105 CMR 721.000: STANDARDS FOR PRESCRIPTION FORMAT AND SECURITY IN MASSACHUSETTS

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721.001: Purpose

The purpose of 105 CMR 721.000 is to specify the requirements for Prescription format and security in Massachusetts.

721.003: Scope and Application

105 CMR 721.000 establishes the standards for format and security in the Commonwealth that all Prescriptions issued by practitioners or reduced to writing by pharmacists must meet in order to comply with M.G.L. c. 112, § 12D and M.G.L. c. 94C.

721.010: Definitions

The terms used in 105 CMR 721.000 shall have the meanings set forth in 105 CMR 721.010. Terms defined in M.G.L. c. 112, § 12D and M.G.L. c. 94C, § 1 and 105 CMR 700.001: *Definitions*, and not defined in 105 CMR 721.010 shall have the meanings set forth therein when used in 105 CMR 721.000, unless the context clearly requires a different interpretation.

Authentication means that the identities of the parties sending and receiving Electronic Prescription data are duly verified.

Commissioner means the Commissioner of the Massachusetts Department of Public Health or his or her designee.

Compounded Drug Preparation means a preparation created through mixing, assembling, altering, packaging, and labeling of a controlled substance as the result of a practitioner's order or in anticipation of such an order based on routine, regularly observed prescribing patterns. A Compounded Drug Preparation shall not include the reconstitution of pre-measured, commercially available controlled substances.

Department means the Massachusetts Department of Public Health.

Drug Product means the final dosage form of a drug that is marketed under a brand or generic name.

Electronic Prescribing System means an Electronic Prescribing System that meets federal requirements for Electronic Prescriptions for controlled substances, including the validation and Authentication requirements pursuant to 21 CFR 1311 Subpart C: *Electronic Prescriptions* for generation of Electronic Prescriptions for controlled substances. Electronic Prescribing Systems may be stand-alone systems, where the sole purpose for the system is the generation and transmission of Electronic Prescriptions, or part of a more comprehensive healthcare system such as an electronic health record.

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Electronic Prescription means a Prescription which is generated on an Electronic Prescribing System and sent by Electronic Transmission to a pharmacy without alteration of the Prescription information. As used in 105 CMR 721.000, Electronic Prescription does not include an order for medication which is dispensed for immediate administration to the ultimate user.

Electronic Signature means an electronic sound, symbol or process attached to or logically associated with a Prescription record and executed or adopted by a practitioner with the intent to sign said Prescription record and which is validated and authenticated in accordance with M.G.L. c. 110G and 21 CFR 1311 Subpart C: *Electronic Prescriptions* and other federal regulations applicable to Electronic Signatures generated through Electronic Prescribing Systems.

Electronic Transmission means that the record is seamlessly generated, transmitted and received on systems which are validated and authenticated in accordance with 21 CFR 1311 Subpart C: *Electronic Prescriptions* and other federal regulations applicable to Electronic Transmission of Prescriptions. The use of third-party intermediaries acting as conduits to route the Prescriptions from a prescriber to a pharmacy, where the systems of such third party intermediary meet the security requirements for Electronic Transmissions, are authorized under 105 CMR 721.000. Transmission by facsimile is not authorized as an Electronic Transmission.

Emergency Situation means

(1) situations in which the prescribing practitioner intends to prescribe a controlled substance, the immediate administration of which is necessary for the proper treatment of the intended ultimate user; and

a. it is not reasonably possible for the prescribing practitioner to generate or transmit an Electronic Prescription to be presented to the person dispensing the controlled substance prior to the dispensing; or

b. the prescribing practitioner determines that the Electronic Prescription requirement would result in a delay that would adversely impact the patient's medical condition; or

(2) any other Emergency Situation defined in Department guidance by the Commissioner, acting pursuant to M.G.L. c. 94C, § 17.

ePrescribing means generating a Prescription on an Electronic Prescribing System and sending by Electronic Transmission to a pharmacy without alteration of the Prescription information.

Failover means a document that originates as a schedule VI Electronic Prescription, but experiences an unforeseen defect, as outlined in Department guidance, during Electronic Transmission, and is converted to a computer generated facsimile.

Oral Prescription means an oral order for medication which is dispensed to or for an ultimate user, but not including an order for medication which is dispensed for immediate administration to the ultimate user.

Prescription means an oral, written or electronic order for a medication or device which is dispensed to or for an ultimate user. A Prescription does not mean an order for medication which is dispensed for immediate administration to the ultimate user.

Qualified Healthcare Professional means a physician, certified nurse practitioner, psychiatric nurse mental health clinical specialist or certified registered nurse anesthetist authorized to supervise prescriptive practice pursuant to M.G.L. c. 94C, § 80H and applicable regulations by the Board of Registration in Nursing.

Registration Number means the registration number assigned to a practitioner by the federal Drug Enforcement Agency authorizing them to generate Prescriptions for controlled substances. Practitioners who do not have a DEA Registration Number, as they prescribe only from schedule VI, shall use their Massachusetts Controlled Substance Registration number.

Written Prescription means a lawful paper-based order from a practitioner for a drug or device for a specific patient that is communicated directly to a pharmacist in a licensed pharmacy; provided, however, that "Written Prescription" shall not include an order for medication which is dispensed for immediate administration to the ultimate user.

721.020: Prescription Formats

(A) Every Prescription generated in the Commonwealth of Massachusetts must be an Electronic Prescription issued in accordance with 105 CMR 721.000 and include an Electronic Signature unless it is a Prescription issued in accordance with an exception listed in 105 CMR 721.070.

(B) A Prescription must enable the practitioner to instruct the pharmacist to dispense a brand name Drug Product by indicating "no substitution", provided that:

(1) the indication of "no substitution" is not the default indication;

(2) the Prescription indicates that "Interchange is mandated unless the practitioner indicates 'no substitution' in accordance with the law"; and

(3) the indication of "no substitution" is a unique element in the Prescription and shall not be satisfied by use of any other element, including the signature.

(C) The name and address of the practitioner shall be clearly indicated on the Prescription. A hospital or clinic Prescription shall have the name and address of the hospital or clinic clearly indicated on the Prescription.

(D) The Prescription shall contain the following information:

(1) the registration number of the practitioner;

(2) date of issuance of the Prescription;

(3) name, dosage, and strength per dosage unit of the controlled substance prescribed, and the quantity of dosage units;

(4) name and address of the patient, except in a veterinary Prescription, a Prescription for naloxone or other opioid antagonist approved by the Department, or a Prescription issued pursuant to 105 CMR 721.070(A)(7) or 105 CMR 721.070(A)(12), in which case the name and address may be left blank; provided however, the person taking delivery of the Prescription for naloxone or other opioid antagonist as approved by the Department may, but is not required to, be used in place of the name of the patient;

(5) directions for use, including any cautionary statements required;

(6) a statement indicating the number of times to be refilled; and

(7) if the Prescription is for an opioid substance in schedule II, a notation that the patient may fill, upon request, the Prescription in an amount less than the recommended full quantity indicated.

(E) A Prescription issued by a certified nurse practitioner, psychiatric nurse mental health clinical specialist, or certified registered nurse anesthetist shall also contain the name of the supervising qualified healthcare professional unless the nurse issuing the Prescription is authorized for independent practice pursuant to 244 CMR: *Board of Registration in Nursing*.

(F) Written Prescriptions, where permitted by state and federal law, shall be issued in accordance with 105 CMR 721.000 on a form that contains the practitioner's signature, must comply with procedures set forth in 105 CMR 721.020(B) through 105 CMR 721.020 (F), and shall either be:

(1) transmitted *via* facsimile or similar technology; or

(2) written on a tamper-resistant form consistent with federal requirements for Medicaid.

(G) A Failover shall be considered an Oral Prescription, and shall not require a Written or Electronic follow-up Prescription, provided:

(1) the Prescription contains all information required by M.G.L. c. 94C, § 20(a) except for the practitioner's signature, and the Prescription is immediately entered into a compliant electronic pharmacy system or otherwise reduced to writing by the dispensing pharmacist;

(2) if the prescribing practitioner is not known to the dispensing pharmacist, the dispensing pharmacist makes a reasonable good faith effort to determine that the Failover was issued by a prescribing practitioner; and

(3) the Prescription is not for an Additional Drug, as defined by 105 CMR 700.001: *Definitions*.

721.040: Invalid Prescriptions

(A) A Prescription in a format that does not conform to 105 CMR 721.000 is invalid and shall not be filled.

(B) A Prescription that does not meet the security requirements of 105 CMR 721.000 is invalid and shall not be filled.

(C) An Electronic Prescription transmitted through means other than Electronic Transmission is invalid, except in the event of a Failover, as verified pursuant to 105 CMR 721.020(G).

721.050: Prescribing More than One Drug Product

Practitioners who wish to prescribe more than one Drug Product, with the same or different dispensing instructions, shall place each Prescription on a separate Prescription form or record. More than one Drug Product may be prescribed in the hospital setting on a single form or record provided, however, that the Prescription provides clear directions for use and interchange of each Drug Product.

721.055: Partial Fill Prescriptions

(A) A pharmacist filling a Prescription for a schedule II controlled substance shall, if requested by the patient, dispense the prescribed controlled substance in a lesser quantity than indicated on the Prescription, pursuant to M.G.L. c. 94C, § 18(d¾). If the Prescription was issued by a prescriber from a location other than the Commonwealth of Massachusetts, as indicated by the address of the prescriber on the Prescription, the Prescription must be presented for initial partial fill not later than five calendar days after the Prescription issue date.

(B) Where a Prescription has been partially filled in accordance with 105 CMR 721.055(A), the remaining portion of the Prescription may be filled upon patient request in accordance with federal law; provided, however, that:

(1) only the same pharmacy that originally dispensed the lesser quantity shall dispense the remaining portion; and

(2) the remaining portion of the Prescription is filled not later than 30 days after the Prescription issue date.

(C) Upon dispensing a partial fill of a Prescription under 105 CMR 721.055(A), or dispensing the remaining portion of the Prescription under 105 CMR 721.055(B), the pharmacist or the pharmacist's designee shall make a notation in the patient's record maintained by the pharmacy, which shall be accessible to the prescribing practitioner by request, indicating that the Prescription was partially filled and the quantity dispensed.

721.060: Prescribing in Emergency Situations

(A) In case of an Emergency Situation, the requirements of 105 CMR 721.000 to use an Electronic Prescribing System to generate, transmit and receive a Prescription are waived. In these situations, Written and Oral Prescriptions may be issued and must comply with all other Prescription requirements, including requirements outlined in 105 CMR 721.070(B).

(B) In case of an Emergency Situation a pharmacist may dispense a controlled substance in schedule II upon receiving the written or orally transmitted authorization of a prescribing practitioner, provided:

(1) the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period;

(2) the Prescription contains all information required by M.G.L. c. 94C, § 20(a), except for the actual signature of the prescribing practitioner, and the Prescription is immediately entered into a compliant electronic pharmacy system or otherwise reduced to writing by the dispensing pharmacist;

(3) if the prescribing practitioner is not known to the dispensing pharmacist, the dispensing pharmacist makes a reasonable good faith effort to determine that the orally transmitted authorization was issued by a prescribing practitioner;

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(4) within seven business days after authorizing an emergency orally transmitted Prescription, the prescribing practitioner shall cause an Electronic or Written Prescription for the emergency quantity prescribed to be delivered to the pharmacy which must have written on its face "Authorization for Emergency Dispensing" and shall comply with federal and state law. The Written Prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the seven day period; and

(5) upon receipt of the Prescription issued under 105 CMR 721.060(B)(4), the dispensing pharmacist shall attach the Prescription to the orally transmitted emergency Prescription which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Drug Enforcement Administration if the prescribing individual practitioner fails to deliver a Written Prescription to the pharmacist in accordance with 105 CMR 721.060(B)(4).

721.070: ePrescribing Exceptions

(A) The following Prescriptions shall not be required to be issued as Electronic Prescriptions, and may be issued as Written or Oral Prescriptions, provided, however, that Oral Prescriptions must comply with 105 CMR 721.070(B) and that no Written or Oral Prescription may be issued under any exception enumerated below in an effort to circumvent the requirement to issue an Electronic Prescription:

(1) Prescriptions issued by veterinarians;

(2) Prescriptions issued or dispensed in circumstances where electronic prescribing is not available due to temporary technological or electrical failure;

(3) Prescriptions issued by practitioners who have applied for and received a waiver pursuant to 105 CMR 721.075;

(4) Prescriptions issued or dispensed in Emergency Situations in accordance with 105 CMR 721.060;

(5) Prescriptions that cannot be issued electronically under federal or state law or regulations, including those issued for a drug for which the U.S. Food and Drug Administration (FDA) requires certain elements that cannot be accomplished with electronic prescribing;

(6) Prescriptions issued outside the jurisdiction of the Commonwealth of Massachusetts;

(7) Prescriptions issued pursuant to 105 CMR 700.003(J) for expedited partner therapy for treatment of chlamydia, which are intended for dispensing to the patient's partner;

(8) Prescriptions for Compounded Drug Preparations, subject to standards outlined in Department guidance;

(9) Prescriptions issued for controlled substances in schedule VI;

(10) Prescriptions for durable medical equipment, as defined in 42 U.S.C. § 1395x(n);

(11) Prescriptions issued prior to January 1, 2025, or such later date as determined by the Department, to residents of Level I, II, or III Long-term Care Facilities, as defined in 105 CMR 150.000: *Standards for Long-term Care Facilities*; and

(12) Prescriptions issued in response to a declared public health emergency, pursuant to M.G.L. c. 17, § 2A, or for the treatment, control and prevention of diseases dangerous to public health, including sexually transmitted infections, pursuant to M.G.L. c. 111, § 6, or for any other urgent public health matter.

(B) A practitioner issuing an Oral Prescription for a controlled substance in schedules II through V, in accordance with 105 CMR 721.070(A), shall, within a period of not more than seven business days, or such shorter period that is required by federal law, cause a Written or Electronic Prescription for the prescribed controlled substance to be delivered to the dispensing pharmacy. The Written Prescription may be delivered to the pharmacy in person or by mail, but shall be postmarked within seven business days or such shorter period that is required by federal law. The practitioner shall indicate on the Written Prescription that such Prescription is being issued to document an Oral Prescription.

(C) A pharmacist who receives an otherwise valid Written or Oral Prescription is not required to verify that such Prescription properly falls under one of the exceptions from the requirement to electronically prescribe, including a waiver under 105 CMR 721.070(A)(3).

721.075: Time Limited Waivers of Electronic Prescribing Requirements

(A) The Commissioner may issue a time limited waiver to a health care facility or a prescriber of one or more of the requirements imposed through 105 CMR 721.000 upon a finding that:

(1) compliance would impose a demonstrable economic hardship on the applicant, or the applicant is impacted by technical limitations that are not reasonably within the applicant's control, or other exceptional circumstances;

(2) the applicant's temporary noncompliance does not jeopardize the health or safety of individuals or the public; and

(3) the applicant has instituted compensating measures that are acceptable to the Commissioner.

(B) The waiver applicant must provide the Commissioner with written documentation supporting its request for a waiver.

721.080: Waiver of Requirements

The Commissioner may issue a waiver of one or more of the requirements imposed through 105 CMR 721.000: *Standards For Prescription Format And Security In Massachusetts* upon a finding that:

(1) compliance would cause undue hardship to the applicant;

(2) the applicant's noncompliance does not jeopardize the health or safety of individuals or the public;

(3) the applicant has instituted compensating measures that are acceptable to the Commissioner; and

(4) the applicant provides to the Commissioner, or their designee, written documentation supporting its request for a waiver.

721.090: Severability

The provisions of 105 CMR 721.000 are severable. If any provision shall be declared invalid by any court, such provision shall be null and void and such determination shall not affect or impair any of the remaining provisions.

REGULATORY AUTHORITY

105 CMR 721.000: M.G.L. c. 94C, §§ 6, 17, 18, 20, 23 and 80H; and M.G.L. c. 112, § 12D.