



# The Commonwealth of Massachusetts

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## Circular: DCP 19-12-108

**TO:** Massachusetts Registered Prescribers and Pharmacies

**FROM:** James Lavery, Director, Bureau of Health Professions Licensure

**DATE:** December 27, 2019

**SUBJECT:** Electronic Prescribing and Dispensing Manual

### Purpose

The purpose of this Manual is to provide guidance to registered prescribers and pharmacies<sup>1</sup> for prescribing and dispensing controlled substances and medical devices by electronic prescription (ePrescription), as outlined in state law<sup>2</sup> and the Department's ePrescribing regulation.<sup>3</sup>

The regulation provides a one-year grace period<sup>4</sup> from the statutory requirements,<sup>5</sup> and authorizes written and oral prescriptions to be issued for all controlled substances and medical devices throughout 2020. Beginning January 1, 2021, unless covered by an exception, all prescriptions for controlled substances and medical devices must be issued electronically.<sup>6</sup>

As used throughout this guidance, the following terms shall have the following meaning:

- In Massachusetts, controlled substances include Federal schedules I-V and Massachusetts schedule VI, consisting of all prescription drugs not included in schedules I-V.<sup>7</sup>
- Medical devices include those with a controlled substance component, which require a prescription, as well as devices and Durable Medical Equipment (DME),<sup>8</sup> regulated by the Federal Food and Drug Administration (FDA), which a patient may purchase without a prescription, and for which insurance coverage may be available with a prescription.

<sup>1</sup> Authorized prescribers and pharmacies must possess a Massachusetts Controlled Substance Registration.

<sup>2</sup> Electronic prescribing requirements are included in M.G.L. c. 94C, §§ 1, 17, 18, 20, and 23.

<sup>3</sup> 105 CMR 721.000: *Standards for Prescription Format and Security in Massachusetts*.

<sup>4</sup> 105 CMR 700.020(H).

<sup>5</sup> Section 110 of chapter 208 of the acts of 2018 makes the ePrescribing requirements effective on January 1, 2020.

<sup>6</sup> M.G.L. c. 94C, §17, as amended by chapter 208 of the acts of 2018.

<sup>7</sup> In addition [to the five schedules of controlled substances under the "Comprehensive Drug Abuse, Prevention and Control Act of 1970" or any amendment thereof] the commissioner shall by regulation as aforesaid establish a sixth schedule which shall include all prescription drugs not included in the first five schedules. M.G.L. c. 94C, § 2(a).

<sup>8</sup> Durable medical equipment is equipment which can withstand repeated use, *and* is primarily and customarily used to serve a medical purpose, *and* generally is not useful to a person in the absence of an illness or injury, *and* is appropriate for use in the home. HI 00610.200, U.S. Social Security Administration, Program Operations Manual System (POMS).

## Exceptions

When an exception applies, prescribers may issue written or oral prescriptions, which may be dispensed by pharmacists as valid prescriptions, provided the prescription meets the format and security requirements outlined in regulation.<sup>9</sup>

An ePrescription is always permitted, even when an exception is applicable to the type of prescription or situation under which the prescription is issued. Just because a prescriber is permitted to issue a written or oral prescription under a given circumstance does not mean that they are required to do so if they would prefer to ePrescribe. The following 12 ePrescribing exceptions authorize the limited use of a written or oral prescriptions where appropriate:

1. Prescriptions issued by veterinarians.  
This exception is available to all licensed veterinarians with a Massachusetts Controlled Substance Registration (MCSR).
2. Prescriptions issued during a temporary technological or electrical failure.  
This exception may apply when a prescriber is usually able to issue electronic prescriptions, but such functions are temporarily unavailable due to technological or electrical failure.  
  
*Examples:*
  - A power outage affecting the prescriber's or facility's Electronic Prescription of Controlled Substances (EPCS) system.
  - A transmission failure for a schedule II-V controlled substance that is returned to the prescriber for re-prescribing.
3. Prescriptions issued by practitioners who have applied for and received a waiver.  
See Time-Limited Waiver Request and Approval Process section below on page 5.
4. Prescriptions issued or dispensed in emergency situations.  
See Emergency Situation section below on page 4.
5. Prescriptions that cannot be issued electronically under federal or state law or regulations.  
This exception may apply when federal or state law sets requirements that prevent ePrescribing.

*Examples:*

- The U.S. Food and Drug Administration (FDA) requires that a signed certification under Risk Evaluation and Mitigation Strategies (REMS) be attached to the prescription, and the EPCS system does not permit the attachment of documents.
- A state or federal law is passed requiring a written prescription for a new drug.

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<sup>9</sup> 105 CMR 721.020: Prescription Formats.

6. Prescriptions issued outside the jurisdiction of the Commonwealth of Massachusetts.  
This exception applies to prescriptions issued from locations physically outside of Massachusetts, as indicated by the address of the prescriber, as well as those issued in federal facilities within Massachusetts, including those operated by the Veterans' Administration or the Indian Health Service.
7. Prescriptions issued for expedited partner therapy for treatment of chlamydia.  
This exception is necessary to allow prescribers to issue prescriptions that are intended for dispensing to the patient's partner(s) without requiring the partner's identification, as authorized by law.<sup>10</sup>
8. Prescriptions for compounded drug preparations.  
A compounded drug preparation is a preparation created through mixing, assembling, altering, packaging, and labeling as a result of a practitioner's order or in anticipation of such an order based on routine, regularly observed prescribing patterns.  
  
Nothing should prevent a prescriber from issuing an ePrescription for a compounded drug preparation if the technology is available to do so. This exception is available for those limited instances when the technology is unsuitable for the complexity, length or urgency of the particular preparation, or other specialized reason.
9. Prescriptions issued for controlled substances in schedule VI.  
This exception authorizes oral and written prescriptions for all non-federally controlled substances, also referred to as Schedule VI substances, which have a lower potential for abuse and misuse than other controlled substances, but does not prohibit ePrescriptions for these medications.  
  
Prescribers choosing to issue, and pharmacists receiving, schedule VI ePrescriptions should refer to Dispensing of Schedule VI ePrescriptions – Failover section on page 6 for further guidance.
10. Prescriptions for durable medical equipment.  
Although a prescription is generally not needed for medical devices, this exception recognizes that patients may request a prescription in order to secure insurance coverage for the item, and that DME<sup>11</sup> suppliers are typically not capable of receiving ePrescriptions.
11. Prescriptions issued prior to January 1, 2023 to nursing home residents.  
This exception is limited in duration until January 1, 2023, or such later date as determined by the Department. The exception applies to Level I, II, or III Long-Term Care Facilities, as defined in regulation.<sup>12</sup>

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<sup>10</sup> M.G.L. c. 111, § 121B.

<sup>11</sup> As defined in 42 U.S.C. § 1395x(n).

<sup>12</sup> 105 CMR 150.000, *Standards for Long-Term Care Facilities*.

## 12. Prescriptions issued in response to urgent public health matters.

This section anticipates the unanticipated by allowing written and oral prescriptions to be issued in rare circumstances when the state acts:

- in response to a public health emergency;<sup>13</sup>
- for the treatment, control and prevention of diseases dangerous to public health, including sexually transmitted infections;<sup>14</sup> or
- in response to urgent public health matters.

These urgent situations may require the immediate prescription of controlled substances to unidentified patients or to large numbers of patients, making ePrescribing impractical or impossible given emergency constraints, such as limited time or geographic difficulties.

### Written or Electronic Follow-Up Prescription

If an oral prescription is issued for a controlled substance in Schedule II-V under one of the exceptions discussed above, state law requires the prescriber issue a written or electronic follow-up prescription to the dispensing pharmacy within seven business days. The follow-up prescription must include on its face a notation that the prescription is being issued “to document an oral prescription.”

Because the original prescription will have been issued under an exception to ePrescribing, the expectation is that most follow-up prescriptions will be written rather than electronic. The written follow-up prescription may be delivered to the pharmacy in person or by mail. If mailed, the follow-up prescription must be postmarked within the seven business day timeframe.

No written follow-up is required for schedule VI oral prescriptions. For additional Federal follow-up requirements for schedule II prescriptions, please refer to Emergency Prescribing of Schedule II Controlled Substances on page 5.

### **Emergency Situations**

The CARE Act authorizes a pharmacist to dispense a schedule II-VI substance upon written or oral prescription in emergency situations. Pursuant to 105 CMR 721.001, an emergency situation arises when the immediate administration of a controlled substance is necessary for the proper treatment of the patient, and-

1. it is not reasonably possible for the prescriber to generate or transmit an electronic prescription prior to dispensing; or
2. the prescriber determines that the electronic prescription requirement would result in a delay that would adversely impact the patient’s medical condition.

### *Examples:*

- An emergency situation may arise when a patient is discharged with from a hospital’s emergency department with a prescription at a time or in a location that does not allow the patient to visit a pharmacy with which she has a routine relationship. In such

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<sup>13</sup> M.G.L. c. 17, § 2A.

<sup>14</sup> M.G.L. c. 111, § 6.

instances, the patient's ability to take a written prescription to a 24-hour pharmacy on route to the patient's home or temporary residence may be essential to the prompt treatment of the patient's condition.

- An emergency situation may arise when a hospice patient is experiencing sudden, breakthrough pain that is not relieved by previously dispensed medication, and the patient's prescriber is on vacation, unable to log into her hospital's EPCS system to generate an electronic prescription, and is unable to reach a covering prescriber to generate such prescription.

As with other exceptions discussed above, an oral prescription for a controlled substance in Federal schedule II-V issued in an emergency situation must be followed within seven business days by a written or electronic prescription for the emergency quantity, including the notation, *"Issued to Document an Oral Prescription."*

#### Emergency Prescribing of Schedule II Controlled Substances

Additional rules apply when issuing an oral prescription for a schedule II controlled substance in an emergency situation. The follow-up written or electronic prescription must include the additional notation, *"Authorization for Emergency Dispensing."* Further, if a prescriber fails to issue a follow-up written or electronic prescription within seven business days, the pharmacist is required to notify the U.S. Drug Enforcement Administration (DEA) of such failure.

#### **Time-Limited Waiver Request and Approval Process**

A prescriber may issue oral and written prescriptions for a limited time as authorized by a DPH-approved waiver. DPH may approve a time-limited waiver for a prescriber or for a health care facility (HCF).

When applying for a time-limited waiver, the applicant must provide DCP with written documentation supporting its request for a waiver. Applicants should use the form provided by DCP for this purpose. The form, which is available online ([waiver](#)), includes space to document support for four key findings that DCP must make to warrant approval:

1. the time period for which the waiver is requested is fact-based and reasonable; and
2. 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
3. the applicant's temporary non-compliance does not jeopardize the health or safety of individuals or the public; and
4. the applicant has instituted compensating measures that are acceptable to the Commissioner.

A time-limited waiver may be requested for up to one year, and renewal may be requested, by submission and approval of a new application. However, this waiver provision is intended to allow only minimal interruption of compliance with ePrescribing requirements until such time as the prescriber's barrier to compliance is relieved. Therefore, an applicant should request the briefest waiver term possible.

*Example:*

- A mid-size adolescent psychiatry practice has been told by its vendor that the compliant EPCS system will not be available to issue schedule II-V ePrescriptions until May 2021. The applicant should request no more than a six month waiver from 1/1/21 to 6/1/21. Prior to expiration, the practitioner may request renewal of the waiver if a new application justifies such extension.

To ensure compliance with waiver terms and procedures by prescribers, including those prescribers operating under a HCF waiver, all prescriptions are subject to periodic review.

DCP will begin accepting waiver applications on January 1, 2020. Prescribers and HCFs may submit an application any time the need arises; however, anyone wishing to have a waiver application approved by January 1, 2021, is strongly encouraged to submit an application by October 1, 2020, to provide sufficient time for processing and follow-up communication, as needed.

### **Responsibilities of Prescribers and Pharmacists**

Exceptions and waivers build flexibility into the ePrescribing requirements, subject to an expectation of responsible prescribing practices. This expectation is reflected in 105 CMR 721.070(A), which states:

*[N]o Written or Oral Prescription may be issued under any [enumerated exception] in an effort to circumvent the requirement to issue an Electronic Prescription.*

The pharmacy community must also be able to rely on the integrity of the ePrescribing requirements, including exceptions from those requirements, to prevent needless confusion or delay that may result from attempts to subvert ePrescribing requirements. Therefore, as stated in 105 CMR 721.070(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 to electronically prescribe, including a waiver.*

DCP will continue to engage in activities to ensure safe and responsible prescribing and dispensing. Prescribers and pharmacists are encouraged to contact DCP and the Board of Registration in Pharmacy to work through any implementation issues. However, a pattern of compliance and communication failures may warrant a referral to an appropriate licensing board or, if necessary, action against an MCSR.

### **Dispensing Schedule VI ePrescriptions – Failovers**

A Failover results when a prescriber issues an electronic prescription for a schedule VI controlled substance and that electronic prescription is converted and transmitted to a pharmacy as a computer-generated facsimile due to a defect in the electronic prescribing system beyond the prescriber's control or awareness. The resulting computer-generated facsimile, or Failover, does not qualify as an electronic prescription and frequently does not meet the signature requirements of a written prescription, because the electronic signature appears encoded and does not appear on the facsimile as an actual signature, leaving the prescription un-signed.

To address this, the ePrescribing regulation allows a pharmacist to dispense a Failover as a valid oral prescription if the following process is followed:<sup>15</sup>

1. The Failover must contain all information required of an oral prescription,<sup>16</sup> but need not contain the practitioner's signature, as required for a written prescription;<sup>17</sup>
2. The prescription must be immediately entered into a compliant electronic pharmacy system or otherwise reduced to writing by the pharmacist;
3. If the prescriber is unknown to the pharmacist, the pharmacist must make a reasonable, good faith effort to determine that a Failover was issued by an authorized prescriber; and
4. The Failover must not be for an Additional Drug<sup>18</sup> (e.g., gabapentin).

In the event that a pharmacist receives a Failover prescription for gabapentin, or any other medication designated as an Additional Drug, the pharmacist may not dispense the medication, and instead must contact the prescriber for a new written or oral prescription. No additional written follow-up is required for a Failover dispensed as an oral prescription.

### **Dispensing Schedule II ePrescriptions – Endorsement**

M.G.L. c. 94C § 23(c) requires a pharmacist filling a Schedule II ePrescription to endorse his own signature on the face thereof. A pharmacist's act of final verification of a Schedule II ePrescription shall fulfill this endorsement requirement.

### **Partial Fill**

As you are aware, the requirement to include a partial fill notation on all opioid prescriptions has been in place since 2016.<sup>19</sup> This law was expanded in 2018<sup>20</sup> to apply to all schedule II controlled substance prescriptions and to allow dispensing of the remainder after the initial partial fill. These updated requirements have been included in this regulation as 105 CMR 721.055.

No change has been made to the notation requirement, which continues to apply as a matter of law to written and electronic prescriptions for schedule II opioids.<sup>21</sup> Prescribers and facilities are expected to make every effort to include this notation in any EPCS system upgrades undertaken as part of their ePrescribing implementation. Pharmacists should continue to dispense under this law pursuant to joint guidance of DCP and the Board of Registration in Pharmacy.<sup>22</sup>

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<sup>15</sup> 105 CMR 721.020(G).

<sup>16</sup> M.G.L. c. 94C, § 20(a).

<sup>17</sup> M.G.L. c. 94C, § 23(i).

<sup>18</sup> Additional Drug means a controlled substance in schedule VI determined by the Department to carry a bona fide potential for abuse. 105 CMR 700.001: *Implementation of M.G.L. c. 94C*. Currently, gabapentin is the only medication on this list. Circular Letter: DHCQ 17-5-101: *Requirements for Gabapentin Data Submission*.

<sup>19</sup> M.G.L. c. 94C, § 18(d $\frac{3}{4}$ ), as inserted by chapter 52 of the acts of 2016.

<sup>20</sup> M.G.L. c. 94C, § 18(d $\frac{3}{4}$ ), as amended by chapter 208 of the acts of 2018.

<sup>21</sup> Any prescription issued by a practitioner for an opioid substance contained in Schedule II of section 3 shall include a notation on the prescription that the patient may fill, upon request, the prescription in compliance with subsection (d 3/4) of section 18 in an amount not to exceed the full prescribed quantity. M.G.L. c. 94C, § 22(c).

<sup>22</sup> Circular Letter: DCP 18-10-104, *Patient Requests for Partial Fill of Schedule II Prescriptions*, November 1, 2018.

**Contact Information**

Questions or concerns regarding this information should be directed to the Drug Control Program: [dcp.dph@mass.gov](mailto:dcp.dph@mass.gov)

**Resources:**

For more information regarding prescription format and security, please find the relevant statutory language and approved, post-comment regulation here:

<https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXV/Chapter94C>

<https://www.mass.gov/lists/standards-for-prescription-format-and-security>

For ePrescribing At-a-Glance, visit our webpage: <https://www.mass.gov/lists/eprescribing>