LEGISLATIVE GENERAL COUNSEL
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H.B. 108

HORMONE RESTORATION AMENDMENTS

2009 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Douglas C. Aagard

Senate Sponsor: Dennis E. Stowell

LONG TITLE

General Description:

This bill amends the Utah Controlled Substances Act and the Naturopathic Physician Practice Act to permit a naturopathic physician to, pursuant to a license issued by the Division of Occupational and Professional Licensing, prescribe or administer testosterone in specified forms for the purpose of restoring a low testosterone level to a normal level.

Highlighted Provisions:

This bill:

- adds "naturopathic physician" to the definition of "practitioner" in the Utah Controlled Substances Act in order to allow a naturopathic physician to prescribe only testosterone, in the form and for the purposes described in this bill;
- requires a naturopathic physician to keep a record of testosterone:
  - received by the naturopathic physician; and
  - administered, dispensed, or professionally used by the naturopathic physician, other than by a prescription;
- permits a naturopathic physician to prescribe or administer testosterone, pursuant to the requirements of federal and state law, if the testosterone is:
  - bio-identical;
  - designed to be administered topically, for transdermal absorption or designed to be absorbed across the mucosal membranes of the mouth; and

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- prescribed solely for the purpose of treating a patient with a low testosterone level in order to restore the patient to a normal testosterone level; Ĥ→ [~~and~~] ←Ĥ

Ĥ→ ▸ **provides that the provisions of Title 58, Chapter 71, Naturopathic Physician Practice Act, do not mandate health insurance coverage for the prescription or administration of testosterone by a naturopathic physician; and** ←Ĥ

▸ makes technical changes.

Monies Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-37-2, as last amended by Laws of Utah 2008, Chapter 382

58-37-6, as last amended by Laws of Utah 2008, Chapters 3 and 382

58-71-102, as last amended by Laws of Utah 2008, Chapter 382

Ĥ→ **58-71-804, as enacted by Laws of Utah 1996, Chapter 282** ←Ĥ

Be it enacted by the Legislature of the state of Utah:

Section 1. Section **58-37-2** is amended to read:

58-37-2. Definitions.

(1) As used in this chapter:

(a) "Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:

(i) a practitioner or, in the practitioner's presence, by the practitioner's authorized agent; or

(ii) the patient or research subject at the direction and in the presence of the practitioner.

(b) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or practitioner but does not include a motor carrier, public warehouseman, or employee of any of them.

(c) "Consumption" means ingesting or having any measurable amount of a controlled substance in a person's body, but this Subsection (1)(c) does not include the metabolite of a controlled substance.

(d) "Continuing criminal enterprise" means any individual, sole proprietorship,

partnership, corporation, business trust, association, or other legal entity, and any union or groups of individuals associated in fact although not a legal entity, and includes illicit as well as licit entities created or maintained for the purpose of engaging in conduct which constitutes the commission of episodes of activity made unlawful by Title 58, Chapters 37, 37a, 37b, 37c, or 37d, which episodes are not isolated, but have the same or similar purposes, results, participants, victims, methods of commission, or otherwise are interrelated by distinguishing characteristics. Taken together, the episodes shall demonstrate continuing unlawful conduct and be related either to each other or to the enterprise.

(e) "Control" means to add, remove, or change the placement of a drug, substance, or immediate precursor under Section 58-37-3.

(f) (i) "Controlled substance" means a drug or substance included in Schedules I, II, III, IV, or V of Section 58-37-4, and also includes a drug or substance included in Schedules I, II, III, IV, or V of the federal Controlled Substances Act, Title II, P.L. 91-513, or any controlled substance analog.

(ii) "Controlled substance" does not include:

(A) distilled spirits, wine, or malt beverages, as those terms are defined or used in Title 32A, Alcoholic Beverage Control Act, regarding tobacco or food;

(B) any drug intended for lawful use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, which contains ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine if the drug is lawfully purchased, sold, transferred, or furnished as an over-the-counter medication without prescription; or

(C) dietary supplements, vitamins, minerals, herbs, or other similar substances including concentrates or extracts, which are not otherwise regulated by law, which may contain naturally occurring amounts of chemical or substances listed in this chapter, or in rules adopted pursuant to Title 63G, Chapter 3, Utah Administrative Rulemaking Act.

(g) (i) "Controlled substance analog" means a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance listed in Schedules I and II of Section 58-37-4, or in Schedules I and II of the federal Controlled Substances Act, Title II, P.L. 91-513:

(A) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to the stimulant, depressant, or hallucinogenic effect on the central

nervous system of controlled substances in the schedules set forth in Subsection (1)(f); or

(B) which, with respect to a particular individual, is represented or intended to have a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to the stimulant, depressant, or hallucinogenic effect on the central nervous system of controlled substances in the schedules set forth in this Subsection (1).

(ii) "Controlled substance analog" does not include:

(A) a controlled substance currently scheduled in Schedules I through V of Section 58-37-4;

(B) a substance for which there is an approved new drug application;

(C) a substance with respect to which an exemption is in effect for investigational use by a particular person under Section 505 of the Food, Drug, and Cosmetic Act, 21 U.S.C. 355, to the extent the conduct with respect to the substance is permitted by the exemption;

(D) any substance to the extent not intended for human consumption before an exemption takes effect with respect to the substance;

(E) any drug intended for lawful use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, which contains ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine if the drug is lawfully purchased, sold, transferred, or furnished as an over-the-counter medication without prescription; or

(F) dietary supplements, vitamins, minerals, herbs, or other similar substances including concentrates or extracts, which are not otherwise regulated by law, which may contain naturally occurring amounts of chemical or substances listed in this chapter, or in rules adopted pursuant to Title 63G, Chapter 3, Utah Administrative Rulemaking Act.

(h) "Conviction" means a determination of guilt by verdict, whether jury or bench, or plea, whether guilty or no contest, for any offense proscribed by Title 58, Chapters 37, 37a, 37b, 37c, or 37d, or for any offense under the laws of the United States and any other state which, if committed in this state, would be an offense under Title 58, Chapters 37, 37a, 37b, 37c, or 37d.

(i) "Counterfeit substance" means:

(i) any substance or container or labeling of any substance that without authorization bears the trademark, trade name, or other identifying mark, imprint, number, device, or any likeness of them, of a manufacturer, distributor, or dispenser other than the person or persons

who in fact manufactured, distributed, or dispensed the substance which falsely purports to be a controlled substance distributed by, any other manufacturer, distributor, or dispenser; or

(ii) any substance that is represented to be a controlled substance.

(j) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not an agency relationship exists.

(k) "Department" means the Department of Commerce.

(l) "Depressant or stimulant substance" means:

(i) a drug which contains any quantity of barbituric acid or any of the salts of barbituric acid;

(ii) a drug which contains any quantity of:

(A) amphetamine or any of its optical isomers;

(B) any salt of amphetamine or any salt of an optical isomer of amphetamine; or

(C) any substance which the Secretary of Health and Human Services or the Attorney General of the United States after investigation has found and by regulation designated habit-forming because of its stimulant effect on the central nervous system;

(iii) lysergic acid diethylamide; or

(iv) any drug which contains any quantity of a substance which the Secretary of Health and Human Services or the Attorney General of the United States after investigation has found to have, and by regulation designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

(m) "Dispense" means the delivery of a controlled substance by a pharmacist to an ultimate user pursuant to the lawful order or prescription of a practitioner, and includes distributing to, leaving with, giving away, or disposing of that substance as well as the packaging, labeling, or compounding necessary to prepare the substance for delivery.

(n) "Dispenser" means a pharmacist who dispenses a controlled substance.

(o) "Distribute" means to deliver other than by administering or dispensing a controlled substance or a listed chemical.

(p) "Distributor" means a person who distributes controlled substances.

(q) "Division" means the Division of Occupational and Professional Licensing created in Section 58-1-103.

(r) "Drug" means:

(i) articles recognized in the official United States Pharmacopoeia, Official Homeopathic Pharmacopoeia of the United States, or Official National Formulary, or any supplement to any of them;

(ii) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

(iii) articles, other than food, intended to affect the structure or function of man or other animals; and

(iv) articles intended for use as a component of any articles specified in Subsection (1)(r)(i), (ii), or (iii); but does not include devices or their components, parts, or accessories.

(s) "Drug dependent person" means any individual who unlawfully and habitually uses any controlled substance to endanger the public morals, health, safety, or welfare, or who is so dependent upon the use of controlled substances as to have lost the power of self-control with reference to the individual's dependency.

(t) "Food" means:

(i) any nutrient or substance of plant, mineral, or animal origin other than a drug as specified in this chapter, and normally ingested by human beings; and

(ii) foods for special dietary uses as exist by reason of a physical, physiological, pathological, or other condition including but not limited to the conditions of disease, convalescence, pregnancy, lactation, allergy, hypersensitivity to food, underweight, and overweight; uses for supplying a particular dietary need which exist by reason of age including but not limited to the ages of infancy and childbirth, and also uses for supplementing and for fortifying the ordinary or unusual diet with any vitamin, mineral, or other dietary property for use of a food. Any particular use of a food is a special dietary use regardless of the nutritional purposes.

(u) "Immediate precursor" means a substance which the Attorney General of the United States has found to be, and by regulation designated as being, the principal compound used or produced primarily for use in the manufacture of a controlled substance, or which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit the manufacture of the controlled substance.

(v) "Indian" means a member of an Indian tribe.

(w) "Indian religion" means any religion:

(i) the origin and interpretation of which is from within a traditional Indian culture or community; and

(ii) which is practiced by Indians.

(x) "Indian tribe" means any tribe, band, nation, pueblo, or other organized group or community of Indians, including any Alaska Native village, which is legally recognized as eligible for and is consistent with the special programs, services, and entitlements provided by the United States to Indians because of their status as Indians.

(y) "Manufacture" means the production, preparation, propagation, compounding, or processing of a controlled substance, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis.

(z) "Manufacturer" includes any person who packages, repackages, or labels any container of any controlled substance, except pharmacists who dispense or compound prescription orders for delivery to the ultimate consumer.

(aa) "Marijuana" means all species of the genus cannabis and all parts of the genus, whether growing or not; the seeds of it; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or resin. The term does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks, except the resin extracted from them, fiber, oil or cake, or the sterilized seed of the plant which is incapable of germination. Any synthetic equivalents of the substances contained in the plant cannabis sativa or any other species of the genus cannabis which are chemically indistinguishable and pharmacologically active are also included.

(bb) "Money" means officially issued coin and currency of the United States or any foreign country.

(cc) "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(i) opium, coca leaves, and opiates;

(ii) a compound, manufacture, salt, derivative, or preparation of opium, coca leaves, or opiates;

(iii) opium poppy and poppy straw; or

(iv) a substance, and any compound, manufacture, salt, derivative, or preparation of the substance, which is chemically identical with any of the substances referred to in Subsection (1)(cc)(i), (ii), or (iii), except narcotic drug does not include decocainized coca leaves or extracts of coca leaves which do not contain cocaine or ecgonine.

(dd) "Negotiable instrument" means documents, containing an unconditional promise to pay a sum of money, which are legally transferable to another party by endorsement or delivery.

(ee) "Opiate" means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability.

(ff) "Opium poppy" means the plant of the species papaver somniferum L., except the seeds of the plant.

(gg) "Person" means any corporation, association, partnership, trust, other institution or entity or one or more individuals.

(hh) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(ii) "Possession" or "use" means the joint or individual ownership, control, occupancy, holding, retaining, belonging, maintaining, or the application, inhalation, swallowing, injection, or consumption, as distinguished from distribution, of controlled substances and includes individual, joint, or group possession or use of controlled substances. For a person to be a possessor or user of a controlled substance, it is not required that the person be shown to have individually possessed, used, or controlled the substance, but it is sufficient if it is shown that the person jointly participated with one or more persons in the use, possession, or control of any substances with knowledge that the activity was occurring, or the controlled substance is found in a place or under circumstances indicating that the person had the ability and the intent to exercise dominion and control over it.

(jj) "Practitioner" means a physician, dentist, <u>naturopathic physician,</u> veterinarian, pharmacist, scientific investigator, pharmacy, hospital, or other person licensed, registered, or

otherwise permitted to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis a controlled substance in the course of professional practice or research in this state.

(kk) "Prescribe" means to issue a prescription orally or in writing.

(ll) "Prescription" means an order issued by a licensed practitioner, in the course of that practitioner's professional practice, for a controlled substance, other drug, or device which it dispenses or administers for use by a patient or an animal. The order may be issued by word of mouth, written document, telephone, facsimile transmission, computer, or other electronic means of communication as defined by rule.

(mm) "Production" means the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(nn) "Securities" means any stocks, bonds, notes, or other evidences of debt or of property.

(oo) "State" means the state of Utah.

(pp) "Ultimate user" means any person who lawfully possesses a controlled substance for the person's own use, for the use of a member of the person's household, or for administration to an animal owned by the person or a member of the person's household.

(2) If a term used in this chapter is not defined, the definition and terms of Title 76, Utah Criminal Code, shall apply.

Section 2. Section **58-37-6** is amended to read:

58-37-6. License to manufacture, produce, distribute, dispense, administer, or conduct research -- Issuance by division -- Denial, suspension, or revocation -- Records required -- Prescriptions.

(1) (a) The division may adopt rules relating to the licensing and control of the manufacture, distribution, production, prescription, administration, dispensing, conducting of research with, and performing of laboratory analysis upon controlled substances within this state.

(b) The division may assess reasonable fees to defray the cost of issuing original and renewal licenses under this chapter pursuant to Section 63J-1-303.

(2) (a) (i) Every person who manufactures, produces, distributes, prescribes, dispenses, administers, conducts research with, or performs laboratory analysis upon any controlled

substance in Schedules II through V within this state, or who proposes to engage in manufacturing, producing, distributing, prescribing, dispensing, administering, conducting research with, or performing laboratory analysis upon controlled substances included in Schedules II through V within this state shall obtain a license issued by the division.

(ii) The division shall issue each license under this chapter in accordance with a two-year renewal cycle established by rule. The division may by rule extend or shorten a renewal period by as much as one year to stagger the renewal cycles it administers.

(b) Persons licensed to manufacture, produce, distribute, prescribe, dispense, administer, conduct research with, or perform laboratory analysis upon controlled substances in Schedules II through V within this state may possess, manufacture, produce, distribute, prescribe, dispense, administer, conduct research with, or perform laboratory analysis upon those substances to the extent authorized by their license and in conformity with this chapter.

(c) The following persons are not required to obtain a license and may lawfully possess controlled substances under this section:

(i) an agent or employee, except a sales representative, of any registered manufacturer, distributor, or dispenser of any controlled substance, if the agent or employee is acting in the usual course of the person's business or employment; however, nothing in this subsection shall be interpreted to permit an agent, employee, sales representative, or detail man to maintain an inventory of controlled substances separate from the location of the person's employer's registered and licensed place of business;

(ii) a motor carrier or warehouseman, or an employee of a motor carrier or warehouseman, who possesses any controlled substance in the usual course of the person's business or employment; and

(iii) an ultimate user, or any person who possesses any controlled substance pursuant to a lawful order of a practitioner.

(d) The division may enact rules waiving the license requirement for certain manufacturers, producers, distributors, prescribers, dispensers, administrators, research practitioners, or laboratories performing analysis if consistent with the public health and safety.

(e) A separate license is required at each principal place of business or professional practice where the applicant manufactures, produces, distributes, dispenses, conducts research with, or performs laboratory analysis upon controlled substances.

(f) The division may enact rules providing for the inspection of a licensee or applicant's establishment, and may inspect the establishment according to those rules.

(3) (a) Upon proper application, the division shall license a qualified applicant to manufacture, produce, distribute, conduct research with, or perform laboratory analysis upon controlled substances included in Schedules I through V, unless it determines that issuance of a license is inconsistent with the public interest. The division shall not issue a license to any person to prescribe, dispense, or administer a Schedule I controlled substance. In determining public interest, the division shall consider whether or not the applicant has:

(i) maintained effective controls against diversion of controlled substances and any Schedule I or II substance compounded from any controlled substance into other than legitimate medical, scientific, or industrial channels;

(ii) complied with applicable state and local law;

(iii) been convicted under federal or state laws relating to the manufacture, distribution, or dispensing of substances;

(iv) past experience in the manufacture of controlled dangerous substances;

(v) established effective controls against diversion; and

(vi) complied with any other factors that the division establishes that promote the public health and safety.

(b) Licenses granted under Subsection (3)(a) do not entitle a licensee to manufacture, produce, distribute, conduct research with, or perform laboratory analysis upon controlled substances in Schedule I other than those specified in the license.

(c) (i) Practitioners shall be licensed to administer, dispense, or conduct research with substances in Schedules II through V if they are authorized to administer, dispense, or conduct research under the laws of this state.

(ii) The division need not require a separate license for practitioners engaging in research with nonnarcotic controlled substances in Schedules II through V where the licensee is already licensed under this act in another capacity.

(iii) With respect to research involving narcotic substances in Schedules II through V, or where the division by rule requires a separate license for research of nonnarcotic substances in Schedules II through V, a practitioner shall apply to the division prior to conducting research.

(iv) Licensing for purposes of bona fide research with controlled substances by a practitioner considered qualified may be denied only on a ground specified in Subsection (4), or upon evidence that the applicant will abuse or unlawfully transfer or fail to safeguard adequately the practitioner's supply of substances against diversion from medical or scientific use.

(v) Practitioners registered under federal law to conduct research in Schedule I substances may conduct research in Schedule I substances within this state upon furnishing the division evidence of federal registration.

(d) Compliance by manufacturers, producers, and distributors with the provisions of federal law respecting registration, excluding fees, entitles them to be licensed under this chapter.

(e) The division shall initially license those persons who own or operate an establishment engaged in the manufacture, production, distribution, dispensation, or administration of controlled substances prior to April 3, 1980, and who are licensed by the state.

(4) (a) Any license pursuant to Subsection (2) or (3) may be denied, suspended, placed on probation, or revoked by the division upon finding that the applicant or licensee has:

(i) materially falsified any application filed or required pursuant to this chapter;

(ii) been convicted of an offense under this chapter or any law of the United States, or any state, relating to any substance defined as a controlled substance;

(iii) been convicted of a felony under any other law of the United States or any state within five years of the date of the issuance of the license;

(iv) had a federal license denied, suspended, or revoked by competent federal authority and is no longer authorized to engage in the manufacturing, distribution, or dispensing of controlled substances;

(v) had the licensee's license suspended or revoked by competent authority of another state for violation of laws or regulations comparable to those of this state relating to the manufacture, distribution, or dispensing of controlled substances;

(vi) violated any division rule that reflects adversely on the licensee's reliability and integrity with respect to controlled substances;

(vii) refused inspection of records required to be maintained under this chapter by a

person authorized to inspect them; or

(viii) prescribed, dispensed, administered, or injected an anabolic steroid for the purpose of manipulating human hormonal structure so as to:

(A) increase muscle mass, strength, or weight without medical necessity and without a written prescription by any practitioner in the course of the practitioner's professional practice; or

(B) improve performance in any form of human exercise, sport, or game.

(b) The division may limit revocation or suspension of a license to a particular controlled substance with respect to which grounds for revocation or suspension exist.

(c) (i) Proceedings to deny, revoke, or suspend a license shall be conducted pursuant to this section and in accordance with the procedures set forth in Title 58, Chapter 1, Division of Occupational and Professional Licensing Act, and conducted in conjunction with the appropriate representative committee designated by the director of the department.

(ii) Nothing in this Subsection (4)(c) gives the Division of Occupational and Professional Licensing exclusive authority in proceedings to deny, revoke, or suspend licenses, except where the division is designated by law to perform those functions, or, when not designated by law, is designated by the executive director of the Department of Commerce to conduct the proceedings.

(d) (i) The division may suspend any license simultaneously with the institution of proceedings under this section if it finds there is an imminent danger to the public health or safety.

(ii) Suspension shall continue in effect until the conclusion of proceedings, including judicial review, unless withdrawn by the division or dissolved by a court of competent jurisdiction.

(e) (i) If a license is suspended or revoked under this Subsection (4), all controlled substances owned or possessed by the licensee may be placed under seal in the discretion of the division.

(ii) Disposition may not be made of substances under seal until the time for taking an appeal has lapsed, or until all appeals have been concluded, unless a court, upon application, orders the sale of perishable substances and the proceeds deposited with the court.

(iii) If a revocation order becomes final, all controlled substances shall be forfeited.

(f) The division shall notify promptly the Drug Enforcement Administration of all orders suspending or revoking a license and all forfeitures of controlled substances.

(5) (a) Persons licensed under Subsection (2) or (3) shall maintain records and inventories in conformance with the record keeping and inventory requirements of federal and state law and any additional rules issued by the division.

(b) (i) Every physician, dentist, naturopathic physician, veterinarian, practitioner, or other person who is authorized to administer or professionally use a controlled substance shall keep a record of the drugs received by him and a record of all drugs administered, dispensed, or professionally used by him otherwise than by a prescription.

(ii) A person using small quantities or solutions or other preparations of those drugs for local application has complied with this Subsection (5)(b) if the person keeps a record of the quantity, character, and potency of those solutions or preparations purchased or prepared by him, and of the dates when purchased or prepared.

(6) Controlled substances in Schedules I through V may be distributed only by a licensee and pursuant to an order form prepared in compliance with division rules or a lawful order under the rules and regulations of the United States.

(7) (a) A person may not write or authorize a prescription for a controlled substance unless the person is:

(i) a practitioner authorized to prescribe drugs and medicine under the laws of this state or under the laws of another state having similar standards; and

(ii) licensed under this chapter or under the laws of another state having similar standards.

(b) A person other than a pharmacist licensed under the laws of this state, or the pharmacist's licensed intern, as required by Sections 58-17b-303 and 58-17b-304, may not dispense a controlled substance.

(c) (i) A controlled substance may not be dispensed without the written prescription of a practitioner, if the written prescription is required by the federal Controlled Substances Act.

(ii) That written prescription shall be made in accordance with Subsection (7)(a) and in conformity with Subsection (7)(d).

(iii) In emergency situations, as defined by division rule, controlled substances may be dispensed upon oral prescription of a practitioner, if reduced promptly to writing on forms

designated by the division and filed by the pharmacy.

(iv) Prescriptions reduced to writing by a pharmacist shall be in conformity with Subsection (7)(d).

(d) Except for emergency situations designated by the division, a person may not issue, fill, compound, or dispense a prescription for a controlled substance unless the prescription is signed by the prescriber in ink or indelible pencil or is signed with an electronic signature of the prescriber as authorized by division rule, and contains the following information:

(i) the name, address, and registry number of the prescriber;

(ii) the name, address, and age of the person to whom or for whom the prescription is issued;

(iii) the date of issuance of the prescription; and

(iv) the name, quantity, and specific directions for use by the ultimate user of the controlled substance.

(e) A prescription may not be written, issued, filled, or dispensed for a Schedule I controlled substance.

(f) Except when administered directly to an ultimate user by a licensed practitioner, controlled substances are subject to the following restrictions:

(i) (A) A prescription for a Schedule II substance may not be refilled.

(B) A Schedule II controlled substance may not be filled in a quantity to exceed a one-month's supply, as directed on the daily dosage rate of the prescriptions.

(ii) A Schedule III or IV controlled substance may be filled only within six months of issuance, and may not be refilled more than six months after the date of its original issuance or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

(iii) All other controlled substances in Schedule V may be refilled as the prescriber's prescription directs, but they may not be refilled one year after the date the prescription was issued unless renewed by the practitioner.

(iv) Any prescription for a Schedule II substance may not be dispensed if it is not presented to a pharmacist for dispensing by a pharmacist or a pharmacy intern within 30 days after the date the prescription was issued, or 30 days after the dispensing date, if that date is specified separately from the date of issue.

(v) A practitioner may issue more than one prescription at the same time for the same Schedule II controlled substance, but only under the following conditions:

(A) no more than three prescriptions for the same Schedule II controlled substance may be issued at the same time;

(B) no one prescription may exceed a 30-day supply;

(C) a second or third prescription shall include the date of issuance and the date for dispensing; and

(D) unless the practitioner determines there is a valid medical reason to the contrary, the date for dispensing a second or third prescription may not be fewer than 30 days from the dispensing date of the previous prescription.

(vi) Each prescription for a controlled substance may contain only one controlled substance per prescription form and may not contain any other legend drug or prescription item.

(g) An order for a controlled substance in Schedules II through V for use by an inpatient or an outpatient of a licensed hospital is exempt from all requirements of this Subsection (7) if the order is:

(i) issued or made by a prescribing practitioner who holds an unrestricted registration with the federal Drug Enforcement Administration, and an active Utah controlled substance license in good standing issued by the division under this section, or a medical resident who is exempted from licensure under Subsection 58-1-307(1)(c);

(ii) authorized by the prescribing practitioner treating the patient and the prescribing practitioner designates the quantity ordered;

(iii) entered upon the record of the patient, the record is signed by the prescriber affirming the prescriber's authorization of the order within 48 hours after filling or administering the order, and the patient's record reflects the quantity actually administered; and

(iv) filled and dispensed by a pharmacist practicing the pharmacist's profession within the physical structure of the hospital, or the order is taken from a supply lawfully maintained by the hospital and the amount taken from the supply is administered directly to the patient authorized to receive it.

(h) A practitioner licensed under this chapter may not prescribe, administer, or dispense a controlled substance to a child, without first obtaining the consent required in

Section 78B-3-406 of a parent, guardian, or person standing in loco parentis of the child except in cases of an emergency. For purposes of this Subsection (7)(h), "child" has the same meaning as defined in Section 78A-6-105, and "emergency" means any physical condition requiring the administration of a controlled substance for immediate relief of pain or suffering.

(i) A practitioner licensed under this chapter may not prescribe or administer dosages of a controlled substance in excess of medically recognized quantities necessary to treat the ailment, malady, or condition of the ultimate user.

(j) A practitioner licensed under this chapter may not prescribe, administer, or dispense any controlled substance to another person knowing that the other person is using a false name, address, or other personal information for the purpose of securing the controlled substance.

(k) A person who is licensed under this chapter to manufacture, distribute, or dispense a controlled substance may not manufacture, distribute, or dispense a controlled substance to another licensee or any other authorized person not authorized by this license.

(l) A person licensed under this chapter may not omit, remove, alter, or obliterate a symbol required by this chapter or by a rule issued under this chapter.

(m) A person licensed under this chapter may not refuse or fail to make, keep, or furnish any record notification, order form, statement, invoice, or information required under this chapter.

(n) A person licensed under this chapter may not refuse entry into any premises for inspection as authorized by this chapter.

(o) A person licensed under this chapter may not furnish false or fraudulent material information in any application, report, or other document required to be kept by this chapter or willfully make any false statement in any prescription, order, report, or record required by this chapter.

(8) (a) (i) Any person licensed under this chapter who is found by the division to have violated any of the provisions of Subsections (7)(k) through (7)(o) is subject to a penalty not to exceed $5,000. The division shall determine the procedure for adjudication of any violations in accordance with Sections 58-1-106 and 58-1-108.

(ii) The division shall deposit all penalties collected under Subsection (8)(a)(i) in the General Fund as a dedicated credit to be used by the division under Subsection 58-37-7.7(1).

(b) Any person who knowingly and intentionally violates Subsections (7)(h) through

(7)(j) is:

(i) upon first conviction, guilty of a class B misdemeanor;

(ii) upon second conviction, guilty of a class A misdemeanor; and

(iii) on third or subsequent conviction, guilty of a third degree felony.

(c) Any person who knowingly and intentionally violates Subsections (7)(k) through (7)(o) shall upon conviction be guilty of a third degree felony.

(9) Any information communicated to any licensed practitioner in an attempt to unlawfully procure, or to procure the administration of, a controlled substance is not considered to be a privileged communication.

Section 3. Section **58-71-102** is amended to read:

58-71-102. Definitions.

In addition to the definitions in Section 58-1-102, as used in this chapter:

(1) "Administrative penalty" means a monetary fine imposed by the division for acts or omissions determined to constitute unprofessional or unlawful conduct, as a result of an adjudicative proceeding conducted in accordance with Title 63G, Chapter 4, Administrative Procedures Act.

(2) "Acupuncture" has the same definition as in Section 58-72-102.

(3) "Board" means the Naturopathic Physicians Licensing Board created in Section 58-71-201.

(4) "Diagnose" means:

(a) to examine in any manner another person, parts of a person's body, substances, fluids, or materials excreted, taken, or removed from a person's body, or produced by a person's body, to determine the source, nature, kind, or extent of a disease or other physical or mental condition;

(b) to attempt to conduct an examination or determination described under Subsection (4)(a);

(c) to hold oneself out as making or to represent that one is making an examination or determination as described in Subsection (4)(a); or

(d) to make an examination or determination as described in Subsection (4)(a) upon or from information supplied directly or indirectly by another person, whether or not in the presence of the person making or attempting the diagnosis or examination.

(5) "Local anesthesia" means an agent, whether a natural medicine or prescription drug, which:

(a) is applied topically or by injection in superficial tissues associated with the performance of minor office procedures;

(b) has the ability to produce loss of sensation at the site of minor office procedures; and

(c) does not cause loss of consciousness or produce general sedation.

(6) "Medical naturopathic assistant" means an unlicensed individual working under the direct and immediate supervision of a licensed naturopathic physician and engaged in specific tasks assigned by the licensed naturopathic physician in accordance with the standards and ethics of the profession.

(7) (a) "Minor office procedures" means:

(i) the use of operative, electrical, or other methods for repair and care of superficial lacerations, abrasions, and benign lesions;

(ii) removal of foreign bodies located in the superficial tissues, excluding the eye or ear; and

(iii) the use of antiseptics and local anesthetics in connection with minor office surgical procedures[~~; and~~].

(b) "Minor office procedures" does not include:

(i) general or spinal anesthesia;

(ii) office procedures more complicated or extensive than those set forth in Subsection (7)(a);

(iii) procedures involving the eye; or

(iv) any office procedure involving tendons, nerves, veins, or arteries.

(8) "Natural medicine" means:

(a) food, food extracts, dietary supplements as defined by the federal Food, Drug, and Cosmetics Act, all homeopathic remedies, and plant substances that are not designated as prescription drugs or controlled substances;

(b) over-the-counter medications;

(c) other nonprescription substances, the prescription or administration of which is not otherwise prohibited or restricted under federal or state law; [~~and~~]

(d) prescription drugs:

(i) that, except as provided in Subsection (8)(e), are not controlled substances as defined in Section 58-37-2;

(ii) the prescription of which is consistent with the competent practice of naturopathic medicine; and

(iii) the prescription of which is approved by the division in collaboration with the naturopathic formulary advisory peer committee[.]; and

(e) testosterone, if the testosterone is:

(i) bio-identical;

(ii) designed to be:

(A) administered topically, for transdermal absorption; or

(B) absorbed across the mucosal membranes of the mouth; and

(iii) prescribed or administered, in accordance with the requirements of federal and state law, solely for the purpose of treating a patient with a low testosterone level in order to restore the patient to a normal testosterone level.

(9) (a) "Naturopathic childbirth" means uncomplicated natural childbirth assisted by a naturopathic physician, and includes the use of:

(i) natural medicines; and

(ii) uncomplicated episiotomy.

(b) "Naturopathic childbirth" does not include the use of:

(i) forceps delivery;

(ii) general or spinal anesthesia;

(iii) caesarean section delivery; or

(iv) induced labor or abortion.

(10) "Naturopathic mobilization therapy":

(a) means manually administering mechanical treatment of body structures or tissues for the purpose of restoring normal physiological function to the body by normalizing and balancing the musculoskeletal system of the body;

(b) does not mean manipulation or adjustment of the joints of the human body beyond the elastic barrier; and

(c) does not include manipulation as defined in Title 58, Chapter 73, Chiropractic

Physician Practice Act.

(11) "Naturopathic physical medicine" means the use of the physical agents of air, water, heat, cold, sound, light, and electromagnetic nonionizing radiation, and the physical modalities of electrotherapy, biofeedback, acupuncture, diathermy, ultraviolet light, ultrasound, hydrotherapy, naturopathic mobilization therapy, and exercise. Naturopathic medicine does not include the practice of physical therapy or physical rehabilitation.

(12) "Practice of naturopathic medicine" means:

(a) a system of primary health care for the prevention, diagnosis, and treatment of human health conditions, injuries, and diseases that uses education, natural medicines, and natural therapies, to support and stimulate the patient's intrinsic self-healing processes:

(i) using naturopathic childbirth, but only if:

(A) the licensee meets standards of the American College of Naturopathic Obstetricians (ACNO) or its successor as determined by the division in collaboration with the board; and

(B) the licensee follows a written plan for naturopathic physicians practicing naturopathic childbirth approved by the division in collaboration with the board, which includes entering into an agreement with a consulting physician and surgeon or osteopathic physician, in cases where the scope of practice of naturopathic childbirth may be exceeded and specialty care and delivery is indicated, detailing the guidelines by which the naturopathic physician will:

(I) refer patients to the consulting physician; and

(II) consult with the consulting physician;

(ii) using naturopathic mobilization therapy;

(iii) using naturopathic physical medicine;

(iv) using minor office procedures;

(v) prescribing or administering natural medicine;

(vi) prescribing medical equipment and devices, diagnosing by the use of medical equipment and devices, and administering therapy or treatment by the use of medical devices necessary and consistent with the competent practice of naturopathic medicine;

(vii) prescribing barrier devices for contraception;

(viii) using dietary therapy;

(ix) taking and using diagnostic x-rays, electrocardiograms, ultrasound, and physiological function tests;

(x) taking of body fluids for clinical laboratory tests and using the results of the tests in diagnosis;

(xi) taking of a history from and conducting of a physical examination upon a human patient; and

(xii) prescribing and administering natural medicines and medical devices, except a naturopathic physician may only administer:

(A) a prescription drug, as defined in Section 58-17b-102, in accordance with Subsection (8)(d); and

(B) local anesthesia that is not a controlled substance, and only in the performance of minor office procedures;

(b) to maintain an office or place of business for the purpose of doing any of the acts described in Subsection (12)(a), whether or not for compensation; or

(c) to use, in the conduct of any occupation or profession pertaining to the diagnosis or treatment of human diseases or conditions, in any printed material, stationery, letterhead, envelopes, signs, or advertisements, the designation "naturopathic physician," "naturopathic doctor," "naturopath," "doctor of naturopathic medicine," "doctor of naturopathy," "naturopathic medical doctor," "naturopathic medicine," "naturopathic health care," "naturopathy," "N.D.," "N.M.D.," or any combination of these designations in any manner that might cause a reasonable person to believe the individual using the designation is a licensed naturopathic physician.

(13) "Prescription drug or device" means:

(a) a drug or device which, under federal law, is required to be labeled with either of the following statements or their equivalent:

(i) "CAUTION: Federal law prohibits dispensing without prescription"; or

(ii) "CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; or

(b) a drug or device that is required by any applicable federal or state law or rule to be dispensed on prescription only or is restricted to use by practitioners only.

(14) "Unlawful conduct" is as defined in Sections 58-1-501 and 58-71-501.

(15) "Unprofessional conduct" is as defined in Sections 58-1-501 and 58-71-502, and as may be further defined by division rule.

Ĥ→ Section 4. Section 58-71-804 is amended to read:

58-71-804. Insurance coverage not mandated.

(1) This chapter does not mandate health insurance coverage for naturopathic medical services.

(2) This chapter does not establish a class of health care providers for the purposes of Section 31A-22-618.

(3) This chapter does not mandate health insurance coverage for the prescription or administration of testosterone, as described in Subsection 58-71-102(8)(e), by a naturopathic physician. ←Ĥ

Legislative Review Note
as of 1-14-09 4:21 PM

Office of Legislative Research and General Counsel

Fiscal Note

H.B. 108 - Hormone Restoration Amendments

2009 General Session

State of Utah

State Impact

Enactment of this bill will not require additional appropriations.

Individual, Business and/or Local Impact

Enactment of this bill likely will not result in direct, measurable costs and/or benefits for individuals, businesses, or local governments.

1/24/2009, 2:49:50 PM, Lead Analyst: Schoenfeld, J.D.

Office of the Legislative Fiscal Analyst