105 CMR: DEPARTMENT OF PUBLIC HEALTH

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

Bold blue = new language
~~Red strikethrough~~ = deleted language
Regular text = existing language
Bold green = changes post comment

Section

721.001: Purpose

The purpose of 105 CMR 721.000 is to specify the requirements for ~~p~~**P**rescription 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 ~~p~~**P**rescriptions issued by practitioners or reduced to writing by pharmacists must meet in order to comply with M.G.L. c. 112, § 12D and 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 c. 94C, § 1, **and 105 CMR 700.001: *Implementation of M.G.L. c. 94C*,** 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 ~~e~~**E**lectronic ~~p~~**P**rescription 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 ~~c~~Compounded ~~d~~Drug ~~p~~Preparation shall not include the reconstitution of pre-measured, commercially available controlled substances.

~~**Confidentiality means that only authorized persons have access to prescription data.**~~

~~**Content Integrity means that the electronic prescription data have not been altered or compromised in transmission.**~~

Comment [A1]: Regulation now includes an exception for all Schedule VI drugs, making this section unnecessary. Reserved.

Comment [A2]: Amended for clarity

Comment [A3]: Provisions restored in 721.060.

Comment [A4]: Clarification added

Comment [A5]: Term no longer used in regulation.

Comment [A6]: Term unnecessary with exception for all Schedule VI.

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

Electronic Prescription means a pPrescription which is generated on an eElectronic pPrescribing sSystem and sent by eElectronic tTransmission to a pharmacy without alteration of the pPrescription information. As used in 105 CMR 721.000, the term eElectronic pPrescription does not include an orders for medication ~~that are~~ which is dispensed for immediate administration to the ultimate user. ~~administered in an inpatient setting.~~

Comment [A7]: Amended for consistency with definitions for "Prescription" and "Written Prescription"

Electronic Signature means an electronic sound, symbol or process attached to or logically associated with a pPrescription record and executed or adopted by a practitioner with the intent to sign said pPrescription 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 eElectronic sSignatures generated through eElectronic pPrescribing sSystems**.

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 eElectronic tTransmission of pPrescriptions. The use of third party intermediaries acting as conduits to route the pPrescriptions from a prescriber to a pharmacy, where the systems of such third party intermediary meets the security requirements for eElectronic tTransmissions, are authorized under 105 CMR 721.000. Transmission by facsimile is not authorized as an eElectronic tTransmission.

Emergency Situation means

Comment [A8]: Definition moved from 721.060

(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 pPrescription on an eElectronic pPrescribing sSystem and sending by eElectronic tTransmission to a pharmacy without alteration of the pPrescription 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.

Comment [A9]: Term added for language in 105 CMR 721.020(G) indicating Failovers may be considered a valid prescription and do not require an follow up written or electronic prescription.

NOTE: In accordance with federal requirements, only Schedule VI prescription Failovers can be converted to facsimile and considered valid.

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.

Comment [A10]: Term added for clarity.

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

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

~~**Technical Non-repudiation means that parties to the generation, transmission, receipt or storage of an electronic prescription cannot reasonably deny having participated in said activities.**~~

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 "~~w~~Written ~~p~~Prescription" shall not include an order for medication which is dispensed for immediate administration to the ultimate user ~~by a practitioner, registered nurse or licensed practical nurse. For the purposes of 105 CMR 721.000, "written prescription" includes a prescription issued on a system that meets the requirements of 105 CMR 721.030, when such prescription is authorized by 105 CMR 721.070(A)(9).~~

Comment [A11]: Added for clarity to show all three prescription types.

Comment [A12]: Term unnecessary with exception for all Schedule VI.

Comment [A13]: Added to distinguish from oral or electronic prescription.

Comment [A14]: Deleted for consistency with Prescription definition

Comment [A15]: Provision unnecessary with exception for all Schedule VI.

721.020: Prescription Formats

(A) Every **p**Prescription ~~written~~ **generated** in the Commonwealth **of Massachusetts** must be ~~in a~~ **an e**Electronic **p**Prescription **and include an e**Electronic **s**Signature **unless it is a p**Prescription **issued in accordance with an exception listed in 105 CMR 721.070.** ~~format that conforms to the following requirements:~~

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

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

(2) the **p**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 **p**Prescription and shall not be satisfied by use of any other element, including the signature~~;~~**.**

~~(B) if the prescription is paper based, including but not limited to a prescription that is transmitted via facsimile or similar technology, or reduced to writing by a pharmacist, the prescription must be on a form that contains a signature line for the practitioner's signature on the lower portion of the form. Hospital and clinic prescription forms shall contain a line directly below the signature line for the practitioner to print or type his or her name. Below the signature line, or in the case of hospital and clinic prescription forms, below the line provided for the practitioner to print or type his or her name, there shall be a space in which the practitioner may indicate "no substitution". Below this space shall be printed the words "Interchange is mandated unless the practitioner indicates 'no substitution' in accordance with the law";~~

~~(C) if the prescription is transmitted electronically, the practitioner shall generate and transmit the prescription in a format that can be read and stored by a pharmacy in a retrievable and readable form;~~

(~~D~~**C**) ~~t~~**T**he name and address of the practitioner shall be clearly indicated on the **p**Prescription. A hospital or clinic **p**Prescription shall have the name and address of the hospital or clinic clearly indicated on the **p**Prescription~~;~~**.**

(~~E~~**D**) ~~t~~**T**he **p**Prescription shall contain the following information:

(1) the registration number of the practitioner;

(2) date of issuance of the **p**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 ~~p~~Prescription**, Prescription for naloxone or other opioid antagonist approved by the Department,** or a ~~p~~Prescription ~~**for expedited partner therapy**~~ issued **pursuant to 105 CMR 721.070(A)(7) or 105 CMR 721.070(A)(12)** ~~**in accordance with 105 CMR 700.003(J)**~~, in which case the ~~**patient, and the**~~ **name and** address may be left blank; ~~or in the case of~~ **provided, however, ~~a prescription for naloxone~~** the person taking delivery of the **prescription for** naloxone **or other opioid agonist as approved by the Department** may**, but is not required to,** be used in place of the name of the patient~~**, and the address may be left blank**~~;
(5) directions for use, including any cautionary statements required;
(6) a statement indicating the number of times to be refilled; and
(7) if the ~~p~~Prescription is for an opioid substance in Schedule II, a notation that the patient may fill, upon request, the ~~p~~Prescription in an amount less than the recommended full quantity indicated.

~~(F) A prescription must be written on a tamper resistant form consistent with federal requirements for Medicaid.~~

(~~G~~**E**) A ~~p~~Prescription issued by a **certified** nurse practitioner, psychiatric **clinical** nurse **specialist or certified registered nurse** anesthetist ~~or pharmacist~~ shall also contain the name of the supervising physician.

(F) Written P~~p~~rescriptions, 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 ~~also~~ comply with procedures set forth in 105 CMR 721.020(B) through 105 CMR 721.020 (F), and shall either be:
(1) ~~Written prescriptions issued in accordance with 105 CMR 721.000, including, but not limited to, a prescription that is t~~Transmitted via facsimile or similar technology~~, or reduced to writing by a pharmacist, must be on a form that contains the practitioner's signature~~; or
(2) Written ~~prescriptions issued in accordance with 105 CMR 721.000 must be 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: *Implementation of M.G.L. c. 94C*.

(H) Prior to January 1, 2021, a Prescription that complies with 105 CMR 721.020(B) through 105 CMR 721.020(F), but does not comply with 105 CMR 721.020(A), shall be a valid Prescription. As of January 1, 2021, all Prescriptions must comply with 105 CMR 721.020.

721.030: [Reserved]~~Security Standards for Prescriptions Issued by Prescribers Registered to Prescribe Schedule VI Controlled Substances Only~~

~~(A) A schedule VI prescription issued pursuant to 105 CMR 721.070(A)(9) may be transmitted through a system that meets the following requirements electronically provided that:~~
~~(A1) if said prescription is for a controlled substance in Schedules II through V, it is validated and authenticated in accordance with M.G.L. c. 94C and applicable Department of Public Health regulations, if any, and 21 CFR 1311 Subpart C and other applicable federal regulations;~~
~~(2) if said prescription is for a controlled substance in Schedule VI that it is validated~~

Comment [A16]: Clarified that name and address are not required for exceptions authorizing non-patient specific prescriptions

Comment [A17]: A written prescription must comply with all but subsection (A).

Comment [A18]: Capitalized like (2) Written

Comment [A19]: Language moved from 721.065(A).

Comment [A20]: Language moved from 721.065(A) and redrafted to mirror M.G.L. c. 94C, § 20(b)

Comment [A21]: Excludes those Schedule VI medications DPH has determined carry a bona fide potential for abuse.

Comment [A22]: Language provides for a one-year grace period where oral, written, and electronic prescriptions considered valid. Effective January 1, 2021, any oral or written prescription that is not issued pursuant to an exception in 105 CMR 721.070 will be considered invalid.

Comment [A23]: Section unnecessary with exception for all Schedule VI drugs.

~~and authenticated in accordance with requirements in M.G.L. c. 94C and applicable Department of Public Health regulations for oral prescriptions or by utilizing a system that includes:~~

~~(1a) a combination of technical security measures, such as, but not necessarily limited to, those listed in Security Standards for the Protection of Electronic Protected Health Information (HIPAA), 45 CFR Part 164, Subpart C, § 164.312, to ensure a reasonable and appropriate level of:~~

~~(a)1. practitioner and dispenser authentication;~~

~~(b)2. technical non-repudiation;~~

~~(c)3. content integrity; and~~

~~(d)4. confidentiality.~~

~~(2b) an electronic signature that is:~~

~~(a)1. unique to an identified practitioner;~~

~~(b)2. originated solely by and under the ultimate control of the practitioner; and~~

~~(c)3. capable of verification.~~

~~(3c) reasonable and appropriate security measures to invalidate a prescription if either the electronic signature or the prescription record to which it is attached or logically associated is altered or compromised; and~~

~~(B3) said prescription meets any other generally applicable requirements of the federal Health Insurance Portability and Accountability Act (HIPAA) and related regulations.~~

~~(B) An electronic signature that meets the requirements of 105 CMR 721.031 shall have the full force and effect of a handwritten signature on a paper-based written prescription.~~

~~(C) A paper-based written prescription must be written and signed by the practitioner in accordance with M.G.L. c. 94C, § 23 and 105 CMR 721.00.~~

721.040: Invalid Prescriptions

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

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

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

Comment [A24]: Indicates Failovers as defined are considered valid prescriptions.

721.050: Prescribing More than One Drug Product

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

721.055: Partial Fill Prescriptions

(A) A pharmacist filling a ~~p~~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 ~~p~~Prescription, pursuant to M.G.L. c. 94C, § 18(d¾). If the ~~p~~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 ~~p~~Prescription, the ~~p~~Prescription must be presented for initial partial fill not later than five calendar days after the ~~p~~Prescription issue date.

(B) Where a ~~p~~Prescription has been partially filled in accordance with 105 CMR 721.055(A), the remaining portion of the ~~p~~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 ~~p~~Prescription is filled not later than 30 days after the ~~p~~Prescription issue date.

(C) Upon dispensing a partial fill of a ~~p~~Prescription under 105 CMR 721.055(A), or dispensing the remaining portion of the ~~p~~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 ~~p~~Prescription was partially filled and the quantity dispensed.

721.060: **~~e~~Prescribing ~~and~~in** Emergency Situations ~~in Which Controlled Substances in Schedule II May Be Dispensed upon Orally or Electronically Transmitted Prescription~~

Comment [A25]: Amended for clarity

~~(A) For the purposes of 105 CMR 721.000, the term "emergency situations" means: , for the purpose of permitting the dispensing of any controlled substance in Schedule II upon orally or electronically transmitted prescription, means those situations in which the practitioner who intends to prescribe a controlled substance in Schedule II determines:~~

Comment [A26]: Term moved to 721.010, Definitions

~~(1) an emergency defined in Department guidance by the Commissioner acting pursuant to M.G.L. c. 94C, § 17; or the immediate administration of the controlled substance is necessary for the proper treatment of the intended ultimate user;~~

~~(2) 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; no appropriate alternative treatment is available, including administration of a controlled substance which is not in Schedule II; and~~

~~(3) a. it is not reasonably possible for the prescribing practitioner to provide a written 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.~~

(**~~A~~B**) In case of an **~~e~~Emergency ~~s~~Situation ~~as defined in 105 CMR 721.060(A)~~, the requirements of 105 CMR 721.000 to use an ~~e~~Electronic ~~p~~Prescribing ~~s~~System to generate, transmit and receive a ~~p~~Prescription are waived. In these situations, ~~w~~Written and ~~o~~Oral ~~p~~Prescriptions may be issued and must comply with all other ~~p~~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 ~~or electronically~~ transmitted authorization of a prescribing practitioner, provided:

Comment [A27]: Restored current language in 721.060 (relocated from 721.065, as section has been removed)

(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 ~~in the case of an oral prescription, or prescription transmitted electronically by computer modem or other similar electronic device, the prescription is immediately~~ reduced to writing by the dispensing pharmacist; ~~and~~

(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 ~~or electronically~~ transmitted authorization was issued by a prescribing ~~an authorized~~ practitioner~~, which effort may include a telephone call callback to the prescribing practitioner or other good faith efforts to ensure the prescribing practitioner's identity;~~.

(4) ~~(C)~~ Within seven business days ~~72 hours~~ after authorizing an emergency orally ~~or electronically~~ transmitted Prescription, the prescribing practitioner shall cause an electronic or~~a~~ 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 transmitted within two business days. If the prescription~~

~~qualifies for an exception under 105 CMR 721.070, a written prescription must be transmitted in accordance with 105 CMR 721.020(F) within seven business days.~~ 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 ~~72 hour~~ seven day period; and

(5) ~~(D)~~ Upon receipt of the ~~written~~ Prescription issued under 105 CMR 721.060(B)(4), the dispensing pharmacist shall attach the Prescription to the orally ~~or electronically~~ transmitted emergency Prescription which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Drug Enforcement Administration~~, U.S. Department of Justice, and the Commissioner of Public Health, Massachusetts Department of Public Health~~ if the prescribing individual practitioner fails to deliver a Written Prescription to the pharmacist in accordance with 105 CMR 721.060(B)(4) ~~within 72 hours~~.

Comment [A28]: Deleted per comments. Federal rules require DEA reports only.

~~721.065: Special Procedures for Emergency Prescribing and Dispensing of Schedule II Controlled Substances~~

~~(A) In case of an emergency situation as defined in 105 CMR 721.060(A), a pharmacist may dispense a controlled substance in schedule II upon receiving the 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) the dispensing pharmacist makes a reasonable good faith effort to determine that the orally transmitted authorization was issued by a prescribing practitioner, which effort may include a telephone call to the prescribing practitioner or other good faith efforts to ensure the prescribing practitioner's identity; and~~

~~(4) after authorizing an emergency orally transmitted prescription, the prescribing practitioner shall cause an electronic prescription for the emergency quantity prescribed to be transmitted to the pharmacy which must include the notation "Authorization for Emergency Dispensing" and shall comply with federal and state law. The electronic prescription must be transmitted within two business days. If the prescriber qualifies under 105 CMR 721.070, a written prescription must be transmitted in accordance with 105 CMR 721.020(F).~~

~~(B) Upon receipt of the prescription issued under 105 CMR 721.065(A)(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, U.S. Department of Justice, and the Commissioner if the prescribing practitioner fails to deliver a prescription to the pharmacist in accordance with 105 CMR 721.065(A)(4).~~

Comment [A29]: Section removed for clarity; necessary provisions relocated to 721.060.

721.070: ePrescribing Exceptions

(A) The following ~~p~~Prescriptions shall not be required to be issued as eElectronic ~~p~~Prescriptions, and may be issued as ~~w~~Written or ~~o~~Oral ~~p~~Prescriptions, provided, however, that ~~o~~Oral ~~p~~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:

Comment [A30]: Added to reinforce when exceptions should be used.

(1) ~~p~~Prescriptions issued by veterinarians;

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

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

(4) ~~p~~Prescriptions issued or dispensed in eEmergency ~~s~~Situations in accordance

with~~pursuant to~~ 105 CMR 721.060;

(5) ~~p~~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) ~~p~~Prescriptions issued outside the jurisdiction of the Commonwealth of Massachusetts;

(7) ~~p~~Prescriptions issued pursuant to 105 CMR 700.003(J): *Implementation of M.G.L. c. 94C* ~~M.G.L. c. 111, § 121B~~ for expedited partner therapy for treatment of chlamydia, which are intended for dispensing to the patient's partner;

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

(9) ~~p~~Prescriptions issued for ~~by prescribers who hold a Massachusetts~~ Controlled Substances in ~~Registration that authorizes~~ schedule VI ~~prescribing only~~; ~~and~~

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

(11) Prescriptions issued prior to January 1, 2023, 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 ~~o~~Oral ~~p~~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 ~~w~~Written or Electronic ~~p~~Prescription for the prescribed controlled substance to be delivered to the dispensing pharmacy. The ~~w~~Written ~~p~~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 ~~w~~Written ~~p~~Prescription that such ~~p~~Prescription is being issued to document an ~~o~~Oral ~~p~~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; and

(2) the applicant's temporary non-compliance 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

Comment [A31]: FDA required elements (e.g. REMS) include attachments that cannot be transmitted

Comment [A32]: Total CVI exception

Comment [A33]: Three-year nursing home exception.

Comment [A34]: In consultation with the Bureau of Infectious Disease and Laboratory Sciences, included an exception for unanticipated PH emergencies or other urgent public health matters that may require non-patient specific prescriptions

Comment [A35]: Clarifies pharmacists' role and responsibility.

Comment [A36]: Language inadvertently left out of draft put forth for comment; added consistent with MGL c. 94C, s. 23(h).

supporting its request for a waiver.

REGULATORY AUTHORITY

105 CMR 721.000: M.G.L. c. 30A, § 2; c. 94C, §**§** 6,~~; c. 94C, §~~17,~~;~~ **18, 20 and 23**; c. 111, § 3; and c. 112, § 12D.