



CHRIS CHRISTIE  
Governor

KIM GUADAGNO  
Lt. Governor

## New Jersey Office of the Attorney General

Division of Consumer Affairs  
Drug Control Unit  
124 Halsey Street, Newark, NJ 07102



JOHN J. HOFFMAN  
Acting Attorney General

STEVE C. LEE  
Acting Director

**Mailing Address:**  
P.O. Box 45045  
Newark, NJ 07101  
(973) 504-6351

September 24, 2014

Re: Notification of the Rescheduling of Hydrocodone

**Effective October 6, 2014, all Hydrocodone Combination Products are rescheduled as a Schedule II Controlled Dangerous Substance** in the State of New Jersey based on the recent federal Drug Enforcement Administration (“DEA”) Final Rule.

Starting on October 6, 2014 and in accordance with New Jersey Controlled Dangerous Substances Act, N.J.S.A. 24:21-15, prescriptions issued by a practitioner for hydrocodone combination products (HCP) are subject to the same restrictions as all other Schedule II CDS medications.

We take this opportunity to remind you of some of the restrictions on Schedule II CDS prescriptions:

- HCPs may only be prescribed by a practitioner with a written prescription or an electronic prescribing system, that is compliant with state and federal controlled substance rules;
- Prescriptions for HCPs cannot be issued via the telephone or facsimile to a pharmacy; and
- No prescription for a Schedule II substance may be refilled.

Patients may need to be advised that prescriptions written/issued prior to October 6, 2014 cannot be refilled by a pharmacy.

A practitioner shall not authorize a quantity of Schedule II CDS medication calculated to exceed 120 dosage units or a 30-day supply, whichever is less. Any exemptions that are allowed pursuant to N.J.A.C. 13:35-7.6 are unchanged and remain in effect.

All HCPs prescriptions presented at a New Jersey pharmacy will be subject to the Schedule II CDS prescription dispensing rules as defined in N.J.A.C. 13:45H-7.8 – 7.12.

Any practitioner who is not authorized by state or federal rules, to prescribe Schedule II CDS medication, cannot prescribe HCPs starting on October 6, 2014.

Due to the Schedule II CDS restrictions, a practitioner/pharmacy may want to consider the effect the changes may have on prescribing or dispensing software systems and storage requirements for Schedule II medication in a pharmacy or medical practice.

For additional information, please visit:

Drug Enforcement Administration: [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov)

The Drug Control Unit: [www.njconsumeraffairs.gov/drug](http://www.njconsumeraffairs.gov/drug)

Board of Pharmacy: [www.njconsumeraffairs.gov/pharm](http://www.njconsumeraffairs.gov/pharm)



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## *New Jersey Office of the Attorney General*

Division of Consumer Affairs  
Office of the Director  
124 Halsey Street, 7<sup>th</sup> Floor, Newark NJ



**JEFFREY S. CHIESA**  
Attorney General

**ERIC T. KANEFSKY**  
Acting Director

# **PHARMACY SECURITY BEST PRACTICES**

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**New Jersey Division of Consumer Affairs**  
**New Jersey State Board of Pharmacy**

**Mailing Address:**  
P.O. Box 45027  
Newark, NJ 07101  
(973) 504-6534

Pharmacy theft and robbery are serious problems fueled by the growing abuse of prescription drugs and their high street value. In discussing pharmacy security with interested parties representing the pharmacy community, the Division of Consumer Affairs has identified certain areas of concern. The intent of this document is to highlight these areas of concern and present potential solutions that pharmacists may consider employing to address those concerns.

The best practices outlined below are recommendations to achieve a safe operating environment for pharmacy employees and customers and lower the potential for adverse events. While implementation of some or all of the recommendations may be impossible for some pharmacies, all pharmacies are encouraged to implement as many of the best practices as they can manage.

### **Physical Security Controls of Controlled Dangerous Substances**

1. Where practical Schedule II (C-II) and Schedule III (C-III) medications in solid dosage form, and other dosage forms (e.g. liquid) as space permits, should be stored in a safe or substantially constructed steel cabinet that is locked at all times (excluding filled C-II/C-III prescriptions located in the secured Will-call bins, see paragraph 3 in this section). All C-II and C-III medications that are required to be refrigerated should be kept in a locked refrigerator. Only licensed pharmacists should be permitted access to the safe/steel cabinet and locked refrigerator, and at no time should anyone else access the safe or locked refrigerator. All other CDS may continue to be dispersed throughout the non-controlled inventory.
2. The safe/steel cabinet should comply with the state and federal requirements for storage of small quantities of CDS by non-practitioners found at N.J.A.C. 13:45H-2.2(a)(1) and 21 C.F.R. 1301.72.
3. Will-call bins for C-II and C-III medications should be located in the secured prescription filling area of the pharmacy department (not on shelves by the cashier) and within unobstructed view of the pharmacist during the hours the pharmacy is open. Where practical, the bin should be constructed so that it can be securely locked at night and at all times when the pharmacy is closed.
4. N.J.A.C. 13:39-4.15(b)(3) requires that there be a secure area for receiving packages known to contain CDS, PLD and devices. No deliveries for prescription drugs shall be accepted during the hours the pharmacy or pharmacy department is closed unless adequate security for the storage of such shipments has been provided.

It is recommended that pharmacies receive deliveries of CDS/PLD only during posted store hours, and only when a pharmacist is present to accept and sign for the delivery.

It is recommended that upon receipt of CDS/PLD the pharmacist, or, if delegated by the pharmacist, a registered pharmacy technician, open and inspect the contents of the containers to ensure that the totes contain the correct CDS in the correct amounts as soon as practical after receiving delivery. Any discrepancy between the receipt/invoice and actual contents must be immediately reported per regulation. N.J.A.C. 13:39-4.15.

### **General Security for Pharmacy**

1. Pharmacies must comply with regulatory requirements for a monitored security system which transmits an audible, visual or electronic signal warning of intrusion. The security system is required to be equipped with a back-up mechanism to ensure notification or continued operation if the security system is tampered with or disabled. The central station monitoring agreement should be paid for and current. N.J.A.C. 13:39-4.15(b)1

Pharmacies should consider a security system with a cellular backup mechanism to ensure notification or continued operation of the system in the event of power failure or the system is disabled.

2. Consider installing a silent panic alarm.
3. Do not allow unescorted, non-essential personnel in the prescription filling area or pharmacy department (plumbers, building inspectors, accountants, etc.). The RPIC should use due diligence in ensuring the security of the pharmacy as per N.J.A.C. 13:39-4.15
4. Pharmacies should consider utilizing video surveillance technology including quality security cameras placed to capture activity anywhere CDS is stored, counted, held, dispensed or returned to stock, and exits from the pharmacy or the “front end” of a retail store. At minimum, the tapes should be retained three months to help ID potential theft identified during random CDS manual counts. Pharmacies should consider updating to digital recording systems to enhance pharmacy security and reduce storage concerns.
5. Routine pharmacy security features include: alarmed doors/windows with central station monitoring, physical barriers (steel window/door curtains), sensors, sufficient lighting levels inside and outside the pharmacy, installation of height markers at exit doors.
6. Train staff for prevention and response to robbery.
7. Advertise security to the public and employees.
8. Unwanted or outdated CDS should be properly disposed of or returned per Federal and State regulations.

### **Frequency of CDS inventory and manual count of pills**

1. A Pharmacist should consider maintaining a perpetual inventory for C-II and C-III medications and other items identified to have high street value, e.g. Alprazolam, diazepam, and possibly erectile dysfunction drugs, tramadol etc. The inventory should include:
  - Date, drug name, quantity received and invoice number or DEA Form 222 (or Electronic 222) for all medications received.
  - Date, drug name, quantity and prescription number for each prescription filled and dispensed.

- Date, drug name, quantity and prescription number for all medication that is filled but not dispensed and is returned to stock
  - Date, drug name, and quantity for all medication sent to a reverse distributor or destroyed as waste.
2. A pharmacist should conduct a random manual reconciliation once each month to include at least 5 drugs that are top 10% risk for diversion and 3 that are lower risk for diversion. The Pharmacist should manually sign and date the inventory and reconciliation paperwork each time he/she conducts a manual reconciliation. If the inventory and/or manual reconciliation paperwork is kept electronically, the pharmacist should print it out and manually sign it.

When a pharmacy employs more than one pharmacist, the same pharmacist should not conduct the monthly reconciliation count any two consecutive months.

3. Inventory and manual reconciliation results should be maintained for two years.
4. *Each* supplier's invoice for Schedule II CDS medications should be stapled to the corresponding DEA -222 Form (or CSOS print-out), on which the pharmacist has recorded the required information for each item received, and should be maintained in a separate file.
5. Inventory for all CDS (Schedule C-II through C-V) should be done once a year on the same day and month that your biennial inventory would usually be completed.

### **Ordering CDS and verification of shipment upon delivery**

1. Only the pharmacist should have the authority to order C-II and C-III CDS.
2. As soon as possible after delivery of the CDS, a pharmacist or pharmacy technician may check-in the order. A pharmacist, other than the individual who did the initial check-in should verify the completeness and accuracy of each order and sign off on each receipt/invoice before placing the CDS into inventory, as described above. Only the pharmacist may physically place the C-II's and C-III's into the safe/steel cabinet.
3. The same person should not have responsibility for ordering and receiving CDS.

### **Interface with Prescribers**

1. A pharmacist who suspects that a practitioner may be indiscriminately prescribing CDS should contact the practitioner to attempt to ascertain whether the prescription is being issued for a legitimate medical purpose. A pharmacist should report practitioners about whom they have substantiated concern to the appropriate professional licensing Board and the Prescription Drug Monitoring Program. N.J.S.A. 45:1-37.
2. A pharmacist who suspects a prescription may be forged or altered<sup>1</sup> should verify the prescriber's phone number to ensure that the number printed on the prescription blank is correct and call to confirm the prescription, verify suspicious oral prescriptions, ask for appropriate practitioner information such as DEA #, utilize caller ID to note telephone number of incoming call, verify ID of person picking up the prescription. A pharmacist

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<sup>1</sup>Some Characteristics of Forged Prescriptions: Prescriber is not from your local area • Patient is unfamiliar to you or is from out of town • Patient exhibits suspicious behavior • Patient is picking up prescription for someone else • Prescription is presented or phoned in near closing time • Prescription is phoned in by practitioner covering after hours or on the weekend • Prescription appears too perfect, or in the alternative, contains errors in spelling or prescribing symbols • Prescription appears to be copied or scanned, is not of proper size or does not appear to have been torn from an official prescription pad.

could also request a faxed confirmation from the practitioner's office, to confirm a telephone prescription.

3. Exercise caution with internet related transactions, especially fee for filling opportunities and deals that seem too good to be true.

### **Interface with Customers**

1. Require individuals picking up CDS prescriptions to show photo identification at time of purchase if the pharmacist is not familiar with the patient. Photocopies of the identification should be stapled to the original prescription or scanned to the computer profile.
2. Written prescription blanks should not be stored in a way that would allow customer access. That is, kept where customers can reach them or see confidential patient information (to steal, wash, alter, etc.)
3. All pharmacists should register with Division's Prescription Monitoring Program, and should regularly access the PMP when filling prescriptions to monitor for instances of doctor-shopping or abuse. Pharmacies may also consider including drug abuse and treatment information on the drug monograph that is provided to each patient.
4. The pharmacist has the right to refuse to fill a prescription if, in his or her professional judgment, the prescription is outside the scope of the practice of the practitioner; or if the pharmacist has sufficient reason to question the validity of the prescription; or to protect the health and welfare of the patient. N.J.A.C. 13:39-7.12

### **Self Assessment**

Registered Pharmacists in Charge should conduct self-assessments annually and whenever there is a change in RPIC, to ensure that federal and state requirements governing the practice of pharmacy are met. The self-assessment procedure evaluates a variety of concerns to include: pharmacy security measures in place, medication inventory review (expired, overfilled, misbranded, substituted, pilfered), prescription dispensing analysis, required equipment and documentation. The Board of Pharmacy is in the process of creating a self-assessment tool that would be New Jersey specific and available in the future.

## REPORTING CDS RELATED THEFT/LOSS

Any theft/loss of CDS and PLD must be reported:

1. Contact local police department and report the theft/loss.
2. Submit a Report of Theft or Loss of Controlled Substances form (DDC-52) to the NJ Department of Law and Public Safety, Drug Control Unit.
3. Electronically submit a Report of Theft or Loss of Controlled Substances form (DEA-Form 106) to the Drug Enforcement Administration, Office of Diversion Control. The website is [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov). A paper version of DEA Form 106 can be obtained by writing DEA Headquarters, Attn: Regulatory Section/ODG, 8701 Morrisette Drive, Springfield, VA 22152.
4. Report the theft/loss to Anthony Rubinaccio, Executive Director, New Jersey Board of Pharmacy by submitting a copy of the DEA-Form 106.

Upon receiving notification that specific NJPB's have been reported lost or stolen by a practitioner and if presented, prior to dispensing:

1. Verify the prescription's authenticity with the prescriber.
2. Contact your local police department.
3. Submit a NJPB Incident Report to the NJPB Unit of the Division of Consumer Affairs.

To report a suspected indiscriminate/overprescribing practitioner, or an impaired practitioner, contact the practitioner's respective licensing Board by telephone. An online complaint form can also be filed (see the New Jersey Division of Consumer Affairs website at: <http://www.nj.gov/oag/ca/boards.htm>)

Disposal of unwanted or outdated CDS is accomplished by first completing a DEA Form 41 and submitting same to the Drug Enforcement Administration (DEA)(1-888-346-1071). The pharmacy would next contact the NJ Drug Control Unit, complete a DDC Form 51, submit same and await further instructions.

**STATE OF NEW JERSEY**  
**CONTROLLED SUBSTANCE RELATED DIRECTORY**

**Drug Control Unit**

ATTN: Matthew Wetzel, Acting  
Manager  
P.O. Box 45045  
Newark NJ 07101  
(973) 504-6351  
[www.NJConsumerAffairs.gov/drug](http://www.NJConsumerAffairs.gov/drug)

**New Jersey Prescription Monitoring  
Program**

P.O. Box 45027  
124 Halsey Street, 6th Floor  
Newark, NJ  
(800)242-5846  
[www.NJConsumerAffairs.gov/pmp](http://www.NJConsumerAffairs.gov/pmp)

**Enforcement Bureau**

New Jersey Division of Consumer  
Affairs  
124 Halsey Street, 3<sup>rd</sup> Floor  
Newark, NJ 07101  
(973) 504-6300

**New Jersey Board of Pharmacy**

ATTN: Anthony Rubinaccio, Executive  
Director  
P.O. Box 45013  
Newark, NJ 07101  
(973)504-6450  
[www.NJConsumerAffairs.gov/pharm](http://www.NJConsumerAffairs.gov/pharm)

**New Jersey State Board of Medical  
Examiners**

ATTN: William Roeder, Executive  
Director  
P.O. Box 183  
Trenton, NJ 08625  
(609) 826-7100  
[www.NJConsumerAffairs.gov/bme](http://www.NJConsumerAffairs.gov/bme)

**New Jersey State Board of Dentistry**

ATTN: Jonathan Eisenmenger,  
Executive Director  
PO Box 45005  
Newark, NJ 07101  
(973) 504-6405  
[www.NJConsumerAffairs.gov/dentistry](http://www.NJConsumerAffairs.gov/dentistry)

**New Jersey Board of Nursing**

ATTN: George Hebert, Executive  
Director  
PO Box 45010  
Newark, NJ 07101  
(973) 504-6430  
[www.NJConsumerAffairs.gov/nursing](http://www.NJConsumerAffairs.gov/nursing)

**Board of Veterinary Medical  
Examiners**

ATTN: Jonathan Eisenmenger,  
Executive Director  
PO Box 45020  
Newark, NJ 07101  
(973) 504-6500  
[www.NJConsumerAffairs.gov/vetmed](http://www.NJConsumerAffairs.gov/vetmed)



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Division of Consumer Affairs  
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124 Halsey Street, Newark, NJ 07102



**JOHN J. HOFFMAN**  
Acting Attorney General

**STEVE C. LEE**  
Acting Director

**Mailing Address:**  
P.O. Box 45045  
Newark, NJ 07101  
(973) 504-6351

Re: Notification of the Rescheduling of Hydrocodone Addendum

*This document is meant to be informational, it does not encompass all relevant laws and regulations.*

## **New Jersey Controlled Dangerous Substances Act**

N.J.S.A. 24:21-15 Prescriptions.

- a. Except when dispensed directly in good faith by a practitioner, other than a pharmacist, in the course of his professional practice only, to an ultimate user, no controlled dangerous substance included in Schedule II, which is a prescription drug as defined in section 2 of P.L.2003, c.280 (C.45:14-41), may be dispensed without the written prescription of a practitioner; provided that in emergency situations, as prescribed by the division by regulation, such drug may be dispensed upon oral prescription reduced promptly to writing and filed by the pharmacist, if such oral prescription is authorized by federal law. Prescriptions shall be retained in conformity with the requirements of section 13 of P.L.1970, c.226 (C.24:21-13). No prescription for a Schedule II substance may be refilled.

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## **New Jersey Board of Medical Examiners Regulations**

N.J.A.C. 13:35-7.6 Limitations on Prescribing, Administering or Dispensing of Controlled Substances; Special Exceptions for Management of Pain

- a) When prescribing, dispensing or administering controlled substances, a practitioner shall ensure that a patient's medical history has been taken and physical examination accomplished, including an assessment of physical and psychological function, underlying or coexisting diseases or conditions, any history of substance abuse and the nature, frequency and severity of any pain. The medical record shall reflect:
  - 1) A recognized medical indication for the use of the controlled substance;
  - 2) The complete name of the controlled substance;
  - 3) The dosage, strength and quantity of the controlled substance; and
  - 4) The instructions as to frequency of use.
- b) With respect to Schedule II controlled substances, unless the requirements of (c) below are met, a practitioner shall not authorize a quantity calculated to exceed 120 dosage units or a 30-day supply, whichever is less.
- c) A practitioner may exceed the 120 dosage unit or 30-day supply limitations for Schedule II controlled substances in (b) above in the following circumstances:

- 1) For the 120 dosage unit limitation, the practitioner follows a treatment plan designed to achieve effective pain management, which has been tailored to the needs of a patient who is suffering pain from cancer, intractable pain or terminal illness. The treatment plan shall state objectives by which treatment success is to be evaluated, such as pain relief and improved physical and psychological function, and shall indicate if any further diagnostic evaluations or other treatments are planned. The practitioner shall discuss the risks and benefits of the use of controlled substances with the patient, guardian or authorized representative;
- 2) With regards to the 30-day supply limitation, a practitioner may prescribe the use of an implantable infusion pump which is utilized to achieve pain management for patients suffering from cancer, intractable pain or terminal illness. A prescription for such an implantable infusion pump may provide up to a 90-day supply, as long as the physician evaluates and documents the patient's continued need at least every 30 days; and
- 3) With regards to the 30-day supply limitation, a practitioner may prescribe multiple prescriptions authorizing a patient to receive a total of up to a 90-day supply of a Schedule II controlled dangerous substance provided that:
  - i) Each separate prescription is issued for a legitimate medical purpose by the practitioner acting in the usual course of professional practice;
  - ii) The practitioner provides written instructions on each prescription, other than the first prescription if it is to be filled immediately, indicating the earliest date on which a pharmacy may fill each prescription;
  - iii) The practitioner determines that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse; and
  - iv) The practitioner complies with all other applicable State and Federal laws and regulations.
- d) When controlled substances are continuously prescribed for management of pain for three months or more, the practitioner:
  - 1) Shall review, at a minimum of every three months, the course of treatment, any new information about the etiology of the pain and the patient's progress toward treatment objectives;
  - 2) Shall remain alert to problems associated with physical and psychological dependence; and
  - 3) Shall periodically make reasonable efforts, unless clinically contraindicated, to either stop the use of the controlled substance, decrease the dosage, try other drugs such as nonsteroidal anti-inflammatories, or treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence.
- e) If treatment objectives are not being met, the practitioner:
  - 1) Shall assess the appropriateness of continued treatment with controlled substances or undertake a trial of other drugs or treatment modalities; and

- 2) Shall consider referring the patient for independent evaluation or treatment in order to achieve treatment objectives.
- f) A practitioner shall remain alert to the possibility that controlled substances may be misused or diverted. A practitioner managing pain in a patient with a history of substance abuse shall exercise extra care by way of monitoring, documentation and possible consultation with addiction medicine specialists, and should consider the use of an agreement between the practitioner and the patient concerning controlled substance use and consequences for misuse.
  - g) The practitioner shall keep accurate and complete records including that information required by (a) above as well as:
    - 1) The medical history and physical examination of the patient;
    - 2) Other evaluations and consultations;
    - 3) Treatment plan objectives;
    - 4) Evidence of informed consent;
    - 5) Treatments and drugs prescribed or provided, as in (a) above;
    - 6) Any agreements with the patient; and
    - 7) Periodic reviews conducted.

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### **New Jersey Controlled Dangerous Substances Regulations**

#### **N.J.A.C. 13:45H-7.8 Requirements of Prescriptions; Schedule II**

- a) A pharmacist may dispense directly a controlled substance listed in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the prescribing individual practitioner, except as provided in (d) and (e) below.
- b) An individual practitioner may administer or dispense directly a controlled substance listed in schedule II in the course of his professional practice without a prescription, subject to N.J.A.C. 13:45H-7.6.
- c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.
- d) In the case of an emergency situation, as defined by the Secretary in the Code of Federal Regulations, Title 21, part 290.10, a pharmacist may dispense a controlled substance listed in schedule II 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 not to exceed 72 hours (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner);
  - 2) The prescription shall be immediately reduced to writing by the pharmacist and shall

contain all information required in N.J.A.C. 13:45H-7.4, except for the signature of the prescribing individual practitioner;

- 3) If the prescribing individual practitioner is not known to the pharmacist, he 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 using his phone number as listed in the telephone directory and/or other good faith efforts to insure his identity; and
- 4) Within 72 hours after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed (not to exceed the amount for a 72 hour period) to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of N.J.A.C. 13:45H-7.4, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. 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 period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the Drug Control Unit and the nearest office of the DEA in his district if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense with a written prescription of a prescribing individual practitioner.
- e) If permitted by Federal law, and in accordance with Federal requirements, an electronic prescription shall serve as the original signed prescription.
- f) A practitioner shall not prescribe or dispense a schedule II controlled substance to an individual patient in excess of the limits set forth at N.J.A.C. 13:35-7.6, except that prescriptions for patients in a Long Term Care Facility (LTCF) may be in amounts as set forth in N.J.A.C. 13:45H-7.10(d).

#### 13:45H-7.9 Refilling Prescriptions; Schedule II

The refilling of a prescription for a controlled substance listed in schedule II is prohibited.

#### 13:45H-7.10 Partial Filling of Prescriptions; Schedule II

- a) The partial filling of a prescription for a controlled substance listed in schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription).
- b) The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner.
- c) No further quantity may be supplied beyond 72 hours without a new prescription.
- d) Prescriptions for schedule II controlled substances written for patients in a Long Term Care Facilities (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question

whether a patient may be classified as having a terminal illness, the pharmacist shall contact the practitioner prior to partially filling the prescription. Both the pharmacist and practitioner shall assure that a controlled substance is for a terminally ill patient. The pharmacist shall record on the prescription whether the patient is “terminally ill” or an “LTCF” patient. A prescription that is partially filled and does not contain the notation that the patient is “terminally ill” or a patient in a “LTCF” shall be deemed to have been filled in violation of N.J.S.A. 24:21. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed and the identification of the dispensing pharmacist. Prior to any subsequent partial filling, the pharmacist shall determine that the additional partial filling is necessary. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions, for patients in a LTCF, or patients with a medical diagnosis documenting a terminal illness, shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of the medication.

- e) Information pertaining to current Schedule II prescriptions for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if this system has the capability to permit:
  - 1) Output (display or printout) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, address of the LTCF or address of the hospital or residence of the patient, identification of medication authorized (to include dosage form, strength and quantity), listing of partial fillings that have been dispensed under each prescription and the information required in (d) above;
  - 2) Immediate (real time) updating of the prescription record each time a partial filling of the prescription is conducted.
  - 3) Retrieval of partially filled schedule II prescription information in accordance with procedures specified in N.J.A.C. 13:45H-7.14(e)1 through 5 for schedule III and IV prescription refill information.

#### 13:45H-7.11 Labeling of Substances; Schedule II

- a) The pharmacist filling a written or emergency oral prescription for a controlled substance listed in schedule II shall affix to the package a label, conforming to the provisions set forth in N.J.S.A. 24:21-17.
- b) The requirements of (a) above do not apply where a controlled substance listed in schedule II is prescribed for administration to an ultimate user who is institutionalized: Provided, that:
  - 1) Not more than a seven day supply of the controlled substance listed in schedule II is dispensed at one time;
  - 2) The controlled substance listed in schedule II is not in the possession of the ultimate user prior to the administration; and

- 3) The institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing, and storage of the controlled substance listed in schedule II; and
- 4) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

#### 13:45H-7.12 Filing of Prescriptions; Schedule II

All written prescriptions and written records of emergency oral prescriptions shall be kept in accordance with requirements of N.J.A.C. 13:45H-5.17.