AN ACT CREATING THE PROFESSIONAL CLASSIFICATION OF CLINICAL PHARMACIST PRACTITIONER; PROVIDING DEFINITIONS AND QUALIFICATIONS; REQUIRING THE BOARD OF PHARMACY AND THE BOARD OF MEDICAL EXAMINERS TO ESTABLISH REQUIREMENTS FOR CLINICAL PHARMACIST PRACTITIONERS; AND AMENDING SECTIONS 37-7-101 AND 37-7-201, MCA.

WHEREAS, the Medicare Payment Advisory Commission has recommended that the Centers for Medicare and Medicaid Services recognize pharmacists engaging in medication therapy management as practitioners under Medicare, thus permitting those professionals to bill the program independently for their patient care services; and

WHEREAS, the introduction of this federal legislation would require each state to define and articulate requirements necessary for a pharmacist to become clinically certified; and

WHEREAS, the Montana Pharmacy Association hopes to be proactive in having this state legislation ready in anticipation of the federal law; and

WHEREAS, advancing pharmacy practitioners within the state of Montana achieves better patient care and advances national goals for health care reform; and

WHEREAS, pharmacists have demonstrated a large role in producing favorable outcomes with medication therapy management because of their drug knowledge, clinical skills, and access to patients; and

WHEREAS, well-trained, credentialed pharmacists are needed to work with physicians in managing patients with chronic medical conditions requiring a large number of medications; and

WHEREAS, pharmacists play a critical role in health care access to patients, especially in rural Montana.

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

Section 1. Section 37-7-101, MCA, is amended to read:

"37-7-101. Definitions. As used in parts 1 through 7 of 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) "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.

(4) "Clinical pharmacist practitioner" means a licensed pharmacist in good standing who meets the requirements specified in [section 2].

~~(4)~~(5) "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.

~~(5)~~(6) "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.

~~(6)~~(7) "Commercial purposes" means the ordinary purposes of trade, agriculture, industry, and commerce, exclusive of the practices of medicine and pharmacy.

~~(7)~~(8) "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.

~~(8)~~(9) "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.

~~(9)~~(10) "Department" means the department of labor and industry provided for in Title 2, chapter 15, part 17.

~~(10)~~(11) "Device" has the same meaning as defined in 37-2-101.

~~(11)~~(12) "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.

~~(12)~~(13) "Distribute" means the delivery of a drug or device by means other than administering or dispensing.

~~(13)~~(14) "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 ~~(13)(a)~~ (14)(a), ~~(13)(b)~~ (14)(b), or ~~(13)(c)~~ (14)(c).

~~(14)~~(15) "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.

~~(15)~~(16) "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.

~~(16)~~(17) "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.

~~(17)~~(18) (a) "Manufacturing" means the production, preparation, propogation, 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.

~~(18)~~(19) "Medicine" means a remedial agent that has the property of curing, preventing, treating, or mitigating diseases or which is used for this purpose.

~~(19)~~(20) "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.

~~(20)~~(21) "Person" includes an individual, partnership, corporation, association, or other legal entity.

~~(21)~~(22) "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.

~~(22)~~(23) "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.".

~~(23)~~(24) "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.

~~(24)~~(25) "Pharmacy technician" means an individual who assists a pharmacist in the practice of pharmacy.

~~(25)~~(26) "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.

~~(26)~~(27) "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.

~~(27)~~(28) "Practice telepharmacy" means to provide pharmaceutical care through the use of information technology to patients at a distance.

~~(28)~~(29) "Preceptor" means an individual who is registered by the board and participates in the instructional training of a pharmacy intern.

~~(29)~~(30) "Prescriber" has the same meaning as provided in 37-7-502.

~~(30)~~(31) "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~~)~~.

~~(31)~~(32) "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.

~~(32)~~(33) "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.

~~(33)~~(34) "Wholesale" means a sale for the purpose of resale."

Section 2. Clinical pharmacist practitioner qualifications. (1) A clinical pharmacist practitioner is a licensed pharmacist in good standing who:

(a) is certified by the board, in concurrence with the board of medical examiners, to provide drug therapy management, including initiating, modifying, or discontinuing therapies, identifying and managing drug-related problems, or ordering tests under the direction or supervision of a prescriber;

(b) has additional education, experience, or certification as required by the board in concurrence with the board of medical examiners; and

(c) has in place a collaborative pharmacy practice agreement.

(2) Only a pharmacist certified by the board may legally be identified as a clinical pharmacist practitioner.

Section 3. Section 37-7-201, MCA, is amended to read:

"37-7-201. Organization -- powers and duties. (1) The board shall meet at least once a year to transact its business. The board shall annually elect from its members a president, vice president, and secretary.

(2) The board shall regulate the practice of pharmacy in this state, including but not limited to:

(a) establishing minimum standards for:

(i) equipment necessary in and for a pharmacy;

(ii) the purity and quality of drugs, devices, and other materials dispensed within the state through the practice of pharmacy, using an official compendium recognized by the board or current practical standards;

(iii) specifications for the facilities, environment, supplies, technical equipment, personnel, and procedures for the storage, compounding, or dispensing of drugs and devices;

(iv) monitoring drug therapy; and

(v) maintaining the integrity and confidentiality of prescription information and other confidential patient information;

(b) requesting the department to inspect, at reasonable times:

(i) places where drugs, medicines, chemicals, or poisons are sold, vended, given away, compounded, dispensed, or manufactured; and

(ii) the appropriate records and the license of any person engaged in the practice of pharmacy for the purpose of determining whether any laws governing the legal distribution of drugs or devices or the practice of pharmacy are being violated. The board shall cooperate with all agencies charged with the enforcement of the laws of the United States, other states, or this state relating to drugs, devices, and the practice of pharmacy. It is a misdemeanor for a person to refuse to permit or otherwise prevent the department from entering these places and making an inspection.

(c) regulating:

(i) the training, qualifications, employment, licensure, and practice of interns;

(ii) the training, qualifications, employment, and registration of pharmacy technicians; and

(iii) under therapeutic classification, the sale and labeling of drugs, devices, medicines, chemicals, and poisons;

(d) examining applicants and issuing and renewing licenses of:

(i) applicants whom the board considers qualified under this chapter to practice pharmacy;

(ii) pharmacies and certain stores under this chapter;

(iii) wholesale drug distributors; and

(iv) persons engaged in the manufacture and distribution of drugs or devices;

(e) in concurrence with the board of medical examiners, defining the additional education, experience, or certification required of a licensed pharmacist to become a certified clinical pharmacist practitioner;

~~(e)~~(f) issuing certificates of "certified pharmacy" under this chapter;

~~(f)~~(g) establishing and collecting license and registration fees;

~~(g)~~(h) approving pharmacy practice initiatives that improve the quality of, or access to, pharmaceutical care but that fall outside the scope of this chapter. This subsection ~~(2)(g)~~ (2)(h) may not be construed to expand on the definition of the practice of pharmacy ~~as defined in 37-7-101~~.

~~(h)~~(i) making rules for the conduct of its business;

~~(i)~~(j) performing other duties and exercising other powers as this chapter requires;

~~(j)~~(k) adopting and authorizing the department to publish rules for carrying out and enforcing parts 1 through 7 of this chapter, including but not limited to:

(i) requirements and qualifications for the transfer of board-issued licenses;

(ii) minimum standards for pharmacy internship programs and qualifications for licensing pharmacy interns;

(iii) qualifications and procedures for registering pharmacy technicians; and

(iv) requirements and procedures necessary to allow a pharmacy licensed in another jurisdiction to be registered to practice telepharmacy across state lines.

(3) The board may:

(a) join professional organizations and associations organized exclusively to promote the improvement of standards of the practice of pharmacy for the protection of the health and welfare of the public and whose activities assist and facilitate the work of the board; and

(b) establish standards of care for patients concerning health care services that a patient may expect with regard to pharmaceutical care."

Section 4. Codification. [Section 2] is intended to be codified as an integral part of Title 37, chapter 7, and the provisions of Title 37, chapter 7, apply to [section 2].

- END -

I hereby certify that the within bill,

SB 0174, originated in the Senate.

Secretary of the Senate

President of the Senate

Signed this _____ day

of _____, 2009.

Speaker of the House

Signed this _____ day

of _____, 2009.

SENATE BILL NO. 174

INTRODUCED BY G. PERRY

AN ACT CREATING THE PROFESSIONAL CLASSIFICATION OF CLINICAL PHARMACIST PRACTITIONER; PROVIDING DEFINITIONS AND QUALIFICATIONS; REQUIRING THE BOARD OF PHARMACY AND THE BOARD OF MEDICAL EXAMINERS TO ESTABLISH REQUIREMENTS FOR CLINICAL PHARMACIST PRACTITIONERS; AND AMENDING SECTIONS 37-7-101 AND 37-7-201, MCA.