13:35-6.7 Minimum standards for the performance of new or novel procedures in the office setting
13:35-6.8 Prescribing, administering or dispensing amygdalin (laetrile)
13:35-6.9 Referral for radiological services
13:35-6.10 Advertising and solicitation practices
13:35-6.11 Excessive fees
13:35-6.12 (Reserved)
13:35-6.13 Fee schedule
13:35-6.14 Delegation of physical modalities to a licensed health care provider or an unlicensed physician aide
13:35-6.15 Continuing medical education
13:35-6.16 Professional practice structure
13:35-6.17 Professional fees and investments, prohibition of kickbacks
13:35-6.18 Medical malpractice coverage; letter of credit
13:35-6.19 Duty to report changes in status
13:35-6.20 Physician delegation of tasks to radiologic technologists and nuclear medicine technologists
13:35-6.21 Hair replacement techniques
13:35-6.22 Termination of licensee-patient relationship
13:35-6.23 Presence of chaperones
13:35-6.24 Reporting of communicable diseases by licensees
13:35-6.25 Cultural competency training
13:35-6.26 Procedures for physician ordered immunizations performed by licensed pharmacists
13:35-6.27 Standards for collaborative practice for drug therapy management with licensed pharmacists

SUBCHAPTER 6A. DECLARATIONS OF DEATH UPON THE BASIS OF NEUROLOGICAL CRITERIA

13:35-6A.1 Purpose
13:35-6A.2 Definitions
13:35-6A.3 Requirements for physicians authorized to declare death on the basis of neurological criteria
13:35-6A.4 Standards for declaration of brain death
13:35-6A.5 Organ donation
13:35-6A.6 Exemption to accommodate personal religious beliefs
13:35-6A.7 Pronouncement of death

SUBCHAPTER 7. PRESCRIPTION, ADMINISTRATION AND DISPENSING OF DRUGS

13:35-7.1 Definitions
13:35-7.1A Examination of patient's condition required prior to dispensing drugs or issuing a prescription; exceptions
13:35-7.2 Requirements for issuing written prescriptions for medicines
13:35-7.3 Verbal prescriptions (Reserved)
13:35-7.4 Facsimile transmitted prescriptions
13:35-7.4A Electronically transmitted prescriptions
13:35-7.5 Requirements for the dispensing of drugs and special limitations applicable to the dispensing of drugs for a fee
13:35-7.5A Limitations on prescribing, administering or dispensing of drugs for the treatment of obesity
13:35-7.6 Limitations on prescribing, administering or dispensing of controlled substances; special exceptions for management of pain
13:35-7.7 Prohibitions on prescribing, administering or dispensing of controlled substances for detoxification; limited exceptions
13:35-7.8 Prohibitions and limitations in the prescribing, administering or dispensing of amphetamines and sympathomimetic amines
13:35-7.9 Prohibitions and special limitations on prescribing, administering, or dispensing anabolic steroids and human growth hormone or its similar analogs
13:35-7.10 Enforcement

SUBCHAPTER 7A. COMPASSIONATE USE MEDICAL MARIJUANA

13:35-7A.1 Purpose and scope
13:35-7A.2 Definitions
13:35-7A.3 Requirement for physician participation
13:35-7A.4 Certification requirements
13:35-7A.5 Written instruction requirements; reassessment; records
13:35-7A.6 Duty to report information to the Division

SUBCHAPTER 8. HEARING AID DISPENSERS

13:35-8.1 Purpose
13:35-8.2 Definitions
13:35-8.3 Training and experience requirements
13:35-8.4 Training permits; issuance and practice
13:35-8.5 Temporary licenses; issuance
13:35-8.6 Temporary licenses; practice
13:35-8.7 Sponsors
13:35-8.8 Scope of practice
13:35-8.9 Fitting and dispensing of deep ear canal hearing aid devices
13:35-8.10 Supervising licensee
13:35-8.11 Notification to the Committee; biennial license renewal; license suspension; reinstatement of suspended license; inactive status; return from inactive status
13:35-8.12 Equipment
13:35-8.13 Hearing testing
13:35-8.14 Advertising and Solicitation
13:35-8.15 Abandonment; excessive fees
13:35-8.16 Itemization of services and equipment; retention of records
13:35-8.17 Licensing examination
13:35-8.18 Violation of the Rules
13:35-8.19 Fee schedule
13:35-8.20 License renewal; continuing education requirement

SUBCHAPTER 9. ACUPUNCTURE

13:35-9.1 Purpose and scope
13:35-9.2 Definitions
13:35-9.3 Credentials required for certification
13:35-9.4 Education required for licensure
13:35-9.5 New Jersey acupuncture safety and jurisprudence examination
13:35-9.6 (Reserved)
13:35-9.7 Prohibited titles
13:35-9.8 Fee schedule
13:35-9.9 Biennial license renewal; license suspension; reinstatement of suspended license; inactive status; return from inactive status
13:35-9.10 Display of license
13:35-9.11 Informed consent; medical malpractice
13:35-9.12 Scope of practice
13:35-9.12A Herbology
13:35-9.13 Guest acupuncturist
13:35-9.14 Unlicensed practice of acupuncture
13:35-9.15 Precautionary and sterilization procedures
13:35-9.16 Preparation of patient records; computerized records; access to or release of information; confidentiality, transfer or disposal of records
13:35-9.17 through 13:35-9.19 (Reserved)
13:35-9.20 Continuing professional education requirements

APPENDIX A. (RESERVED)

SUBCHAPTER 10. ATHLETIC TRAINERS

13:35-10.1 Scope and purpose
13:35-10.2 Definitions
13:35-10.3 Application for licensure

13:35-10.4 Licensure; biennial license renewal; license suspension; reinstatement of suspended license; inactive status; return from inactive status
13:35-10.5 Plan of care guidelines
13:35-10.6 Practice outside of schools and professional teams
13:35-10.7 Scope of practice
13:35-10.8 Records
13:35-10.9 Use of personal or other computer to prepare records
13:35-10.10 Release of records
13:35-10.11 Advertising and solicitation practices
13:35-10.12 Advertising free or discounted services; required disclosures
13:35-10.13 Testimonial advertising
13:35-10.14 Minimum content
13:35-10.15 Advertising by a business entity offering athletic training
13:35-10.16 Advertising record retention
13:35-10.17 Use of professional credentials and certifications
13:35-10.18 Violations
13:35-10.19 Fees
13:35-10.20 Sexual misconduct

SUBCHAPTER 11. ALTERNATIVE RESOLUTION PROGRAM

13:35-11.1 Definitions
13:35-11.2 Creation of Impairment Review Committee
13:35-11.3 Duties of an approved professional assistance program
13:35-11.4 Duties of the Impairment Review Committee
13:35-11.5 Professional assistance program: approval and discontinuance
13:35-11.6 Colleague referrals
13:35-11.7 (Reserved)

SUBCHAPTER 12. ELECTROLOGISTS ADVISORY COMMITTEE; LICENSURE OF ELECTROLOGISTS AND ELECTROLOGY INSTRUCTORS; ELECTROLOGY STANDARDS OF PRACTICE

13:35-12.1 Purpose and scope
13:35-12.2 Definitions
13:35-12.3 Office of the Committee
13:35-12.4 Notification of change of address
13:35-12.5 (Reserved)
13:35-12.6 Licensing requirements for electrologist
13:35-12.7 Licensing requirements for electrology instructor
13:35-12.8 Application for license: electrologist
13:35-12.9 Application for license: electrology instructor
13:35-12.10 Licensing requirements for office premises
13:35-12.11 Infection control standards
13:35-12.12 Posting of licenses and required notices
13:35-12.13 Examination requirements; reexamination
13:35-12.14 License issuance, renewal; change of license status: inactive to active; reinstatement of suspended license
13:35-12.15 Unlicensed practice
13:35-12.16 Licensure by credentials (comity license)
13:35-12.17 Suspension, revocation or refusal to renew license
13:35-12.18 Recordkeeping
13:35-12.19 Continuing education, programs, standards
13:35-12.20 Sexual misconduct
13:35-12.21 Advertising and solicitation practices
13:35-12.22 Fee schedule

SUBCHAPTER 13. PERFUSIONISTS ADVISORY COMMITTEE

13:35-13.1 Purpose and scope
13:35-13.2 Definitions
13:35-13.3 Office of the Committee
13:35-13.4 Notification of change of address and record
13:35-13.5 Licensure under grandfathering
13:35-13.6 Licensing requirements for perfusionist
13:35-13.7 Grace period for practicing without licensure pending application
13:35-13.8 Licensure by reciprocity
13:35-13.9 License required for designation as perfusionist
13:35-13.10 Temporary license; supervision
13:35-13.11 License renewal
13:35-13.12 Change of license status: inactive to active
13:35-13.13 Reinstatement of suspended license
13:35-13.14 Duty to report change in status
13:35-13.15 Suspension, revocation or refusal to renew license
13:35-13.16 Continuing education
13:35-13.17 Fee schedule

SUBCHAPTER 14. GENETIC COUNSELING ADVISORY COMMITTEE

13:35-14.1 Purpose and scope
13:35-14.2 Definitions
13:35-14.3 Application for licensure
13:35-14.4 Practice prior to passing the examination for licensure
13:35-14.5 Out-of-State genetic counselor
13:35-14.6 Renewal of license
13:35-14.7 Continuing education
13:35-14.8 Scope of practice
13:35-14.9 Sexual misconduct
13:35-14.10 Change in address of record or name
13:35-14.11 Advertising and solicitation practices
13:35-14.12 Advertising free or discounted services; required disclosures
13:35-14.13 Testimonial advertising
13:35-14.14 Minimum content
13:35-14.15 Recordkeeping
13:35-14.16 Client access to records
13:35-14.17 Confidentiality
13:35-14.18 Fee schedule

SUBCHAPTER 1. MEDICAL SCHOOLS, COLLEGES, EXTERNSHIPS AND CLERKSHIPS

13:35-1.1 Observership program

(a) "Observer" shall mean an undergraduate medical student of an allopathic or osteopathic school accredited either by the Liaison Committee on Medical Education or the American Osteopathic Association or a foreign medical school listed in either the World Health Organization Directory published by the World Health Organization or the International Medical Education Directory (IMED) published by the Educational Commission for Foreign Medical Graduates (ECFMG) and whose graduates are accepted by the New Jersey Board of Medical Examiners as eligible to sit for the licensure examination. Observerships are limited to the student's vacation period in an extra-curricular professional experience as delineated in this section.

(b) An observership program shall be limited to:

1. Observation of operative procedures;

2. The taking of histories;

3. The performance of physical examinations;

4. The performance of non-invasive procedures under the direct supervision of and in the immediate presence of the supervising licensed physician; and

13:35-2A.13 Well woman care

(a) A certified nurse midwife or certified midwife may provide well woman care throughout the life cycle which shall include:

1. Gynecological and primary health care screening, assessment and treatment; and

2. Contraceptive services.

New Rule, R.2003 d.210, effective May 19, 2003.
See: 34 N.J.R. 3433(a), 35 N.J.R. 2227(a).

13:35-2A.14 Prescriptive authorization

(a) A CNM who is licensed with the Board of Medical Examiners may apply for authorization to prescribe drugs (as used within this section, the term "drugs" shall include drugs, medicine and devices). The CNM shall make application on forms prescribed by the Board and shall demonstrate:

1. Current registration with the Board;

2. A.C.N.M. or A.C.C. certification in good standing; and

3. Evidence of satisfactory completion of a minimum of 30 contact hours in pharmacology, which included instruction in fundamentals of pharmacology and therapeutics, including principles and terminology of pharmacodynamics and pharmaco-kinetics, which was either:

i. Part of the midwifery program the CNM completed pursuant to N.J.A.C. 13:35-2A.4(a)3; or

ii. A pharmacology course offered by, or affiliated with, a college or university accredited by an accrediting association recognized by the U.S. Department of Education.

(b) If the 30 contact hours in pharmacology required pursuant to (a)3 above was included as part of the midwifery program the CNM completed pursuant to N.J.A.C. 13:35-2A.4(a)3, the CNM shall have graduated from the midwifery program within the two years immediately preceding the date on which the application for prescriptive authority is made.

(c) If the 30 contact hours in pharmacology required pursuant to (a)3 above was not part of the midwifery program the CNM completed pursuant to N.J.A.C. 13:35-2A.4(a)3, the CNM shall have completed the pharmacology course within the two years immediately preceding the date on which the application for prescriptive authority is filed.

(d) Notwithstanding (a), (b) and (c) above, a CNM who holds prescriptive authorization in another state shall be authorized to prescribe drugs in New Jersey, if the CNM submits proof to the Committee that he or she:

1. Holds current prescriptive authorization, without disciplinary restrictions, in another state; and

2. Has completed 30 contact hours in pharmacology, which meets the requirements of (a)3 above.

(e) Notwithstanding (a), (b) and (c) above, a CNM who also holds certification as an advanced practice nurse from the New Jersey Board of Nursing shall be authorized to prescribe drugs pursuant to N.J.S.A. 45:10-17 et seq., if the CNM submits proof to the Committee that he or she:

1. Holds current, unencumbered certification as an advanced practice nurse from the New Jersey Board of Nursing; and

2. Has completed 30 contact hours in pharmacology, which meets the requirements of (a)3 above.

(f) A CNM who is authorized to prescribe drugs may prescribe only those drugs which are categorized in the formulary of drugs established in the clinical guidelines.

(g) A CNM's authorization to prescribe drugs, medicine, or devices may, upon notice and an opportunity for a hearing pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq., be revoked or otherwise limited by the Board if the CNM:

1. Fails to maintain current licensure and registration with the Board;

2. Fails to maintain certification in good standing with the ACNM or ACC, or their successors;

3. Uses prescriptive authorization for other than therapeutic purposes; or

4. Uses prescriptive authorization to prescribe substances or devices not included in the formulary of drugs established in the CNM's clinical guidelines.

(h) Prescriptions written by a CNM shall conform to the dictates of N.J.S.A. 45:14-14 et seq. and N.J.A.C. 13:35-7.2.

Recodified from N.J.A.C. 13:35-2A.11 and amended by R.2003 d.210, effective May 19, 2003.
See: 34 N.J.R. 3433(a), 35 N.J.R. 2227(a).
Rewrote the section.
Amended by R.2010 d.099, effective June 21, 2010.
See: 41 N.J.R. 2204(a), 42 N.J.R. 1214(a).
In the introductory paragraph of (a), substituted "licensed" for "currently registered"; rewrote the introductory paragraph of (a)3; added (a)3i and (a)3ii; added new (b) and (c); recodified former (b) as (d); deleted former (b)2 and (b)3; rewrote the introductory paragraph of (d); in (d)1, inserted "and" at the end; recodified former (b)4 as (d)2; rewrote (d)2; added new (e); and recodified former (c) through (e) as (f) through (h).

13:35-2A.15 Limited ultrasound examination

(a) A licensee who has completed a course as required in (b) below may perform a limited ultrasound examination. For purposes of this section, "limited ultrasound" shall mean the use of ultrasound to assess any of the following: fetal number, fetal cardiac activity, fetal position and presentation, placental location, amniotic fluid parameters, biophysical profile parameters, uterine position, uterine size, the number and size

of early gestational sac and the presence and length of embryonic poles.

(b) A licensee who wishes to perform limited ultrasound shall complete a 12-hour course given by a college or university accredited by an accrediting association recognized by the U.S. Department of Education or an organization which grants ACNM, American College of Obstetrics and Gynecology (ACOG), American Osteopathic Association (AOA) or American Medical Association-Physicians Recognition Award (AMA-PRA) category one continuing education credits.

(c) Limited ultrasound course instruction shall include:

1. Ultrasound instrumentation;

2. Accountability of the licensee;

3. Components of informed consent;

4. Principles of anatomy and physiology relevant to limited ultrasound examinations;

5. Elements of antepartum and intrapartum fetal surveillance;

6. Components of ultrasound examination:

i. Fetal number;

ii. Fetal cardiac activity;

iii. Fetal position and presentation;

iv. Placental location;

5. The supervisory ratio shall be no more than four physician assistants to one physician at any one time.

(c) Upon application to the Board, the Board may alter the supervisory ratios set forth in (b) above.

(d) A supervising physician may assign physician assistants under his or her supervision to a physician designee, who shall be responsible for the practice of the physician assistant during the assignment.

Amended by R.2000 d.349, effective August 21, 2000.
See: 31 N.J.R. 2132(a), 32 N.J.R. 3174(a).
In (b)4ii, inserted an exception.
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
In (b), inserted "or physician designee" following "The supervising physician' in the introductory paragraph of 4; rewrote (d).
Petition for Rulemaking.
See: 42 N.J.R. 859(b), 1255(d), 2150(c).
Amended by R.2011 d.185, effective July 5, 2011.
See: 42 N.J.R. 2001(a), 43 N.J.R. 1539(b).
Rewrote (b)5.

13:35-2B.11 Recordkeeping

(a) Licensees shall make contemporaneous, permanent entries into professional treatment records which shall accurately reflect the treatment or services rendered. To the extent applicable, professional treatment records shall reflect:

1. The dates and times of all treatments;

2. The patient complaint;

3. The history;

4. Findings on appropriate examination;

5. Any orders for tests or consultations and the results thereof;

6. Diagnosis or medical impression; and

7. Treatment ordered. If medications are ordered, the patient record shall include:

i. Specific dosages, quantities and strengths of medications;

ii. A statement indicating whether the medication order is written pursuant to protocol or specific physician direction. Acceptable abbreviations are "prt" for protocol and "spd" for specific physician direction;

iii. The physician assistant's full name, printed or stamped, and the license number; and

iv. The supervising physician's full name, printed or stamped.

(b) If the information required pursuant to (a)8iii and iv appears at least once in the patient record, it need not be repeated each time a medication order is entered in the patient record.

(c) The physician assistant shall sign each entry in the patient record and record the designation "PA-C" following his or her signature.

(d) To the extent a physician assistant is charged with independent responsibility for the provision of information used to prepare bills and claims forms, such information shall accurately reflect the treatment or services rendered.

Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
In (a), deleted former 5 and recodified former 6 through 8 as 5 through 7.

13:35-2B.12 Requirements for issuing prescriptions for medications; special requirements for issuance of CDS

(a) A physician assistant may issue prescriptions for medications only in accordance with the requirements contained in this section.

(b) A physician assistant shall provide the following on all prescription blanks:

1. The physician assistant's full name, professional identification ("PA-C"), license number, address and telephone number. This information shall be printed on all prescription blanks;

2. The supervising physician's full name, printed or stamped;

3. A statement indicating whether the prescription is written pursuant to protocol or specific physician direction. Acceptable abbreviations are "prt" for protocol and "spd" for specific physician direction;

4. The full name, age and address of the patient;

5. The date of issuance of the prescription;

6. The name, strength and quantity of drug or drugs to be dispensed and route of administration;

7. Adequate instruction for the patient. A direction of "p.r.n." or "as directed" alone shall be deemed an insufficient direction;

8. The number of refills permitted or time limit for refills, or both;

9. The signature of the prescriber, hand-written;

10. The words "substitution permissible" and "do not substitute" and shall contain space for the physician assistant's initials next to the chosen option, in addition to the space required for the signature required by (b)9 above; and

11. The physician assistant's Drug Enforcement Administration (DEA) registration number, if the physician assistant is authorized to issue CDS.

(c) A physician assistant may order or prescribe controlled dangerous substances (CDS) if:

1. A supervising physician has authorized a physician assistant to order or prescribe Schedule II, III, IV or V controlled dangerous substances in order to:

i. Continue or reissue an order or prescription for a controlled dangerous substance issued by the supervising physician;

ii. Adjust the dosage of an order or prescription for a controlled dangerous substance originally ordered or prescribed by the supervising physician, provided there is prior consultation with the supervising physician;

iii. Initiate an order or prescription for a controlled dangerous substance for a patient, provided there is prior consultation with the supervising physician if the order or prescription is not pursuant to iv below; or

iv. Initiate an order or prescription for a controlled dangerous substance as part of a treatment plan for a patient with a terminal illness, which for the purposes of this subparagraph means a medical condition that results in a patient's life expectancy being 12 months or less as determined by the supervising physician; and

2. The physician assistant has registered with and obtained authorization to order or prescribe controlled dangerous substances from the appropriate State and Federal agencies.

(d) Only one controlled dangerous substance shall appear on a prescription blank.

(e) Written prescriptions shall be issued only on New Jersey Prescription Blanks (NJPB), secured from an approved vendor and subject to the required security mandates of the prescription blank program pursuant to N.J.S.A. 45:14-55.

Amended by R.1999 d.356, effective October 18, 1999.
See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).
In (a), deleted a former 1, and recodified former 2 and 3 as 1 and 2.
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
In (a), added 3.
Amended by R.2008 d.135, effective June 2, 2008.
See: 39 N.J.R. 2201(a), 40 N.J.R. 3316(a).
Section was "Requirements for issuing prescriptions for medications; memorialization of verbal orders for CDS given by physicians". In the introductory paragraph of (a), inserted "for medications" and substituted "requirements contained in this section" for "following conditions:"; added (b); recodified former (a)1 as the introductory paragraph of (c) and rewrote (c); deleted former (a)2 through (a)3; and added (d) and (e).
Amended by R.2011 d.155, effective June 6, 2011.
See: 42 N.J.R. 1310(a), 43 N.J.R. 1359(b).
In (e), updated the N.J.S.A. reference.

13:35-2B.13 Eligibility for temporary licensure

(a) An individual who has filed an application for licensure and is waiting to take the next scheduled examination administered by the National Commission on Certification of Physician Assistants (NCCPA) or awaiting the results of the examination may apply to the Board for a temporary license to be employed under the direct supervision of a physician, as defined in N.J.A.C. 13:35-2B.2 and 2B.15.

(b) An applicant for temporary licensure shall submit to the Board, with the completed application form, the documents required pursuant to N.J.A.C. 13:35-2B.5, the required fee, and evidence that the applicant has filed an application for the NCCPA examination.

New Rule, R.1995 d.423, effective August 7, 1995.
See: 27 N.J.R. 1526(a), 27 N.J.R. 2959(a).

13:35-2B.14 Temporary licensure; scope of practice

(a) A temporary license holder who has complied with the practice requirements set forth in N.J.A.C. 13:35-2B.3 may perform all of the procedures within the scope of practice of a physician assistant, as set forth in N.J.A.C. 13:35-2B.4(a) and (b) and subject to the limitations therein, except that a temporary license holder shall not issue prescriptions. A temporary license holder may write orders for medication, treatment, or testing consistent with the provisions of N.J.A.C. 13:35-2B.15.

(b) A temporary license holder shall engage in practice only under the direct supervision of a physician pursuant to the provisions of N.J.A.C. 13:35-2B.15.

New Rule, R.1995 d.423, effective August 7, 1995.
See: 27 N.J.R. 1526(a), 27 N.J.R. 2959(a).
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
In (a), added the last sentence.

13:35-2B.15 Supervision of temporary license holder

(a) A temporary license holder shall not render care unless the following conditions are met:

1. In any setting, the supervising physician, physician designee or a designated physician assistant:

i. Is continuously present on-site; and

ii. Countersigns, immediately after its entry in the chart, any order for medication, treatment, or testing written by the temporary license holder.

2. In the event that the countersignature in (a)1 above is that of a designated physician assistant, the supervising physician or physician designee, within the appropriate conditions set in N.J.A.C. 13:35-2B.10(b) 4, shall:

i. Personally review all charts and patient records and the temporary license holder's entry in the chart and record; and

ii. Countersign any order for medication, treatment, or testing written by the temporary licensee.

New Rule, R.1995 d.423, effective August 7, 1995.
See: 27 N.J.R. 1526(a), 27 N.J.R. 2959(a).
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
Rewrote (a).

13:35-2B.16 Expiration of temporary license; renewal

(a) A temporary license shall expire 30 days after the temporary license holder has received notification of successful completion of the examination or immediately upon the applicant's receipt of notification of failure to pass the examination referenced in N.J.A.C. 13:35-2B.13(a).

(b) An applicant who fails an examination shall cease and desist from the performance of his or her duties.

(c) Except in extenuating circumstances such as the applicant's critical illness or incapacitation, a temporary license may not be renewed. An applicant seeking to renew based upon extenuating circumstances shall be required to present to the Board satisfactory documentation of the basis for the renewal request.

New Rule, R.1995 d.423, effective August 7, 1995.
See: 27 N.J.R. 1526(a), 27 N.J.R. 2959(a).
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
In (a), inserted "referenced in N.J.A.C. 13:35-2B.13(a)" following "pass the examination".

pharmacist has a question regarding the authenticity, accuracy or appropriateness of the prescription. A practitioner's authorized agent may provide verbal verification of the facsimile prescription to the pharmacy when the pharmacist has a question regarding the authenticity or legibility of the prescription.

(e) A practitioner or his or her authorized agent may transmit a facsimile prescription to a pharmacy for a Schedule II controlled substance, provided that the patient is given the original signed NJPB which is presented to the pharmacist prior to the dispensing of the controlled substance, except as provided in (e)1, 2 and 3 below:

1. A prescription for a Schedule II narcotic substance prescribed for pain management to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription.

2. A prescription for a Schedule II substance prescribed for pain management for a resident of a long term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription.

3. A prescription for a Schedule II narcotic substance prescribed for pain management for a patient receiving services from a hospice certified by Medicare under Title XVIII or licensed by the State may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent shall note on the facsimile prescription that the patient is a hospice patient. The facsimile shall serve as the original written prescription.

(f) A practitioner or his or her authorized agent may transmit a facsimile prescription to a pharmacy for a Schedule III, IV, or V controlled substance consistent with the requirements of this section. The facsimile shall serve as the original written prescription.

(g) If a facsimile prescription is provided for a Schedule II substance prescribed for pain management to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion, or for a resident of a long term care facility, or for a patient receiving services from a hospice certified by Medicare under Title XVIII or licensed by the State, or for a Schedule III, IV or V controlled substance, the practitioner shall not provide the patient, the patient's guardian, or the patient's authorized representative with the original written prescription.

(h) A practitioner shall not enter into any agreement with a pharmacy that requires facsimile prescriptions be transmitted to that particular pharmacy or in any way denies a patient the right to have his or her prescription transmitted by facsimile to a pharmacy of the patient's choice.

New Rule, R.2003 d.372, effective September 15, 2003.
See: 34 N.J.R. 3059(a), 35 N.J.R. 4287(a).

13:35-7.4A Electronically transmitted prescriptions

(a) A practitioner, acting within his or her scope of lawful practice and after an examination of the patient's condition, consistent with the requirements of N.J.A.C. 13:35-7.1A, may transmit, or have an authorized agent transmit, an electronic prescription to a pharmacy that has been approved by a patient, a patient's guardian or a patient's authorized representative, consistent with the requirements of this section. For purposes of this section, "electronic prescription" means a prescription, which is transmitted by a computer device in a secure manner, including computer-to-computer and computer-to-facsimile transmissions.

(b) A practitioner shall comply with all requirements set forth in this subchapter, and shall ensure that all information required to be included on a written prescription pursuant to N.J.A.C. 13:35-7.2(d) is provided in each electronic prescription, except that a handwritten original signature and an NJPB shall not be required for the prescription.

(c) A practitioner's electronic signature, or other secure method of validation, shall be provided with the electronic prescription unless the prescription is transmitted by an authorized agent as provided in (e) below.

(d) To maintain confidentiality of electronic prescriptions, the practitioner shall ensure that the electronic system used to transmit the electronic prescription has adequate security and system safeguards designed to prevent and detect unauthorized access, modification or manipulation of such records, and shall include, at a minimum, electronic encryption.

(e) A practitioner may authorize an agent to electronically transmit a prescription provided that the full name and title of the transmitting agent is included on the transmission, and provided that the practitioner's authorized agent does not sign the electronic prescription.

(f) A practitioner shall provide verbal verification of an electronic prescription upon request of the pharmacy when the pharmacist has a question regarding the authenticity, accuracy or appropriateness of the prescription. A practitioner's authorized agent may provide verbal verification of the electronic prescription to the pharmacy when the pharmacist has a question regarding the authenticity or legibility of the prescription.

(g) A practitioner or the practitioner's authorized agent may transmit an electronic prescription to a pharmacy for a Schedule II controlled substance, provided that the original signed prescription is presented to the pharmacist prior to the dispensing of the controlled substance. If permitted by Federal law, and in accordance with Federal requirements, the electronic prescription shall serve as the original signed prescription and the practitioner shall not provide the patient, the patient's guardian, or the patient's authorized representative with a signed, written prescription.

(h) A practitioner or his or her authorized agent may transmit an electronic prescription to a pharmacy for a Schedule III, IV, or V controlled substance, provided that the original signed prescription for presentation at the pharmacy, an oral prescription, or a facsimile prescription is provided. If permitted by Federal law, and in accordance with Federal requirements, the electronic prescription shall serve as the original signed prescription and the practitioner shall not provide the patient, the patient's guardian, or the patient's authorized representative with a signed, written prescription.

(i) A practitioner shall not enter into any agreement with a pharmacy which requires that electronic prescriptions be transmitted to a particular pharmacy or in any way denies a patient the right to have his or her prescription transmitted electronically to a pharmacy of the patient's choice.

New Rule, R.2003 d.372, effective September 15, 2003.
See: 34 N.J.R. 3059(a), 35 N.J.R. 4287(a).
Amended by R.2011 d.155, effective June 6, 2011.
See: 42 N.J.R. 1310(a), 43 N.J.R. 1359(b).
In (a), substituted "consistent with the requirements of" for "as defined in" and "that" for the first occurrence of "which", updated the N.J.A.C. reference, and deleted a comma following "guardian".

13:35-7.5 Requirements for the dispensing of drugs and special limitations applicable to the dispensing of drugs for a fee

(a) A practitioner, acting within the scope of lawful practice and after an examination or evaluation of the patient's condition, may dispense a drug directly to a patient, guardian or authorized representative under the circumstances and limitations set forth in this section. The practitioner shall assure that appropriate follow-up is provided and that the effects of the drug are properly evaluated and integrated into the treatment plan for the patient.

(b) A practitioner who dispenses drugs in the office shall maintain those drugs in an area kept in an orderly and sanitary manner, and in accordance with standard pharmaceutical practice and manufacturer recommendations concerning storage conditions, including refrigeration, where necessary. A practitioner shall not maintain in inventory any drugs which are outdated, misbranded, deteriorated, adulterated, recalled, unlabeled, damaged, discontinued or which were previously dispensed to a patient. A practitioner shall be responsible for the disposal of such drugs in a manner which will not pose a health hazard and in accordance with all local, State and Federal requirements.

(c) All drugs dispensed shall be recorded in the applicable patient record.

(d) All drugs dispensed, with the exception of samples of drugs which are not controlled substances and which are packaged and labeled by the manufacturer, shall be recorded in a permanent, contemporaneous dispensing log which shall contain, at a minimum, the following:

1. The full name of the patient;
2. The complete name of each drug dispensed;
3. The strength and quantity of the drug dispensed;
4. Instructions as to the frequency of use;
5. The date of dispensing; and
6. The identity of the dispensing practitioner, if more than one practitioner dispenses in the office.

(e) Each different drug dispensed, in whatever dosage form, shall be placed in a separate container with a safety closure cap, unless the patient requests otherwise or the drug is a pharmaceutical sample which has been packaged and labeled by the manufacturer.

(f) Each drug dispensed, including pharmaceutical samples, shall bear a legible label which includes the following:

1. The complete name of the drug dispensed;
2. The strength and quantity of the drug dispensed;
3. Instructions as to the frequency of use;
4. Special precautions, as appropriate; and
5. The expiration date of the drug.

(g) With respect to any drug which is not packaged by the manufacturer as a sample, the label shall also include the following:

1. The full name of the patient;
2. A list of the ingredients if the drug was compounded, not manufactured;
3. The date of dispensing; and
4. The identity of the dispensing practitioner.

(h) A practitioner shall not charge any patient a fee for a drug packaged and labeled by a manufacturer as a sample. For any drug dispensed which is not packaged by the manufacturer as a sample, a practitioner may charge a fee to allow for a recoupment of a portion of overhead and administrative costs, which fee shall not exceed the actual acquisition cost plus an additional sum not to exceed 10 percent of the actual acquisition cost.

(i) Subject to the exception in (j) below, if a practitioner charges a fee for the drug dispensed, either directly or through a global office visit charge which is more than that practitioner's usual and customary visit charge, the practitioner:

1. Shall not dispense that drug or a substantially equivalent drug in a quantity or in dosages greater than that which would allow the patient a seven-day supply;
2. Shall not dispense that medicine or a substantially equivalent medicine at a frequency greater than once every 30 days;
3. Shall assure that information is given to the patient regarding the alternative availability of the drug outside of the practitioner's office; and
4. Shall disclose to the patient in advance of purchase and again on the bill the actual acquisition cost of the drug.

(j) In accordance with N.J.S.A. 45:9-22.11, the requirements set forth at (h) and (i) above shall not apply to a practitioner:

1. If the office at which the dispensing occurs is situated 10 or more miles from the nearest licensed pharmacy;

2. If the drug is dispensed pursuant to an oncological or AIDS protocol;

3. If the drug dispensed is a salve, ointment or drops; or

4. If the drug is dispensed in, and directly related to, the services rendered to the patient at:

i. A hospital emergency room;

ii. A student health center at an institution of higher education; or

iii. A publicly subsidized community health center, family planning clinic or prenatal clinic.

(k) The requirements set forth in (d) through (g) above shall not apply to the dispensing of non-prescription substances.

Amended by R.2000 d.400, effective October 2, 2000.
See: 31 N.J.R. 2454(a), 32 N.J.R. 3576(a).
Rewrote (i)2; inserted (k).
Amended by R.2011 d.155, effective June 6, 2011.
See: 42 N.J.R. 1310(a), 43 N.J.R. 1359(b).
In the introductory paragraph of (j), inserted "(h) and".

13:35-7.5A Limitations on prescribing, administering or dispensing of drugs for the treatment of obesity

(a) The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

"Bariatric practice" means the practice of medicine by any physician relating to the treatment of obesity, in conjunction with those co-morbidities affected by obesity.

"Body mass index" means a calculation determined by dividing the measured body weight in kilograms by body height in meters square (kg/m^2).

"Co-morbidities" means any disease, psychiatric or medical condition that may be negatively influenced by obesity, such as diabetes, hypertension, hyperlipidemia, osteoarthritis, cardiac conditions, stroke, respiratory disease and certain cancers.

"Informed consent" means the agreement of the patient to follow the therapeutic regimen established by a practitioner, which follows the disclosure by a practitioner of that information which a patient needs as to available choices with respect to the proposed treatment, including the inherent and potential risks of such treatment.

"Obesity" means a complex, multi-factorial condition characterized by a documented diagnosis of excess adipose tissue as determined by the calculation of a body mass index greater than 27.

(b) A practitioner who engages in bariatric practice shall not prescribe, order, dispense, administer, sell or transfer any drug for the treatment of obesity except in accordance with the provisions of this subchapter and in conformity with the following requirements:

1. A practitioner shall personally, or through a licensed health care practitioner working within his or her lawful scope of practice and acting on the treating practitioner's order or protocol, take a complete history of the patient and conduct a comprehensive physical examination and order or perform any laboratory and/or diagnostic tests as indicated by the clinical evaluation. The history, physical examination and laboratory and/or diagnostic tests shall be undertaken in an effort to determine the existence of any co-morbidities and if the use of any prescription medication is contraindicated. The practitioner shall also assess the possible existence of any psychiatric or psychological condition (such as, but not limited to, depression or substance abuse) which shall be evaluated and treated prior to or contemporaneous with the treatment of obesity and which may pose a contraindication to the use of prescription medications. The practitioner shall fully document the findings of the history, physical examination and laboratory and/or diagnostic tests in the patient record and shall also indicate the methods and goals of treatment in the patient record;

2. A practitioner shall provide for nutritional counseling, recommendations for behavior modification and appropriate exercise for weight loss, and document such recommendations in the patient record;

3. A practitioner shall obtain written or verbal informed consent from the patient before prescribing, ordering, dispensing, administering, selling or transferring medication, pursuant to the provisions of this subchapter, for the treatment of obesity. The practitioner shall, either verbally or in writing, identify the risks associated with the use of such medications; and

4. (Reserved)

5. A practitioner shall monitor the progress of the patient's weight loss or gain at the time of each of the patient's follow-up visits. The practitioner shall personally, or through a licensed health care practitioner working within his or her lawful scope of practice and acting on the treating practitioner's order or protocol, conduct a physical examination and shall perform laboratory tests as indicated by the clinical evaluation. The findings of the physical examination shall be fully documented in the patient record.

6. (Reserved)

(c) Any violations of this section shall be subject to the enforcement provisions of N.J.A.C. 13:35-7.10.

New Rule, R.2000 d.401, effective October 2, 2000.
See: 31 N.J.R. 2457(a), 32 N.J.R. 3577(a).

13:35-7.6 Limitations on prescribing, administering or dispensing of controlled substances; special exceptions for management of pain

(a) When prescribing, dispensing or administering controlled substances, a practitioner shall ensure that a patient's medical history has been taken and physical examination accomplished, including an assessment of physical and psychological function, underlying or coexisting diseases or conditions, any history of substance abuse and the nature, frequency and severity of any pain. The medical record shall reflect:

1. A recognized medical indication for the use of the controlled substance;

2. The complete name of the controlled substance;

3. The dosage, strength and quantity of the controlled substance; and

4. The instructions as to frequency of use.

(b) With respect to Schedule II controlled substances, unless the requirements of (c) below are met, a practitioner shall not authorize a quantity calculated to exceed 120 dosage units or a 30-day supply, whichever is less.

(c) A practitioner may exceed the 120 dosage unit or 30-day supply limitations for Schedule II controlled substances in (b) above in the following circumstances:

1. For the 120 dosage unit limitation, the practitioner follows a treatment plan designed to achieve effective pain management, which has been tailored to the needs of a patient who is suffering pain from cancer, intractable pain or terminal illness. The treatment plan shall state objectives by which treatment success is to be evaluated, such as pain relief and improved physical and psychological function, and shall indicate if any further diagnostic evaluations or other treatments are planned. The practitioner shall discuss the risks and benefits of the use of controlled substances with the patient, guardian or authorized representative;

2. With regards to the 30-day supply limitation, a practitioner may prescribe the use of an implantable infusion pump which is utilized to achieve pain management for patients suffering from cancer, intractable pain or terminal illness. A prescription for such an implantable infusion pump may provide up to a 90-day supply, as long as the physician evaluates and documents the patient's continued need at least every 30 days; and

3. With regards to the 30-day supply limitation, a practitioner may prescribe multiple prescriptions authorizing a patient to receive a total of up to a 90-day supply of a Schedule II controlled dangerous substance provided that:

i. Each separate prescription is issued for a legitimate medical purpose by the practitioner acting in the usual course of professional practice;

ii. The practitioner provides written instructions on each prescription, other than the first prescription if it is to be filled immediately, indicating the earliest date on which a pharmacy may fill each prescription;

iii. The practitioner determines that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse; and

iv. The practitioner complies with all other applicable State and Federal laws and regulations.

(d) When controlled substances are continuously prescribed for management of pain for three months or more, the practitioner:

1. Shall review, at a minimum of every three months, the course of treatment, any new information about the etiology of the pain and the patient's progress toward treatment objectives;

2. Shall remain alert to problems associated with physical and psychological dependence; and

3. Shall periodically make reasonable efforts, unless clinically contraindicated, to either stop the use of the controlled substance, decrease the dosage, try other drugs such as nonsteroidal anti-inflammatories, or treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence.

(e) If treatment objectives are not being met, the practitioner:

1. Shall assess the appropriateness of continued treatment with controlled substances or undertake a trial of other drugs or treatment modalities; and

2. Shall consider referring the patient for independent evaluation or treatment in order to achieve treatment objectives.

(f) A practitioner shall remain alert to the possibility that controlled substances may be misused or diverted. A practitioner managing pain in a patient with a history of substance abuse shall exercise extra care by way of monitoring, documentation and possible consultation with addiction medicine specialists, and should consider the use of an agreement between the practitioner and the patient concerning controlled substance use and consequences for misuse.

(g) The practitioner shall keep accurate and complete records including that information required by (a) above as well as:

1. The medical history and physical examination of the patient;

2. Other evaluations and consultations;

3. Treatment plan objectives;

4. Evidence of informed consent;

5. Treatments and drugs prescribed or provided, as in (a) above;

6. Any agreements with the patient; and

7. Periodic reviews conducted.

Amended by R.2003 d.263, effective July 7, 2003.
See: 34 N.J.R. 3441(a), 35 N.J.R. 2935(a).
Rewrote (c).
Amended by R.2011 d.155, effective June 6, 2011.
See: 42 N.J.R. 1310(a), 43 N.J.R. 1359(b).
In (c)1, deleted "and" from the end; in (c)2, substituted "; and" for a period at the end; and added (c)3.

Case Notes

Five-year revocation of a physician's license was appropriate where the physician fraudulently prescribed Percocet and deliberately falsified medical records to justify the issuance of those prescriptions. Two undercover officers testified that the physician prescribed the medication over a period of time without conducting a thorough physical examination and medical history and in spite of their statements that they were in no pain whatsoever. In re Costino License Revocation, OAL Dkt. No. BDS 736-08, 2009 N.J. AGEN LEXIS 276, Initial Decision (May 14, 2009), adopted (N.J. State Bd. of Medical Examiners June 8, 2009); aff'd per curiam, A-2348-09T2, 2010 N.J. Super. Unpub. LEXIS 2455 (App. Div. December 21, 2009).

Partial summary decision was warranted pursuant to N.J.A.C. 1:1-12.5(b) in a complaint filed by the Attorney General for the State of New Jersey for disciplinary action against a psychiatrist licensed by the State Medical Board based on evidence that the psychiatrist did not hold a valid Drug Enforcement Agency Controlled Dangerous Substance (CDS) license for a period exceeding four years, but the psychiatrist continued to issue CDS scheduled prescriptions on 23 separate occasions during the period at issue, and the psychiatrist further admitted under oath in an earlier proceeding that she had made illegal CDS prescriptions to two different patients. The N.J. Attorney General was also entitled to summary judgment on the issue of whether or not the psychiatrist had falsified medical records in violation of N.J.S.A. 45:1-21(b), N.J.A.C. 13:35-6.5(b) and N.J.A.C. 13:35-7.6(a) and (g) because the psychiatrist had originally submitted certified records dated June 1, 2004 and July 1, 2004 on the same page with no physical break as part of an earlier hearing, certifying that the records were true and complete, and then did not offer an explanation why handwritten notes dated June 22, 2004 and June 28, 2004 were not part of that earlier chronological record. In re the Suspension or Revocation of the License of Ilem, M.D. to Practice Medicine and Surgery in New Jersey, OAL DKT. NO. BDS01850-06. 2006 N.J. AGEN LEXIS 1174, Partial Summary Decision (August 29, 2006).

13:35-7.7 Prohibitions on prescribing, administering or dispensing of controlled substances for detoxification; limited exceptions

(a) A practitioner shall not issue a prescription for a narcotic drug or for a depressant drug listed in any schedule which drug is intended for the purpose of "detoxification" or "maintenance treatment."

(b) Unless registered with the Division of Consumer Affairs to conduct a narcotic treatment program pursuant to N.J.S.A. 24:21-10 and N.J.A.C. 13:45H-11.2, a practitioner shall not dispense or administer a narcotic drug or a depressant drug listed in any schedule which drug is intended for the purpose of "detoxification" or "maintenance treatment," except:

1. To relieve acute withdrawal symptoms, provided that:

i. Such treatment shall not exceed 72 hours;

ii. No more than one day's supply of the drug is provided to the patient at a time; and

iii. Arrangements are made for referring the patient to an addiction specialist or a drug treatment program for treatment; or

2. As an adjunct to other medical or surgical treatment for conditions other than addiction in a licensed health care facility.

Amended by R.2000 d.400, effective October 2, 2000.
See: 31 N.J.R. 2454(a), 32 N.J.R. 3576(a).
In (a), and (b), inserted references to depressant drugs.
Administrative change.
See: 43 N.J.R. 1204(b).

13:35-7.8 Prohibitions and limitations in the prescribing, administering or dispensing of amphetamines and sympathomimetic amines

(a) A practitioner shall not prescribe, order, dispense, administer, sell or transfer any amphetamine or sympathomimetic amine designated as a Schedule II controlled substance for use in weight management, dieting or any other anorectic purpose, or for the treatment of fatigue.

(b) A practitioner may prescribe, dispense or administer amphetamine or sympathomimetic amine drugs or compounds designated as Schedule II controlled substances, only as follows:

1. For the treatment of the following conditions:

i. Narcolepsy established by recognized diagnostic criteria;

ii. Idiopathic Central Nervous System Hypersomnia established by recognized diagnostic criteria;

iii. Attention Deficit Disorder established by recognized diagnostic criteria;

iv. Drug-induced brain dysfunction;

v. Epilepsy;

vi. Depression shown to be refractory to other therapeutic modalities; and

vii. Senile apathetic behavior;

2. For immediate use in a hospital for acute conditions such as depression associated with illness or surgery;

3. For the differential diagnostic psychiatric evaluation of depression; or

4. For the clinical investigation of the effects of such drugs or compounds in which case, in addition to other requirements of applicable law, prior application therefor

shall have been made to the Board and approval granted before any such investigation is begun.

(c) A practitioner who prescribes, dispenses or administers amphetamines or sympathomimetic amines shall prepare and maintain patient medical records which accurately reflect the utilization of any drug subject to this section, the specific diagnosis, the information upon which the diagnosis is based, including testing and consultations, and the treatment objectives for which the drug is being prescribed.

(d) The following list, although not exhaustive or exclusive, includes many of the generic and brand-name Schedule II drugs which are subject to this section:

Adderall
Amphetamine
Desoxyn
Dexedrine
Dextroamphetamine
Methamphetamine
Methylphenidate
Ritalin

13:35-7.9 Prohibitions and special limitations on prescribing, administering, or dispensing anabolic steroids and human growth hormone or its similar analogs

(a) A practitioner shall not prescribe, order, dispense, administer, sell, or transfer any anabolic steroid or human growth hormone or its similar analogs, unless there is a bona fide relationship with the patient, a medical history has been obtained, and a full physical examination has been performed, establishing a valid medical indication and necessity as provided in (b), (c), or (d) below.

(b) Valid medical indication and necessity for human growth hormone or its similar analogs is established when there is:

1. A documented diagnosis of hormonal deficiency causing short stature in children;

2. A record of long-term treatment of growth failure due to lack of endogenous GH secretion;

3. A record of long-term treatment of short stature associated with Turner's syndrome;

4. A documented diagnosis of adult short bowel syndrome;

5. A documented diagnosis of adult deficiency due to pituitary tumors or their treatment or muscle wasting disease associated with HIV/AIDS; or

6. A documented diagnosis of any other medical condition specifically recognized by the U.S. Secretary of Health and Human Services as appropriate for treatment with human growth hormone or its similar analogs.

(c) Valid medical indication and necessity for use of anabolic steroids may be established when there is:

1. A documented diagnosis of the condition specified in this paragraph in an adult male patient, associated with a deficiency or absence of endogenous testosterone:

i. Primary hypogonadism (congenital or acquired); or

ii. Hypogonadotropic hypogonadism (congenital or acquired);

2. A record of treatment of delayed puberty in males;

3. A documented need in a female patient for palliative treatment of breast cancer; or

4. A documented diagnosis of a valid medical indication specific to an identified anabolic steroid for the following conditions:

i. AIDS wasting syndrome;

ii. Anemia accompanying renal failure;

iii. Bone marrow failure anemia;

iv. Refractory red cell production anemia;

v. Constitutional delay in growth (androgenic anabolic steroids);

vi. Growth failure in children with growth hormone deficiency (treatment adjunct);

vii. Endometriosis, fibrocystic breast disease, or hereditary angioedema;

viii. Microphallus (androgenic anabolic steroids);

ix. Severe burn injury;

x. Weight loss from cancer chemotherapy; or

xi. Wasting due to prolonged corticosteroid use.

(d) Valid medical indication and necessity for human growth hormone or its similar analogs and anabolic steroids also may be established for use in treatment of conditions other than those identified at (b) and (c) above, only if the practitioner:

1. Obtains and maintains documentation of the receipt of informed consent after the provision of information concerning the risks and benefits of short- and long-term treatment and its less-intrusive alternatives, the consequences of the cessation of treatment, and the financial costs associated with treatment;

2. Obtains and maintains documentation of the appropriate clinical data and laboratory tests undertaken prior to the start of treatment that support the medical indication and necessity; and