

MEDICATION THERAPY SERVICES COMPLIANCE GUIDE

In 2007, [§ 338.010](#), RSMo was amended to grant Missouri pharmacists authority to perform “medication therapy services” after obtaining a certificate of medication therapeutic plan authority from the Missouri Board of Pharmacy. The Board will begin issuing certificates on August 30, 2012. This Guide provides basic information on the new requirements.¹

WHAT ARE MEDICATION THERAPY SERVICES?

“Medication therapy services” are defined in rule [20 CSR 2220-6.060\(1\)\(F\)](#) as “the designing, initiating, implementing, or monitoring of a plan to monitor the medication therapy or device usage of a specific patient, or to enhance medication therapeutic outcomes of a specific patient, by a pharmacist who has **authority to initiate or implement a modification of the patient’s medication therapy or device usage pursuant to a medication therapy protocol.**” Pharmacists must obtain a certificate of medication therapeutic plan authority (“MT certificate”) from the Board prior to performing medication therapy services (“MT services”).

MT services are different from “medication therapy management.” As commonly defined, medication therapy management includes a group of pharmacist provided services designed to optimize patient therapeutic outcomes. Medication therapy management is within the scope of the “practice of pharmacy” and can be performed by any Missouri licensed pharmacist (i.e.- Medicare Part D medication therapy management). [A MTS certificate is only required if a pharmacist is engaged in or has authority to initiate or modify drug/device therapy.](#)



Modification of drug therapy includes, but is not limited to,:

- ☑ Selecting a new, different or additional medication or device (including initiating therapy)
- ☑ Discontinuing any current medication/device
- ☑ Selecting a new, different or additional strength, dose, dosage form or dosage schedule
- ☑ Selecting, adding or changing a new or different route of administration [[20 CSR 2220-6.060\(1\)\(D\)](#)].

Modification does not include dispensing a drug/device pursuant to a valid prescription from an authorized prescriber or selecting a generic substitution as authorized by [§ 338.056](#). Additionally, “medication therapy services” do not include administering medication by prescription order pursuant to [20 CSR 2220-6.040](#) or administering vaccines by protocol pursuant to [20 CSR 2220-6.050](#).

Prior to performing MT services, a pharmacist must have:

- ☑ A MT certificate issued by the Board, and
- ☑ A protocol with a Missouri licensed physician who is actively practicing medicine in Missouri.

¹ *This document is provided for informational purposes only and is solely applicable to persons and entities under the jurisdiction of the Missouri Board of Pharmacy. Licensees should review the full text of the rules to ensure compliance. This document does not constitute a rule statement of general applicability or binding law. In the event of a conflict or inconsistency, duly promulgated or enacted state or federal law shall control. The Board expressly reserves the right to revise the contents as deemed appropriate or necessary.*

Note: The Board does not have jurisdiction over hospital inpatient pharmacy practice and is legally reviewing the applicability of the new MTS rules to licensees practicing in a hospital inpatient setting. In the interim, licensees should consult with legal counsel to ensure compliance.

SCOPE OF AUTHORITY

Licensees holding a current MT certificate may perform medication therapy services as authorized by their governing protocol. However, the following restrictions/prohibitions apply:

- **Pharmacists may not initiate or modify any controlled substance.**
- **Pharmacists may not independently prescribe.** Instead, medication may only be modified or initiated as authorized by a written protocol with a Missouri physician.
- **Pharmacists may not diagnose.**
- **MT services may not be delegated.** Pursuant to [§ 338.010](#), MT services may only be performed by a pharmacist who holds a MT certificate. Pharmacy technicians and intern pharmacists may assist in providing services under the supervision of a pharmacist. However, technicians and interns may not initiate or modify drug therapy or perform any act that requires the professional judgment of a pharmacist.

CERTIFICATE REQUIREMENTS

Pharmacists performing MT services in Missouri must have a MT certificate issued by the Board (*see below for inpatient hospital services*). An MT certificate is not required to administer medication by prescription order pursuant to [20 CSR 2220-6.040](#) or to administer vaccines by protocol under [20 CSR 2220-6.050](#). For detailed information on obtaining a MT certificate, see [20 CSR 2220-6.070](#) and the [Board's Medication Therapy Services Q&A](#) on the website.

MT certificate holders must complete 6 hours of continuing education in courses/programs related to medication therapy management each pharmacist biennial renewal period. [\[20 CSR 2220-6.070\(3\)\]](#). The required CE may be used to satisfy Missouri's biennial pharmacist CE requirements.

Residents: Pharmacy residents must satisfy all MTS certificate requirements. However, the Board does not have jurisdiction over hospital inpatient pharmacy practice and is legally reviewing the applicability of the MTS rules to pharmacy residents practicing in a hospital inpatient setting. In the interim, licensees should consult with legal counsel to ensure compliance.

PROTOCOLS

Prior to performing MT services, pharmacists must have a written protocol with a Missouri licensed physician who is actively practicing medicine in the state of Missouri and whose practice location is no more than fifty (50) miles by road from the pharmacist. [\[20 CSR 2220-6.080\(3\)\]](#).

The Board does not have a form or recommended protocol. However, protocols should clearly delineate the pharmacist's scope of authority. As detailed in [20 CSR 2220-6.080\(4\)](#), protocols must include:

- ☑ The names and signatures of the participating physician(s) and pharmacists(s)
- ☑ The effective date of the protocol
- ☑ A description of MT services the pharmacist is authorized to provide. Authorized MT services must be within the skill, education, training and competence of the authorizing physician and pharmacist.
- ☑ A list of clinical conditions, diagnoses and diseases included in the written protocol and the type of medication therapy allowed in each case
- ☑ The specific drugs or drug categories included in the protocol
- ☑ A statement of the methods, procedures, decision criteria and plan the pharmacist is to follow when providing MT services

- ☑ A description of any authority granted to the pharmacist to administer medication
- ☑ A list of drugs the pharmacist is authorized to administer
- ☑ A description of drug therapy related patient assessment procedures or testing the pharmacist may order or perform
- ☑ Procedures for documenting the pharmacist's MT decisions
- ☑ Procedures and requirements for communicating and reporting MT decisions to the authorizing physician
- ☑ Criteria for timely communication between the pharmacist and authorizing physician
- ☑ A statement prohibiting the pharmacist from delegating the responsibility of MT services
- ☑ Methods for physician review of MT activities
- ☑ Provisions allowing the authorizing physician to access patient records
- ☑ Mechanisms and procedures that allow the authorizing physician to override, rescind or otherwise modify the protocol
- ☑ Procedures the pharmacist is authorized to follow to address emergency situations, including, anaphylactic or other adverse medication reactions, adverse needle sticks or other adverse events
- ☑ All notification requirements required by [20 CSR 2220-6.080\(5\)](#) (*see below*)
- ☑ An address where required records will be maintained. [\[20 CSR 2220-6.080\(4\)\(B\)\]](#).

Practicing outside of the authority granted by protocol constitutes grounds for discipline by the Board under [§ 338.055](#).

Protocols must be signed and dated by both the authorizing physician and participating pharmacist. [\[20 CSR 2220-6.080\(4\)\(D\)\]](#). If multiple physicians and pharmacists are involved, a separate protocol is not required for each participating physician/pharmacist if all authorizing physicians and pharmacists sign and date a statement agreeing to be governed by the terms of the protocol. [\[20 CSR 2220-6.080\(4\)\(D\)\]](#).

Modifications/amendments to the protocol must be documented in writing and signed and dated by both the pharmacist and the authorizing physician prior to implementing the modification/amendment. [\[20 CSR 2220-6.080\(4\)\(E\)\]](#). Protocols may be rescinded by the authorizing physician or pharmacist with or without cause, provided the rescission is documented in writing. [\[20 CSR 2220-6.080\(4\)\(B\)6.\]](#).

Protocols should be regularly reviewed to ensure appropriateness of services. At a minimum, protocols must be reviewed and signed annually by the authorizing physician and pharmacist. [\[20 CSR 2220-6.080\(4\)\(C\)\]](#). The annual review date must be documented on the written protocol.

Protocols do not have to be filed with the Board. Instead, protocols must be retained and provided to the Board or the Board's designee upon request. Both the pharmacist and authorizing physician must retain signed copies of the written protocol for eight (8) years after the protocol is terminated. [\[20 CSR 2220-6.080\(4\)\(G\)\]](#).

Pharmacy Residents: In lieu of an individual protocol, a pharmacy resident may perform MT services under the written protocol of another Missouri pharmacist if:

- ☑ The resident holds a MT certificate from the Board,
- ☑ The resident is enrolled in a residency training program accredited by the American Society of Health System Pharmacists (ASHP) or a residency training program with a valid application for accreditation pending with ASHP, and;
- ☑ The resident is providing MT services under the supervision of a Missouri pharmacist with a current MT certificate issued by the Board. [\[20 CSR 2220-6.080\(4\)\(I\)\]](#).

Note: The Board does not have jurisdiction over hospital inpatient pharmacy practice and is legally reviewing the applicability of the new MTS rules to pharmacy residents practicing in a hospital inpatient setting. In the interim, licensees should consult with legal counsel to ensure compliance.

PREScription ORDERS

To provide MT services for a specific patient, a pharmacist must obtain a prescription order from their authorizing physician authorizing the pharmacist to perform MT services. [\[20 CSR 2220-6.080\(2\)\(A\)\]](#).

The prescription order must include:

- The patient's name, address and date of birth
- The date the prescription order was issued
- The clinical indication for MT services (i.e. - the patient's clinical condition, diagnosis or disease)
- The authorizing physician's name and address
- The length of time for providing MT services, if less than one (1) year. [\[20 CSR 2220-6.080\(2\)\(A\)\]](#).

Prescription orders for MT services are valid for no more than one (1) year and may be transmitted verbally, electronically or in writing. [\[20 CSR 2220-6.080\(2\)\(A\)\]](#). Written orders for MT services must be in the 2-line format required by [§ 338.056](#). For verbal orders, all information required by [20 CSR 2220-6.080\(2\)](#) must be documented in the patient record required by [20 CSR 2220-6.080\(2\)\(D\)](#) (*see Records section below*). [\[20 CSR 2220-6.080\(2\)\(B\)\]](#).

Prescription orders must be maintained in the required patient record along with documentation of any changes or alterations made to the prescription order based on contact with the prescriber. [\[20 CSR 2220-6.080\(2\)\(D\)\]](#).

DOCUMENTATION OF MT SERVICES

Pharmacists must document and maintain an adequate patient record of MT services provided for each patient. [\[20 CSR 2220-6.080\(7\)\]](#). At a minimum, the patient record must include:

- The patient's name, birthdate, address and telephone number
- The dates of any patient visits/consultations and the reason for the visit/consultation
- Any pertinent assessments, observations or findings
- Any diagnostic testing recommended or performed
- The name of any medication or device modified. All therapy modifications made by the pharmacist must be documented in the patient record.
- The strength, dose, dosage schedule or route of administration of any medication modified or administered
- Referrals to the authorizing physician
- Referrals for emergency care
- Any contact with the authorizing physician concerning the patient's treatment or MT services plan
- Any informed consent for procedures, medications or devices
- Any consultation with other treatment providers for the patient and the results of the consultation. [\[20 CSR 2220-6.080\(7\)\]](#)

If a modification of therapy results in a drug/device being dispensed or initiated, a prescription must be created under the authorizing physician's name for the medication or device dispensed or initiated. [\[20 CSR 2220-6.080\(6\)\(A\)\]](#). The authorizing physician should be the designated prescriber. Prescriptions created pursuant to [20 CSR 2220-6.080\(6\)\(A\)](#) must be maintained in the pharmacy's prescription records and may be dispensed by a licensed pharmacy.

NOTIFICATIONS

[20 CSR 2220-6.080\(5\)](#) requires the following notifications:

| TYPE | RECIPIENT | TIMEFRAME |
|---|--|--------------------------------|
| Anaphylactic or adverse medication reactions, adverse needle sticks or other adverse events | Authorizing physician or physician's authorized designee | 24-Hours |
| Therapy modifications | Authorizing physician or physician's authorized designee | 24-Hours |
| <i>Other notifications required by protocol</i> | <i>As governed by protocol</i> | <i>As governed by protocol</i> |

Notifications must be in writing unless otherwise authorized by the authorizing physician. [\[20 CSR 2220-6.080\(5\)\(D\)\]](#). Pharmacists providing MT services for, or on behalf of, a health care entity may satisfy the notification requirements if the notification is recorded in a patient medical record that the health care entity is required to maintain under state or federal law. [\[20 CSR 2220-6.080\(5\)\(C\)\]](#).

Protocols may include more stringent notification requirements. Failure to comply with protocol requirements constitutes grounds for discipline by the Board.

RECORDS

Records required by [20 CSR 2220-6.080](#) must be maintained for the following timeframes:

| TYPE | TIMEFRAME |
|--|---------------------------------------|
| Patient records required by 20 CSR 2220-6.080(7) | 7-years after termination of protocol |
| Protocols, including, protocol changes or amendments | 8-years after termination of protocol |
| Prescription orders for MT services | 7-years after termination of protocol |
| Other records required by protocol | As governed by protocol |

Records may be maintained electronically provided the records are subject to retrieval and review by the Board of Pharmacy or the Board of Registration for the Healing Arts. [\[20 CSR 2220-6.080\(7\)\(A\)\]](#). Records maintained at a pharmacy must be produced during an inspection or investigation if requested by the Board or its authorized designees. [\[20 CSR 2220-6.080\(8\)\]](#). Records not maintained at a pharmacy must be produced within three (3) business days of a request.

QUESTIONS

Questions regarding MT services may be addressed to lawquestions@pr.mo.gov. The full text of § 338.010 and the medication therapy services rules [\[20 CSR 2220-6.060 to 20 CSR 2220-6.080\]](#) are available on the Board's website.