

*The legislature passed and Governor Jan Brewer signed Senate Bill 1298, which significantly modified the authority granted by the legislature for pharmacist administered immunizations and collaborative practice agreements that were authorized by previous legislatures. These changes will take effect on July 20, 2011. Unfortunately the governor's office has placed a moratorium on rules changes by state agencies including the Arizona State Board of Pharmacy, which has been in effect for at least the last two years and will continue indefinitely. In the absence of a rules moratorium, the Board's normal practice would have been to write rules that "flesh out" the statutes and the Board would modify and/or eliminate those rules that have been made obsolete by the new statutes. Since the Board is bound to abide by the existing rules moratorium, the existing rules will continue to be published and will contradict the new statutes resulting in a state of confusion which may persist for some period of time. As a general "rule of thumb" statutes passed by the legislature and signed by the governor "trump" or take precedence over rules promulgated by the Board. Therefore, until the Board's proposed rules have been finalized (hopefully by early 2012), the Board will be enforcing the legislative statute changes in Senate Bill 1298 and not enforcing the Board administrative rules in all cases of conflict between them.*

#### **ARTICLE 4. PROFESSIONAL PRACTICES**

##### **R4-23-421. Drug Therapy Management Repeal**

- A.** ~~A pharmacist qualified under R4 23 424 may provide drug therapy management under A.R.S. § 32 1970 after a physician's initial diagnosis of a patient if drug therapy management:~~
- ~~1. Is guided by a Board approved drug therapy management agreement; and~~
  - ~~2. Occurs in one of the following pharmacy practice sites:
    - ~~a. An acute care hospital,~~
    - ~~b. A nursing care institution,~~
    - ~~c. A staff model HMO, or~~
    - ~~d. A community health center as defined in A.R.S. § 32 1921 and A.R.S. § 36 2907.06.~~~~
- B.** ~~A drug therapy management agreement shall contain the following:~~
- ~~1. The criteria and medical conditions under which the pharmacist may modify a patient's drug therapy;~~
  - ~~2. The specific modifications of drug therapy that the pharmacist may make including drug, dose, and dosage form;~~
  - ~~3. The criteria and medical conditions under which the pharmacist may implement a patient's drug therapy;~~
  - ~~4. The specific drug therapy that a pharmacist may implement including drug, dose, and dosage form;~~
  - ~~5. The subjective and objective patient assessment parameters that a pharmacist uses to evaluate a patient's drug therapy at each patient visit, including ordering and interpreting a patient's laboratory tests;~~
  - ~~6. The subjective and objective patient assessment criteria that indicate when a pharmacist shall consult with a supervisory physician or if unavailable, an~~

- alternate physician, including the timing and nature of a consultation with or referral to a supervisory or alternate physician and the specific procedures for a consultation with or referral to a supervisory or alternate physician;
7. ~~The content and frequency of the periodic status report on a patient that a pharmacist shall provide in writing to or in a meeting with the supervisory physician;~~
  8. ~~The procedure for terminating the drug therapy management agreement;~~
  9. ~~The names of the supervisory physician, the alternate physician, and the pharmacist authorized to provide services under the agreement; and~~
  10. ~~The signature of all persons named in subsection (B)(9).~~

**R4-23-422. ~~Drug Therapy Management – Duties of the Board~~ Repeal**

- A.** ~~The Board shall:~~
1. ~~Appoint a Drug Therapy Management Advisory Committee;~~
  2. ~~In consultation with Board staff and the Drug Therapy Management Advisory Committee, approve or deny an initial drug therapy management agreement and the annual renewal of an existing drug therapy management agreement;~~
  3. ~~Terminate a pharmacist's drug therapy management agreement if the pharmacist:~~
    - a. ~~Does not renew the agreement on or before the approval date anniversary; or~~
    - b. ~~Is found by the Board to lack the qualifications required in R4 23 424; and~~
  4. ~~In processing a drug therapy management agreement application, comply with the application process established in R4 23 602, except the substantive review time frame is 180 days and the overall time frame is 200 days.~~
- B.** ~~The Board may terminate a pharmacist's drug therapy management agreement if the Board determines that the pharmacist is violating the requirements of the drug therapy management agreement or federal or state drug laws.~~

**R4-23-423. ~~Drug Therapy Management Advisory Committee~~ Repeal**

- A.** ~~The Drug Therapy Management Advisory Committee shall:~~
1. ~~Consist of an osteopathic physician, an allopathic physician, and two pharmacists with prior or current experience in drug therapy management;~~
  2. ~~Serve at the pleasure of the Board;~~
  3. ~~Serve for a term of two years unless removed or reappointed by the Board;~~
  4. ~~Review initial and renewal drug therapy management agreement applications; and~~
  5. ~~Advise the Board regarding the approval or denial of reviewed drug therapy management agreement applications.~~
- B.** ~~The Drug Therapy Management Advisory Committee members are not eligible for compensation from the Board.~~

**R4-23-424. ~~Drug Therapy Management – Pharmacist and Physician Qualifications~~ Repeal**

- A.** ~~Pharmacist qualifications:~~
1. ~~Before initiating a drug therapy management agreement with a supervisory~~

physician, a pharmacist shall have:

- a. ~~A current, unrestricted license issued by the Board; and~~
- b. ~~Proof of one of the following:~~
  - i. ~~Completion of a pharmacy practice residency accredited by the American Society of Health Systems Pharmacists or the American Pharmaceutical Association;~~
  - ii. ~~Current board specialty certification from the Board of Pharmaceutical Specialists or current certification as a Certified Geriatric Pharmacist;~~
  - iii. ~~A Doctor of Pharmacy degree and completion of an American Council on Pharmaceutical Education approved certificate program in each area of practice covered in the drug therapy management agreement; or~~
  - iv. ~~A Bachelor's degree in Pharmacy, satisfactory completion of an American Council on Pharmaceutical Education approved certificate program in each area of practice covered in the drug therapy management agreement, and appropriate credentialing issued by the governing body of a qualifying Arizona practice site described in A.R.S. § 32-1970.~~

2. ~~To ensure that a pharmacist who provides drug therapy management is competent to continue providing the services delineated in a drug therapy management agreement, a pharmacist shall annually complete six contact hours (0.6 CEU's) of continuing education for each area of practice covered by the pharmacist's drug therapy management agreement. The continuing education hours may be used to satisfy the continuing education requirements for licensure as a pharmacist.~~

**B.** ~~Supervisory physician qualifications. Before initiating a drug therapy management agreement with a pharmacist, a supervisory physician shall:~~

1. ~~Have a current, unrestricted license from the Allopathic Board of Medical Examiners or the Board of Osteopathic Examiners in Medicine and Surgery; and~~
2. ~~Not be a resident in a post-graduate medical training program.~~

**C.** ~~Alternate physician qualifications. Before initiating a drug therapy management agreement with a pharmacist, an alternate physician shall:~~

1. ~~Have a current, unrestricted license from the Allopathic Board of Medical Examiners or the Board of Osteopathic Examiners in Medicine and Surgery; and~~
2. ~~Not be a resident in a post-graduate medical training program.~~

#### **R4-23-425. Drug Therapy Management – Pharmacist Duties Repeal**

**A.** ~~To obtain initial approval for a drug therapy management agreement, a pharmacist shall submit a completed application, on a form furnished by the Board, that includes:~~

1. ~~Pharmacist name and Arizona pharmacist license number;~~
2. ~~Documentation of the pharmacist's qualifications as specified in R4-23-424;~~
3. ~~Practice site name, address, mailing address if different, telephone number;~~

- and fax number;
- ~~4. Documentation of practice site qualification under A.R.S. § 32-1970;~~
  - ~~5. Supervisory physician name, office address, mailing address if different, telephone number, and fax number;~~
  - ~~6. Documentation of the supervisory physician's qualifications as specified in R4-23-424;~~
  - ~~7. Alternate physician name, office address, mailing address if different, telephone number, and fax number;~~
  - ~~8. Documentation of the alternate physician's qualifications as specified in R4-23-424;~~
  - ~~9. Description of the pharmacist's practice area or areas for which approval is sought;~~
  - ~~10. An original and 11 copies of the drug therapy management agreement covering each practice area for which Board approval is sought;~~
  - ~~11. Dated and signed affirmation of the supervisory physician's acceptance of the responsibility for oversight of the pharmacist's drug therapy management;~~
  - ~~12. Dated and signed affirmation of an alternate physician's acceptance of the responsibility for temporary oversight of the pharmacist's drug therapy management; and~~
  - ~~13. Dated and signed affirmation of the pharmacist's acceptance of the responsibility to provide drug therapy management as described in the drug therapy management agreement.~~
- ~~B. To renew an existing drug therapy management agreement, a pharmacist shall submit a completed renewal application, on a form furnished by the Board, that includes, in addition to the requirements of subsection (A), the following:~~
- ~~1. Documentation that the supervisory physician, alternate physician, and participating pharmacist reviewed the protocols contained in the agreement;~~
  - ~~2. Documentation that the participating pharmacist completed the continuing education requirements specified in R4-23-424; and~~
  - ~~3. An original and 11 copies of the drug therapy management agreement covering each practice area for which renewal is sought, including highlighting any requested modifications to the agreement.~~
- ~~C. A pharmacist who participates in a Board-approved drug therapy management agreement shall:~~
- ~~1. Renew the agreement annually on or before the initial approval date anniversary;~~
  - ~~2. Before submitting the application to renew the agreement, participate with the supervisory physician in reviewing the agreement;~~
  - ~~3. Notify the Board within ten days of termination of the drug therapy management agreement;~~
  - ~~4. During the first appointment with a patient under a Board-approved drug therapy management agreement:
    - ~~a. Verify that a copy of the drug therapy management agreement, which includes the signature of the supervisory physician, alternate physician, and pharmacist, is placed in the patient's medical record;~~
    - ~~b. Verify that a copy of the supervisory physician's written order, which~~~~

- authorizes the pharmacist to collaboratively manage the patient's drug therapy, is placed in the patient's medical record; and
- c. — Verify that a copy of the patient's written consent, which shows that the patient understands the pharmacist's role in the patient's care, the nature of the relationship with the supervisory physician, and the procedure for revoking consent, is placed in the patient's medical record;
  - 5. — Ensure compliance with the documentation requirements of R4-23-427;
  - 6. — Ensure compliance with quality assurance program required in R4-23-428;
  - 7. — Ensure compliance with the privacy requirements of R4-23-429; and
  - 8. — Comply with the Board approved drug therapy management agreement.

**R4-23-426. Drug Therapy Management – Physician Duties Repeal**

- A. — Before referring a patient to a pharmacist, a supervisory physician who participates in a Board approved drug therapy management agreement shall:
  - 1. — Have a physician-patient relationship with the patient and make a diagnosis of the patient;
  - 2. — Review the approved drug therapy management agreement with the patient;
  - 3. — Obtain the patient's consent to participate in the drug therapy management agreement;
  - 4. — Document the patient's consent to participate in the drug therapy management agreement by obtaining the patient's dated and signed consent that states that the patient has read, understood, and agreed to participate in the drug therapy management agreement. The dated and signed consent shall be placed in the patient's medical records;
  - 5. — Authorize a specific pharmacist to collaboratively manage a patient's drug therapy by placing a written order in the patient's medical record; and
  - 6. — Place a copy of the approved drug therapy management agreement in the patient's medical record to provide notice to other health care providers of the drug therapy management.
- B. — Physician supervision. A supervisory physician who supervises a pharmacist under a Board approved drug therapy management agreement shall:
  - 1. — Before submitting the application to renew the agreement and in consultation with the participating alternate physician and pharmacist, review and approve the drug therapy management agreement;
  - 2. — Review and initial the pharmacist's documented care for appropriateness of care and compliance with the drug therapy management agreement when the patient visits the supervisory physician for follow-up or any other services;
  - 3. — Routinely evaluate the patient care provided by the pharmacist as specified in the drug therapy management agreement; and
  - 4. — Ensure that the supervisory physician or the alternate physician is readily available to the pharmacist for consultation, assistance, and direction by direct telecommunication or physical presence at the practice site.
- C. — Alternate physician duties. An alternate physician who participates in a Board approved drug therapy management agreement shall ensure that the alternate physician is available to:
  - 1. — Temporarily assume responsibility for supervision and evaluation of the drug

- therapy management performed by the pharmacist;
2. Provide consultation, assistance, and direction to the pharmacist when the supervisory physician is unavailable; and
  3. Before submitting the application to renew the agreement, participate with the supervisory physician and pharmacist in reviewing the agreement.

**R4-23-427. Drug Therapy Management – Documentation Repeal**

Documenting pharmacist provided drug therapy management. A pharmacist who participates in drug therapy management under a Board-approved drug therapy management agreement shall:

1. After each patient pharmacist appointment, document the drug therapy management for the patient in the patient's medical record at the practice site, including patient data, assessment of patient status, and treatment plan;
2. Date and sign the documentation required in subsection (1) in a patient's medical record with the pharmacist's first and last name, title, and Arizona pharmacist license number;
3. Document a consultation with or referral to the supervisory physician or the alternate physician; and
4. Document a consultation with a supervisory or alternate physician that results in a pharmacist's need to generate the physician's verbal prescription order for a drug not included in the drug therapy management agreement. The documentation shall include:
  - a. The phrase "verbal order by Dr." and the name of the supervisory physician or alternate physician authorizing the verbal prescription order,
  - b. The date and signature of the pharmacist generating the verbal prescription order in the same manner described in subsection (2), and
  - c. The countersignature of the supervisory physician or alternate physician authorizing the verbal prescription order within 72 hours of the pharmacist generated verbal prescription order.

**R4-23-428. Drug Therapy Management – Quality Assurance Repeal**

- A. A pharmacist who provides drug therapy management shall, in cooperation with the supervisory physician and the appropriate committee of the practice site, develop and implement a continuous quality assurance and improvement program that includes standards and procedures to identify, evaluate, and improve the quality of pharmacist provided drug therapy management.
- B. Periodic status reports or meetings between a pharmacist and supervisory physician regarding care of a patient under the drug therapy management agreement shall include evaluating and documenting patient status and the quality of care provided by the pharmacist.

**R4-23-429. Drug Therapy Management – Privacy Repeal**

- A. A pharmacist who provides drug therapy management shall perform drug therapy

~~management activities in a private and distinct area of the practice site.~~

- ~~**B.** In a practice site where a pharmacist provides drug therapy management under a drug therapy management agreement, a pharmacy permittee shall ensure that a private and distinct area of similar size and environment to that used by other primary care providers at the practice site is available for the performance of pharmacist provided drug therapy management activities.~~