Disease State Management

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Regulation 09-01

Disease State Management
A pharmacist licensed by the Arkansas State Board of Pharmacy and credentialed in DSM may enter into a written protocol agreement with a:

a. Physician Assistant
b. Dentist
c. Nurse Practitioner
d. Chiropractor

To practice DSM a pharmacist must:

a. offer 4 hours of DSM services weekly
b. complete a disease-specific, disease state management program
c. complete requirements for a credential as established by a Board of Pharmacy approved organization
d. obtain 15 hours of CE every year in DSM
Disease State Management patient records may be released without the written consent of the patient to:

a. the patient’s spouse
b. a Board of Pharmacy Inspector
c. the patient’s attorney
d. a Pharmacy Benefits Manager representative

All are requirements of a written protocol EXCEPT:

a. identification of the individual practitioner authorized to prescribe.
b. identification of the individual pharmacist engaged in DSM.
c. types of DSM decisions the pharmacist is authorized to make.
d. dates and times DSM will be offered.
What is Disease State Management?

Disease State Management (DSM) means the performance of specific acts of disease state management delegated to a pharmacist for an individual patient by an authorized practitioner through a written protocol.

Pharmacy Practice Act

(A) DSM is a strategy which utilizes a team-oriented, multi-disciplinary approach to improve health care outcomes and quality of care, and when possible, control health care cost through management of targeted chronic disease states

(B) DSM focuses on improving health care from prevention to diagnosis and treatment to on-going follow-up

(C) DSM will involve, but not be limited to, patient education, self-care techniques, and outpatient drug therapy management pursuant to a patient care plan;
What is a Written Protocol?

(A) “Written protocol” means a physician’s order, standing medical order, standing delegation order, or other order or protocol as defined by regulation of the Arkansas State Medical Board under the Arkansas Medical Practices Act, §§17-95-201 – 17-95-207, 17-95-301 – 17-95-305, and 17-95-401 – 17, 95-411.

(B) Except for immunizations and vaccinations, which may be general protocols, protocols shall be patient or physician or pharmacist-specific for prescriptions or orders given by the physician authorizing the protocol.
Written Protocols

- Individual Patient-Specific Protocol
- Standard Protocol
- Standard Protocol with patient-specific deviations

What is required of a Written Protocol?
Protocol Components

- Authority
- Scope of Practice
- Documentation
- Reporting
- Record Retention
- Agreement Review and Duration
- Rescindment of Agreement
- Signatures
Protocol Requirements

- Identification of practitioner authorized to prescribe drugs and responsible for the delegation of disease state management

- Identification of pharmacist authorized to dispense and to engage in DSM

AUTHORITY
As a physician who holds an active license to practice from the Arkansas Board of Medicine, I, __________, M.D./D.O. authorize __________, Pharm.D./P.D., a pharmacist who holds an active license to practice from the Arkansas State Board of Pharmacy, to manage and/or treat patients under my care pursuant to a written order from me. This authority follows the laws of the Arkansas Pharmacy Practice Act, ACA § 17-92-100 et. seq. and Regulation 09 of the Arkansas State Board of Pharmacy.
Protocol Requirements

AUTHORITY
As the Northwest Area Health Education Center Medical Director and a physician who holds an active license to practice from the Arkansas Board of Medicine, I, __________, M.D./D.O. authorize the below mentioned pharmacists who hold active licenses to practice from the Arkansas State Board of Pharmacy, to manage and/or treat patients of the Northwest AHEC Clinic pursuant to written, patient-specific orders from me or my designee. This authority follows the laws of the Arkansas Pharmacy Practice Act, ACA § 17-92-100 et. seq. and Regulation 09 of the Arkansas State Board of Pharmacy.

Protocol Components

- Authority
- Scope of Practice
- Documentation
- Reporting
- Record Retention
- Agreement Review and Duration
- Rescindment of Agreement
- Signatures
Protocol Requirements

- Statement identifying the types of disease state management decisions that the pharmacist is authorized to make which shall include:
  - ailments or diseases involved, drugs, types of drug therapy management authorized
  - specific statement of procedures, decision criteria, or the plan the pharmacist shall follow when exercising DSM authority

SCOPE OF PRACTICE

Upon receipt of a written order from (the physician practitioner), (pharmacist) will have the authority to manage and/or treat patients in accordance with this section. In managing and/or treating patients, (pharmacist) may modify drug therapy as described below.
Protocol Requirements

SCOPE OF PRACTICE
The pharmacist will coordinate the therapeutic interchange process by substituting dose equivalent medications according to the chart below and third-party payer coverage for patients presenting with prescription medications treating GERD and PUD.

With each therapeutic interchange the pharmacist will counsel the patient or his or her representative about the recommended drug substitution to ensure no drug allergies, drug interactions, previous adverse reactions or treatment failure, or other special needs exist.

Protocol Requirements

SCOPE OF PRACTICE
In managing and/or treating patients, the clinical pharmacist shall assess response to pharmacotherapy, which may involve performing limited physical assessments, may initiate, modify or discontinue drug therapy to optimize disease outcomes, authorize refills for chronic medications, may order laboratory tests or perform point of care testing appropriate to specific medication/disease monitoring, educate patients regarding their medications or disease entities, and may exercise other patient care management measures related to the monitoring or improving the outcomes of drug or device therapy.
Protocol Requirements

SCAPE OF PRACTICE

The clinical pharmacist will have the authority to manage diabetes therapy as outlined in American Diabetes Association Clinical Practice Recommendations 2010. In doing so, he/she will have authority to manage the use of medications in the following classes:

- Sulfonylureas
- Biguanides
- Alpha-glucosidase inhibitors
- Meglitinides
- Thiazolidinediones
- Amylinomimetics
- Incretin mimetics
- Dipeptidyl peptidase-4 inhibitors
- Insulins

Protocol Recommendations

- References for Scope of Practice
  - National Practice Guidelines
    - www.guidelines.gov
  - Updates to Guidelines
  - Current literature
  - Reputable Sources
Protocol Components

- Authority
- Scope of Practice
- Documentation
- Reporting
- Record Retention
- Agreement Review and Duration
- Rescindment of Agreement
- Signatures

Protocol Requirements

A statement of the activities the pharmacist shall follow in the course of exercising disease state management authority, including the method for documenting decisions made......

Documentation shall be recorded within a reasonable time of each intervention and may be performed on the patient medication record, patient medical chart, or in a separate log book.
Protocol Requirements

- Pharmaceutical Care record keeping requirements:
  - written request for consultation
  - practitioner approved protocol
  - complete medication history/profile
  - pharmacy progress notes
  - laboratory data

Arkansas State Board of Pharmacy Regulation 09-01-0003(c)

DOCUMENTATION

The practitioner shall document a written request for Disease State Management Services.

The patient’s Pharmaceutical Care Record will contain the written request for DSM Services from the ordering physician and/or patient and the Written Protocol. The pharmacist shall document each encounter with the patient in the patient’s Pharmaceutical Care Record. That documentation will include as a minimum: the reason for the encounter, any changes in the patient’s condition, complete medication history any test results, and any changes made to the patient’s treatment plan.
Protocol Requirements

**DOCUMENTATION**
The practitioner shall document a written request for Disease State Management Services.

The pharmacist shall document each encounter with the patient in the patient’s medical record. That documentation will include as a minimum: the reason for the encounter, any changes in the patient’s condition, any test results, and any changes made to the patient’s treatment plan.

Protocol Components

- Authority
- Scope of Practice
- Documentation
- Reporting
- Record Retention
- Agreement Review and Duration
- Rescindment of Agreement
- Signatures
Protocol Requirements

A statement of the activities the pharmacist shall follow in the course of exercising disease state management authority, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made.

A statement that describes appropriate mechanisms and time schedule for the pharmacist to report to the physician monitoring the pharmacist's exercise of delegated disease state management and the results of the disease state management.

Arkansas State Board of Pharmacy Regulation 09-01-0001(a)

REPORTING

The pharmacist shall report back to the authorizing physician any specific decisions made during the course of Disease State Management within _______ days of exercising the delegated Disease State Management by means of electronic mail, hand-delivered mail, fax or the patient’s clinical medical record.
Protocol Requirements

REPORTING
The pharmacist shall report back to the authorizing physician any specific decisions made during the course of Disease State Management by means of documentation in the patient’s clinical medical record.

Protocol Components

- Authority
- Scope of Practice
- Documentation
- Reporting
- Record Retention
- Agreement Review and Duration
- Rescindment of Agreement
- Signatures
Protocol Requirements

A copy of the written protocol and any patient-specific deviations from the protocol shall be maintained by the pharmacist and available for inspection by a Board Inspector upon request.

Every patient record required to be kept under this regulation shall be kept by the pharmacist and be available, for at least two (2) years from the date of such record, for inspecting and copying by the Board or its representative and to other authorized local, state, or federal law enforcement or regulatory agencies.

Arkansas State Board of Pharmacy Regulation 09-01-0001(c)

Protocol Requirements

RECORD RETENTION

Each signatory to this agreement shall keep a signed copy of this agreement on file at their primary place of practice.

The records maintained in the Pharmaceutical Care Record shall be kept by the pharmacist and be available, for at least two (2) years from the date of such record.
Protocol Components

- Authority
- Scope of Practice
- Documentation
- Reporting
- Record Retention
- Agreement Review and Duration
- Rescindment of Agreement
- Signatures

Protocol Requirements

Written protocols, including standard protocols, any patient specific deviations from a standard protocol, and any individual patient protocol, shall be reviewed by the practitioner and pharmacist at least annually and revised, if necessary.
Protocol Requirements

AGREEMENT REVIEW AND DURATION
This agreement may be reviewed and revised at any time at the request of any signatories. In no case will the time between reviews exceed one year.

Written Protocols

• RESCINDMENT OR ALTERATION OF AGREEMENT

• AGREEMENT SIGNATURES
DSM Patient Records

Other Considerations

Maintenance of Records

- Alternative data retention systems
  - data processing systems
  - direct imaging systems
- Must contain all information required on a manual record
- Must be capable of producing hard copy

Arkansas State Board of Pharmacy Regulation 09-01-0001(d)
Confidentiality

- Must have adequate security
- Must only release records to authorized personnel

Regulation 09-01-0003

Qualifications, Resources, and Record Keeping Required for Practicing Disease State Management in Arkansas
Qualifications

- licensed pharmacist in the State of Arkansas
- complete requirements for credential

Resource Requirements

- Distinct area that provides privacy
- References
  - current copy/edition of applicable national practice guidelines
  - other necessary resources
- Devices, supplies, furniture and equipment
(1) The pharmacist shall be capable of identifying and accessing the patient’s current health status, health-related needs and problems, and desired therapeutic outcomes.
DSM Competencies

(2) The pharmacist shall be capable of implementing, and evaluating a pharmaceutical care plan that assures the appropriateness of the patient’s medication(s), dosing regimens, dosage forms, routes of administration, and delivery systems.

Arkansas State Board of Pharmacy Regulation 09-01-0004(a)

DSM Competencies

(3) The pharmacist shall be capable of communicating appropriate information to the patient and/or caregiver and other health care professionals regarding prescription or non-prescription medications and/or medical devices, disease states, or medical conditions, and the maintenance of health and wellness.

Arkansas State Board of Pharmacy Regulation 09-01-0004(a)
DSM Competencies

(4) The pharmacist shall be capable of monitoring and documenting the patient’s progress toward identified endpoints and outcomes of the pharmaceutical care plan and shall intervene when appropriate.

Resources

- “Building a Successful Collaborative Pharmacy Practice” APhA
- “Collaborative Drug Therapy Management Handbook” ASHP
- ACCP Ambulatory Care PRN Listserv
- Pharmacist’s Letter