**TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING**

**CHAPTER 2 ACUPUNCTURE AND ORIENTAL MEDICINE PRACTITIONERS**

**PART 19 EXPANDED PRACTICE CERTIFICATIONS**

**16.2.19.1 ISSUING AGENCY:**  New Mexico Board of Acupuncture and Oriental Medicine.

[16.2.19.1 NMAC - N, 11-28-09]

**16.2.19.2 SCOPE:** All doctors of oriental medicine who are certified for expanded practice or who are applicants for certification for expanded practice, as well as all educational programs and students enrolled in an educational program.

[16.2.19.2 NMAC - N, 11-28-09]

**16.2.19.3 STATUTORY AUTHORITY:** This part is promulgated pursuant to the Acupuncture and Oriental Medicine Practice Act, Section 61-14A-8.1.

[16.2.19.3 NMAC - N, 11-28-09]

**16.2.19.4 DURATION:** Permanent.

[16.2.19.4 NMAC - N, 11-28-09]

**16.2.19.5 EFFECTIVE DATE:** November 28, 2009, unless a later date is cited at the end of a section.

[16.2.19.5 NMAC - N, 11-28-09]

**16.2.19.6 OBJECTIVE:** This part lists the certification requirements for each of the following expanded practice categories: basic injection therapy, injection therapy, intravenous therapy and bioidentical hormone therapy.

[16.2.19.6 NMAC - N, 11-28-09]

**16.2.19.7 DEFINITIONS:**

A. The[ ~~definition~~ ]in this section[ ~~is~~ ]are in addition to those in the act and 16.2.1 NMAC.

B. [~~The following definition~~ ~~applies to the rules and the act:~~ **~~“educational course”~~** ~~is a comprehensive foundation of studies, approved by the board leading to demonstration of entry level competence in the specified knowledge and skills required for the four respective certifications in expanded practice; an educational course is not an educational program as this term is used in the act and the rules and as defined in 16.2.1 NMAC~~.]The following definitions are from 16.19.36 NMAC for clarification of regulations for doctors of oriental medicine, certified in expanded practice;

1. “Aseptic Technique” means proper manipulation of preparations to maintain sterility

2 "ASHP" American Society of Health-Systems Pharmacists.

3. Beyond-use date**”** (BUD) means the date, or as appropriate, date and time, after which a compounded preparation is not to be used and is determined from the date and time the preparation is compounded.

4.“Certification**”** means independent third party documentation declaring that the specific requirements *have been* met

5. “Cleanroom” means a room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class.  Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.

6. “Compounded sterile preparations”(CSP’s) include, but are not limited, to the following dosage forms which must be sterile when administered to patients:

(a) parenteral preparations;

(b) aqueous bronchial and nasal inhalations;

(c) injections (e.g. colloidal dispersions, emulsions, solutions, suspensions);

(d) irrigations for wounds and body cavities;

(e) ophthalmic drops and ointments; and

7. “Compounding aseptic isolator” (CAI) means an enclosed ISO Class 5 environments for compounding pharmaceutical ingredients or preparations.  It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes.  Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum).

8.  “Critical area” means an ISO Class 5 environment.

9. “Critical site” means a location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampules, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination.  Risk of microbial particulate contamination of the critical site increases with the size of the openings and exposure time

10. “Immediate use”means administration begins not later than one hour following the start of the compounding procedure. Use of Immediate use products is reserved to those events in which delay in preparation would subject the patient to additional risk due to delay in therapy and meeting USP/NF <797> (*Immediate-Use CSP Provision*) criteria.

11 “ISO 5” means air containing no more than 100 particles per cubic foot of air of a size at least 0.5 micron or larger in diameter (3520 particles per cubic meter)

12. “ISO 7” means air containing no more than 10,000 particles per cubic foot of air of a size at least 0.5 micron or larger in diameter (352,000 particles per cubic meter)

13. “ISO 8” means air containing no more than 100,000 particles per cubic foot of air of a size at least 0.5 micron or larger in diameter (3,520,000 particles per cubic meter).

14. “Laminar airflow” means a non-turbulent, non-mixing streamline flow of air in parallel layers

15. “Laminar airflow workbench” (LAFW) means a ventilated cabinet for compounding of sterile preparations. Provides preparation protection with high-efficiency particulate air (HEPA) filtered laminar airflow, ISO Class 5. Airflow may be horizontal (back to front) or vertical (top to bottom) in direction.  
 16. “Media-fill test” means a test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile preparation without microbial contamination. During this test, a microbiological growth medium such as soybean-casein digest medium is substituted for the actual drug product to simulate admixture compounding.  The issues to consider in the development of a media-fill test are media-fill procedures, media selection, fill volume, incubation, time, and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required.

16 “Multiple-dose container**”** means a multiple-unit container for articles or preparations intended for parenteral administration only and usually containing antimicrobial preservatives. Once opened or entered, a multiple dose container with antimicrobial preservative has a BUD of 28 days unless otherwise specified by the manufacturer.

17.“Parenteral product” means any preparation administered by injection through one or more layers of skin tissue.

18. “Personal protective equipment” (PPE) means items such as gloves, gowns, respirators, goggles, face shields, and others that protect individual workers from hazardous physical or chemical exposures.

19. “Positive pressure room” means a room that is at a higher pressure than the adjacent spaces and, therefore, the net airflow is *out* ofthe room.

20. “Preparation” means a CSP that is a sterile drug or nutrient compounded in a licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed prescriber; the article may or may not contain sterile products.

21. “Product” means a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.  Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer’s labeling or product package insert.

22. “Quality assurance” means a program for the systematic monitoring and evaluation of the various aspects of a service or facility to ensure that standards of quality are being met.

23. “Quality control” means a system for verifying and maintaining a desired level of quality in a preparations or process, as by planning, continued inspection, and corrective action as required.

24. “Single-dose container”means a single-dose, or a single-unit, container for articles or preparations intended for parenteral administration only.  It is intended for a single use.  Examples of single-dose containers include prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.

25. “Standard operating procedure” (SOP) means a written protocol detailing the required standards for performance of tasks and operations within a facility.

26. “Sterile” means free from bacteria or other living microorganisms.

27. “Unidirectional flow” means airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.

28. “USP 797” United States Pharmacopeia Chapter <797> Pharmaceutical Compounding- 29. Sterile Preparations- This general Chapter provides procedures and requirements for compounding sterile preparations. General Chapter<797> describes conditions and practices to prevent harm to patients that could result from microbial contamination, excessive bacterial endotoxins, variability in intended strength, unintended chemical and physical contaminants, and ingredients of inappropriate quality in compounded sterile preparations.

[16.2.19.7 NMAC - N, 11-28-09]

**30.** “USP/NF standards” means United States pharmacopeia/national formulary

C. The following definition applies to the rules and the act: **“educational course”** is a comprehensive foundation of studies, approved by the board leading to demonstration of entry level competence in the specified knowledge and skills required for the four respective certifications in expanded practice; an educational course is not an educational program as this term is used in the act and the rules and as defined in 16.2.1 NMAC.

[16.2.19.7 NMAC - N, 11-28-09]

**16.2.19.8 EXPANDED PRACTICE CERTIFICATION GENERAL PROVISIONS:** The four categories of expanded practice certification authorized by 61-14A-8.1. NMSA 1978 and defined in 16.2.19 NMAC that include, basic injection therapy, injection therapy, intravenous therapy and bioidentical hormone therapy shall all include the following provisions:

A. a doctor of oriental medicine or[ ~~oriental medicine student~~ ]enrolled in an educational course shall be authorized to perform the techniques and shall have the prescriptive authority, for the duration of the course, to administer and compound the substances that are authorized in the expanded practice formulary for which he is studying under the supervision of the board approved teacher for that educational course; under other circumstances the student shall not be authorized to obtain, prescribe or dispense such substances;

[~~B~~.] [~~students enrolled in an educational program as defined in 16.2.1 NMAC shall be authorized to participate in a board approved basic injection therapy course and shall comply with the provisions of Subsection A of this section; upon successful completion of the course and submission of a complete application for certification to the board, such a student shall be appropriately certified by the board for basic injection therapy at the time of licensure as a doctor of oriental medicine~~;]

[~~C~~.] B. the board shall maintain a list of each doctor of oriental medicine who is certified for each expanded practice category and shall notify the New Mexico board of pharmacy of all such certified licensees;

~~D.~~ C upon receipt of a current copy of CPR/BLS card the board[ ~~shall~~] will annually renew the expanded practice certification(s)[ ~~or certifications~~ ]of a doctor of oriental medicine in good standing[ ~~who is certified for expanded practice~~ ]if the licensee has completed all continuing education required by 16.2.9 NMAC;

D. Proof of completion of an ASHP accredited Course relative to USP 797 will be required for:

(1) first time renewal, July 31, 2016, of Basic Injection Therapy Certification,

(2) doctors of oriental medicine certified in Basic Injection or Injection Therapy and Intravenous Therapy, and

(3) prior to enrolling in Injection Therapy or Intravenous Therapy Expanded Practice Education Courses.

E. all expanded practice and prescriptive authority certifications shall automatically terminate when licensure as a doctor of oriental medicine:

(1) is placed on inactive status as specified in 16.2.15 NMAC;

(2) expires as specified in 16.2.8 NMAC; or

(3) is suspended, revoked or terminated for any reason as defined in 16.2.12 NMAC;

F. an expanded practice certification that is revoked or terminated shall not be reinstated; the doctor of oriental medicine must reapply for expanded practice certification as a new applicant;

G. all expanded practice certifications that were automatically terminated due to inactive status, expiration or suspension as specified in Subsection E of this section, shall be automatically reinstated when licensure as a doctor of oriental medicine is reinstated, provided that:

(1) all fees required by 16.2.10 NMAC have been paid;

(2) all continuing education requirements specified in 16.2.9 NMAC have been completed; and

(3) all other relevant, reinstatement provisions, required by board rule, have been completed;

H. each year the board may review the expanded practice formularies for necessary amendments; when new substances are added to a formulary, appropriate education in the use of the new substances shall be approved and required by the board and the board of pharmacy for doctors of oriental medicine applying for new certification or as continuing education for renewal of the applicable expanded practice certification or certifications;

I. a doctor of oriental medicine certified for a category of expanded practice under 16.2.19 NMAC that authorizes the use of testosterone, a controlled substance, and any other drug that is classified as a controlled substance, shall register with the federal DEA (drug enforcement agency) prior to obtaining, prescribing, administering, compounding or dispensing the controlled substance;

J. a doctor of oriental medicine certified for expanded practice, when prescribing, shall use prescription pads printed with his or her name, address, telephone number, license number and his or her specific expanded practice certifications; if a doctor of oriental medicine is using a prescription pad printed with the names of more than one doctor of oriental medicine, the above information for each doctor of oriental medicine shall be on the pad and the pad shall have a separate signature line for each doctor of oriental medicine; each specific prescription shall indicate the name of the doctor of oriental medicine for that prescription and shall be signed by the prescribing doctor of oriental medicine;

K. a doctor of oriental medicine certified for expanded practice shall always, when diagnosing and treating a patient, use the skill and care ordinarily used by reasonably well-qualified doctors of oriental medicine similarly certified and practicing under similar circumstances, giving due consideration to the locality involved; failure to comply with this fundamental requirement may result in denial, suspension or revocation of licensure or certification, or other disciplinary measures, pursuant to the provisions of the act, NMSA 1978, Section 61-14A-17, and the Uniform Licensing Act, NMSA 1978, Section 61-1-1, et seq.;

L. when a doctor of oriental medicine is certified for injection therapy, this certification automatically supersedes his certification for basic injection therapy; and

M. the provisions for certification transition from extended prescriptive authority (Rx1) and expanded prescriptive authority (Rx2) to the expanded practice categories specified in 16.2.19 NMAC.

[16.2.19.8 NMAC - N, 11-28-09]

**16.2.19.9 EXPANDED PRACTICE CERTIFICATION BOARD REQUIREMENTS:**

A. The board shall have final authority for certification of all applicants.

B. The board shall notify the applicant in writing by mail postmarked no more than 30 days after the receipt of the initial application as to whether the application is complete or incomplete and missing specified application documentation.

C. The board shall notify the applicant in writing by mail postmarked no more than 30 days after the notice of receipt of the complete application sent out by the board, whether the application is approved or denied.

D. If the application is denied, the notice of denial shall state the reason the application was denied.

E. In the interim between regular board meetings the board’s chairman or an authorized[ ~~representative~~ ]designee of the board[ ~~shall~~] will approve[ ~~issue~~ ]an[ ~~interim temporary~~ ]expanded practice certification to a qualified applicant who has filed, with the board, a complete application and complied with all requirements for expanded practice certification The[~~interim~~]temporary expanded practice certification[ ~~shall automatically expire~~] will be ratified by the board on the date of the next regular board meeting.  Final expanded practice certification shall only be granted by the board.

F. The board shall have the authority to deny, suspend, revoke or otherwise discipline an expanded practice certification, in accordance with the Uniform Licensing Act, 61-1-1 to 61-1-31 NMSA 1978, for reasons authorized in the act and clarified in 16.2.12 NMAC.

[16.2.19.9 NMAC - N, 11-28-09]

**16.2.19.10 EXPANDED PRACTICE SCOPE OF PRACTICE:**

A. In addition to the scope of practice outlined in section 16.2.2 NMAC for a doctor of oriental medicine in New Mexico, the scope of practice for those certified in expanded practice shall include certification in any or all of the following modules: (61-14A-8.1BNMSA1978) basic injection therapy, injection therapy, intravenous therapy and bio-identical hormone therapy as specified in 16.2.19 NMAC.

B. The scope of practice for those doctors of oriental medicine certified in expanded practice shall also include the expanded practice and prescriptive authority defined in 61-14A-8.1C NMSA1978.

[16.2.19.10 NMAC - N, 11-28-09]

**16.2.19.11 BASIC INJECTION THERAPY CERTIFICATION:** The board shall issue, to a doctor of oriental medicine, certification for basic injection therapy upon completion of the course prerequisites including 30 hours of Pharmacology as specified in 16.2.18.9 and the following requirements.

A. The doctor of oriental medicine shall be a doctor of oriental medicine in good standing.

B. The doctor of oriental medicine shall submit to the board the completed application form provided by the board.

C. The doctor of oriental medicine shall pay the application fee for expanded practice certification specified in 16.2.10 NMAC.

D. The doctor of oriental medicine shall submit, with the application, proof of successful completion of the basic injection therapy educational course specified in 16.2.18 NMAC.

[16.2.19.11 NMAC - N, 11-28-09]

**16.2.19.12 INJECTION THERAPY CERTIFICATION:** The board shall issue to a doctor of oriental medicine, certification for injection therapy, upon completion of the following requirements.

A. The doctor of oriental medicine shall be a doctor of oriental medicine in good standing.

B. The doctor of oriental medicine shall submit to the board the completed application form provided by the board.

C. The doctor of oriental medicine shall pay the application fee for expanded practice certification specified in 16.2.10 NMAC.

D. The doctor of oriental medicine shall submit, with the application, proof of:

(1) current certification by the board for basic injection therapy; or

(2 any course combining basic injection therapy and injection therapy, as they are specified in the board’s rules, or otherwise in accordance with law, must be completed within two years of the start of the course.

E. The doctor of oriental medicine shall submit, with the application, proof of successful completion of the injection therapy educational course approved by the board.

[16.2.19.12 NMAC - N, 11-28-09; A, 03-02-14]

**16.2.19.13 INTRAVENOUS THERAPY CERTIFICATION:** The board shall issue to a doctor of oriental medicine, certification for intravenous therapy, upon completion of the course prerequisites including board certification in basic injection therapy, and 3 hours of college level biochemistry, and the following requirements.

A. The doctor of oriental medicine shall be a doctor of oriental medicine in good standing.

B. The doctor of oriental medicine shall submit to the board the completed application form provided by the board.

C. The doctor of oriental medicine shall pay the application fee for expanded practice certification specified in 16.2.10 NMAC.

D. The doctor of oriental medicine shall submit, with the application, proof of successful completion of [~~any~~] an intravenous therapy educational course approved by the board.

[16.2.19.13 NMAC - N, 11-28-09]

**16.2.19.14 BIOIDENTICAL HORMONE THERAPY CERTIFICATION:** The board shall issue to a doctor of oriental medicine, certification for bioidentical hormone therapy, upon completion of the following requirements:

A. the doctor of oriental medicine shall be a doctor of oriental medicine in good standing;

B. the doctor of oriental medicine shall submit to the board the completed application form provided by the board;

C. the doctor of oriental medicine shall pay the application fee for expanded practice certification specified in 16.2.10 NMAC; and

D. the doctor of oriental medicine shall submit, with the application, proof of successful completion of the bioidentical hormone therapy educational course approved by the board.

[16.2.19.14 NMAC - N, 11-28-09]

**16.2.19.15 EXPANDED PRACTICE CERTIFICATION RENEWAL:**

A. If a doctor of oriental medicine certified for expanded prescriptive authority does not complete all expanded prescriptive authority continuing education requirements specified in 16.2.9.9 NMAC within the 60 day grace period, the expanded prescriptive authority certification is expired and that licensee shall not be certified for expanded prescriptive authority until the continuing education is completed. Provided that all other renewal requirements have been received by the board, such a licensee shall continue to be licensed as a doctor of oriental medicine and is authorized for that scope of practice but shall not be authorized for the relevant expanded prescriptive authority scope of practice.  For an expired expanded prescriptive authority certification, if a properly completed application for certification renewal, including proof of completion of the required expanded prescriptive authority continuing education, is received at the board office within one year of the last regular renewal date, the expanded prescriptive authority certification shall be renewed if all the requirements of late certification renewal during the 60 day grace period provided by Section 61-14A-15 NMSA 1978 are completed, in addition to the requirements of 16.2.8.11 NMAC, and the licensee also pays the fee for expired certification renewal specified in 16.2.10 NMAC.[ ~~For each licensee whose expanded prescriptive authority certification has expired, the board shall notify the licensee by return receipt mail sent to the address on record that the expanded prescriptive authority certification has expired and shall notify the licensee that he or she must not practice those areas authorized by the expanded prescriptive authority certification until the prescriptive authority certification is renewed.  This notification shall also contain an explanation of the procedures and fees for renewing the expanded prescriptive authority certification and the consequences of not renewing the expanded prescriptive authority.  The board is responsible for sending the notification by return receipt mail in a timely manner to the address on record for the licensee and for maintaining a record of all such notifications sent, including the return receipt documents.  The board is not responsible for verifying that the return receipt was returned by the post office to the board, for further follow up to verify that the notification was received or to locate and notify a licensee who has changed address without properly notifying the board of the new address~~.]The licensee is responsible for notifying the board of the correct current address and of any address changes. Any licensee, after being properly notified as described above, who fails to renew, including completion of any required continuing education, his expired expanded prescriptive authority certification by the next July 31 annual license renewal date, after the notification shall be required to apply as a new applicant for expanded prescriptive authority certification. except that there shall be a limited expanded prescriptive authority certification reinstatement period as specified in 16.2.8.13 NMAC.

[~~B. The board may, on an individual basis, renew a license that has expired for more than one year if the former licensee can demonstrate good cause as specified in 16.2.1.7 NMAC~~.]

[~~C~~.] B. The board shall report to the New Mexico board of pharmacy any expired license that was previously held by a doctor of oriental medicine who was is certified for the expanded prescriptive authority prescriptive authority and shall report to the New Mexico board of pharmacy any renewed or reinstated license of a doctor of oriental medicine who is certified for the expanded prescriptive authority.

[16.2.19.15 NMAC - N, 11-28-09]

**16.2.19.16 TRANSITION PROVISIONS:**

A. A doctor of oriental medicine, previously certified for extended prescriptive authority including prolotherapy, (Rx1) as of the effective date of this section, shall be automatically certified for basic injection therapy and prolotherapy using previously taught and appropriate injection routes and only substances listed in Paragraph (1) of Subsection F of 16.2.20.8 NMAC under the provisions of 16.2.19.10 NMAC.

B. A doctor of oriental medicine, previously certified for the expanded prescriptive authority (Rx2) as of the effective date of this section, shall be automatically certified for:

(1) injection therapy under the provisions of 16.2.19.11 NMACbasic injection therapy certification is automatically superseded by injection therapy certification;

(2) intravenous therapy under the provisions of 16.2.19.12 NMAC; and

(3) bioidentical hormone therapy under the provisions of 16.2.19.13 NMAC.

[16.2.19.16 NMAC - N, 11-28-09; A, 02-08-13]

**16.2.19.17 LICENSE DESIGNATION:** The designation for expanded practice shall follow the license number on the license and shall reflect the respective modules of certification: Rx basic injection,[ ~~Rx1 basic injection,~~]Rx injection, Rx intravenous, Rx hormones.

[16.2.19.17 NMAC - N, 02-08-13; A, 03-02-14]

**16.2.19.18 ULTRASOUND CREDENTIALING:** A licensed doctor of oriental medicine may utilize musculoskeletal diagnostic ultrasound and ultrasound guidance of procedures with the RMSK credential from ARDMS, the American registry of diagnostic medical sonography. A licensed doctor of oriental medicine (DOM) who wishes to practice diagnostic musculoskeletal ultrasound and ultrasound guidance of procedures shall register with the board of acupuncture and oriental medicine (BAOM) to be provisionally credentialed to practice diagnostic musculoskeletal ultrasound and ultrasound guided procedures upon completion of a minimum of 30 hours in BAOM approved courses. Within 36 months of provisional credentialing, the doctor of oriental medicine shall submit to the BAOM proof of scheduling for RMSK testing with ARDMS. If the provisional credentialing period is continued to 36 months without ARDMS RMSK credentialing, the provisionally credentialed DOM shall submit proof of 30 hours of continuing education in courses approved by the BAOM.  Provisional credentialing shall lapse within 48 months of initial provisional credentialing. Ultrasound credentialing does not require certification in expanded practice.

[16.2.19.18 NMAC - N, 03-02-14]

**History of 16.2.19 NMAC:** [RESERVED]