California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

NOTICE OF MEETING and AGENDA
Enforcement Committee

Contact Person: Virginia Herold
(916) 574-7911

Date: September 28, 2006
Time: 9:30 a.m. – 12 noon
Place: Radisson Hotel Sacramento
500 Leisure Lane
Sacramento, CA 95815
(916) 922-2020

This committee meeting is open to the public and will be held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at (916) 574-7912, at least five working days before the meeting.

Opportunities are provided for public comment on each agenda item. Board members who are not on the committee may also attend and comment.

MEETING AGENDA

Note: Pharmacists and pharmacy technicians who attend the full committee meeting can be awarded two hours of CE, in accordance with the board's CE policy. A maximum of four CE hours can be earned each year by attending the meetings of two different board committees.

Call to Order 9:30 a.m.

1. Formulary of Drugs Under Development by the Bureau of Naturopathic Medicine for Naturopathic Physicians

2. Plan B Emergency Contraception Becomes Over-the-Counter for Patients 18 and Older

3. Work Group on E-Pedigree
   - Discussion and Presentation regarding the Delay in Implementation of the E-Pedigree Requirements in California -- an Overview of the Requirements of SB 1476 (Figueroa)
   - Status of Progress of the EPC-Global Workgroup
   - Revised Questions and Answers
   - Update by Manufacturers, Wholesalers and Pharmacies on Implementation Progress
   - RFID Presentation from Vendors on Emerging Technology

B. Adjournment 12:30 p.m.

Meeting materials will be on the board's Web site by September 10, 2006

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee **Date: September 19, 2006**

From: Board of Pharmacy – Virginia Herold

Subject: Formulary of Drugs Under Development by the Bureau of Naturopathic Medicine for Naturopathic Doctors

Since 2004, California has begun licensing naturopathic doctors. The licensing functions are assigned the Bureau of Naturopathic Medicine, which is housed in the Department of Consumer Affairs.

A key component of work for this bureau currently is developing a formulary of drugs that a naturopathic doctor can prescribe, administer or furnish.

Supervising Inspector Ratcliff has had discussions with the bureau's Formulary Committee and its Bureau Chief Tonya Blood. Ms. Blood is unable to attend our meeting, but Gloria St. John, who is with the naturopaths' association, will attend our meeting to provide an overview of the work of the formulary committee and California's general regulatory structure for naturopathic doctors.

The Board of Pharmacy's role in this is not direct, but individual pharmacists or the board itself may want to provide comments on the development of the formulary.

I am including background information in this tab section of an overview of the regulatory structure used by various states for the licensure of naturopathic doctors, and the types of drugs that they are legally able to prescribe.

There is no draft formulary list yet available to review from the California bureau.

NOTE: The order of business is subject to change.

Naturopathic Formulary Advisory Committee

Public Site:
Department of Consumer Affairs
1625 North Market Blvd.,
Second Floor, San Diego Room
Sacramento, CA 95834
(916) 574-7991

Teleconference Site:
The Khalsa Medical Clinic
436 North Bedford Drive
Suite 308
Beverly Hills, CA 90210

Teleconference Site:
Dr. Trevor Holly Cates
Santa Barbara Ctr for Natural Medicine
34 E. Sola St., Rm. 5
Santa Barbara, CA 93101
(805) 966-3003

Teleconference Site:
Dr. Larry Woodhouse
17 Jasmine Creek Dr.
Corona Del Mar, CA 92625
(949) 706-1967

Teleconference Site:
Dr. Paul Mittman
Southwest College of Naturopathic Medicine
2140 East Broadway Road
Tempe, AZ 85282
(480) 222-9232

Teleconference Site:
Dr. Michael Traub
73-1138 Oluolu Street
Kailua Kona, HI 96740
(808) 329-2114

Teleconference Site:
Dr. Peter Wannigman
Center for Health & Wellbeing
3737 Moraga Ave, Suite A-305
San Diego, CA 92117
(858) 454-9771 x 379

Teleconference Site:
Dr. Cynthia Watson
3201 Wilshire Blvd.
Suite 211
Santa Monica, CA 90403
(310) 315-9101

Bureau of Naturopathic Medicine
1625 North Market Blvd. Suite S-209
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(916) 574-7991
(916) 322-1700 – TDD
(916) 574-8645 – Fax

www.naturopathic.ca.gov

Tonya Blood, Chief

Linda Brown
Francine Davies

Naturopathic Formulary Advisory Committee Members:

Peter Wannigman, ND/Pharmacist
Chair

Soram Khalsa, MD
Vice-Chair

Cynthia Watson, MD

Mary Hardy, MD

Trevor Holly Cates, ND

Michael Traub, ND

Paul Mittman, ND

Larry Woodhouse, Pharmacist

Arthur Presser, Pharmacist

Monday, September 11, 2006 @ 6:00 p.m. *(Pacific Daylight Time)*

AGENDA

I. Call to Order and Roll Call

II. Approval of August 29 Meeting Minutes

III. Chairperson's Report

IV. Bureau Report

V. Discussion, Review, and Approval of IV Formulary

VI. Discussion, Review, and Approval of Inclusionary Formulary

VII. Review of Draft Report

VIII. Future Meeting Date(s) - ?

IX. Public Comment

X. Adjournment

Teleconference Notice (Government Code Section 11123(b)). One or more Committee members may participate in this meeting via teleconference for the benefit of the Committee. The public may attend at any site listed above. A quorum of the Advisory Council may be present at the Formulary Committee meeting. However, Advisory Council members who are not on the Formulary Committee may observe, but may not participate or vote. Action may be taken on any item on the agenda. The meeting is accessible to the physically disabled. A person who needs disability-related accommodations or modifications in order to participate in the meeting shall make a request no later than five working days before the meeting to the Bureau of Naturopathic Medicine at (916) 574-7991 or TDD No. at (916) 322-1700, or may send a written request to Linda Brown at 1625 North Market Blvd., Suite S-209, Sacramento, CA 95834. Requests for further information or directions to the meeting site should be directed to Linda Brown at the same address and telephone number.

NOTE: The order of business is subject to change.

Naturopathic Formulary Advisory Committee

Primary Site:
Department of Consumer Affairs
1625 North Market Blvd.,
Second Floor, San Diego Room
Sacramento, CA 95834
(916) 574-7991

Teleconference Site:
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436 North Bedford Drive
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Suite 211
Santa Monica, CA 90403
(310) 315-9101

Teleconference Site:
Dr. Arthur Presser
47 Alta Drive
La Selva Beach, CA 95076
(831) 684-0214

Tuesday, August 29, 2006 @ 5:30 p.m. *(Pacific Daylight Time)*

AGENDA

I. Call to Order and Roll Call

II. Approval of July 23 Meeting Minutes

III. Chairperson's Report

IV. Discussion and Approval of Rationale for ND Prescribing

V. Report from Dr. Khalsa
   a. Discussion with CMA Regarding Committee Recommendations
   b. Discussion with SCIPE Regarding Malpractice Insurance Surcharge for Supervising an ND

VI. Discussion, Review, and Approval of IV Formulary

VII. Discussion and Approval of Recommendation of Additional Formulary for NDs Meeting Current (48 hour) Prescribing Requirements

VIII. Review of Draft Report

IX. Future Meeting Date(s) - Monday, September 11, 6:00 p.m. ?

X. Public Comment

XI. Adjournment

Teleconference Notice (Government Code Section 11123(b)). One or more Committee members may participate in this meeting via teleconference for the benefit of the Committee. The public may attend at any site listed above. A quorum of the Advisory Council may be present at the Formulary Committee meeting. However, Advisory Council members who are not on the Formulary Committee may observe, but may not participate or vote. Action may be taken on any item on the agenda. The meeting is accessible to the physically disabled. A person who needs disability-related accommodations or modifications in order to participate in the meeting shall make a request no later than five working days before the meeting to the Bureau of Naturopathic Medicine at (916) 574-7991 or TDD No. at (916) 322-1700, or may send a written request to Francine Davies at 1625 North Market Blvd., Suite S-209, Sacramento, CA 95834. Requests for further information or directions to the meeting site should be directed to Francine Davies at the same address and telephone number.

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Tonya Blood, Chief

Linda Brown
Francine Davies

Naturopathic Formulary Advisory Committee Members:

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Chair

Soram Khalsa, MD
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Cynthia Watson, MD

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Michael Traub, ND

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NATUROPATHIC FORMULARY ADVISORY COMMITTEE

Meeting Minutes

July 23, 2006

COMMITTEE MEMBERS PRESENT:	Peter Wannigman, Naturopathic Doctor (Chairman) Soram Khalsa, Medical Doctor (Vice Chair) Cynthia Watson, Medical Doctor Trevor Holly Cates, Naturopathic Doctor Michael Traub, Naturopathic Doctor Paul Mittman, Naturopathic Doctor Larry Woodhouse, Pharmacist
COMMITTEE MEMBERS ABSENT:	Mary Hardy, Medical Doctor Arthur Presser, Pharmacist
STAFF PRESENT:	Linda Brown Tonya Blood

I. Call to Order and Roll Call

Chairman Wannigman called the meeting to order. Roll call was taken and a quorum was present.

II. Approval of the June 4, 2006 Meeting Minutes

Dr. Khalsa made a motion that the minutes be approved as written. Dr. Cates seconded the motion. Roll was called and the minutes were approved as written.

III. Chairperson's Report

- Chairman Wannigman asked if the opinion from the Pharmacy Board had been received and Tonya reported that the Bureau had not yet received it.
- Linda reported that she had received a letter from NCMIC stating that there were no claims against NDs for prescribing.
- Dr. Mittman is working on "Why NDs need to Prescribe" and will have it completed by the next meeting.

The Medical Board was asked to comment. Linda Whitney, Director of Legislation for the Medical Board, reported that two members of the Medical Board had a task force meeting for discussion of the ND formulary. The task force had some concerns and issues with what the protocols and procedures would be that an ND would follow and that should be addressed in more detail as far as what would be done in terms of reducing medication or changing prescriptions. She recommended a thoroughly developed white paper on why NDs want to prescribe,

when they would, and when they would make recommendations on changing prescriptions.

There was discussion that NDs should work with MDs in collaboration to reduce medication or get a patient off of a medication.

- Dr. Khalsa will check with his malpractice company regarding the charge or surcharge for supervising an ND.

IV. Bureau Report

The Bureau now has 191 licensed NDs. They do not have the budget figures yet for the end of the year. There was nothing further to report.

V. Discussion, Review, and Approval of IV Formulary

Dr. Virginia Osborne and the committee discussed research and the safety of glandulars – particularly thymus and adrenal. The committee decided to review the documents and research before taking a vote at the next meeting. Any documents on adrenal and thymus should be emailed to Linda Brown for distribution.

VI. Discussion and Approval of 60-hour Course for Enhanced Prescribing Rights

The course modules were reviewed and the committee voted to approve successful completion of the course (or its equivalent) as continuing education required for enhanced independent prescribing rights for California NDs. It was discussed that the course is available on CDs for $1200. Dr. Traub made a motion to approve the 60-hour course for enhanced independent prescribing rights, using the four modules that were used in Arizona. Dr. Cates seconded the motion. Dr. Khalsa commented that when the recommendations hit the statutory realm that they will probably be shot down by CMA and others. Dr. Watson commented that the course alone would not make NDs proficient at prescribing that many drugs. Dr. Traub commented that prescribing medications is included in the current curriculum of the naturopathic medical schools. The main concern is for individuals that graduated a long time ago who did not have pharmacology so that they can have the knowledge they need to safely prescribe. Roll was called and the motion passed. Dr. Khalsa made a motion that an examination needs to be passed, in a continuing education format, to allow credit for this course for enhanced independent prescribing rights. Dr. Cates seconded the motion. Roll was called and the motion was passed.

VII. Discussion and Approval of Inclusionary/Exclusionary Pharmaceutical Formulary for Recommendation

Dr. Khalsa asked Tonya to give him a contact at CMA that he could call and discuss what the committee has been working on.

The committee reviewed the last category, Respiratory Agents. Lung Surfactants were added to the exclusionary list.

Dr. Wannigman pointed out that the final inclusionary formulary is 5 pages long and the exclusionary formulary is less than one and a half pages. Dr. Traub made a motion that the exclusionary list be approved. Dr. Cates second the motion. Roll call was taken and the motion was passed.

Dr. Wannigman stated that if the exclusionary formulary becomes law then there would be a problem when a new drug comes out because it would not be approved for use by NDs until it has been reviewed. He suggested that the Bureau purchase and maintain a subscription to the online Drug Facts and Comparisons so they could identify when a new drug comes online. It was stated that the Advisory Council or a committee of the Bureau should seek to have legal authority to review and update the formulary annually.

VIII. Discussion and Approval of Recommendation of Additional Formulary for NDs Meeting the Current Prescribing Requirements

Linda stated that the Bureau would like the committee to consider as part of the recommendations developing a small inclusionary list that NDs having the current requirement of 48 hours of pharmacology could prescribe in addition to the hormones and epinephrine allowed by existing law. There was discussion that because of opposition from the medical community the proposed exclusionary list may not be a workable plan and that something more conservative would have a better change of getting through. Dr. Wannigman asked for volunteers to work on the list within the next 3 weeks and send the list out to everyone for approval at the next meeting. Drs. Watson, Woodhouse, and Traub will be working on this.

IX. Future Meeting Dates

The next meeting will be by teleconference on Tuesday, August 29, 2006 at 5:30 p.m. A follow-up meeting date was set for September 11 at 6:00 p.m.

X. Public Comment

Dr. Gina Nick made comments about glandulars. She said she had a lot of research on using IV thymus extract IV and said she would be happy to provide the information to the committee. She also stated that she was not aware of any other healthcare practitioners that are trained in using IV glandulars and that patients should not be limited access to these highly effective therapies.

XI. Adjournment

The meeting was adjourned.

BUREAU OF NATUROPATHIC MEDICINE
1625 North Market Blvd., Suite S-209
Sacramento, CA 95834
(916) 574-7991 – Office / (916) 574-8645 - FAX

NATUROPATHIC FORMULARY ADVISORY COMMITTEE

Meeting Minutes

June 4, 2006

COMMITTEE MEMBERS PRESENT:	Peter Wannigman, Naturopathic Doctor (Chairman) Soram Khalsa, Medical Doctor (Vice Chair) Mary Hardy, Medical Doctor Cynthia Watson, Medical Doctor Trevor Holly Cates, Naturopathic Doctor Michael Traub, Naturopathic Doctor Paul Mittman, Naturopathic Doctor Larry Woodhouse, Pharmacist
COMMITTEE MEMBERS ABSENT:	Arthur Presser, Pharmacist
STAFF PRESENT:	Linda Brown Tonya Blood

I. Call to Order and Roll Call

Chairman Wannigman called the meeting to order. Roll call was taken and a quorum was present.

II. Approval of the April 2 and May 7, 2006 Meeting Minutes

The April 2 meeting minutes were approved as submitted. The May 7 meeting minutes were corrected so that under Other States' Laws, "Iowa" was corrected to read "Idaho." On page 2, under Bureau Report, Item 4, it should be added that the ND to be insured is "employed by" the MD. Also, the word "insurance" was corrected to read "insure". Also, "Dr. Herrier" was changed to read "Dr. Rick Herrier from the University of Arizona College of Pharmacy." Page 3, Item V, "independent prescribing rights" was changed to read "restricted independent prescribing rights." The minutes were approved as corrected.

III. Chairperson's Report

Dr. Wannigman reminded the committee that if they do not receive their meeting packet by Friday before the meeting to contact Linda to have the material faxed to them. Linda reminded everyone to let her know whether or not they will be teleconferencing as soon as possible because it holds up the agenda and the packets.

Dr. Wannigman reported on the Advisory Council meeting and stated that it went very well. The IV Formulary was amended to add glandulars, against the vote of the MDs. The Formulary Committee will need to revisit it at a future meeting. Virginia Osborne would be invited back for the discussion. It was also discussed that Michael Smith, a naturopath and

pharmacist and Paul Saunders, a naturopath, may be able to participate. It was tabled for another meeting.

There was discussion about the ability of the Advisory Council, with lay members, being able to override a decision of an expert committee, and it was stated that Dr. Hangee-Bauer needed to develop a policy or protocol so that it would not happen in the future.

Dr. Wannigman also stated that the Formulary Committee is not dissolved on January 1, 2007.

Dr. Wannigman asked if the Bureau had documentation from NCMIC regarding any malpractice issues. Dr. Traub said he would follow up on it. The Bureau is also going to collect data from ND licensing boards in other states regarding discipline.

Dr. Wannigman also asked members to review the information on the AZNMA pharmacology site to review the material there for a vote on the 60-hour pharmacology course material at the next meeting.

It was discussed that NABNE is not changing the pharmaceutical portion of the NPLEX.

Dr. Mittman was reminded to provide Linda with "Why NDs Need to Prescribe." Dr. Mittman stated it was high on his to-do list and would be done before the next meeting.

IV. Bureau Report

Linda stated that the Bureau may end the fiscal year with a few thousand dollars in the black but that has yet to be determined.

V. Review/Discussion of Responses from Malpractice Insurance Companies Regarding Insurance for NDs and Supervising MDs

The committee reviewed the responses received from the malpractices companies that have responded to the Bureau's questionnaire. Dr. Khalsa stated he would present a scenario to his malpractice company to see what their response would be.

VI. Discussion Regarding Request for Written Statement from Pharmacy Board on Substances/Routes of Administration

Tabled.

VII. Discussion of Inclusionary/Exclusionary Pharmaceutical Formulary for Recommendation

The committee reviewed both the inclusionary and exclusionary formulary lists provided in the meeting packets. The committee went through the inclusionary list and moved several drug categories from the inclusionary list to the exclusionary list. The committee will review the last category, Respiratory Agents, at the next meeting.

VIII. Future Meeting Dates

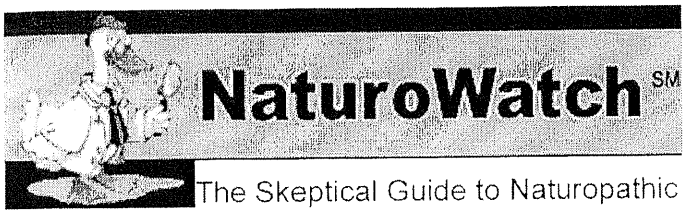
The next meeting will be at Dr. Khalsa's office on July 23 at 10 a.m.

IX. Public Comment

There was no public comment.

X. Adjournment

The meeting was adjourned.



The Skeptical Guide to Naturopathic History, Theories, and Practices

Overview of Naturopathic Regulation

Colorado Department of Regulatory Agencies
October 14, 2005

The legal status of naturopathy varies from state to state. In some states, the practice of naturopathy, though not regulated, is protected through court rulings or attorney general opinions. In most states, naturopathic physician status is unprotected or unclear. Two states, Florida and Nevada, have repealed regulation of this profession. Nevada ceased licensing naturopathic physicians in 1987 (in Nevada naturopathic physicians were required to be supervised by medical doctors). Although naturopathic licensing in Florida was discontinued in 1959, there are still laws and a board regulating those naturopaths still practicing. Florida allows naturopathic physicians licensed prior to program termination dates to continue to practice. In Tennessee and in South Carolina, the practice of naturopathy is illegal. Tennessee law, for example, provides that the practice of naturopathy is a Class B misdemeanor, but renders this prohibition inapplicable to "persons who comply with the regulatory laws of the state with respect to the practice of the various healing arts." Without a similar textual qualification, however, a South Carolina statute prohibits the practice of naturopathy and subjects offenders to a fine not to exceed $500 or imprisonment for a period not exceeding one year, or both.

The multiplicity of therapies and techniques that typically comprise the statutory definition of naturopathy may often fall within the scope of practice for other professions. The Montana Naturopathic Practice Act expressly acknowledges this fact by recognizing that many of the therapies used by naturopathic physicians, such as the use of nutritional supplements, herbs, foods, homeopathic preparations, and such physical forces as heat, cold, water, touch, and light, are not the exclusive privilege of naturopathic physicians, and their use, practice, prescription, or administration by persons not licensed to practice naturopathic medicine is not prohibited by this practice act.

Currently, 15 states and the District of Columbia license naturopathic physicians: Alaska, Arizona, California, Connecticut, Florida, Hawaii, Idaho, Kansas, Maine, Montana, New Hampshire, Oregon, Utah, Vermont, and Washington. In several states, licensed naturopathic physicians must also qualify for a certificate to practice natural childbirth, acupuncture, or to dispense a natural substance or device. The following highlights the regulatory programs found in the 15 states.

Alaska

Alaska's law places several restrictions on the practice of naturopathy. A person who practices naturopathy may not prescribe a prescription drug, perform surgery, or use the word "physician" as a title. There are currently 36 licensed naturopathic doctors in Alaska.

Arizona

Arizona's Naturopathic Physicians Board of Medical Examiners (Arizona Board) was established in 1935. Arizona remains the state with the third highest number of licensed naturopathic physicians (400). The Arizona Board has the statutory authority to adopt rules for recognizing naturopathic specialties. The Arizona Board has approved training programs in four specialty areas and has issued certificates to at least 16 naturopaths in the specialty of family medicine. Additionally, the Arizona Board has assembled a formulary of more than 460 items that naturopathic physicians may dispense including both prescription drugs and some controlled substances. In 2000, the Arizona Board underwent a performance audit. The review concluded that terminating the Arizona Board would not significantly harm the public's health and safety since the practice of medicine would continue to be regulated by the Allopathic Board of Medical Examiners. Naturopaths could continue to perform many traditional activities, but would no longer be allowed to act as primary medical care providers. However, the review further stated that terminating the Arizona Board could harm the public's welfare by potentially limiting access to alternative medical care. Subsequently, there was no action taken by the Arizona legislature to repeal the Arizona Board.

California

California's Bureau of Naturopathic Medicine (Bureau) within the Department of Consumer Affairs was established to administer the Naturopathic Doctor's Act and was authorized to collect fees and receive license applications beginning January 1, 2004. This act authorizes the creation of an advisory committee comprised of three licensed naturopathic doctors, three licensed physicians, and three public members. The committee's first meeting was convened on December 13, 2004. Additionally, a naturopathic formulary advisory committee was formed and a naturopathic childbirth attendance advisory committee was created to issue recommendations concerning the practice of naturopathic childbirth attendance. The scope of practice for licensed naturopathic doctors includes diagnosis and treatment of patients, including the authority to order lab tests and prescribe most drugs subject to supervision of a medical or osteopathic physician. Licensed naturopathic doctors may perform minor procedures, such as treating lacerations and removing moles and growths. The program began accepting license applications in January 2005. Currently there are 129 licensed naturopathic doctors in California.

Connecticut

Connecticut's law, which was enacted in 1920, does not allow licensed naturopathic physicians to perform minor surgery, prescribe drugs, or practice obstetrics and gynecology. The statute requires that naturopathic physicians maintain professional liability insurance. There are currently 196 licensed naturopaths in Connecticut.

District of Columbia

In May 2004, final approval was given to the Naturopathic Medicine Licensing Amendment Act of 2004 to license naturopathic physicians as primary care providers. The act recognized naturopathic physicians who have completed four-years of naturopathic medical college training and successfully passed the NPLEX. Prior to the passage of this act, the District of Columbia had a registration program for naturopaths. A person registered to practice naturopathy was entitled to use the title "Doctor of Naturopathy." The only requirements for registration were that applicants must be at least 18 years of age and not have been convicted of a crime of moral turpitude that bears directly on the applicant's fitness to be registered. The practice specifically excluded the use of x-rays, performing any surgical procedure, injecting any substance into a person by needle, or performing any invasive procedure. As of September 2005, the District of Columbia had not promulgated any rules or issued any licenses.

Florida

Florida's licensing authority for naturopathic physicians was abolished in 1959 and licensees who were licensed at that time were allowed to continue practicing naturopathic medicine. Draft legislation proposed by the Florida Naturopathic Physician Association was introduced in 2004 to reestablish regulation of naturopathic medicine through licensure and to create the Board of Naturopathic Medicine within the Department of Health. A 2004 Sunrise Report on Proposed Licensure of Naturopathic Physicians, by the Florida House of Representatives, Committee on Health Care, concluded that while there is evidence for support of licensure based on the existence of accredited training programs and licensure examinations, there is no documented evidence of substantial risk from not licensing naturopathic physicians. Moreover, there is potential risk from licensing naturopathic physicians and allowing them to provide a broad range of primary care services.

Hawaii

Hawaii has regulated naturopathic physicians since 1925. There are currently 81 licensed naturopaths. Originally, the Board of Health was responsible for conducting examinations and issuing licenses. In 1969, the regulation was transferred to the Department of Regulatory Agencies, now the Department of Commerce and Consumer Affairs. The regulation of naturopathy was reviewed in 1978 and 1985, with continued regulation recommended in both instances.

Idaho

Idaho became the 15th state in 2005 to create a licensure program for naturopathic physicians. The legislation is a full scope and title protection act. The law requires the creation of a formulary council to determine pharmaceutical privileges for naturopathic physicians.

Kansas

Kansas passed legislation during the 2002 legislative session to regulate the practice of naturopathic medicine. The bill, signed into law in May 2003, provides registration for naturopathic doctors, rather than licensing, yet requires educational and testing requirements. Naturopathic medicine is defined to include such procedures as venipuncture, naturopathic

acupuncture, and minor office procedures. Naturopathic doctors may not perform surgery, practice obstetrics, administer ionizing radiation or prescribe, dispense or administer any controlled substances or any prescription-only drugs except those listed on the naturopathic formulary adopted by the Kansas board.

Maine

Maine's Board of Complimentary Health Care Providers regulates 19 naturopathic doctors. Naturopathic doctors have the exclusive right to the use of the terms "naturopathic doctors," "naturopathic," "naturopath," "doctor of naturopathic medicine," "Doctor of Naturopathy," "naturopathic medicine," "naturopathic health care," "naturopathy," and "N.D." Use of the term "physician" by a licensee is prohibited. Naturopathic Doctors have a limited scope of prescriptive authority.

Montana

Montana's Naturopathic Health Care Practice Act was enacted in 1991 to regulate lay midwives and naturopathic physicians. Naturopathic physicians are authorized to perform minor surgery, attend a natural childbirth if in possession of a certificate of specialty practice, and prescribe certain drugs as established by the natural substance formulary list. When the program first began there were only five licensed naturopathic physicians in the state, however, as of August 2005, there were 66.

New Hampshire

New Hampshire's Naturopathic Health Care Practice Act was enacted in 1994. Specialty certificates in naturopathic childbirth and acupuncture are offered. Doctors of naturopathic medicine with specialty certification in naturopathic childbirth are authorized to use oxytocin and pitocin. There are currently 36 licensed naturopathic physicians in New Hampshire.

Oregon

Oregon first began licensing naturopathic physicians in 1927, although they were able to practice before then under an exemption in the Osteopathic Practice Act. The total number of licensed naturopathic physicians in Oregon equals 636, ranking second for licensees in a state. Oregon also has the most encompassing law as practitioners are allowed to prescribe drugs, perform minor surgery, and practice natural childbirth with a certificate of special competency.

Utah

Utah's Naturopathic Physicians Licensing Board was created in 1996. The board currently issues five different categories of licenses: naturopath, naturopath including surgery/obstetrics, naturopathic physician, temporary naturopathic physician, and naturopathic controlled substance. In order to perform naturopathic childbirth, a licensee must satisfy the standards of the American College of Naturopathic Obstetricians or its successor.

Vermont

Vermont's licensed naturopathic physicians may order, prescribe, dispense, and administer certain medications of mineral, animal, or botanic origin and must adhere to the Naturopathic Physician Formulary Rules promulgated by the Vermont Department of Health. Licensees may not practice naturopathic childbirth unless they have obtained a special endorsement that requires specific education; training; passage of an examination; and actual childbirth assistance, participation, and observation.

Washington

Washington has regulated naturopathic physicians since 1919, as part of its law created to regulate professions engaged in "drugless healing." The law was substantially amended in 1988 to reflect the current practice of naturopathic physicians. The total number of licensed naturopathic physicians in Washington is 650, ranking first for licensees in a state.

This article was extracted from the Sunrise Review of Naturopathic Physicians, published by the Colorado Department of Regulatory Agencies' Office of Policy, Research and Regulatory Reform in October 2005.

This article was posted on November 20, 2005.

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OR

850-060-0225 **Effective December 12, 2005**

Naturopathic Formulary Compendium

The following substances have been recommended for addition to the Formulary Compendium after review by the Board of Naturopathic Examiners Formulary Council established by the 65th Oregon Legislature. Substances listed on the formulary compendium can be prescribed in any dosage or any dosage form. Products marked with an asterisk (*) may be used by Naturopathic Physicians, but may not be prescribed. Combination products containing only active ingredients listed in the Formulary may be prescribed. Combination products containing any active ingredient(s), not listed in the Formulary, except non-legend drugs, may not be prescribed.

(1) Abacavir;
(2) Acarbose;
(3) Acetic Acid;
(4) Acetylcysteine;
(5) Acitretin;
(6) Acyclovir;
(7) Adapalene;
(8) Adenosine Monophosphate;
(9) Albuterol Sulfate;
(10) Alendronate;
(11) Allopurinol;
(12) Alprostadil;
(13) Amino Acids;
(14) Amino Aspirins;
(15) Aminoglycosides;
(16) Aminolevulinic Acid;
(17) Aminophylline;
(18) Aminosalicylic Acid;
(19) Ammonium Chloride;
(20) Ammonium lactate lotion 12%;
(21) Amoxicillin;
(22) Amoxicillin & Clavulanate;
(23) Amphotericin B;
(24) Ampicillin;
(25) Ampicillin & Sulbactam;
(26) Anastrozole;
(27) Anthralin;
(28) Atorvastatin;
(29) Atropine;
(30) Atropine Sulfate;
(31) Auranofin;
(32) Azelaic Acid;
(33) Azithromycin;
(34) Bacampicillin;
(35) Bacitracin;
(36) Baclofen;
(37) Becaplermin;
(38) Belladonna;
(39) Benazepril;
(40) Benzodiazepines;
(41) Benzoic Acid;
(42) Benzonatate;
(43) Betaine;
(44) Betamethasone;
(45) Bethanechol Chloride;
(46) Bichloracetic Acid*;
(47) Bimatoprost Solution 0.03%;
(48) Biologicals;
(49) Biphosphonate;
(50) Bromocriptine;
(51) Budesonide;
(52) Buprenorphine;
(53) Butorphanol;
(54) Cabergoline;
(55) Calcipotriene;
(56) Calcitonin;
(57) Calcitriol;
(58) Carbamide Peroxide;
(59) Carbidopa;
(60) Carbol-Fuchsin;
(61) Captopril;
(62) Cefaclor;
(63) Cefdinir;
(64) Cefibuten;
(65) Cefadroxil;
(66) Cefditoren;
(67) Cefixime;
(68) Cefonicid Sodium;
(69) Cefpodoxime Proxetil;
(70) Cefprozil;
(71) Ceftibuten;
(72) Cefuroxime;
(73) Celecoxib;
(74) Cellulose Sodium Phosphate;
(75) Cenestin;
(76) Cephalexin;

32-1522. Basic qualifications for license

A. To be eligible for a license to practice naturopathic medicine pursuant to this chapter, the applicant shall:

1. Be a graduate of an approved school of naturopathic medicine.

2. Have satisfactorily completed an approved internship, preceptorship or clinical training program in naturopathic medicine.

3. Possess a good moral and professional reputation.

4. Be physically and mentally fit to practice as a doctor of naturopathic medicine.

5. Not be guilty of any act of unprofessional conduct or any other conduct that would be grounds for refusal, suspension or revocation of a license under this chapter.

6. Not have had a license to practice any profession refused, revoked or suspended by any other state, district or territory of the United States or another country for reasons that relate to the applicant's ability to skillfully and safely practice as a physician in this state.

7. File a completed application pursuant to section 32-1524 and meet the examination requirements provided for in section 32-1525.

B. The board may:

1. Require an applicant to submit credentials or other written or oral proof.

2. Make investigations it deems proper to adequately advise itself with respect to the qualifications of an applicant.

C. Within ninety days after it receives a completed application for initial licensure, the board shall issue a license if the application demonstrates to the board's satisfaction that the applicant complies with this chapter and board rules.

32-1501. Definitions

In this chapter, unless the context otherwise requires:

1. "Accepted therapeutic purpose" means treatment of a disease, injury, ailment or infirmity that is competent and generally recognized as safe and effective.

2. "Active license" means a current valid license to practice naturopathic medicine.

3. "Adequate medical records" means medical records containing sufficient information to identify the patient, the diagnosis and the treatment prescribed.

4. "Approved clinical training program" or "clinical training program" means a program for naturopathic medical students in which the training occurred or is being conducted by or in conjunction with an approved school of naturopathic medicine.

5. "Approved internship program" or "internship" means that the program in which the training occurred or is being conducted has been approved for internship training for physicians or for graduates of a school of naturopathic medicine by the board or was approved or accredited by an educational or professional association recognized by the board or by another state's or country's licensing agency recognized by the board.

6. "Approved postdoctoral training" or "postdoctoral training" means that the program in which the training occurred or is being conducted has been approved for specialty training or for graduate medical education in naturopathic medicine by the board or approved or accredited by an educational or professional association recognized by the board or by another state's or country's licensing agency recognized by the board.

7. "Approved preceptorship program" or "preceptorship" means that the program in which the training occurred or is being conducted has been approved for preceptorship training for physicians or for graduates of a school of naturopathic medicine by the board or was approved or accredited by an educational or professional association recognized by the board or by another state's or country's licensing agency recognized by the board.

8. "Approved school of naturopathic medicine" or "school of naturopathic medicine" means a school or college determined by the board to have an educational program that meets standards prescribed by the council on naturopathic medical education, or its successor agency, and that offers a course of study that, on successful completion, results in the awarding of the degree of doctor of naturopathic medicine and whose course of study is either of the following:

(a) Accredited or a candidate for accreditation by an accrediting agency recognized by the United States secretary of education as a specialized accrediting agency for schools of naturopathic medicine or its successor.

(b) Accredited or a candidate for accreditation by an accrediting agency recognized by the council for higher education accreditation or its successor.

9. "Board" means the naturopathic physicians board of medical examiners.

10. "Chelation therapy" means an experimental medical therapy to restore cellular homeostasis through the use of intravenous, metal-binding and bioinorganic agents such as ethylene diamine tetraacetic acid. Chelation therapy does not include experimental therapy used to treat heavy metal poisoning.

11. "Completed application" means that the applicant paid the required fees and supplied all documents and information as requested by the board and in a manner acceptable to the board.

12. "Controlled substance" means a drug, substance or immediate precursor in schedules I through V of title 36, chapter 27, article 2.

13. "Direct supervision" means that a physician who is licensed pursuant to this chapter or chapter 13, 17 or 29 of this title:

(a) Is physically present and within sight or sound of the person supervised and is available for consultation regarding procedures that the physician has authorized and for which the physician remains responsible.

(b) Has designated a person licensed pursuant to this chapter or chapter 13, 17 or 29 of this title to provide direct supervision in the physician's absence.

14. "Doctor of naturopathic medicine" or "doctor" means a natural person licensed to practice naturopathic medicine under this chapter.

15. "Drug" has the same meaning prescribed in section 32-1901 but does not include:

(a) Intravenous administration of legend drugs, except for:

(i) Vitamins, chelation therapy and drugs used in emergency resuscitation and stabilization.

(ii) Minerals.

(b) Controlled substances listed as schedule I or II controlled substances as defined in the federal controlled substances act of 1970 (21 United States Code section 802), except morphine and any homeopathic preparations that are also controlled substances.

(c) Cancer chemotherapeutics classified as legend drugs.

(d) Antipsychotics.

16. "General supervision" means that the physician is available for consultation regarding procedures that the physician has authorized and for which the physician remains responsible.

17. "Legend drug" means any drug defined by section 503(b) of the federal food, drug and cosmetic act and under which definition its label is required to bear the statement "Rx only".

18. "Letter of concern" means a nondisciplinary advisory letter that is issued by the board to a person who is regulated under this chapter and that states that while there is insufficient evidence to support disciplinary action the board believes that the person should modify or eliminate certain practices and that continuation of the activities that led to the information being submitted to the board may result in action against the person's license, certificate or registration.

19. "Letter of reprimand" means a disciplinary letter that is issued by the board and that informs a person who is regulated under this chapter that the person's conduct violates state or federal law but does not require the board to restrict the person's license, certificate or registration because the person's conduct did not result in harm to a patient or to the public.

20. "Limit" means taking a nondisciplinary action that alters the physician's practice or professional activities if the board determines that there is evidence that the physician is or may be mentally or physically unable to safely engage in the practice of medicine.

21. "Medical assistant" or "naturopathic medical assistant" means a person who is certified by the board as a medical assistant, who assists a doctor of naturopathic medicine and who may perform delegated procedures that are commensurate with the assistant's education and training under the direct supervision of a doctor of naturopathic medicine and that do not include diagnosing, designing or modifying established treatment programs or those procedures prohibited by the board or by this chapter.

22. "Medically incompetent" means a person who is licensed, certified or registered pursuant to this chapter and who lacks sufficient naturopathic medical knowledge or skills, or both, to a degree that is likely to endanger the health of patients.

23. "Naturopathic medical student" means a person who is enrolled in a course of study at an approved school of naturopathic medicine.

24. "Naturopathic medicine" means medicine as taught in approved schools of naturopathic medicine and in clinical, internship, preceptorship and postdoctoral training programs approved by the board and practiced by a recipient of a degree of doctor of naturopathic medicine licensed pursuant to this chapter.

25. "Nurse" means a person licensed pursuant to chapter 15 of this title.

26. "Physician" means a doctor of naturopathic medicine licensed pursuant to this chapter.

27. "Practice of naturopathic medicine" means a medical system of diagnosing and treating diseases, injuries, ailments, infirmities and other conditions of the human mind and body including by natural means, drugless methods, drugs, nonsurgical methods, devices, physical, electrical, hygienic and sanitary measures and all forms of physical agents and modalities.

28. "Restrict" means taking a disciplinary action that alters the physician's practice or professional activities if the board determines that there is evidence that the physician is or may be medically incompetent or guilty of unprofessional conduct.

29. "Specialist" means a physician who has successfully completed approved postdoctoral training, who is certified by a specialty board of examiners recognized by the board and who is certified by the board to practice the specialty pursuant to this chapter.

30. "Unprofessional conduct" includes the following, whether occurring in this state or elsewhere:

(a) Intentionally disclosing a professional secret or intentionally disclosing a privileged communication except as either of these may otherwise be required by law.

(b) Any dishonorable conduct reflecting unfavorably on the profession.

(c) Committing a felony, whether or not involving moral turpitude, or a misdemeanor involving moral turpitude. In either case conviction by any court of competent jurisdiction or a plea of no contest is conclusive evidence of the commission of the felony or misdemeanor.

(d) Habitual intemperance in the use of alcohol or any substance abuse.

(e) The illegal use of any narcotic or hypnotic drugs, or illegal substances.

(f) Conduct that the board determines is gross malpractice, repeated malpractice or any malpractice resulting in the death of a patient.

(g) Impersonating another doctor of naturopathic medicine or any other practitioner of the healing arts.

(h) Falsely acting or assuming to act as a member, an employee or an authorized agent of the board.

(i) Procuring or attempting to procure a license or a certificate pursuant to this chapter by fraud, by misrepresentation or by knowingly taking advantage of the mistake of another person or agency.

(j) Having professional connection with or lending one's name to enhance or continue the activities of an illegal physician or an illegal practitioner of any healing art.

(k) Representing that a manifestly incurable disease, injury, ailment or infirmity can be permanently cured, or falsely or fraudulently representing that a curable disease, injury, ailment or infirmity can be cured within a stated time.

(l) Offering, undertaking or agreeing to cure or treat a disease, injury, ailment or infirmity by a secret means, method, treatment, medicine, substance, device or instrumentality.

(m) Refusing to divulge to the board on demand the means, method, treatment, medicine, substance, device or instrumentality used in the treatment of a disease, injury, ailment or infirmity.

(n) Giving or receiving, or aiding or abetting the giving or receiving of, rebates, either directly or indirectly.

(o) Knowingly making any false or fraudulent statement, written or oral, in connection with the practice of naturopathic medicine or any naturopathic treatment method.

(p) Immorality or misconduct that tends to discredit the naturopathic profession.

(q) Refusal, revocation or suspension of a license by any other state, district or territory of the United States or any other country, unless it can be shown that this action was not due to reasons that relate to the ability to safely and skillfully practice as a doctor of naturopathic medicine or to any act of unprofessional conduct in this paragraph.

(r) Any conduct or practice that is contrary to recognized standards of ethics of the naturopathic profession, any conduct or practice that does or might constitute a danger to the health, welfare or safety of the patient or the public, or any conduct, practice or condition that does or might impair the ability to safely and skillfully practice as a doctor of naturopathic medicine.

(s) Failure to observe any federal, state, county or municipal law relating to public health as a physician in this state.

(t) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate any of the provisions of this chapter or board rules.

(u) False, fraudulent, deceptive or misleading advertising or advertising the quality of a medical or health care service by a physician or by the physician's staff, employer or representative.

(v) Failing or refusing to maintain adequate medical records on a patient or failing or refusing to make medical records in the physician's possession promptly available to another physician or health care provider who is licensed pursuant to chapter 7, 8, 13, 15, 17 or 29 of this title on request and receipt of proper authorization to do so from the patient, a minor patient's parent, the patient's legal guardian or the patient's authorized representative or failing to comply with title 12, chapter 13, article 7.1.

(w) Referring a patient to a diagnostic or treatment facility or prescribing goods and services without disclosing in writing to the patient that the physician has a pecuniary interest in the facility, goods or services to which the patient is referred or prescribed. This subdivision does not apply to a referral by one physician or practitioner to another physician or practitioner within a group of physicians or practitioners practicing together.

(x) Sexual intimacies with a patient in the course of direct treatment.

(y) Failing to dispense drugs and devices in compliance with article 4 of this chapter.

(z) Administering, dispensing or prescribing any drug or a device for other than an accepted therapeutic purpose.

(aa) Falsely representing or holding oneself out as being a specialist or representation by a doctor of naturopathic medicine or the doctor's staff, employer or representative that the doctor is boarded or board certified if this is not true or that standing is not current.

(bb) Delegating professional duties and responsibilities to a person if the person has not been approved or qualified by licensure or by certification to perform these duties or responsibilities.

(cc) Failing to appropriately supervise a naturopathic medical student, a nurse, a medical assistant, a health care provider or a technician employed by or assigned to the physician during the performance of delegated professional duties and responsibilities.

(dd) Using experimental forms of diagnosis or treatment without adequate informed consent of the patient or the patient's legal guardian and without conforming to experimental criteria including protocols, detailed records, periodic analysis of results and periodic review by a medical peer review committee as approved by the federal food and drug administration or its successor agency.

(ee) Failing to furnish information in a timely manner to the board or investigators or representatives of the board if this information is legally requested by the board and failing to allow properly authorized board personnel on demand to examine and have access to

documents, reports and records maintained by the physician that relate to the physician's medical practice or medically related activities.

(ff) Failing to report in writing to the board evidence that a person licensed, certified or registered pursuant to this chapter is or may be medically incompetent, guilty of unprofessional conduct or mentally or physically unable to safely practice or assist in the practice of naturopathic medicine.

(gg) Conducting or engaging in an internship, preceptorship or clinical training program in naturopathic medicine without being approved and registered by the board for that internship, preceptorship or clinical training program.

(hh) Signing a blank, undated or predated prescription form.

(ii) Conduct that the board determines is gross negligence, repeated negligence or negligence resulting in harm or death to a patient.

(jj) Knowingly making a false or misleading statement in oral testimony to the board on a form required by the board or in written correspondence to the board, including attachments to that correspondence.

(kk) The failure of a physician who is the chief medical officer, the executive officer or the chief of staff of an internship, a preceptorship or a clinical training program to report in writing to the board that the privileges of a doctor of naturopathic medicine, a naturopathic medical student or a medical assistant have been denied, limited, revoked or suspended because that doctor's, student's or assistant's actions appear to indicate that the person is or may be medically incompetent, is or may be guilty of unprofessional conduct or is or may be unable to safely engage or assist in the practice of naturopathic medicine.

(ll) Action taken against a doctor of naturopathic medicine by a licensing or regulatory board in another jurisdiction due to that doctor's mental or physical inability to engage safely in the practice of naturopathic medicine, the doctor's medical incompetence or for unprofessional conduct as defined by that licensing or regulatory board and that corresponds directly or indirectly to an act of unprofessional conduct prescribed by this paragraph. The action taken may include refusing, denying, revoking or suspending a license, otherwise limiting, restricting or monitoring a licensee or placing a licensee on probation by that licensing or regulatory board.

(mm) Sanctions imposed by an agency of the federal government, including restricting, suspending, limiting or removing a person from the practice of naturopathic medicine or restricting that person's ability to obtain financial remuneration.

(nn) Violating any formal order, probation, consent agreement or stipulation issued or entered into by the board pursuant to this chapter.

(oo) Refusing to submit to a body fluid examination pursuant to a board investigation of alleged substance abuse by a doctor of naturopathic medicine.

(pp) Charging a fee for services not rendered or dividing a professional fee for patient referrals among health care providers or health care institutions or between these providers and institutions or a contractual arrangement that has this effect.

(qq) Obtaining a fee by fraud, deceit or misrepresentation.

(rr) Charging or collecting a clearly excessive fee. In determining if a fee is clearly excessive the board shall consider the fee or range of fees customarily charged in this state for similar services, in light of modifying factors such as the time required, the complexity of the service and the skill required to perform the service properly. This subdivision does not apply if there is a clear written contract for a fixed fee between the physician and the patient that was entered into before the service was provided.

(ss) With the exception of heavy metal poisoning, using chelation therapy in the treatment of arteriosclerosis or as any other form of therapy without adequate informed patient consent and without conforming to generally accepted experimental criteria, including protocols, detailed records, periodic analysis of results and periodic review by a medical peer review committee.

(tt) Using a controlled substance unless it is prescribed by another physician for use during a prescribed course of treatment.

(uu) Prescribing, dispensing or administering anabolic androgenic steroids for other than therapeutic purposes.

(vv) Except in an emergency or urgent care situation, prescribing or dispensing a controlled substance to a member of the naturopathic physician's immediate family.

(ww) Prescribing, dispensing or furnishing a prescription medication or a prescription-only device as defined in section 32-1901 to a person unless the licensee first conducts a physical examination of that person or has previously established a doctor-patient relationship. This subdivision does not apply to:

(i) A licensee who provides temporary patient supervision on behalf of the patient's regular treating licensed health care professional.

(ii) An emergency medical situation as defined in section 41-1831.

(iii) Prescriptions written to prepare a patient for a medical examination.

(iv) Prescriptions written or prescription medications issued for use by a county or tribal public health department for immunization programs or emergency treatment or in response to an infectious disease investigation, a public health emergency, an infectious disease outbreak or an act of bioterrorism. For the purposes of this item, "bioterrorism" has the same meaning prescribed in section 36-781.

32-1581. Dispensing of natural substances, drugs and devices; conditions; civil penalty; dispensing minerals; definitions

A. A doctor of naturopathic medicine may dispense a natural substance, drug or device to a patient for a condition being diagnosed or treated by the doctor if:

1. The doctor is certified to dispense by the board and the certificate has not been suspended or revoked by the board.

2. The natural substance, drug or device is dispensed and properly labeled with the following dispenser information:

(a) The dispensing doctor's name, address and telephone number and a prescription number or other method of identifying the prescription.

(b) The date the natural substance, drug or device is dispensed.

(c) The patient's name.

(d) The name and strength of the natural substance, drug or device, directions for proper and appropriate use and any cautionary statements for the natural substance, drug or device. If a generic drug is dispensed the manufacturer's name must be included.

3. The dispensing doctor enters into the patient's medical record the name and strength of the natural substance, drug or device dispensed, the date the natural substance, drug or device is dispensed and the therapeutic reason.

4. The dispensing doctor keeps all prescription-only drugs, controlled substances and prescription-only devices in a secured cabinet or room, controls access to the cabinet or room by a written procedure and maintains an ongoing inventory of its contents.

B. Except in an emergency, a doctor of naturopathic medicine who dispenses a natural substance, drug or device without being certified to dispense by the board is subject to a civil penalty by the board of not less than three hundred dollars and not more than one thousand dollars for each transaction and may be prohibited from further dispensing for a period of time as determined by the board.

C. Before dispensing a natural substance, drug or device pursuant to this section, the treating doctor shall give the patient or the patient's legal guardian a written prescription and must inform the patient or the patient's legal guardian that the prescription may be filled by the prescribing doctor or the pharmacy of the patient's choice. If the patient chooses to have the medication dispensed by the doctor, the doctor must retrieve the written prescription and place it in a prescription file kept by the doctor.

D. A doctor of naturopathic medicine shall provide direct supervision of a nurse or attendant involved in the dispensing process. In this subsection, "direct supervision" means that a doctor of naturopathic medicine is present and makes the determination as to the necessary use or the advisability of the natural substance, drug or device to be dispensed.

E. The board shall enforce this section. The board shall adopt rules regarding the dispensing of a natural substance, drug or device including the labeling, record keeping, storage and packaging of natural substances that are consistent with the requirements of chapter 18 of this title. The board may conduct periodic inspections of dispensing practices to assure compliance with this section and applicable rules.

F. This section does not prevent a licensed practical or professional nurse employed by a doctor of naturopathic medicine from assisting in the delivery of natural substances, drugs and devices in accordance with this chapter.

G. Before prescribing or dispensing a mineral to a patient, the treating physician shall perform necessary clinical examinations and laboratory tests to prevent toxicity due to the excessive intake of magnesium, calcium and other minerals. The board shall adopt rules necessary for the safe administration of minerals. These rules shall require prior certification of a physician who prescribes or dispenses minerals to a patient.

H. For the purposes of this section:

1. "Device" means an appliance, apparatus or instrument administered or dispensed to a patient by a doctor of naturopathic medicine.

2. "Dispense" means the delivery by a doctor of naturopathic medicine of a natural substance, drug or device to a patient and only for a condition being diagnosed or treated by that doctor, except for free samples packaged for individual use by licensed manufacturers or repackagers, and includes the prescribing, administering, packaging, labeling and security necessary to prepare and safeguard the natural substance, drug or device for delivery to the treating doctor's own patient.

3. "Natural substance" means a homeopathic, botanical or nutritional supplement that does not require a prescription by federal law before it is dispensed, but is prescribed to treat a medical condition diagnosed by the doctor.

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BOARD OF NATUROPATHIC EXAMINERS

DIVISION 60

PRESCRIBING AUTHORITY; EDUCATION; FORMULARY

850-060-0212

Education Requirements for Injections/ IV Chelation Therapy

(1) Before using therapeutic injections of vitamins and minerals, or preventive injections of any substance, whether intramuscular (IM) or subcutaneous (SC) or intravenous (IV), licensee must provide proof of Board approved qualifying continuing education prior to using these applications as set forth in this rule, or proof of Board approved qualifying education received at an approved medical institution equivalent to the prescribed continuing education.

(2) Non-IV therapeutic injections of vitamins or minerals require a one-time two hour qualifying education on this subject.

(3) IV therapeutic injections of vitamins or minerals require a one-time 12 hour qualifying education on this subject.

(4) Preventive injections (IM, SC, IV) require an additional one-time four hours of qualifying education in addition to the CE hours noted in OAR 850-060-0212(2) and (3).

(5) The use of any IV chelation therapy requires 12 hours of Board approved qualifying education in addition to the education required in (2), (3) and (4) of this rule.

(6) Licensee must stay current in IV chelation training. Current means licensee has completed the education and obtained a certificate of competence within the last five years.

(7) Qualifying chelation therapy education must be provided by faculty with at least five years of experience in IV chelation therapy and current training approved by the Board. The qualifying education must contain all of the following:

(a) Current/ historical research on IV chelation therapy;

(b) Indications/contraindications of IV chelation therapy;

(c) IV Chelation therapy side effects and toxicity;

(d) IV Chelation therapy and practical application;

(e) IV solutions;

(f) Initial evaluation and treatment monitoring requirements;

(g) Frequency of IV treatment and remineralization;

(h) Charting requirements, standards of care, office procedures, consent to treat, nutrition and lifestyle recommendations during treatment;

(i) Heavy metal toxicity and disease;

(j) Practical on mixing and administering IV Chelation solutions;

(k) Examination for certification (exam subject to Board approval).

Stat Auth.: ORS 685.125
Stats. Implemented: ORS 685
Hist: BNE 6-2004, f. & cert. ef. 6-10-04; BNE 6-2005, f. & cert. ef. 8-15-05; Renumbered from 850-010-0212, BNE 8-2005, f. & cert. ef. 10-27-05

850-060-0215

Drug Enforcement Administration Registration

(1) Licensees may register with the United States Department of Justice for the issuance of a Drug Enforcement Administration (DEA) Number.

(2) Licensees with DEA registration have authority to prescribe from Schedules II, III, IIIN, IV and V, only those drugs as listed on the Formulary compendium, OAR 850-060-0225.

(3) Licensees shall not prescribe from Schedules II, III, IIIN, IV and V without a current DEA registration.

Stat. Auth.: ORS 685.125
Stats. Implemented: ORS 685.145
Hist.: NE 6-1980, f. & ef. 9-11-80; NE 2-1984, f. & ef. 2-28-84; BNE 2-2004, f. & cert. ef. 4-14-04; Renumbered from 850-010-0215, BNE 8-2005, f. & cert. ef. 10-27-05

850-060-0220

Authority to Prescribe, Dispense, and Order

Naturopathic physicians shall be allowed to prescribe, dispense, and order the following:

(1) All substances recommended by the Formulary Council and approved by the Board.

(a) All biological substances including extracts and/or their products and residues.

(b) All topical preparations.

(2) All vitamins, minerals, trace minerals, enzymes, and food.

(3) All mechanical devices, except those that require major surgical intervention.

(4) All homeopathic preparations.

(5) All laboratory and diagnostic procedures.

Stat. Auth.: ORS 685.125
Stats. Implemented: 685.030
Hist.: NE 2-1984, f. & ef. 2-28-84; BNE 2-2005, f. & cert. ef. 2-4-05; Renumbered from 850-010-0220, BNE 8-2005, f. & cert. ef. 10-27-05

850-060-0225

Naturopathic Formulary Compendium

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(1) Abacavir;

(2) Acarbose;

(3) Acetic Acid;

Naturopathic Formulary by Classification

The following classifications for substances listed in 850-060-0225 have been recommended by the Board of Naturopathic Examiners Formulary Council established by the 65th Oregon Legislature. Substances listed on the formulary compendium can be prescribed in any dosage or any dosage form. Products marked with an asterisk (*) may be used by Naturopathic Physicians, but may not be prescribed. Combination products containing only active ingredients listed in the Formulary may be prescribed. Combination products containing any active ingredient(s), not listed in the Formulary, except non-legend drugs, may not be prescribed. A double asterisk (**) indicates examples include but are not limited to the substances listed.

(1) Antiestrogens;
- (a) Nafarelin Acetate;
- (b) Tibolone;

(2) Antigout;
- (a) Colchicine;
- (b) allopurinol;

(3) Anti-infective Agents;
- (a) Antihelmintics;
  - (A) Thiabendazole.
  - (B) Oxamniquine.
  - (C) Mebendazole.
- (b) Antibacterials;
  - (A) Aminoglycosides**;
    - (i) Gentamicin;
    - (ii) Kanamycin Sulfate;
    - (iii)Tobramycin;
  - (B) Cephalosporins**;
    - (i) Cefaclor;
    - (ii) Cefadroxil;
    - (iii) Cefdinir;
    - (iv) Cefditoren;
    - (v) Cefibuten;
    - (vi) Cefixime;
    - (vii) Cefonicid Sodium;
    - (viii) Cefpodoxime Proxetil;
    - (ix) Cefprozil;
    - (x) Ceftibuten;
    - (xi) Cefuroxime;
    - (xii) Cephalexin;
    - (xiii)Cephradine;
  - (C) Chloramphenicol;.
  - (D) Macrolides and Ketolides**;
    - (i) Azithromycin;
    - (ii) Clarithromycin;
    - (iii) Dirithromycin;
    - (iv) Erythromycins;
    - (v) Telithromycin;
    - (vi) Troleondomycin;
  - (E) Penicillins**;
    - (i) Amoxicillin and Clavulanate;
    - (ii) Amoxicillin;
    - (iii) Ampicillin and Sulbactam;
    - (iv) Ampicillin;
    - (v) Bacampicillin;
    - (vi) Cloxacillin;
    - (vii) Dicloxacillin;
    - (viii) Oxacillin;
    - (ix) Penicillin;
  - (F) Quinolones**;
    - (i) Fluoroquinolines;
    - (ii) Quinolines -all;
  - (G) Sulfonamides;
    - (i) Sulfonamide/ Trimethoprim/ Sulfones;
  - (H) Tetracyclines**;
    - (i) Demeclocycline Hydrochloride;
    - (ii) Doxycycline;
    - (iii) Minocycline;
    - (iv) Oxytetracycline;
    - (v) Tetracycline;
  - (I) Misc. antibacterials;
    - (i) Bacitracin;
    - (ii) Clindamycin;
    - (iii) Colistimethate;
    - (iv) Lincomycin;
    - (v) Novobiocin;
    - (vi) Polymyxin B Sulfate;
    - (vii) Spectinomycin;
    - (viii) Vancomycin;
- (c) Antifungals;
  - (A) Azoles**;
    - (i) Fluconazole;
    - (ii) Itraconazole;
    - (iii) Ketoconazole;
    - (iv) Tinidazole;
  - (B) Amphotericin B;
  - (C) Gentian Violet;
  - (D) Griseofulvin;

(E) Nystatin;
(d) Antimycobacterials;
(A) Aminosalicylic Acid;
(B) Cycloserine;
(C) Pyrazinamide;
(D) Rifabutin;
(E) Rifampin;
(e) Antivirals;
(A) Interferon**;
(B) Nucleoside/nucleotide analogs**;
(i) Abacavir;
(ii) Acyclovir;
(iii) Didanosine;
(iv) Emtricitabine;
(v) Famciclovir;
(vi) Ganciclovir;
(vii) Lamivudine;
(viii) Penciclovir;
(ix) Stavudine;
(x) Tenofovir;
(xi) Valacyclovir;
(xii) Viarabine;
(xiii) Zalcitabine;
(xiv) Zidovudine;
(f) Antiprotozoal;
(A) Iodoquinol;
(B) Metronidazole;
(C) Quinines;
(i) Chloroquine;
(ii) Hydroxychloroquine;
(iii) Mefloquine;
(iv) Quinine Sulfate;
(g) Misc;
(A) Immune Globulins* **;
(B) Lindane;
(C) Permethrin;
(D) Pyrethrins;
(4) Antineoplastic Agents;
(a) Anastrozole;
(b) Letrozole;
(5) Anti-thyroid;
(a) Thionamides;
(A) Methimazole;
(B) Propylthiouracil;
(6) Autonomic Drugs;
(a) Parasympathomimetic;
(A) Bethanechol;
(B) Galantamine H. Br;
(b) Anticholinergic;
(A) Atropine Sulfate;
(B) Atropine;
(C) Belladonna;
(D) Flavoxate;
(E) Homatropine Hydrobromide*;
(F) Hyoscyamine;
(G) Meclizine;
(H) Methscopolamine;
(I) Physostigmine;
(J) Pilocarpine;
(K) Scopolamine;
(c) Sympathomimetic;
(A) Ephedrine;
(B) Epinephrine*;
(C) Epinephrine (auto-inject);
(d) Sympatholytic;
(A) Yohimbine;
(e) Skeletal Muscle Relaxants;
(A) Clostridium botulinum toxin (ab);
(B) Baclofen;
(f) Misc;
(A) Nicotine;
(7) Biologicals;
(a) Enzymes**;
(A) Collagenase;
(B) Desoxyribonuclease;
(C) Fibrinolysin;.
(D) Hyaluronidase;
(E) Pancrelipase;
(F) Papain;
(b) Hormones - see hormone;
(c) Immune gobulins - see anti-infective, misc;
(d) Interferons - see antivirals;
(e) Prostaglandins**;
(A) Alprostadil;
(B) Bimatoprost;
(C) Iloprost;
(D) Dinoprostone;
(E) Misoprostal;
(f) Blood derivatives;
(8) Blood Formation and Coagulation;
(a) Coumarin;
(b) Erythropoietin;
(c) Heparin; subcutaneous, sublingual and heparin locks;
(9) Cardiovascular Drugs;
(a) Cardiac;
(A) Adenosine Monophosphate;
(B) Digitalis;
(C) Digitoxin;
(D) Digoxin;
(E) Quinidine;
(b) Antilipemic;
(A) HMG CoA Reductase Inhibitors**;

(i) Atorvastatin;
(ii) Fluvastatin;
(iii) Lovastatin;
(iv) Pravastatin;
(v) Simvastatin;
(B) Ezetimibe;
(c) Diuretics;
(A) Spironolactone;
(B) Triamterene;
(d) Hypotensive;
(A) Lisuride;
(B) Rauwolfia Alkaloids;
(e) Vasodilating;
(A) Nitrates**;
(i) Isosorbide Dinitrate;
(ii) Mononitrate;
(iii) Nitroglycerin;
(B) Papavarine;
(f) Calcium Channel blockers;
(A) Phenylalkyamine**;
(i) Verapamil;
(g) ACE inhibitors**;
(A) Benazepril;
(B) Captopril;
(C) Enalapril;
(D) Fosinopril;
(E) Lisinopril;
(F) Moexipril;
(G) Perindopril;
(H) Quinapril;
(I) Ramopril;
(J) Trandolapril;
(10) Central Nervous System Agents;
(a) Analgesics and Antipyretics;
(A) NAIDS;
(i) Amino Aspirins;
(ii) Celecoxib;
(iii) Mesalamine;
(iv) Olsalazine;
(v) Oxaprozin;
(vi) Proprionic Acid Derivatives**;
(aa) Fenoprofen;
(bb) Flurbiprofen;
(cc) Ibuprofen;
(dd) Ketoprofen;
(ee) Oxaprozin;
(ff) Naproxen;
(vii) Salicyclic Acid;
(viii) Salicylamide;
(ix) Salicylate Salts;
(x) Salsalate;
(xi) Sulfasalizine;
(B) Opioids**;
(i) Buprenorphine;
(ii) Butorphanol;
(iii) Codeine;
(iv) Dextromethorphan;
(v) Fentanyl;
(vi) Hydrocodone;
(vii) Hydromorphone;
(viii) Levorphanol;
(ix) Methadone;
(x) Morphine;
(xi) Opium;
(xii) Oxycodone;
(xiii) Oxymorphone;
(xiv) Paregoric;
(xv) Tramadol;
(b) Opioid Antagonists;
(A) Naloxone;
(c) Anticonvulsants;
(A) Gaba Analogues**;
(i) Gabapenten;
(ii) Pregabalin;
(iii) Tigabine;
(d) Anti-Parkinson's;
(A) Bromocriptine;
(B) Carbidopa;
(C) Cabergoline;
(D) Levodopa;
(E) Pergolide;
(e) Psychotherapeutic;
(A) Anxiolytics, sedatives and hypnotics;
(i) Benzodiazepines**;
(ii) Zolpidem;
(B) Anti-Manic;
(i) Lithium;
(f) Misc;
(A) Triptans**;
(11) Diabetic;
(a) Acarbose;
(b) Insulin;
(c) Metformin;
(d) Miglitol;
(e) Nateglinide;
(12) Electrolytic;
(a) Ammonium Chloride;
(b) Bisphosphonates**;
(A) Alendronate;
(B) Etidronate;
(C) Risendronate;
(D) Tiludronate;

(c) Cellulose Sodium Phosphate (calcium removing);
(d) Dextran;
(e) Dextrose;
(f) Electrolyte Solutions;
(g) Fluorides;
(h) Iodine;
(i) Iron Preparations;
(j) Minerals (Oral & Injectable);
(k) Polysaccharide-Iron Complex;
(l) Potassium Iodide;
(m) Potassium Supplements;
(n) Sodium Polystyrene Sulfonate;
(13) Ergot Derivatives**;
(a) Dihydroergotamine;
(b) Ergoloid Mesylates;
(c) Ergonovine Maleate;
(d) Ergotamine;
(14) EENT preparations;
(a) Acetic Acid;
(b) Ophthalmic Solution (0.03%);
(c) Carbamide Peroxide;
(d) Natamycin;
(e) Phenylephrine;
(f) Prostaglandins - see Biologicals;
(15) GI drugs;
(a) Antidiarrhea -see opioids;
(b) Cathartics and laxatives;
(A) Lactulose;
(c) Antiemetics;
(A) Dronabinol;
(d) Antiulcer and acid suppressants;
(A) Misoprostol;
(B) Proton Pump Inhibitors**;
(i) Omeprazole;
(C) Sucralfate;
(e) Misc;
(A) Citrate Salts;
(B) Ursodiol;
(16) Gold Compounds;
(a) Auranofin;
(17) Heavy Metal antagonists (see 850-060-225 for specific education requirements);
(a) Deferoxamine/Desferroxamine;
(b) DMPS;
(c) DMSA;
(d) EDTA;
(e) Penicillamine;
(f) Sodium Thiosulfate;
(18) Hormones and synthetic substitutes**;
(a) Adrenals;
(A) Betamethasone;
(B) Budesonide;
(C) Cortisone;
(D) Dexamethasone;
(E) Fludrocortisone Acetate;
(F) Flunisolide;
(G) Fluticasone Propionate;
(H) Hydrocortisone;
(I) Paramethasone;
(J) Prednisolone;
(K) Prednisone;
(L) Tibolone;
(M) Triamcinolone;
(b) Androgens;
(A) Danazol;
(B) Methyltestosterone;
(C) Testosterone;
(c) Contraceptives;
(A) Estrogen-Progestin Combinations;
(B) Progestins;
(d) Estrogens and antiestrogens;
(A) Cenestin;
(B) Estradiol;
(C) Estriol;
(D) Estrogen, Esterified;
(E) Estrogens, Conjugated;
(F) Estrone;
(G) Estropipate;
(e) Pituitary;
(A) Desmopressin;
(B) Human Growth Hormone;
(C) Oxytocin;
(f) Progestins;
(A) Medroxyprogesterone;
(B) Medrysone;
(C) Megestrol Acetate;
(D) Methylprednisolone;
(E) Progesterone;
(F) Progestins;
(g) Thyroid;
(A) Dextrothyroxine;
(B) Levonorgestrel;
(C) Levothyroxine;
(D) Liothyronine;
(E) Liotrix;
(F) Thyroxine;
(19) Immunological;
(a) Tacrolimus;
(b) Rho(D) Immune globulins*;
(20) Local anesthetics**;
(a) Benzocaine*;
(b) Betaine;
(c) Bupivacaine*;

(d) Chirocaine*;
(e) Chloroprocaine*;
(f) Dyclonine*;
(g) Ethyl Chloride;
(h) Etidocaine*;
(i) Hydroxypolyetho-xydodecane*;
(j) Lidocaine (non-injectable dosage form);
(k) Lidocaine*;
(l) Mepivocaine*;
(m) Pramoxine;
(n) Prilocaine*;
(o) Procaine*;
(p) Tetracaine*;

(21) Prostaglandins - see Biologicals;

(22) Skin and mucous membrane agents;
(a) Anti-infectives;
(A) Benzoic Acid;.
(B) Carbol-Fuchsin;
(C) Clioquinol;
(D) Hexachlorophene;
(E) Iodoquinol;
(F) Mercury, Ammoniated;
(G) Mupirocin;
(H) Selenium Sulfide;
(I) Silver Nitrate;
(J) Undecylenic Acid;
(b) Anti-inflammatory;
(A) Topical steroids;
(c) Antipruritics and local anesthetics;
(A) Pentosan;
(B) Phenazopyridine;
(d) Cell stimulants and proliferants;
(A) Anthralin;
(B) Tretinoin;
(e) Keratolytic;
(A) Adapalene;
(B) Aminolevulinic Acid;
(C) Bichloracetic Acid;
(D) Imiquimod Cream (5%);
(E) Isotretinoin;
(F) Podophyllum Resin;
(G) Trichloracetic Acid*;
(H) Urea;
(f) Misc;
(A) Acitretin;
(B) Ammonium lactate lotion 12%;
(C) Azelaic Acid;
(D) Becaplermin;
(E) Calcipotriene;
(F) Condylox;
(G) Fluorouracil;
(H) Hydroquinone;
(I) Methoxsalen;
(J) Monobenzone;
(K) Pimecrolimus Cream 1%;
(L) Tazarotene topical gel;
(M) Trioxsalen;

(23) Skin Tests**;
(a) Diphtheria*;
(b) Mumps*;.
(c) Tuberculin*;

(24) Upper Respiratory;
(a) Acetylcysteine;
(b) Albuterol Sulfate;
(c) Benzonatate;
(d) Cromolyn Sodium;
(e) Guaifenesin;
(f) Levalbuteral;
(g) Nedocromil;.
(h) Xanthines**;
(A) Aminophylline;
(B) Diphylline;
(C) Oxtriphylline;
(D) Pentoxifylline;
(E) Theophylline;

(25) Vaccines**;
(a) BCG*;
(b) Cholera*;
(c) Diphtheria*;
(d) DPT*;.
(e) Haemophilus b Conjugate*;
(f) Hepatitus A Virus*;
(g) Hepatitus B*;
(h) Influenza Virus*;
(i) Japanese Encephalitis Virus*;
(j) Measles Virus*;
(k) Mumps Virus*;
(l) Pertussis*;
(m) Plague*;
(n) Pneumococcal*;
(o) Poliovirus - Inactivated*;
(p) Poliovirus - Live Oral*;
(q) Rabies*;
(r) Rubella*;
(s) Smallpox*;
(t) Tetanus IG*;.
(u) Tetanus Toxoid*;
(v) Typhoid*;
(w) Varicella*;
(x) Yellow Fever*;

(26) Vitamins**;
(a) Calcitonin;
(b) Calcitriol;

(c) Cyanocobalamin;
(d) Doxercalciferol;
(e) Leucovorin Calcium;
(f) Vitamins (Oral & Injectable);
(27) Misc;
(a) Colchicine (gout);
(b) Dimethyl Sulfone (DMSO);
(c) Hyaluronic Acid;
(d) Hydrogen Peroxide;
(e) MSM;
(f) OTC Substances;
(g) Oxygen;
(h) Urised

Stat. Auth.: ORS 685.125
Stats. Implemented: ORS 685.145
Hist.: BNE 1-2002, f. & cert. ef. 2-19-02; BNE 4-2002, f. & cert. ef. 8-8-02; BNE 3-2003, f. & cert. ef. 6-9-03; BNE 5-2003, f. & cert. ef. 12-5-03; BNE 5-2004, f. & cert. ef. 6-10-04; Renumbered from 850-010-0226, BNE 8-2005, f. & cert. ef. 10-27-05

Please refer to our web site for updates
www.obne.state.or.us

850-060-0225 **Effective December 12, 2005**

Naturopathic Formulary Compendium

The following substances have been recommended for addition to the Formulary Compendium after review by the Board of Naturopathic Examiners Formulary Council established by the 65th Oregon Legislature. Substances listed on the formulary compendium can be prescribed in any dosage or any dosage form. Products marked with an asterisk (*) may be used by Naturopathic Physicians, but may not be prescribed. Combination products containing only active ingredients listed in the Formulary may be prescribed. Combination products containing any active ingredient(s), not listed in the Formulary, except non-legend drugs, may not be prescribed.

(1) Abacavir;
(2) Acarbose;
(3) Acetic Acid;
(4) Acetylcysteine;
(5) Acitretin;
(6) Acyclovir;
(7) Adapalene;
(8) Adenosine Monophosphate;
(9) Albuterol Sulfate;
(10) Alendronate;
(11) Allopurinol;
(12) Alprostadil;
(13) Amino Acids;
(14) Amino Aspirins;
(15) Aminoglycosides;
(16) Aminolevulinic Acid;
(17) Aminophylline;
(18) Aminosalicylic Acid;
(19) Ammonium Chloride;
(20) Ammonium lactate lotion 12%;
(21) Amoxicillin;
(22) Amoxicillin & Clavulanate;
(23) Amphotericin B;
(24) Ampicillin;
(25) Ampicillin & Sulbactam;
(26) Anastrozole;
(27) Anthralin;
(28) Atorvastatin;
(29) Atropine;
(30) Atropine Sulfate;
(31) Auranofin;
(32) Azelaic Acid;
(33) Azithromycin;
(34) Bacampicillin;
(35) Bacitracin;
(36) Baclofen;
(37) Becaplermin;
(38) Belladonna;
(39) Benazepril;
(40) Benzodiazepines;
(41) Benzoic Acid;
(42) Benzonatate;
(43) Betaine;
(44) Betamethasone;
(45) Bethanechol Chloride;
(46) Bichloracetic Acid*;
(47) Bimatoprost Solution 0.03%;
(48) Biologicals;
(49) Biphosphonate;
(50) Bromocriptine;
(51) Budesonide;
(52) Buprenorphine;
(53) Butorphanol;
(54) Cabergoline;
(55) Calcipotriene;
(56) Calcitonin;
(57) Calcitriol;
(58) Carbamide Peroxide;
(59) Carbidopa;
(60) Carbol-Fuchsin;
(61) Captopril;
(62) Cefaclor;
(63) Cefdinir;
(64) Cefibuten;
(65) Cefadroxil;
(66) Cefditoren;
(67) Cefixime;
(68) Cefonicid Sodium;
(69) Cefpodoxime Proxetil;
(70) Cefprozil;
(71) Ceftibuten;
(72) Cefuroxime;
(73) Celecoxib;
(74) Cellulose Sodium Phosphate;
(75) Cenestin;
(76) Cephalexin;

(77) Cephradine;
(78) Chirocaine*;
(79) Chloramphenicol;
(80) Chloroquine;
(81) Citrate Salts;
(82) Clarithromycin;
(83) Clindamycin;
(84) Clioquinol;
(85) Clostridium botulinum toxin (ab);
(86) Cloxacillin;
(87) Codeine;
(88) Colchicine;
(89) Colistimethate;
(90) Collagenase;
(91) Condylox;
(92) Cortisone;
(93) Coumadin;
(94) Cromolyn Sodium;
(95) Cyanocobalamin;
(96) Cycloserine;
(97) Danazol;
(98) Deferoxamine / Desferroxamine (Board approved certification required before therapeutic IV chelation is allowed);
(99) Demeclocycline Hydrochloride;
(100) Desmopressin;
(101) Desoxyribonuclease;
(102) Dexamethasone;
(103) Dextran;
(104) Dextromethorphan;
(105) Dextrose;
(106) Dextrothyroxine;
(107) Dicloxacillin;
(108) Dihydroergotamine Migranal;
(109) Didanosine;
(110) Dimethyl Sulfone (DMSO);
(111) Digitalis;
(112) Digitoxin;
(113) Digoxin;
(114) Dinoprostone;
(115) Diphylline;
(116) Dirithromycin;
(117) DMPS (Board approved certification required before therapeutic IV chelation is allowed);
(118) DMSA;
(119) Doxercalciferol;
(120) Doxycycline;
(121) Dronabinol;
(122) Dyclonine;
(123) EDTA (Board approved certification required before therapeutic IV chelation is allowed);
(124) Electrolyte Solutions;
(125) Emtricitabine;
(126) Enalapril;
(127) Ephedrine;
(128) Epinephrine*;
(129) Epinephrine (auto-inject);
(130) Ergoloid Mesylates;
(131) Ergonovine Maleate;
(132) Ergotamine;
(133) Erythromycins;
(134) Erythropoietin;
(135) Estradiol;
(136) Estriol;
(137) Estrogen-Progestin Combinations;
(138) Estrogens, Conjugated;
(139) Estrogen, Esterified;
(140) Estrone;
(141) Estropipate;
(142) Ethyl Chloride;
(143) Etidronate;
(144) Ezetimibe;
(145) Famciclovir;
(146) Fentanyl;
(147) Fibrinolysin;
(148) Flavoxate;
(149) Fluconazole;
(150) Fludrocortisone Acetate;
(151) Flunisolide;
(152) Fluorides;
(153) Fluoroquinolones;
(154) Fluoroquinolines;
(155) Fluorouracil;
(156) Fluticasone propionate;
(157) Fluvastatin;
(158) Fosinopril;
(159) Gaba Analogs;
(160) Gabapentin;
(161) Galantamine H. Br.;
(162) Ganciclovir;
(163) Gentamicin;
(164) Gentian Violet;
(165) Griseofulvin;
(166) Guaifenesin;
(167) Heparin - subcutaneous, sublingual and heparin locks;
(168) Hexachlorophene;
(169) Homatropine Hydrobromide*;
(170) Human Growth Hormone;
(171) Hyaluronic Acid;

(172) Hyaluronidase;
(173) Hydrocodone;
(174) Hydrocortisone;
(175) Hydrogen Peroxide;
(176) Hydromorphone;
(177) Hydroquinone;
(178) Hydroxychloroquine;
(179) Hydroxypolyethoxydodecane*;
(180) Hyoscyamine;
(181) Iloprost Inhalation Solution;
(182) Imiquimod Cream (5%);
(183) Immune Globulins*;
(184) Insulin;
(185) Interferon Alpha b w/Ribaviron;
(186) Iodine;
(187) Iodoquinol;
(188) Iron Preparations;
(189) Isosorbide Dinitrate;
(190) Isotretinoin;
(191) Itraconazole;
(192) Kanamycin Sulfate;
(193) Ketoconazole;
(194) Lactulose;
(195) Lamivudine;
(196) Letrozole;
(197) Leucovorin Calcium;
(198) Levalbuteral;
(199) Levodopa;
(200) Levonorgestrel;
(201) Levorphanol;
(202) Levothyroxine;
(203) Lincomycin;
(204) Lindane;
(205) Liothyronine;
(206) Liotrix;
(207) Lisinopril;
(208) Lisuride;
(209) Lithium;
(210) Lovastatin;
(211) Mebendazole;
(212) Meclizine;
(213) Medroxyprogesterone;
(214) Medrysone;
(215) Mefloquine;
(216) Megestrol Acetate;
(217) Mercury, Ammoniated;
(218) Mesalamine;
(219) Metformin;
(220) Methadone;
(221) Methimazole;
(222) Methoxsalen;
(223) Methscopolamine;
(224) Methylergonovine;
(225) Methylprednisolone;
(226) Methylsulfonylmethane (MSM);
(227) Methyltestosterone;
(228) Methysergide;
(229) Metronidazole;
(230) Miglitol;
(231) Minerals (Oral & Injectable);
(232) Minocycline;
(233) Misoprostol;
(234) Moexipril;
(235) Monobenzone;
(236) Morphine;
(237) Mupirocin;
(238) Nafarelin acetate;
(239) Naloxone;
(240) Natamycin;
(241) Nateglinide;
(242) Nicotine;
(243) Nitroglycerin;
(244) Novobiocin;
(245) Nystatin;
(246) Olsalazine;
(247) Omeprazole;
(248) Opium;
(249) Over the Counter (OTC)
(250) Oxacillin;
(251) Oxamniquine;
(252) Oxaprozin;
(253) Oxtriphylline;
(254) Oxycodone;
(255) Oxygen;
(256) Oxymorphone;
(257) Oxytetracycline;
(258) Oxytocin*;
(259) Pancrelipase;
(260) Papain;
(261) Papavarine;
(262) Paramethasone;
(263) Paregoric;
(264) Penciclovir;
(265) Penicillamine (Board approved certification required before therapeutic IV chelation is allowed);
(266) Penicillin;
(267) Pentosan;
(268) Pentoxifylline;
(269) Pergolide;
(270) Perindopril;
(271) Permethrin;
(272) Phenazopyridine;
(273) Phenylalkylamine;

(274) Phenylephrine*;
(275) Physostigmine;
(276) Pilocarpine;
(277) Pimecrolimus Cream 1%;
(278) Podophyllum Resin;
(279) Polymyxin B Sulfate;
(280) Polysaccharide-Iron Complex;
(281) Potassium Iodide;
(282) Potassium Supplements;
(283) Pramoxine;
(284) Pravastatin;
(285) Prednisolone;
(286) Prednisone;
(287) Pregabalin;
(288) Progesterone;
(289) Progestins;
(290) Propionic Acids;
(291) Propylthiouracil;
(292) Prostaglandins;
(293) Proton Pump inhibitor;
(294) Pyrazinamide;
(295) Pyrethrins;
(296) Quinapril;
(297) Quinidine;
(298) Quinilones;
(299) Quinine Sulfate;
(300) Quinines;
(301) Quinolines;
(302) Ramopril;
(303) Rauwolfia Alkaloids;
(304) Rho(D) Immune globulins*;
(305) Rifabutin;
(306) Rifampin;
(307) Risendronate;
(308) Salicylamide;
(309) Salicylate Salts;
(310) Salicylic Acid;
(311) Salsalate;
(312) Scopolamine;
(313) Selenium Sulfide;
(314) Silver Nitrate;
(315) Simvastatin;
(316) Sodium Polystyrene Sulfonate;
(317) Sodium Thiosulfate;
(318) Spironolactone;
(319) Stavudine;
(320) Spectinomycin;
(321) Sucralfate;
(322) Sulfasalizine;
(323) Sulfonamide/Trimethoprim/Sulfones;
(324) Tazarotene topical gel;
(325) Tacrolimus;
(326) Telithromycin;
(327) Tenofovir;
(328) Testosterone;
(329) Tetracycline;
(330) Theophylline;
(331) Thiabendazole;
(332) Thyroid;
(333) Thyroxine;
(334) Tiagabine;
(335) Tibolone;
(336) Tiludronate;
(337) Tinidazole;
(338) Tobramycin;
(339) opical steroids;
(340) Tramadol;
(341) Trandolapril;
(342) Troleondomycin;
(343) Tretinoin;
(344) Triamcinolone;
(345) Triamterene;
(346) Trichloracetic Acid*;
(347) Trioxsalen;
(348) Triptans;
(349) Troleandomycin;
(350) Undecylenic Acid;
(351) Urea;
(352) Urised;
(353) Ursodiol;
(354) Valacyclovir;
(355) Vancomycin;
(356) Verapamil;
(357) Vidarabine;
(358) Vitamins (Oral & Injectable);
(359) Yohimbine;
(360) Zalcitabine;
(361) Zidovudine;
(362) Zolpidem;
(363) Local Anesthetics:
(a) Benzocaine*;
(b) Bupivacaine*;
(c) Chloroprocaine*;
(d) Dyclonine*;
(e) Etidocaine*;
(f) Lidocaine*;
(g) Lidocaine (non-injectable dosage form);
(h) Mepivocaine*;
(i) Prilocaine*;
(j) Procaine*;
(k) Tetracaine*.
(364) Vaccines:
(a) BCG*;
(b) Cholera*;

(c) Diptheria*;
(d) DPT*;
(e) Haemophilus b Conjugate*;
(f) Hepatitis A Virus*;
(g) Hepatitis B*;
(h) Influenza Virus*;
(i) Japanese Encephalitis Virus*;
(j) Measles Virus*;
(k) Mumps Virus*;
(l) Pertussis*;
(m) Plague*;
(n) Pneumococcal*;
(o) Poliovirus Inactivated*;
(p) Poliovirus-Live Oral*;
(q) Rabies*;
(r) Rubella*;
(s) Smallpox*;
(t) Tetanus IG*;
(u) Tetanus Toxoid*;
(v) Typhoid*;
(w) Varicella*;
(x) Yellow Fever*;
(365) SkinTests:
(a) Diptheria*;
(b) Mumps*;
(c) Tuberculin*

Stat. Auth.: ORS 685.125
Stats. Implemented: ORS 681.145
Hist.: NE 2-1990, f. & cert. ef. 11-8-90; NE 1-1997, f. 10-13-97, cert. ef. 10-20-97; BNE 1-1999, f. 6-24-99, cert. ef. 6-25-99; BNE 1-2000, f. & cert. ef. 1-10-00; BNE 3-2000, f. & cert. ef. 8-16-00; BNE 2-2001, f. & cert. ef. 2-7-01; BNE 4-2001, f. & cert. ef. 5-25-01; BNE 8-2001, f. & cert. ef. 12-7-01; BNE 4-2002, f. & cert. ef. 8-8-02; BNE 3-2003, f. & cert. ef. 6-9-03; BNE 5-2003, f. & cert. ef. 12-5-03; BNE 5-2004, f. & cert. ef. 6-10-04; BNE 3-2005, f. & cert. ef. 2-4-05; BNE 5-2005, f. & cert. ef. 6-10-05; Renumbered from 850-010-0225, BNE 8-2005, f. & cert. ef. 10-27-05

Please refer to our web site for updates. www.obne.state.or.us

State of California | Department of Consumer Affairs

Memorandum

To: **Enforcement Committee** **Date: September 19, 2006**

From: **Board of Pharmacy – Virginia Herold**

Subject: **Emergency Contraception**

In mid-August, the FDA reclassified Plan B from prescription status to over-the-counter status for emergency contraception for patients aged 18 and older. For patient 17 years and younger, Plan B remains a prescription drug.

In California existing law contains provisions that allow a specially qualified pharmacist to prescribe and dispense emergency contraception, using a variety of drugs, including Plan B (California Business and Professions Code section 4052 and California Code of Regulations section 1746, *both included in this tab section).*

In response to questions asked of the board initially upon the reclassification, the following draft questions and answers have been developed. These Qs and As will be added to the board's Web site.

I am also including in this tab section background information from the FDA on the reclassification of Plan B to OTC status.

Questions and Answers about Emergency Contraception

How does FDA's reclassification of Plan B to over-the-counter status for women 18 and over affect California law?

For women and men age 18 and over, the pharmacy may sell Plan B emergency contraception (EC) without a prescription.

Who may sell Plan B drugs?

The law does not require any specific individual to sell the product – that is a pharmacist, pharmacist intern, pharmacy technician or clerk may sell it.

The directive states that Plan B may only be sold in a pharmacy staffed by a pharmacist. Plan B medication must be stored behind the pharmacy counter.

Does a pharmacist need to consult a patient when selling Plan B?

No, unless in the pharmacist's judgment consultation is warranted.

Does the pharmacist need to keep records of dispensing to women/men over the age 18?

No.

Can a pharmacy sell Plan B to women younger than 18?

Yes, under California Business and Professions Code section 4052, a pharmacist who has either 1 hour of CE or has a protocol with a prescriber may have the pharmacist write a prescription for such a patient and dispense Plan B. The pharmacist may also dispense Plan B to a minor under 18 who requests it.

As a prescription drug – the pharmacist in this case needs to keep a record and to provide consultation. The record must be kept for 3 years.

Is there a cap on the maximum charge a pharmacy may charge for Plan B drugs to a patient 18 and over?

Not in California or federal law.

Is there a cap on the maximum charge a pharmacy may charge for Plan B drugs dispensed to a patient 17 and younger?

No. A provision that capped the maximum charge at $10 was repealed once the FDA reclassified the drugs as over-the-counter.

When do the over-the-counter provisions for Plan B take effect?

Once Plan B is relabeled for over-the-counter use. The manufacturer believes that this will occur towards the end of 2006.

How does the pharmacy determine whether a patient is 18 and over?

Check the patient's identification.

What if the patient lacks the identification?

The pharmacy needs to determine if a patient is 18 or older, the same way retailers need to determine whether a customer is 18 for cigarettes or 21 for alcohol sales.

Alternatively, a pharmacy unable to determine whether a patient is under 18 may have a qualified pharmacist write a prescription for a drug.

The California EC protocol developed by the Board of Pharmacy and Medical Board of California lists a number of other products that can be used for EC and provided by a qualified pharmacist. Are these products now also over-the-counter when used for EC?

No. Only Plan B has been reclassified for OTC use for patients 18 and over.

4052. Furnishing to Prescriber; Permissible Procedures by Pharmacist in Health Care Facility or Clinic or for Other Health Care Provider

(a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded medication to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(A) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(B) Ordering drug therapy-related laboratory tests.

(C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(5)(A) Perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):

(i) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(ii) Ordering drug therapy-related laboratory tests.

(iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(iv) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.

(B) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:

(i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(ii) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

(8)(A) Furnish emergency contraception drug therapy in accordance with either of the following:

(i) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(ii) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.

(B) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(C) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients

shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(D) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this paragraph.

(b)(1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (A) successfully completed clinical residency training or (B) demonstrated clinical experience in direct patient care delivery.

(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

(c) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(d) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(e) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

(Amended Stats. 2004, Chapter 191)

4052.1. Skin Puncture by Pharmacist; Conditions Permitting

Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for himself or herself, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

(Added Stats. 2001, Chapter 501)

prescriber. The pharmacist may not supply the drug after 72 hour period has expired without a new prescription.

(Amended Effective 10-7-2005)

1746. Emergency Contraception

(a) A pharmacist furnishing emergency contraception pursuant to Section 4052(a)(8)(A)(ii) of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Emergency Contraception (EC).

(1) Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the Board of Pharmacy and the Medical Board of California. Use of the following protocol satisfies that requirement.

(2) Purpose: To provide access to emergency contraceptive medication within required limits and ensure that the patient receives adequate information to successfully complete therapy.

(3) Procedure: When a patient requests emergency contraception the pharmacist will ask and state the following:

Are you allergic to any medications?

Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) of unprotected intercourse. EC effectiveness declines gradually over five days and EC use will not interfere with an established pregnancy.

(4) The pharmacist shall provide the fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medication record by Section 1707.1 of Title 16 of the California Code of Regulations.

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy as required by Business and Professions Code Section 4052(b)(3).

(5) Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(6) The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

(7) Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

(8) EC Product Selection: The pharmacist will provide emergency contraception medication compatible with product information from the list of products specified in this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC. Patients will be provided information concerning dosing and potential adverse effects.

(9) Documentation: Each prescription authorized by a pharmacist will be documented in a patient medication record as required by law.

(10) Training: Prior to furnishing emergency contraception, pharmacists who participate in the protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

(11) Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.

Dedicated Emergency Contraception

Brand	Manufacturer	Tablets per Dose	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
One Dose Regimen				
Plan B	Women's Capital Corporation	2 tablets	0	1.5
Two Dose Regimens				
Plan B	Women's Capital Corporation	1 tablet per dose	0	0.75
Preven	Gynétics	2 tablets per dose	100	0.50

Oral Contraceptive Pills

Brand	Manufacturer	Tablets per Dose (two doses 12 hours apart*)	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
Levora	Watson	4 white tablets	120	0.60
Ovral	Wyeth	2 white tablets	100	0.50
Ogestrel	Watson	2 white tablets	100	0.50
Nordette	Wyeth	4 light-orange tablets	120	0.60
Tri-Levlen	Berlex	4 yellow tablets	100	0.50
Alesse	Wyeth	5 pink tablets	100	0.50
Aviane	Duramed	5 orange tablets	100	0.50
Triphasil	Wyeth	4 yellow tablets	120	0.50
Levlen	Berlex	4 light-orange tablets	120	0.60
Trivora	Watson	4 pink tablets	120	0.50
Levlite	Berlex	5 pink tablets	100	0.50
Lo/Ovral	Wyeth	4 white tablets	120	0.60

Brand	Manufacturer	Tablets per Dose	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
Low-Ogestrel	Watson	4 white tablets	120	0.60
Ovrette	Wyeth	20 yellow tablets	0	0.75

(12) Anti-nausea Treatment Options for use with Emergency Contraception

Drug	Dose	Timing of Administration
Non-prescription Drugs		
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules.	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first ECP dose; repeat as needed every 4-6 hours
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

(New section filed 11-2-2004; operative 12-2-2004 (Register 2004, No. 45). For prior history, see Register 80, No. 8)

Article 6. Fees and Penalties

(Renumbered from Article 7, 9-11-2002)

1749. Fee Schedule

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with section 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a pharmacy license is three hundred forty dollars ($340). The fee for the annual renewal of pharmacy license is one hundred seventy-five dollars ($175). The penalty for failure to renew is eighty-seven dollars and fifty cents ($87.50).

(b) The fee for the issuance of a temporary license is one hundred seventy-five dollars ($175).

(c) The fee for the issuance of a pharmacy technician license shall be fifty dollars ($50). The fee for the biennial renewal of a pharmacy technician license shall be fifty dollars ($50). The penalty for failure to renew a pharmacy technician license is twenty-five dollars ($25).

(d) The fee for application and examination as a pharmacist is one hundred fifty-five dollars ($155).

(e) The fee for regrading an examination is seventy-five dollars ($75).

FDA News

FOR IMMEDIATE RELEASE
P06-118
August 24, 2006

Media Inquiries:
Julie Zawisza, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Approves Over-the-Counter Access for Plan B for Women 18 and Older
Prescription Remains Required for Those 17 and Under

The U.S. Food and Drug Administration (FDA) today announced approval of Plan B, a contraceptive drug, as an over-the-counter (OTC) option for women aged 18 and older. Plan B is often referred to as emergency contraception or the "morning after pill." It contains an ingredient used in prescription birth control pills--only in the case of Plan B, each pill contains a higher dose and the product has a different dosing regimen. Like other birth control pills, Plan B has been available to all women as a prescription drug. When used as directed, Plan B effectively and safely prevents pregnancy. Plan B will remain available as a prescription-only product for women age 17 and under.

Duramed, a subsidiary of Barr Pharmaceuticals, will make Plan B available with a rigorous labeling, packaging, education, distribution and monitoring program. In the CARE (Convenient Access, Responsible Education) program Duramed commits to:

- Provide consumers and healthcare professionals with labeling and education about the appropriate use of prescription and OTC Plan B, including an informational toll-free number for questions about Plan B;
- Ensure that distribution of Plan B will only be through licensed drug wholesalers, retail operations with pharmacy services, and clinics with licensed healthcare practitioners, and not through convenience stores or other retail outlets where it could be made available to younger women without a prescription;
- Packaging designed to hold both OTC and prescription Plan B. Plan B will be stocked by pharmacies behind the counter because it cannot be dispensed without a prescription or proof of age; and
- Monitor the effectiveness of the age restriction and the safe distribution of OTC Plan B to consumers 18 and above and prescription Plan B to women under 18.

Today's action concludes an extensive process that included obtaining expert advice from a joint meeting of two FDA advisory committees and providing an opportunity for public comment on issues regarding the scientific and policy questions associated with the application to switch Plan B to OTC use. Duramed's application raised novel issues regarding simultaneously marketing both prescription and non-prescription Plan B for emergency contraception, but for different populations, in a single package.

The agency remains committed to a careful and rigorous scientific process for resolving novel issues in order to fulfill its responsibility to protect the health of all Americans.

For more information on Plan B and today's action, please see:
http://www.fda.gov/cder/drug/infopage/planB/default.htm.

Plan B: Questions and Answers
August 24, 2006

1. What is FDA announcing today?

FDA is announcing the approval of the emergency contraceptive drug Plan B as an over-the-counter (OTC) option for women aged 18 and older. A prescription-only form of Plan B will remain available for young women aged 17 and younger.

2. What is emergency contraception?

Emergency contraception is a method of preventing pregnancy after a contraceptive fails or after unprotected sex. It is not for routine use. These pills contain higher levels of a hormone found in daily oral hormonal contraceptives. FDA has approved two products for this prescription use – Preven (approved in 1998 but is no longer being marketed) and Plan B (approved in 1999).

3. What is Plan B?

Plan B is emergency contraception, a backup method to birth control. It is in the form of two levonorgestrel pills (0.75 mg in each pill) that are taken by mouth after a contraceptive fails or after unprotected sex. Levonorgestrel is a synthetic hormone used in birth control pills for over 35 years. Plan B can reduce the chances of a woman becoming pregnant when taken as directed if she has had unprotected sex. Prior to this action, Plan B was available only by prescription.

4. How does Plan B work?

Plan B works like other oral birth control pills to prevent pregnancy. Plan B acts primarily by stopping the release of an egg from the ovary (ovulation). It may prevent the union of sperm and egg (fertilization).

5. Are there any side effects?

According to reports from clinical trials, some women will experience non-serious side effects, such as nausea, stomach pain, headache, dizziness, or breast tenderness. These are similar to the side effects of regular birth control pills.

6. How should Plan B be administered?

Plan B should be taken orally as soon as possible and within 72 hours of unprotected sex. The second tablet should be taken 12 hours after the first tablet. Data shows Plan B is more effective the sooner treatment is started following unprotected sex.

7. How can I purchase over-the-counter Plan B?

Plan B will only be sold in pharmacies/stores staffed by a licensed pharmacist. In order to purchase Plan B over-the-counter, personal identification showing proof of age (18) is required. Plan B will be available behind the counter at the pharmacy in order to manage both prescription (17 years and under) and OTC (18 years and over) dispensing. This means Plan B will not be sold at gas stations or convenience stores, where other OTC products are routinely available.

8. What should I do if I have questions about Plan B?

If you have questions or need more information about Plan B from the company you should:

- Call the toll free number, 1-800-330-1271
- Visit their website www.go2planB.com

If you want more information about Plan B from FDA:

- Visit our Drug Information web page at: www.fda.gov/cder
- Call Drug Information at: 888-INFO-FDA (888-463-6332)
- Questions regarding previous regulatory actions regarding Plan B can be found on our web site at http://www.fda.gov/cder/drug/infopage/planB/default.htm.

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Date created: August 24, 2006

MEMORANDUM

DATE: 8/23/06

FROM: Dr. Andrew C. Von Eschenbach
Acting Commissioner
United States Food and Drug Administration

TO: NDA 21-045, S-011

SUBJECT: Appropriate age restriction for Plan B®

This memorandum regards Barr Laboratories' (Barr or the sponsor[1]) supplemental new drug application (sNDA) dated April 22, 2003, and Barr's subsequent amendments, including its amended sNDA dated August 17, 2006. Barr's most recent sNDA requests that FDA switch Plan B's prescription (Rx) status to non-prescription for women 18 years of age and older, and to have Plan B® remain Rx for girls under 18 years of age.

In an August 26, 2005 memo written by Dr. Steven Galson, the Director of the Center for Drug Evaluation and Research (CDER), CDER found that for women 17 and older the existing Rx dispensing requirements for Plan B® are not necessary to protect the public health and that an Rx-only to non-prescription switch for those consumers is authorized under 21 U.S.C. 353(b)(3) and 21 CFR 310.200. CDER also determined, however, that Barr had not established that Plan B® could be used safely and effectively by young adolescents – girls 16 and younger – for emergency contraception without the professional supervision of a practitioner licensed by law to administer the drug. As a result of this scientific conclusion (with which I concur), Plan B® may not lawfully be made available without a prescription to this group under section 503(b) of the Federal Food, Drug, and Cosmetic Act.

In considering the difficulty of enforcing an age-based restriction on the availability of this oral hormonal contraceptive, I have concluded that 18 (rather than 17) is the more appropriate cutoff point to best promote and protect the public health. The state-regulated pharmacies that will be dispensing Plan B® under Barr's voluntary CARE℠ program (as well as society as a whole) are more familiar with 18 as a cutoff age. I understand that in all 50 states, 18 is the age of majority (i.e., the legal delineation between minor and adult), and retail outlets, including pharmacies, are familiar with using 18 as the age restriction for the sale of certain products. With regard to drug products, for example, the legal age to purchase FDA approved non-prescription nicotine replacement therapy products is 18. Moreover, I also understand that as a matter of state law many products routinely sold by pharmacies, e.g., tobacco products and non-prescription cough-cold products like pseudoephedrine, are restricted to consumers 18 and older.

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[1] The current applicant for the Plan B sNDA is Duramed Research Pharmaceuticals (Duramed), a wholly-owned subsidiary of Barr. For ease of reference, this memo will refer to both entities as Barr.

This approach builds on well-established state and private-sector infrastructures to restrict certain products to consumers 18 and older. Indeed, the agency selected 18 as the appropriate age for non-prescription nicotine replacement therapy products, in part, because the States had already uniformly restricted the sale of tobacco products to those 18 and older. By so doing, FDA was able to utilize the existing state-created infrastructure limiting the sale of tobacco products to minors to ensure the enforcement of its age-based restriction on non-prescription nicotine replacement therapy products. Here, Barr's CARE℠ program specifically utilizes state-licensed pharmacies to implement its restricted distribution plan. Given this fact, and the existing experience pharmacies have enforcing the age-based restriction of 18, I have determined that to best protect and promote the public health non-prescription Plan B® should be available for ages 18 and above.

Leveraging well-established state and private-sector infrastructures will allow for comprehensive and effective enforcement of the age-based restrictions. As a result, this approach should minimize the likelihood that younger girls for whom Plan B® has not been found safe and effective for non-prescription use will have access to the product without professional supervision. Therefore, this approach should help ensure safe and effective use of the product.

MEMORANDUM

DATE: August 24, 2006

FROM: Steven Galson, MD, MPH
Director, Center for Drug Evaluation and Research

TO: NDA 21-045, S-011

SUBJECT: Plan B®

I. Introduction

On April 16, 2003, Barr Pharmaceuticals (Barr or the sponsor[1]) submitted a supplement to NDA 21-045 to switch Plan B®, (levonorgestrel) Tablets, 0.75 mg, to over-the-counter (OTC) status. The supplement, S-011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act), was received April 23, 2003. On May 6, 2004, I issued a Not Approvable letter because the supplement did not contain data demonstrating that the product was safe and effective for OTC use by women under age 16.

On July 21, 2004, Barr resubmitted its supplement to NDA 21-045, S-011, seeking to switch Plan B®'s prescription (Rx) status to OTC for women 16 years of age and older, and to have Plan B® remain Rx for women under 16 years of age. This resubmission of July 21, 2004, constituted a complete response to our May 6, 2004, Not Approvable letter. The resubmitted supplemental new drug application proposed to switch Plan B® to OTC status for women ages 16 years or greater and maintenance of prescription status for women under age 16.

On August 26, 2005, then Commissioner Lester M. Crawford, DVM, PhD, sent the sponsor a letter indicating that the Center for Drug Evaluation and Research (CDER) had completed its review of the application, as amended, and had concluded that the available scientific data are sufficient to support the safe use of Plan B® as an OTC product, but only for women who are 17 years of age and older.

The letter went on to state, however, that the Agency was unable, at that time, to reach a decision on the approvability of the application because of unresolved issues that related to the NDA. The letter mentioned three issues: whether the same active ingredient could be marketed both Rx and OTC based solely on the age of the individual using the drug; how, as a practical matter, an age-based distinction could be enforced; and whether the Rx and OTC versions of the same active ingredient may be marketed in a single package. The letter also stated that the agency had decided to ask for public comments on whether we should initiate a rulemaking to codify our interpretation of section 503(b) of the Federal Food, Drug, and Cosmetic Act regarding when an active ingredient can be

[1] The current applicant for the Plan B sNDA is Duramed Research Pharmaceuticals, a wholly-owned subsidiary of Barr. For ease of reference, this memo will refer to both entities as Barr.

simultaneously marketed in both a prescription drug product and an OTC drug product through an advance notice of proposed rulemaking (ANPRM) that published on September 1, 2005 (70 FR 52050). The comment period closed on November 1, 2005, and the agency received about 47,000 comments. The agency hired a contractor to summarize and categorize the comments and the contractor submitted a final report on May 19, 2006.

On July 31, 2006, Dr. Andrew von Eschenbach, Acting Commissioner of Food and Drugs, sent the sponsor a letter indicating that the agency had reviewed the comments received in response to the ANPRM and determined it was not necessary to engage in rulemaking to resolve the novel regulatory issues raised by the application and that we were now proceeding with further evaluation of the application.

CDER staff met with the sponsor on August 8, 2006, and discussed how to address the issues raised in Dr. von Eschenbach's letter regarding the restriction on OTC sales of Plan B® to ages 18 and over, the packaging of prescription and OTC Plan B® in one package, and the Convenient Access Responsible Education (CARE℠) Program.

On August 17, 18, and 23, 2006, the sponsor amended its application to propose revisions to the labeling and to the CARE℠ Program.

II. Approval Standards

FDA must require Rx dispensing of any drug that is not safe for use "except under the supervision of a practitioner licensed by law to administer such drug."[2] A drug sponsor may submit a supplemental application to "switch" a drug that FDA has already approved for Rx use to OTC status. FDA will grant a supplemental application to "switch" when it finds that Rx dispensing is:

> not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, and . . . the drug is safe and effective for use in self-medication as directed in proposed labeling.[3]

Such switch applications generally include data from actual use and labeling comprehension studies to demonstrate that the product can be safely and effectively used without the supervision of a practitioner licensed by law to administer the drug. FDA may approve an NDA application only when, among other things, the investigations submitted in the application include adequate tests showing whether or not the drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling and when there is sufficient information to determine from the application whether the drug is safe for use.[4]

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[2] 21 U.S.C. § 353(b)(1).
[3] 21 C.F.R. § 310.200(b).
[4] See 21 U.S.C. § 355(d).

III. Findings

I have completed my review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use under the conditions set forth in the draft labeling submitted August 23, 2006. My previous memoranda on this application (May 6, 2004, and August 25, 2005) describe my reasoning for concluding that Plan B® is safe and effective for OTC use for ages 17 and older, but, in the absence of additional data demonstrating that it is safe and effective for OTC use in women under 17, it must remain Rx for this age group.[5] This memorandum addresses the three issues raised in Dr. von Eschenbach's July 31, 2006 letter: the age 18 restriction, the packaging of the product, and the CARE℠ program.

A. Restriction to Rx Use for Women Under 18

Regarding the restriction on OTC use to age 18 and older, Dr. von Eschenbach decided that this was the appropriate age for OTC use for the reasons described in his memorandum of August 23, 2006. I have read that memorandum and, although I previously concluded that OTC use should be restricted to women 17 or older, I have now determined that for the reasons Dr. von Eschenbach outlines, the approval of this application should reflect a restriction to OTC use for those age 18 and older.

B. Packaging

Regarding the packaging of the Rx and OTC products in a single package, Barr has proposed to package Plan B® in a package that is designed to satisfy both the Rx and OTC labeling requirements. On the front of the package, the statement will appear: "Rx only for age 17 and younger." In addition, the package will have the Drug Facts box required for all OTC products, and will have space for a pharmacist to apply the standard prescription drug labeling before dispensing the product pursuant to a prescription. These proposals make it clear that the product is Rx for age 17 and younger, and OTC for ages 18 and older, satisfying the requirements of section 503(b)(4)(A) of the Act that a drug that is subject to the prescription requirement in section 503(b)(1) bear the "Rx

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[5] As I noted in my August 26, 2005, memo, various CDER reviewers recommended that Plan B® should be switched OTC for the entire population of women who might use the product, including women under age 18. Similar views were expressed by various CDER reviewers in this review cycle (see for example, August 22, 2006, review of the Director, Office of New Drugs, the Director, Office of Nonprescription Products (ONP), and the Acting Director, Office of Drug Evaluation III). For the same reasons described in my August 26, 2005, memo, I do not agree with those recommendations.

I would, however, like to clarify for the record a statement in my August 25, 2005 memo. On page 5, I stated that if Plan B® was used routinely for contraception (a use inconsistent with the labeling), the well-known risks associated with hormonal contraceptives, such as blood clots and stroke, are likely to be higher than with the use of other contraceptives. While it would be inappropriate to use Plan B® for routine contraception because this dose of levonorgestrel has not been shown to be safe and effective for such a use, the relationship between progestin-only oral contraceptives, such as levonorgestrel, and strokes and blood clots has not been fully defined. This clarification does not change my view that the sponsor did not establish that Plan B® can be used safely and effectively by women under 17 without the supervision of a licensed practitioner.

only" symbol. Because section 503(b)(1) applies here, section 503(b)(4)(B), does not. Section 503(b)(4)(B) states: "A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A) [the "Rx only" symbol]."

Furthermore, there are important policy reasons for approving this packaging configuration related to implementing the restriction of the OTC product to ages 18 and over. Because the package will be labeled with the "Rx only" symbol, State and Federal law will require that the packages be dispensed only by pharmacies and other healthcare providers such as physicians and clinics authorized to dispense prescription drugs. The product will not be available through convenience stores and gas stations because they will not be authorized to sell the prescription product. As described in the CARE℠ program, wholesale distributors and retail chain drug stores confirmed to the sponsor that they will distribute Plan B® only to licensed pharmacies or heath care clinics. Furthermore, since Plan B® has both Rx and OTC labeling, pharmacies will keep Plan B® behind-the-counter, and either a prescription or government-issued proof of age will be presented before sale of the product.

C. The CARE℠ Program

In its July 2004 submission, Barr submitted proposed labeling that included a consumer information leaflet that elaborates on the information contained on the Plan B® outer carton and inner packaging. Among the important information that is included in the consumer information leaflet is information about how Plan B® works, when it is appropriate to use Plan B®, how often it should be used, side effects and warnings, and directions for use. In addition, Barr Laboratories proposed an educational program (Convenient Access Responsible Education Program, CARE℠) with the following elements: (1) labeling, packaging, web site, and informational 24-hour toll-free number, (2) education initiatives for healthcare providers and pharmacists, (3) distribution plans, and (4) monitoring efforts to assess whether the Rx/OTC age distinction is understood and adhered to.

In response to Dr. von Eschenbach's letter of July 31, 2006, describing several issues that he asked be addressed concerning the enforceability of the age restriction, representatives from CDER met with Barr to discuss proposed changes to the CARE℠ program to address these concerns. On August 17 and 18, and 23, 2006, Barr submitted amendments to Supplement O11 proposing changes to the CARE℠ program.

Specifically, Barr:

- Made changes throughout the program to reflect that Plan B® would be made available only by prescription to women age 17 and younger and would be made available OTC to those age 18 and older who show a government-issued identification of their age.
- Clarified that wholesale distributors and chain drug companies will only distribute Plan B® to licensed pharmacies or other licensed healthcare clinics.
- Clarified that since Plan B® will be labeled as both Rx and OTC, pharmacies will keep the product behind the counter to effectuate the restriction of the OTC

product to ages 18 and older.

- Clarified that if violations of the age restriction are observed, the sponsor will increase its educational efforts regarding the age restriction and focus on improving the level of understanding among pharmacists and pharmacy staff, and will also report repeat violators to the relevant State Boards of Pharmacy.[6]
- Committed to report to FDA the results of its surveys to provide signals of program effectiveness and potential problems, and the point-of-purchase monitoring program to determine whether the Rx requirement for those ages 17 and younger is being adhered to at the point of purchase. These results will be reported to FDA at six-month intervals beginning 30 calendar days after the six-month interval commencing on the date of the approval of the amended sNDA.
- Made additional editorial and clarifying changes to the CARE℠ program to reflect changes in packaging.

I have determined that with the changes the sponsor has proposed, the CARE℠ program is adequate to support my finding that Plan B® can be safely distributed in the package configuration proposed by Barr.

To ensure that Plan B® will be used safely and effectively by Rx consumers age 17 and below and OTC consumers age 18 and above, the sponsor has agreed to the following activities:

- Monitor trends in the use of emergency contraception to evaluate the effectiveness of the CARE℠ program. Specifically, the sponsor agreed to conduct a market research survey or surveys of a subset of healthcare professionals annually, and when practicable, in collaboration with established professional groups. These surveys will be designed to determine whether the Rx requirement for those ages 17 and younger is being adhered to at the point of purchase and to provide signals of program effectiveness and potential problems

[6] I disagree with the recommendation by the Office of Surveillance and Epidemiology (OSE) that the CARE℠ program should require the sponsor to notify FDA instead of the State Boards of Pharmacy when pharmacists repeatedly fail to comply with the age restriction (OSE Plan B® CARE℠ Program Review Team Review, August 22, 2006). The Director, ONP, accepted OSE's recommendation (Director, ONP Review, August 22, 2006). OSE explained that it believed such a measure of monitoring the compliance with the age restriction was "overly punitive" and may have a negative impact on the availability of this product OTC. OSE states that a lack of pharmacy compliance may be reflective of an inadequate education plan and this information could be used as an opportunity to improve and/or revise the CARE℠ program. I disagree that the sponsor's proposal is overly punitive, or that it is proposed as a substitute for adequate education. The CARE℠ program states that "findings from the [point-of-purchase] study will be communicated to the pharmacy and the corporate office, if appropriate, since education and retraining will be the first course of remedial action." (CARE℠ Program, August 22, 2006, p. 11) The plan states that only in the case of repeat violators will the violator's State Board of Pharmacy be notified. (Id.) Furthermore, these reports to a State Board of Pharmacy do not mean that FDA will not be informed of violations. The CARE℠ program provides that the sponsor will report to FDA periodically the findings of the point-of-purchase monitoring program. I believe the sponsor's proposed approach to monitoring will increase the likelihood that pharmacists will dispense Plan B® appropriately, and it is within the sponsor's discretion to propose such action.

associated with consumers' understanding of the purpose and proper use of Plan B®.

- Using relevant survey data regularly collected by others (e.g., Centers for Disease Control's Behavioral Risk Factor Safety Surveillance (CDC BRFSS), Youth Risk Behavior Safety Surveillance (YRBSS)), to monitor for potential indicators that Plan B® is being used in an inappropriate manner. Potential areas of monitoring and reporting include evaluating possible correlations between increases in sexually transmitted infections (STIs) based on geographic areas and data and trends in pregnancy and/or abortion rates based on geographic areas.
- Conduct a "Point-of-Purchase Monitoring Program" to track how Plan B® is being sold at the time of purchase, including using anonymous shoppers who will be directed to visit locations where Plan B® is available and purchase the product. Using the data collected, the sponsor will document and analyze the level of comprehension of the Plan B® prescription age requirement and how it is handled at the point of purchase. The program will be conducted twice in the first year and annually thereafter. The sponsor will report repeat violators to the relevant State Boards of Pharmacy.
- Report to FDA on the results of these activities on a six-month interval beginning 30 calendar days after the six-month interval commencing on the date of the approval of the amended sNDA.

Finally, I note and agree with the other elements of the CARE℠ program described in the submission of August 23, 2006, which are designed to help ensure compliance with the approved labeling, and particularly the restriction of OTC use to ages 18 and older. The program includes the following elements:

- The sponsor and third party distributors, wholesalers, and chain drug companies will only distribute Plan B® to licensed pharmacies or other licensed healthcare clinics. As a result, Plan B® will not be sold at gas stations or convenience stores. Given that Plan B® will have both Rx and OTC labeling, the pharmacies will keep Plan B® behind-the-counter.
- The sponsor will conduct an education campaign that will focus initially on healthcare professionals (including prescribers and pharmacists) to raise awareness and knowledge levels about emergency contraception. The education campaign will clearly communicate the prescription age requirement and the appropriate use of emergency contraception. The campaign will include continuing education by certified professionals and educational materials (including websites and toll free numbers) that can be accessed easily and at any time.
- The sponsor will make available to State Boards of Pharmacy continuing education programs for use at annual meetings and other regional programs.
- The sponsor will provide to prescribers and healthcare professional associations materials for distribution to patients that will encourage patients to discuss any questions about emergency contraception with a healthcare professional.
- The sponsor plans to educate consumers, in part by targeting consumers ages 18 to 44 to convey critical awareness and educational messages as well as

information about product availability, time sensitivity of use, and the age requirements to obtain Plan B® as a prescription or OTC product.

I conclude that the CARE℠ program is sufficiently rigorous to prevent young women from obtaining Plan B® over-the-counter without the supervision of a practitioner licensed by law to prescribe the drug. Monitoring of the program's effectiveness will allow FDA to assess whether further modifications will be necessary to prevent inappropriate use of Plan B®.

IV. Conclusion

In conclusion, I find that Barr's sNDA, as amended most recently on August 23, 2006, meets the statutory standards for approval as set forth in 21 U.S.C. 355(d).

CARE[SM]
(CONVENIENT ACCESS, RESPONSIBLE EDUCATION) PROGRAM:

THE PROPOSED MARKETING, EDUCATION, DISTRIBUTION, MONITORING PROGRAM FOR PLAN B®

Introduction

The CARE[SM] (Convenient Access, Responsible Education) Program has been carefully constructed to help ensure that Plan B® will be used responsibly and appropriately. Plan B® is being proposed as an OTC product with a prescription-only requirement for women ages 17 years and younger. The sales and marketing plan has been designed to limit the availability of Plan B®, to the extent practical, to pharmacies and clinics, and to educate healthcare professionals and consumers within the target age groups regarding the availability and responsible use of Plan B®. The need to take Plan B® in as timely a manner as possible dictates that any responsible marketing program not only address healthcare professionals but also include extensive consumer education which includes a direct access component as a means of gaining such information. Thus, the CARE[SM] program contains elements that include an appropriate consumer education component. In addition, the sponsor will work closely with retail pharmacies and drug wholesalers to ensure that they will carry Plan B®, and that they will understand and follow the prescription age requirement for the dispensing of product to women age 17 years and younger.

Data suggests that there are several critical issues currently limiting access to Plan B®:

- The prescription requirement delays timely access to Plan B®;
- Pharmacies may not routinely stock Plan B®;
- Awareness of the availability of Plan B® is lacking among healthcare professionals as well as women of childbearing age, and

- Access to accurate sources of information about the product is limited.

The CARE^{SM} program is intended to address these issues by providing sources of accurate and responsible information to both healthcare providers and consumers. It is also designed to provide a framework for pharmacies to ensure availability of Plan B® as an OTC product when sought by knowledgeable consumers who are 18 years and older. Women age 17 years and younger will require a prescription from their healthcare provider in order to obtain Plan B®. The CARE^{SM} program is not intended to impact or change, who can lawfully prescribe or dispense Plan B® under prevailing state laws.

Four core elements of CARE^{SM} contribute to the achievement of program objectives.

- Labeling/Packaging/Informational toll free number (to provide essential information to consumers in an accessible, easy to understand format. The proposed Plan B® packaging is designed to meet both prescription and OTC requirements.)
- Education (to provide information intended to educate physicians, pharmacists, pharmacy staff, nurse practitioners, and patients and to provide healthcare professionals with educational materials that they can supply to their patients to stimulate discussion. Educational initiatives will also focus on clearly instructing all audiences on the age requirement that will require women age 17 years and younger to obtain a prescription for Plan B®.)
- Distribution (to ensure, that Plan B® will be available only to licensed drug wholesalers, retail operations with pharmacy services and clinics with licensed healthcare practitioners, and to successfully facilitate the Plan B® prescription-only age requirement. These settings will also provide easy access by the consumer to a pharmacist or other healthcare professional should questions arise.)
- Monitoring (to evaluate the effectiveness of the program by determining if the age restriction is understood by all audiences and is properly being adhered to. Adjustments to the program will be made as appropriate.)

I. Labeling/Packaging

The proposed Plan B® labeling was developed to provide clear and comprehensive communication of the key messages outlined above, and to make known additional sources of information. The proposed Plan B® packaging is designed to meet all requirements of both a prescription and over-the-counter product and is consistent with that studied in the Plan B® Label Comprehension Study and the Plan B® Actual Use Study. In addition, minor changes to the packaging were made to reflect the comments from the FDA Joint Advisory Committee meeting of December 16, 2003. The proposed Plan B® packaging will allow pharmacies to appropriately dispense Plan B® as either a prescription or OTC product. The proposed package also provides educational information to the consumer in a patient friendly format.

Proposed elements of the package are as follows:

- The back of the package includes the Drug Facts as well as a space for the pharmacy to place the required prescription labeling;

- The statement, "Rx only for age 17 and younger" appears on the Principal Display Panel and "prescription only for age 17 and under" has been added to the Drug Facts panel of the package;

- The inner package houses the 2 Plan B® tablets and clearly states the steps for when to take Plan B®;

- The Plan B® Package Insert and an educational booklet designed for the consumer will be housed with the inner card;

- The toll-free number for the Plan B® 24-hour Information Line and the Plan B® web address are clearly displayed in the Drug Facts panel of the package should the consumer have additional questions on Plan B®.

II. Education

Given the very low levels of awareness of the availability of emergency contraception, the CARE^{SM} Program provides for an intensively educational approach to the introduction of Plan B® as an OTC product for those age 18 years and older. The sponsor is proposing an educational program that will initially focus on healthcare professionals but will include limited direct-to-consumer advertising designed to stimulate discussions with healthcare providers. The program will assist healthcare providers in developing an adequate knowledge base so that they can provide responsible and accurate counseling to patients.

Efforts directed to raising consumer awareness of the product and its appropriate use will follow appropriate professional education programs. The educational materials will address not only Plan B® but will encourage healthcare professionals to urge users to adopt routine forms of contraception and avoid reliance on Plan B® as their primary form of birth control.

A. Educational Program to Healthcare Professionals.

Plan B® will be introduced and explained to healthcare professionals to raise awareness and knowledge levels as to emergency contraception. Education will also clearly communicate the prescription age requirement for Plan B®. Given the current lack of understanding of emergency contraception, this program is intended to ensure that healthcare professionals are prepared to support their patient populations.

1. Physicians, physician assistants, nurse practitioners, office staff, pharmacists and pharmacy staff are the primary audiences for this educational program. Pharmacists and pharmacy staff are especially important because they will need to be prepared to answer questions at the point of purchase and follow the protocol, when appropriate, for asking customers to provide government-issued identification of their age. Additional communication will be focused on pharmacists and their staff to ensure that they are knowledgeable of the prescription requirement for women age 17 years and younger, and that they understand how to appropriately dispense the Plan B® package in both prescription and OTC scenarios. Programs will include continuing education by certified professionals and educational materials (including websites and toll free numbers) that can be accessed easily and at any time. The sponsor will make available to the state boards of pharmacy continuing education programs for use at annual meetings and other regional programs. The sponsor will also encourage state boards of pharmacy to provide information to their members regarding the availability and appropriate use of Plan B®, as well as the prescription-only requirement for women age 17 years and younger. In addition, the sponsor will work closely with retail pharmacies to ensure that they have access to appropriate training materials for their pharmacists and pharmacy staff.

2. The sponsor's sales representatives[1] will communicate the prescription requirement for women age 17 years and younger, as well as the OTC availability of Plan B® for those 18 years of age and older. The sales representatives will also provide materials targeted for patients. Physicians, physician assistants and nurse practitioners will be asked to distribute the materials to patients. Materials will encourage patients to discuss any questions they have about emergency contraception or the specific use of Plan B® with

[1] The sponsor's sales force for female healthcare products, currently consisting of approximately 230 sales representatives, visit the offices of approximately 30,000 physicians, mostly Obstetricians and Gynecologists.

their physician or the nurse practitioner. Efforts to reach healthcare professionals to reinforce these messages will continue on an ongoing basis as part of the sponsor's professional communications program. The sponsor also will work with the relevant healthcare professional associations to provide educational programming and materials to reach those healthcare providers who will not be reached personally.

3. Key messages for consumers and healthcare providers will be tested through market research, including field-testing to ensure communication objectives are met.

B. Educational Campaign to Consumers

An information campaign to consumers will commence once the healthcare professional audience has been introduced to the product. This consumer education campaign is anticipated to begin about six months following product launch.

1. The campaign will be designed to convey critical awareness and educational messages as well as information about product availability, the time sensitivity of use, and the age requirements to obtain Plan B® as a prescription or OTC product. The intent will be to make consumers aware of the availability of emergency contraception, its appropriate use and the need to use it as soon as possible. Women age 17 years and younger will be encouraged to contact their healthcare professional to learn about emergency contraception, routine forms of birth control, and sexually transmitted infection (STI)/human immunodeficiency virus (HIV).

2. The direct to consumer campaign will be designed to target those ages 18 to 44.
   i) The language and visuals used will be appropriate and of interest to this targeted age group. New promotional materials will be provided for comment to FDA during the development process and will be tested via market research

to ensure appropriate communication according to current practices.

ii) Media placements that target audiences age 17 years and younger will not be used.

III. Distribution

The sponsor believes that in the interest of responsible usage (and in recognition of the circumstances of the need for emergency contraception), Plan B® should be available in those retail pharmacy outlets that typically sell a broad range of OTC medications and that have pharmacy services staffed with pharmacists (or, in the case of clinics, other healthcare professionals) during normal business hours to answer questions. Since Plan B® will have a prescription only requirement for women age 17 years and younger, Duramed Pharmaceuticals and the third party distributors, wholesaler distribution and chain drug companies, will only be allowed to distribute Plan B® to licensed pharmacies or other licensed healthcare clinics, as it would be unlawful to distribute a prescription product to any business that does not have a valid pharmacy license and/or physician license. Duramed has been in contact with at least three of the largest wholesaler distributors in the country as well as some of the largest retail chain drug accounts that purchase Plan B® directly from Duramed. Each of the wholesaler distributors and chain drug companies confirmed that, since Plan B® has both Rx and OTC labeling, they will treat Plan B® as any other Rx product for distribution purposes; specifically, that it would only be distributed to licensed pharmacies or healthcare clinics. Therefore, Plan B® will not be available at gas stations or convenience stores. Additionally, since Plan B® has both Rx and OTC labeling, the pharmacies will keep the product behind the counter and control it as an Rx product. The pharmacy and clinic settings will also allow pharmacists and other healthcare providers to properly restrict OTC access to those age 18 years and older.

IV. Monitoring

The sponsor intends to monitor trends in the use of emergency contraception to evaluate the effectiveness of the CARE℠ program and will make adjustments as appropriate. Monitoring will be accomplished in several ways, with information gathered from both healthcare professionals and consumers.

Monitoring actual use of Plan B® is complex due to the difficulties inherent in identifying those who have purchased the product and in gathering useful, generalizable information. Consequently, the monitoring component will rely on a variety of sources intended to provide trend data, observational data, and signals of program effectiveness and potential problems. Monitoring components will include the following:

1. A market research survey or surveys of a subset of healthcare professionals (e.g. OB/GYN, family practice, pharmacists, nurses, family planning and health clinic personnel) annually, and when practicable, in collaboration with established professional groups e.g., National Association of Boards of Pharmacy (NABP), College of Obstetricians and Gynecologists (ACOG), American College Health Association (ACHA), National Association of Chain Drug Store (NACDS), Consumer Healthcare Products Association (CHPA), Healthcare Distribution Management Association (HDMA) to determine:

    - Whether the prescription requirement for women ages 17 and younger is understood and is being adhered to at the point of purchase
    - Attitudes toward and experience with patients' usage of Plan B®
    - Trends among emergency contraception users within their patient population (especially source of awareness, repeat use, use instead of more effective forms of contraception, incidence of STIs, etc.)

- Nature of interactions with Plan B® users (Does the contact with the healthcare professional occur prior to product usage? after usage? Are the women in search of contraceptive counseling? What types of side effects are being seen in use?)
- Areas where additional information is needed in the marketplace, as identified by the questions raised by the users

2. Using relevant survey data regularly collected by others (e.g. Centers for Disease Control's Behavioral Risk Factor Safety Surveillance (CDC BRFSS), Youth Risk Behavior Safety Surveillance (YRBSS), Foundations and Nongovernmental Organizations (NGO) surveys) the sponsor will monitor for potential indicators that Plan B® is being used in an inappropriate manner. Where existing surveys do not include relevant data, the sponsor may seek inclusion of appropriate questions. Potential areas of monitoring and reporting include:
   - Data and trends in STIs based on geographic areas;
   - Data and trends in pregnancy and/or abortion rates based on geographic areas;
   - The sponsor recognizes that the use of these sources may not give timely enough data to evaluate the CARE℠ program in the first few months of marketing. However, the commitment to monitoring extends beyond the initial stages of product introduction, and working with data sources to enhance collection of data relevant to use of Plan B® will be ongoing.
3. Gathering data from actual users of Plan B® is difficult because the number of users will be relatively small and because the decision to use emergency contraception is a private and emotional one. Women choosing to use the product are expected to wish to remain anonymous and are entitled to maintain their privacy. Nevertheless, the sponsor will work with a variety of sources in an effort to obtain and analyze consumer data in accordance with HIPAA

regulations to assess the effectiveness of the CARE^{SM} program elements.

The sponsor proposes to provide FDA a monitoring report with the available results from the above monitoring activities on a six-month interval, with submission of the report within 30 calendar days after the six-month interval date, commencing on the date of the approval ofboth the Rx and OTC versions of Plan B®.

V. Monitoring Compliance with the Prescription Age Requirement

Monitoring compliance of the Plan B® Prescription age requirement can be somewhat complex because there will be no documented information on the purchasers of Plan B® who were old enough to obtain it as an OTC product. The Sponsor intends to monitor the level of comprehension of the Prescription age requirement particularly at the pharmacy level, where the age of consumers must be assessed at the point of purchase. The following program will provide accurate information directly related to accessing compliance:

- Point of Purchase Monitoring Program:

  The Sponsor will conduct a "Point-of-Purchase Monitoring Program", which intends to track how Plan B® is being sold at the time of purchase. Due to the challenges of obtaining specific purchase data on an OTC product and respecting consumer privacy, this program will include anonymous shoppers who will be directed to visit locations where Plan B® is available and purchase the product. These transactions will be documented and analyzed to determine the level of comprehension of the Plan B® prescription age requirement and how it is handled at the point of purchase. The shoppers in this program will be 15 to 18 years old. Parental consent will be obtained for shoppers under the age of 18 years. Locations for this program will be selected based on areas where Plan B® use is high, and will be in different regions of the US to provide a national representation of the findings. These findings would provide concrete

information on how the prescription age requirement for Plan B® is being addressed at the pharmacy and if it is properly being followed. The Sponsor will use these findings to identify areas where more education on the prescription age restriction is needed and will focus their efforts on improving the level of understanding among pharmacists and the pharmacy staff. Findings from the study will be communicated to the pharmacy, and the corporate office, if appropriate, since education and retraining will be the first course of remedial action. In the case of repeat violators, the violator's State Board of Pharmacy will be notified. Results of this point of purchase program will be provided to FDA as part of the 6-month report (see Section IV – Monitoring). The Point-of-Purchase Monitoring Program will be conducted twice in the first year (6 months after product launch and 12 months after product launch). This time period will allow the Sponsor to compare findings and identify areas where improvement was made and whether additional education is needed. The program will be conducted annually after the first year.

State of California | Department of Consumer Affairs

Memorandum

To: **Enforcement Committee** **Date: September 19, 2006**

From: **Board of Pharmacy – Virginia Herold**

Subject: **Work Group on E-Pedigree**

In March 2006, the board held its first Work Group on E-Pedigree Meeting, in conjunction with the Enforcement Committee Meeting.

This is the third of these quarterly meetings to discuss and resolve issues arising from implementation of the electronic pedigree requirements for prescription drugs.

At this meeting, Board Supervising Inspector Judi Nurse will provide a Power Point presentation of provisions in SB 1476 (Figueroa), which was enrolled at the end of August. The Governor has until September 30 to sign, veto or let SB 1476 become law without his signature.

In SB 1476, there are a number of provisions proposed modify the pedigree requirements initially enacted in 2004 by SB 1307. Perhaps the most significant would be a delay until 2009 of the pedigree requirements, unless the board acts to delay implementation until 2011. Dr. Nurse will provide an overview of these changes in her presentation.

Additionally, Bob Celeste of EPCglobal will provide a presentation of where EPCglobal is with respect to its standards setting project, and the next steps in EPCglobal's work.

Board staff is working to revise the online questions and answers on implementation of the e-pedigree requirements, which may not be available in time for this meeting, pending the Governor's action on SB 1476.

Time is also built into the agenda so that drug wholesalers, manufacturers and pharmacies can discuss implementation progress and issues to the board members present at this meeting.

Senate Bill No. 1476

Passed the Senate August 31, 2006

_____

Secretary of the Senate

Passed the Assembly August 31, 2006

_____

Chief Clerk of the Assembly

This bill was received by the Governor this _____ day of _____, 2006, at _____ o'clock ____M.

_____

Private Secretary of the Governor

CHAPTER _____

An act to amend Sections 30, 101, 205, 473.15, 1601.1, 1616.5, 1742, 1770, 2460, 2570.4, 2570.19, 2602, 2668, 2701, 2708, 2920, 2933, 3010.5, 3014.6, 3504, 3512, 3516.1, 3685, 3710, 3716, 3765, 4001, 4003, 4034, 4162, 4162.5, 4163.5, 4169, 4200.1, 4800, 4804.5, 4928, 4934, 5510, 5517, 5620, 5621, 5622, 5810, 5811, 6704, 6710, 6712, 6714, 6716, 6726.2, 6730, 6732.3, 6738, 6740, 6750, 6753, 6754, 6787, 7000.5, 7011, 7200, 7215.6, 7810, 7815.5, 8000, 8710, 8729, 8740, 8745, and 22251 of, to amend and repeal Sections 1760, 1760.5, 1761, 1762, 1763, 1764, 1765, 1766, 1768, 1769, 1772, 1774, 1775, and 4163 of, to amend, repeal, and add Sections 1621, 1670.1, 1680, 1721, 1721.5, 1741, 1742.1, 1743, 1744, 1771, 4999.2, and 4999.7 of, to add Sections 1900.5, 2660.5, 4163.1, 6732.5, and 6746.1 to, and to repeal Section 4163.6 of, the Business and Professions Code, to amend, repeal, and add Section 44876 of the Education Code, and to amend, repeal, and add Sections 1348.8 and 128160 of the Health and Safety Code, relating to professions and vocations, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 1476, Figueroa. Professions and vocations.

(1) Existing law regulates various professions and vocations by various boards within the Department of Consumer Affairs. Existing law requires those boards, and the State Bar of California and the Department of Real Estate, to require a licensee, at the time of issuance or renewal of a license, to provide the licensee's federal employer identification number, if the licensee is a partnership, or his or her social security number.

This bill would instead impose that requirement only when a license is issued.

(2) Existing law provides for the licensing and regulation of dentists by the Dental Board of California, and authorizes the board to appoint an executive officer. These provisions will become inoperative on July 1, 2008, and will be repealed on January 1, 2009.

(d) The performance of respiratory care in an emergency situation by paramedical personnel who have been formally trained in these modalities and are duly licensed under the provisions of an act pertaining to their speciality.

(e) Respiratory care services in case of an emergency. "Emergency," as used in this subdivision, includes an epidemic or public disaster.

(f) Persons from engaging in cardiopulmonary research.

(g) Formally trained licensees and staff of child day care facilities from administering to a child inhaled medication as defined in Section 1596.798 of the Health and Safety Code.

(h) The performance by a person employed by a home medical device retail facility or by a home health agency licensed by the State Department of Health Services of specific, limited, and basic respiratory care or respiratory care related services that have been authorized by the board.

SEC. 61. Section 4001 of the Business and Professions Code is amended to read:

4001. (a) There is in the Department of Consumer Affairs a California State Board of Pharmacy in which the administration and enforcement of this chapter is vested. The board consists of 13 members.

(b) The Governor shall appoint seven competent pharmacists who reside in different parts of the state to serve as members of the board. The Governor shall appoint four public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600.

(c) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall include at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. For the purposes of this subdivision, a "chain community pharmacy" means a chain of 75 or more stores in California under the same

ownership, and an "independent community pharmacy" means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.

(d) Members of the board shall be appointed for a term of four years. No person shall serve as a member of the board for more than two consecutive terms. Each member shall hold office until the appointment and qualification of his or her successor or until one year shall have elapsed since the expiration of the term for which the member was appointed, whichever first occurs. Vacancies occurring shall be filled by appointment for the unexpired term.

(e) Each member of the board shall receive a per diem and expenses as provided in Section 103.

(f) In accordance with Sections 101.1 and 473.1, this section shall become inoperative on July 1, 2010, and, as of January 1, 2011, is repealed, unless a later enacted statute, that becomes effective on or before January 1, 2011, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 62. Section 4003 of the Business and Professions Code is amended to read:

4003. (a) The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter. The executive officer may or may not be a member of the board as the board may determine.

(b) The executive officer shall receive the compensation as established by the board with the approval of the Director of Finance. The executive officer shall also be entitled to travel and other expenses necessary in the performance of his or her duties.

(c) The executive officer shall maintain and update in a timely fashion records containing the names, titles, qualifications, and places of business of all persons subject to this chapter.

(d) The executive officer shall give receipts for all money received by him or her and pay it to the Department of Consumer Affairs, taking its receipt therefor. Besides the duties required by this chapter, the executive officer shall perform other duties

pertaining to the office as may be required of him or her by the board.

(e) In accordance with Sections 101.1 and 473.1, this section shall become inoperative on July 1, 2010, and, as of January 1, 2011, is repealed, unless a later enacted statute, that becomes effective on or before January 1, 2011, deletes or extends the dates on which it becomes inoperative and is repealed.

SEC. 63. Section 4034 of the Business and Professions Code is amended to read:

4034. (a) "Pedigree" means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. The pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution.

(b) A pedigree shall include all of the following information:

(1) The source of the dangerous drug, including the name, the federal manufacturer's registration number or a state license number as determined by the board, and principal address of the source.

(2) The trade or generic name of the drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

(3) The business name, address, and the federal manufacturer's registration number or a state license number as determined by the board, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.

(4) A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.

(c) A single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging

or assignment of another National Drug Code (NDC) Directory number.

(d) A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler, and received by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug.

(e) Any return of a dangerous drug to a wholesaler or manufacturer shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the party returning it.

(f) If a licensed health care service plan, hospital organization, and one or more physician organizations have exclusive contractual relationships to provide health care services, drugs distributed between these persons shall be deemed not to have changed ownership.

(g) The following transactions are not required to be recorded on a pedigree:

(1) The provision of samples of dangerous drugs by a manufacturer's employee to an authorized prescriber, provided the samples are dispensed to a patient of the prescriber without charge.

(2) An injectable dangerous drug that is delivered by the manufacturer directly to an authorized prescriber or other entity directly responsible for administration of the injectable dangerous drug, only for an injectable dangerous drug that by law may only be administered under the professional supervision of the prescriber or other entity directly responsible for administration of the drug. Injectable dangerous drugs exempted from the pedigree requirement by this paragraph may not be dispensed to a patient or a patient's agent for self-administration, and shall only be administered to the patient, as defined in Section 4016, by the prescriber or other authorized entity that received the drug directly from the manufacturer.

(3) The exemption in paragraph (2) shall expire and be inoperative on January 1, 2010, unless prior to that date the board receives, at a public hearing, evidence that entities involved in the distribution of the injectable dangerous drugs subject to that paragraph are not able to provide a pedigree in compliance with all of the provisions of California law, and the board votes to

extend the expiration date for the exemption until January 1, 2011. The decision as to whether to extend the expiration date shall be within the sole discretion of the board, and shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of the Government Code.

(h) If a manufacturer, wholesaler, or pharmacy has reasonable cause to believe that a dangerous drug in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler, or pharmacy shall notify the board within 72 hours of obtaining that knowledge. This subdivision shall apply to any dangerous drug that has been sold or distributed in or through this state.

(i) "Interoperable electronic system" as used in this chapter means an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree of a dangerous drug.

(j) The application of the pedigree requirement in pharmacies shall be subject to review during the board's sunset review to be conducted as described in subdivision (f) of Section 4001.

(k) This section shall become operative on January 1, 2009. However, the board may extend the date for compliance with this section and Section 4163 until January 1, 2011, in accordance with Section 4163.5.

SEC. 64. Section 4162 of the Business and Professions Code is amended to read:

4162. (a) (1) An applicant for the issuance or renewal of a wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars ($100,000) if the annual gross receipts of the previous tax year for the wholesaler is ten million dollars ($10,000,000) or less, in which

case the surety bond shall be twenty-five thousand dollars ($25,000).

(3) A person to whom an approved new drug application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application, and is licensed or applies for licensure as a wholesaler, shall not be required to post a surety bond as provided in paragraph (1).

(4) For licensees subject to paragraph (2) or (3), the board may require a bond up to one hundred thousand dollars ($100,000) for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days after the order imposing the fine, or costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

(d) This section shall become operative on January 1, 2006, and shall remain in effect only until January 1, 2015, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2015, deletes or extends those dates.

SEC. 65. Section 4162.5 of the Business and Professions Code is amended to read:

4162.5. (a) (1) An applicant for the issuance or renewal of a nonresident wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000), or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purpose of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars ($100,000) if the annual gross receipts of the previous tax year for the nonresident wholesaler is ten million dollars ($10,000,000) or

less in which the surety bond shall be twenty-five thousand dollars ($25,000).

(3) For applicants who satisfy paragraph (2), the board may require a bond up to one hundred thousand dollars ($100,000) for any nonresident wholesaler who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(4) A person to whom an approved new drug application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application, and is licensed or applies for licensure as a nonresident wholesaler, shall not be required to post a surety bond as provided in this section.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

(d) This section shall become operative on January 1, 2006, and shall become inoperative and is repealed on, January 1, 2015, unless a later enacted statute, that is enacted before January 1, 2015, deletes or extends those dates.

SEC. 66. Section 4163 of the Business and Professions Code, as amended by Section 31 of Chapter 857 of the Statutes of 2004, is repealed.

SEC. 67. Section 4163 of the Business and Professions Code, as added by Section 32 of Chapter 857 of the Statutes of 2004, is amended to read:

4163. (a) A manufacturer or wholesaler may not furnish a dangerous drug or dangerous device to an unauthorized person.

(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. When the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

(c) Except as otherwise provided in Section 4163.5, commencing on January 1, 2009, a wholesaler or pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

(d) Except as otherwise provided in Section 4163.5, commencing on January 1, 2009, a wholesaler or pharmacy may not acquire a dangerous drug without receiving a pedigree.

SEC. 68. Section 4163.1 is added to the Business and Professions Code, to read:

4163.1. It is the intent of the Legislature that commencing on January 1, 2007, and continuing through the full implementation of the pedigree requirements specified by Section 4163, manufacturers and wholesalers shall use best efforts to provide in the most readily accessible form possible, information regarding the manufacturer's specific relationships in the distribution of dangerous drugs with wholesalers.

SEC. 69. Section 4163.5 of the Business and Professions Code is amended to read:

4163.5. The board may extend the date for compliance with the requirement for a pedigree set forth in Sections 4034 and 4163 until January 1, 2011, if it determines that manufacturers or wholesalers require additional time to implement electronic technologies to track the distribution of dangerous drugs within the state. A determination by the board to extend the deadline for providing pedigrees shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

SEC. 70. Section 4163.6 of the Business and Professions Code is repealed.

SEC. 71. Section 4169 of the Business and Professions Code, as added by Section 39 of Chapter 857 of the Statutes of 2004, is amended to read:

4169. (a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy, in violation of Section 4163.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of

Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Health Services.

(e) This section shall remain in effect only until January 1, 2008, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2008, deletes or extends that date.

SEC. 72. Section 4169 of the Business and Professions Code, as added by Section 40 of Chapter 857 of the Statutes of 2004, is amended to read:

4169. (a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other provision of law, a violation of this section or of subdivision (c) or (d) of Section 4163 may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Health Services.

(e) This section shall become operative on January 1, 2008.

SEC. 73. Section 4200.1 of the Business and Professions Code is amended to read:

4200.1. (a) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination four times, and may take the Multi-State Pharmacy Jurisprudence Examination for California four times.

(b) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California four additional times each if he or she successfully completes, at minimum, 16 additional semester units of education in pharmacy as approved by the board.

(c) The applicant shall comply with the requirements of Section 4200 for each application for reexamination made pursuant to subdivision (b).

(d) An applicant may use the same coursework to satisfy the additional educational requirement for each examination under subdivision (b), if the coursework was completed within 12 months of the date of his or her application for reexamination.

(e) For purposes of this section, the board shall treat each failing score on the pharmacist licensure examination administered by the board prior to January 1, 2004, as a failing score on both the North American Pharmacist Licensure

Examination and the Multi-State Pharmacy Jurisprudence Examination for California.

(f) From January 1, 2004, to July 1, 2008, inclusive, the board shall collect data on the applicants who are admitted to, and take, the licensure examinations required by Section 4200. The board shall report to the Joint Committee on Boards, Commissions, and Consumer Protection before September 1, 2008, regarding the impact on those applicants of the examination limitations imposed by this section. The report shall include, but not be limited to, the following information:

(1) The number of applicants taking the examination and the number who fail the examination for the fourth time.

(2) The number of applicants who, after failing the examination for the fourth time, complete a pharmacy studies program in California or another state to satisfy the requirements of this section and who apply to take the licensure examination required by Section 4200.

(3) To the extent possible, the school from which the applicant graduated and the school's location and the pass/fail rates on the examination for each school.

(g) This section shall remain in effect only until January 1, 2010, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2010, deletes or extends that date.

SEC. 74. Section 4800 of the Business and Professions Code is amended to read:

4800. There is in the Department of Consumer Affairs a Veterinary Medical Board in which the administration of this chapter is vested. The board consists of seven members, three of whom shall be public members.

This section shall become inoperative on July 1, 2011, and, as of January 1, 2012, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 2012, deletes or extends the dates on which it becomes inoperative and is repealed.

The repeal of this section renders the board subject to the review provided for by Division 1.2 (commencing with Section 473).

SEC. 75. Section 4804.5 of the Business and Professions Code is amended to read: