of the request and who is under the person's care or has been referred to the person for care;

(b) a prescriber who requests information relating to the prescriber's own prescribing information if the prescriber certifies that the requested information is for a purpose in accordance with board rule;

(c) an individual requesting the individual's registry information if the individual provides evidence

satisfactory to the board that the individual requesting the information is the person about whom the data entry was made;

(d) a designated representative of a government agency responsible for licensing, regulating, or disciplining licensed health care professionals who are authorized to prescribe, administer, or dispense drugs, in order to conduct investigations related to a health care professional who is the subject of an active investigation for drug misuse or diversion;

(e) a county coroner or a peace officer employed by a federal, state, tribal, or local law enforcement agency if the county coroner or peace officer has obtained an investigative subpoena;

(f) an authorized individual under the direction of the department of public health and human services for the purpose of reviewing and enforcing that department's responsibilities under the public health, medicare, or medicaid laws; or

(g) a prescription drug registry in another state if the data is subject to limitations and restrictions similar to those provided in [sections 3 through 14].

(2) The board shall maintain a record of each individual or entity that requests information from the registry and whether the request was granted pursuant to this section.

(3) The board may release information in summary, statistical, or aggregate form for educational, research, or public information purposes. The information may not identify a person or entity.

(4) Information collected by or obtained from the registry may not be used:

(a) for commercial purposes; or

(b) as evidence in any civil or administrative action, except in an investigation and disciplinary proceeding by the department or the agency responsible for licensing, regulating, or disciplining licensed health care professionals who are authorized to prescribe, administer, or dispense prescription drugs.

(5) Information obtained from the registry in accordance with the requirements of this section may be used in the course of a criminal investigation and subsequent criminal proceedings.

(6) The board shall adopt rules to ensure that only authorized individuals have access to the registry and only to appropriate information from the registry. The rules must be consistent with:

(a) the privacy provisions of the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. 1320d, et seq.;

(b) administrative rules adopted in connection with that act;

(c) Article II, section 10, of the Montana constitution; and

(d) the privacy provisions of Title 50, chapter 16.

(7) The procedures established by the board under this section may not impede patient access to prescription drugs for legitimate medical purposes.

Section 8. Prescription drug registry -- immunity. (1) A person or entity that complies with the reporting requirements of [section 4] is not subject to civil liability or other legal or equitable relief for reporting the information to the board.

(2) Unless a court of competent jurisdiction finds that a person or entity committed an unlawful act pursuant to [section 14], a person or entity in proper possession of information pursuant to [sections 1 through 15] is not subject to civil liability or other legal or equitable relief for any of the following acts or omissions:

(a) furnishing information pursuant to [sections 3 through 7];

(b) receiving, using or relying on, or not using or relying on information received pursuant to [sections 3 through 7]; or

(c) relying on information that was entered into the registry in error, was factually incorrect, or was released by the board to the wrong person or entity.

(3) The immunity provisions of this section do not apply to the board, a state agency, or any political subdivision of the state.

Section 9. Registry information retention -- destruction. The board shall retain the information collected for the registry for up to 3 years, as established by rule. After 3 years, the board shall destroy the information unless it is being used as part of an active investigation.

Section 10. Administration of prescription drug registry. The board may hire or contract for other professional, technical, or clerical staff as necessary to operate the registry. A contractor shall comply with the provisions regarding confidentiality of prescription information in [sections 6 and 7] and is subject to the penalties specified in [section 14] for unlawful acts.

Section 11. Prescription drug registry -- advisory group. (1) The board shall establish an advisory

group to provide information and advice about the development and operation of the registry, including but not limited to information on:

(a) the criteria for reporting information from the registry to prescribers and pharmacists;

(b) the design and implementation of educational courses about the registry;

(c) standards for evaluating the effectiveness of the registry; and

(d) administrative rules for establishing and maintaining the registry.

(2) The advisory group consists of but is not limited to representatives of:

(a) health care licensing boards that oversee health care providers who have authority to prescribe or dispense drugs;

(b) associations that represent health care professionals who have authority to prescribe or dispense drugs;

(c) associations that advocate for patients;

(d) entities involved in tribal health services or issues; and

(e) the department of justice provided for in 2-15-2001.

(3) The advisory group may identify other individuals for appointment to the group.

(4) The board shall establish rules for the conduct of advisory group business.

(5) The advisory group may not receive or access confidential health care information contained in the registry.

Section 12. Prescription drug registry -- funding. (1) Each person licensed under Title 37 who prescribes, dispenses, or distributes controlled substances shall pay to the board a nonrefundable fee that is set by rule and that may not exceed $15.

(2) The board may apply for any available grants and may accept gifts, grants, or donations to assist in establishing and maintaining the registry.

(3) Funds collected pursuant to [sections 3 through 15] must be deposited into a state special revenue account to the credit of the department. The money must be used to defray the expenses of the board in establishing and maintaining the registry and in discharging its administrative and regulatory duties under [sections 3 through 15].

Section 13. Rulemaking authority. The board shall adopt rules to carry out and enforce [sections 3 through 15], including but not limited to rules that:

(1) specify the type of information to be reported on prescription drug orders involving controlled substances;

(2) establish the requirements for transmitting from a pharmacy to the board prescription drug order information involving controlled substances;

(3) define the electronic format for submission of information;

(4) define the circumstances under which a pharmacy may receive a waiver from the requirement to submit information electronically;

(5) specify the procedure through which a pharmacy may request an extension of the time limit for submitting information;

(6) establish how a person or entity authorized to receive information from the registry may submit a request for the information;

(7) specify the ways in which the board may use records involving requests for registry information to document and report on statistics involving the registry;

(8) set the fees to be charged for establishing and maintaining the registry; and

(9) establish confidentiality provisions to ensure that the privacy of patient information is maintained.

Section 14. Unlawful acts -- sanctions -- civil penalties. (1) A pharmacist who fails to submit prescription drug order information to the board as required by [section 4] or who willfully submits incorrect prescription drug order information must be referred to the board for consideration of administrative sanctions.

(2) A person or entity authorized to possess registry information pursuant to [sections 5 through 7] who willfully discloses or uses the registry information in violation of [sections 5 through 7] or a rule adopted pursuant to [sections 3 through 15] must be referred to the appropriate licensing board or regulatory agency for consideration of administrative sanctions.

(3) In addition to the administrative sanction provided in subsection (2), a person or entity who willfully discloses or uses information from the registry in violation of [sections 5 through 7] or a rule adopted pursuant to [sections 3 through 15] is liable for a civil penalty of up to $10,000 for each violation.

(4) The board may institute and maintain in the name of the state any enforcement proceedings under

this section. Upon request of the department, the attorney general shall petition the district court to impose, assess, and recover the civil penalty.

(5) An action under subsection (3) or to enforce [sections 3 through 15] or a rule adopted under [sections 3 through 15] may be brought in the district court of any county where a violation occurs or, if mutually agreed on by the parties in the action, in the district court of the first judicial district.

(6) Civil penalties collected pursuant to [sections 3 through 15] must be deposited into the state special revenue account created pursuant to [section 12] and must be used to defray the expenses of the board in establishing and maintaining the registry and in discharging its administrative and regulatory duties in relation to [sections 3 through 15].

Section 15. Report to legislature. The board shall provide a report to the appropriate interim committees of the legislature each interim, including but not limited to information on:

(1) the cost of establishing and maintaining the registry;

(2) any grants, gifts, or donations received to assist in establishing and maintaining the registry;

(3) how registry information was used; and

(4) how quickly the board was able to answer requests for information from the registry.

Section 16. Notification to tribal governments. The secretary of state shall send a copy of [this act] to each tribal government located on the seven Montana reservations and to the Little Shell Chippewa tribe.

Section 17. Codification instruction. [Sections 1 and 3 through 15] are intended to be codified as an integral part of Title 37, chapter 7, and the provisions of Title 37, chapter 7, apply to [sections 1 and 3 through 15].

Section 18. Severability. If a part of [this act] is invalid, all valid parts that are severable from the invalid part remain in effect. If a part of [this act] is invalid in one or more of its applications, the part remains in effect in all valid applications that are severable from the invalid applications.

Section 19. Effective date. [This act] is effective July 1, 2011.

Section 20. Termination. [Section 12(1)] terminates July 1, 2015.

- END -

I hereby certify that the within bill,

HB 0083, originated in the House.

Chief Clerk of the House

Speaker of the House

Signed this _____ day

of _____, 2011.

President of the Senate

Signed this _____ day

of _____, 2011.

HOUSE BILL NO. 83

INTRODUCED BY T. BERRY, BELCOURT, BOLAND, BRODEHL, DRISCOLL, EVANS, FUREY, GIBSON, GREEF, HINER, HOLLENBAUGH, HOVEN, HOWARD, HUNTER, KLOCK, LAVIN, MACDONALD, MACLAREN, MALEK, MCCHESNEY, MCCLAFFERTY, MEHLHOFF, MENAHAN, NOONAN, O'HARA, PRICE, READ, REGIER, ROBERTS, ROSENDALE, SCHMIDT, F. SMITH, SQUIRES, TAYLOR, WILMER, GALLUS, GILLAN, HAMLETT, HUTTON, LARSEN, OLSON, TUTVEDT, VUCKOVICH, ZINKE

BY REQUEST OF THE DEPARTMENT OF JUSTICE

AN ACT CREATING A PRESCRIPTION DRUG REGISTRY; PROVIDING DEFINITIONS; ESTABLISHING PRESCRIPTION DRUG REPORTING REQUIREMENTS; PROVIDING FOR THE USE OF PRESCRIPTION DRUG REGISTRY INFORMATION; PROVIDING FOR FEES TO FUND THE PROGRAM; ALLOWING SANCTIONS AND PENALTIES; PROVIDING FOR IMMUNITY; PROVIDING RULEMAKING AUTHORITY; AMENDING SECTION 37-7-101, MCA; AND PROVIDING AN EFFECTIVE DATE AND A TERMINATION DATE.