

# COMPLIANCE CUE

## Emergency CII Controlled Substance Dispensing

### BACKGROUND

Prescription drug orders for controlled substance medications (schedule CII – CV) are subject to strict regulations as a means to mitigate fraud, diversion, and abuse. CII medications are drugs with the highest abuse potential that still maintain acceptable medical use within the US; as such, they face the highest level of regulatory scrutiny.

A key stipulation enforced against these scheduled drugs disallows prescribers from issuing verbal orders for the regular ordering and dispensing of CII medications.

However, emergency situations may arise in caring for long-term care residents that require pharmacies to dispense CII medications in an expedient manner that is not delayed by the standard practice of waiting on hardcopy written prescriptions.

**Title 21 Code of Federal Regulations Part 1306, Section 1306.11** addresses this concern and provides rules governing the **emergency verbal ordering of CII medications**.

### REQUIREMENTS

**21 CFR, Part 1306, Section 1306.11** (Requirements of a Prescription; abridged)

- (d) In the case of an [emergency situation](#)<sup>1</sup> a pharmacist may dispense a CII medication upon receiving oral authorization of a prescribing individual practitioner, provided that:
- (1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period;
  - (2) The prescription is immediately reduced to writing by the pharmacist and contains all information required in [§1306.05](#),<sup>2</sup> except for the signature of the prescribing individual practitioner;
  - (3) If the prescribing individual practitioner is not known to the pharmacist, they must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner and/or other good faith efforts to ensure their identity;
  - (4) Within **7 days** after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist.

<sup>1</sup><https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-290/subpart-A/section-290.10>

<sup>2</sup><https://www.ecfr.gov/current/title-21/chapter-II/part-1306/subject-group-ECFR1eb5bb3a23fddd0/section-1306.05>

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In addition to conforming to the [requirements of §1306.05](#),<sup>3</sup> the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order.

The paper prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 7-day period.

Upon receipt, the dispensing pharmacist must attach this paper prescription to the oral emergency prescription that had earlier been reduced to writing.

For electronic prescriptions, the pharmacist must annotate the record of the electronic prescription with the original authorization and date of the oral order.

The pharmacist must notify the nearest office of the Administration if the prescribing individual practitioner fails to deliver a written prescription to them; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner.

### KEYS TO FACILITY COMPLIANCE

- ✓ Ensure that Emergency CII Dispensing only occurs in the context of definitive emergencies, when:
  - Immediate administration of the medication is necessary, and
  - No appropriate non-CII alternative treatment is readily feasible, and
  - It is not reasonable for the prescriber to provide the order to the pharmacy as a written prescription instead.
- ✓ Train facility prescribers that:
  - **They must follow up within 7 days of the original verbal order to provide the dispensing pharmacy a written prescription authorizing said verbal order.**
  - The follow-up hardcopy must have written on its face "Authorization for Emergency Dispensing" and the date of the oral order.
  - Transmission of this written prescription via facsimile is preferred, but if delivered by mail it must be postmarked within the 7-day period.
  - The pharmacy may need to contact the prescriber prior to dispensing the Emergency Verbal CII prescription, and as such the prescriber should be readily available to respond.
- ✓ Communicate to all relevant staff the risks of noncompliance with this regulation, including mandatory reporting of the infraction to the DEA and the pharmacy's inability to accept further Emergency Verbal CII orders from the prescriber until outstanding hardcopies are received.

<sup>3</sup><https://www.ecfr.gov/current/title-21/chapter-III/part-1306/subject-group-ECFR1eb5bb3a23fddd0/section-1306.05>

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### HOW PHARMERICA CAN HELP

- ✓ PharMerica will accept and process valid Emergency Verbal CII Orders.
- ✓ PharMerica will provide timely notification to prescribers issuing Emergency Verbal CII Orders in manners inconsistent with these applicable regulations.
- ✓ Upon dispensing a valid Emergency Verbal CII, PharMerica will provide an initial request to the issuing prescriber for the requisite hardcopy.
- ✓ PharMerica will further provide a courtesy notification if the requested hardcopy is not received by the pharmacy after 3 days.
- ✓ If the hardcopy is not received within 7 days of processing the Emergency CII Verbal Order, the pharmacy must notify the local DEA office for compliance.
- ✓ PharMerica provides standard forms for prescribers to navigate these regulations, including:
  - **Emergency Authorization for Schedule II Controlled Substance Prescriptions**
    - Outlines information prescribers must enter and submit back to pharmacy to retroactively authorize a prior Emergency CII Verbal Order within 7 days.
  - **NEW or Continuance Schedule II Controlled Substance Prescription**
    - Can be used to proactively request a NEW or Continuance of a CII drug order to be submitted by the prescriber via fax, with all required information outlined, to avoid the need for Emergency CII Verbal Ordering.