



# DELAWARE CONTROLLED SUBSTANCE MANDATORY ONE-HOUR COURSE

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# Trends in Opioid Abuse & Mortality

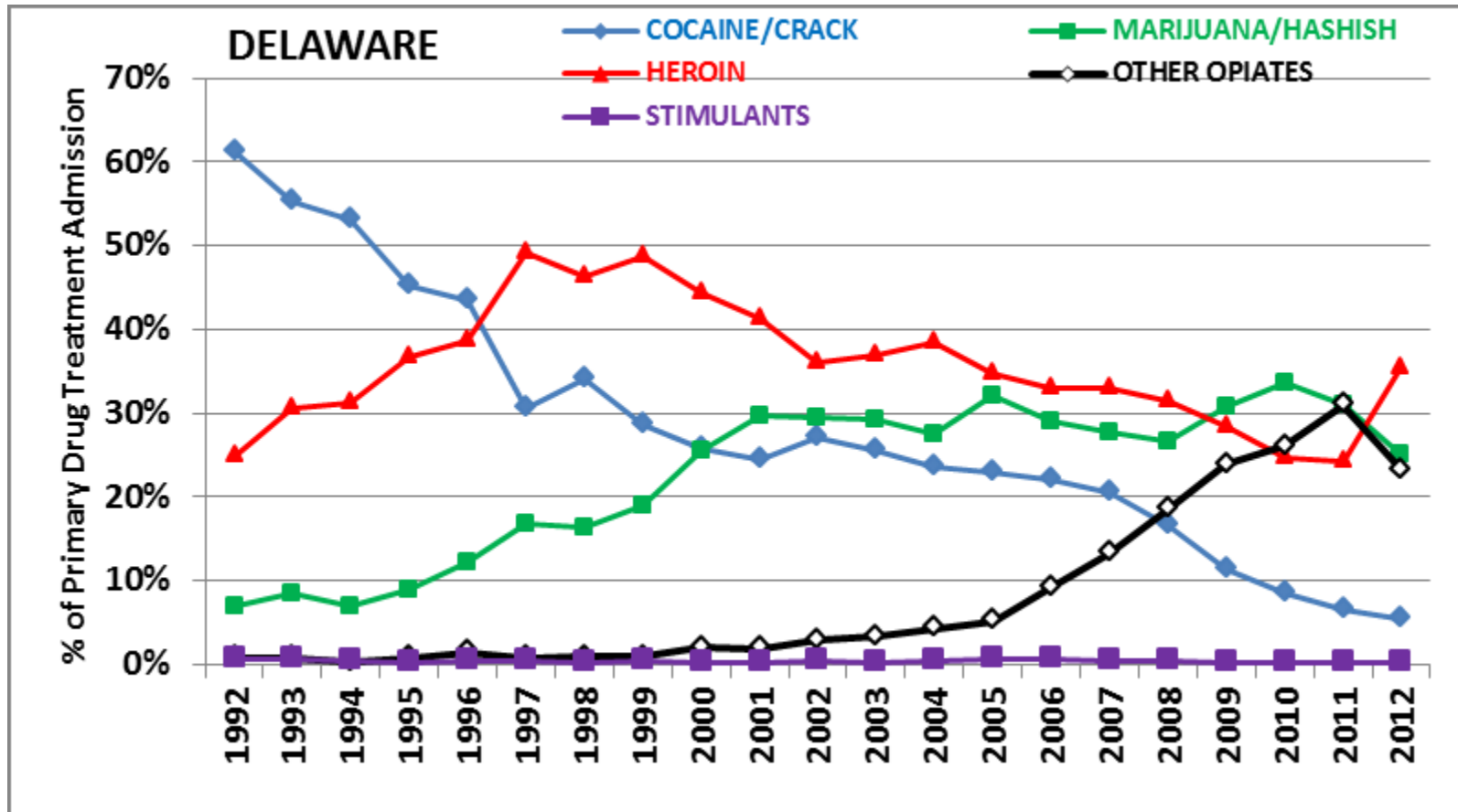
The use of prescription opioid medications has increased greatly in the United States during the past two decades.

In 2013, there were 7,590 admissions for addiction into Delaware state-funded treatment facilities – the second highest number of annual admissions in five years.

In 2014, 185 Delawareans died from suspected overdoses.



# Substance Abuse Treatment Data



- Source: Treatment Episode Data Set, Substance Abuse and Mental Health Services Administration: <http://www.samhsa.gov/data/DASIS.aspx#teds>



# Continuing Education Requirement

In response to the increase in use, abuse, and diversion of controlled substances, federal, state and local interventions have been implemented.

Under Delaware Controlled Substance Regulation 3.1.1, controlled substance registered practitioners must attest to completing a one-hour educational course on Delaware law, regulation and programs.



# Education Responsibilities

This course meets the one-hour educational requirement on Delaware law, regulation and programs.

- Practitioners renewing their registrations will be required to attest to completing the one-hour course on their 2015 CSR renewal application.
- Practitioners applying for a new controlled substance registration will be required to attest to completing the one-hour course on their Delaware Controlled Substance registration application.



# Registration Required

Every practitioner must have a controlled substance registration:

- to prescribe controlled substances
- to store controlled substances
- to dispense controlled substances



- You must obtain a Delaware practitioner license (e.g., Physician, Dentist, etc.) prior to receiving your controlled substance registration (CSR) .
- Once your Delaware CSR is approved, you must then file for a federal DEA registration.
- You must have both a Delaware CSR *and* DEA registration for Delaware *before* you prescribe controlled substances in Delaware.



# Registration to Prescribe

Your first Delaware CSR covers all Delaware locations where you may ***prescribe*** controlled substances. Typically, your main practice address is the location associated with this registration.





# Multiple Registrations

- If you ***dispense*** (i.e., give out) and/or ***store*** controlled substances for patient administration at *additional* locations, you ***or*** another practitioner must apply for a ***separate CSR for each such location.***
- If no other practitioner holds a CSR for a location where you will store/dispense controlled substances, you must file for an additional CSR for the location.



# Prescribing in Two States

- If you prescribe controlled substances in two different states, you will need separate DEA registrations each associated with the state practice sites.

For example, a practitioner prescribes controlled substances in both DE and PA. One DEA registration will be associated with DE and another DEA registration will be associated with PA.



# Records and Inventory

Uniform Controlled Substance Regulation 3 requires that all patient records include the following:

- name and address of patient
- date controlled substance was prescribed
- name, strength and amount of medication

In addition, all records must be:

- available for inspection by the Office of Controlled substances
- audited every two years
- retained for at least two years



# Transfer of Controlled Substances Between Registrants

- Both parties must be registered with DEA.
- A DEA Form 222 must be completed to transfer Schedule II controlled substances.
- An invoice must be completed to transfer Schedule III-V controlled substances.



# Persons Entitled to Issue Prescriptions

Uniform Controlled Substance Regulation 4 requires:

- issuance of controlled substance prescriptions only by an individual practitioner who is authorized to prescribe controlled substances
- verbal controlled substance prescriptions to be communicated to a pharmacist only by the prescriber.



# Prescriptions

Uniform Controlled Substance Regulation 4 requires prescriptions be issued:

- for a legitimate medical purpose
- by a practitioner acting in the usual course of their professional practice



## Prescriptions (cont'd)

Prescriptions should not be written for:

- continuing a dependence unless approved by State and Federal law
- supplying the individual practitioner for the purpose of general dispensing to patients

Prescribing controlled substances for family members is not recommended.



# Manner of Issuance of Prescriptions

Uniform Controlled Substance Regulation 4 requires that all controlled substance prescriptions:

- be dated and signed on the day when issued
- bear the full name and address of the patient
- bear the name, address and registration number of the practitioner





# Tamper Resistant Prescription Program (TRPP)

- The Tamper Resistant Prescription Program was launched in March of 2012.
- The purpose of tamper-resistant prescription form is to reduce prescription fraud.
- This program requires all medical practitioners in the State of Delaware to write their prescriptions on Delaware-specific tamper resistant prescription paper.



# Tamper Resistant Prescription Program (cont'd)

The Division of Professional Regulation is responsible for ensuring compliance with statutory and regulatory requirements for tamper-resistant prescriptions by registering vendors that manufacture and sell tamper-resistant prescription forms for use by Delaware healthcare practitioners.

A list of prescription vendors and distributors may be found at [www.dpr.delaware.gov](http://www.dpr.delaware.gov)



# Tamper Resistant Prescription Program (cont'd)

The Division of Professional Regulation is responsible for ensuring compliance with statutory and regulatory requirements for tamper-resistant prescriptions by:

- maintaining a Provider Verification System (PVS) that enables vendors to assure that only licensed healthcare providers and authorized institutions are permitted to purchase prescription forms



# Delaware Tamper Resistant Security Features

Prescription forms will be required for each practitioner, group practice or institution. The printing on each form must include name, street, city, state, zip code, telephone number, and the prescriber's Delaware professional license/registration number. Computer software can print the actual prescriber's/institution's name and other required information.



## Delaware Tamper Resistant Security Features (cont'd)

- **Repetitive Void Pattern** – The word “VOID” must appear in a pattern across the entire face of the prescription form when it is scanned, photocopied or faxed.
- **Watermark** – A printed watermark consisting of the words “Delaware Security Prescription,” which is visible to the human eye at a 45-degree angle, must be printed on the back of the prescription blank.
- **Coin Reactive Ink** – The words “Delaware Security Prescription” must appear on the back of the prescription when rubbed with a coin.



## Delaware Tamper Resistant Security Features (cont'd)

- **Chemical Void** – To prevent alteration by chemical washing, this feature causes a “VOID” pattern to appear when any area of the form is exposed to ink solvent (i.e., acetone).
- **Thermochromic Ink Feature** – The back of the prescription must contain a friction-activated ink feature (e.g., RX) in several locations that will disappear or change color when rubbed. It should return to its original color when cooled.
- **Solid-Colored Background**



# Delaware Tamper Resistant Security Features (cont'd)

- **Security Back Print** – The back of the prescription must include a chart listing all of the security features.
- **Refill Indicator**
- **Controlled Substance** – Only one controlled substance may be listed on each prescription form. The quantity must be written in both number and text format (e.g., #35 (thirty-five)).



## Delaware Tamper Resistant Security Features (cont'd)

- **Serial Numbers** – A unique serial number must be printed on each form. No two forms may have the same serial number.
- **Signature Lines** – Two signature lines must be printed at the bottom of the face of the form. Under the first line, the words “Substitution Permissible” must be printed. Under the second line, the phrase “In order for a brand name product to be dispensed, the prescriber must hand write ‘Brand Necessary’ or ‘Brand Medically Necessary’ in the space provided” (24 Del. C. §2549).





# Prescription Form

- 24 **Del. C.** §2549 requires that *“Every prescription written in this State by a person authorized to prescribe drugs and licensed in Delaware shall be on a prescription form containing a line for the prescriber's signature. Alongside or beneath the line shall be clearly printed the words, 'Substitution Permitted'. Beneath the signature line shall be clearly printed the statement, 'In order for a brand name product to be dispensed, the prescriber must hand write 'Brand Necessary' or 'Brand Medically Necessary' in the space below'. Beneath the statement shall be a second line to accommodate the above-mentioned wording.”*



# Sample Prescription Form

**Doctors of Delaware** 999999  
**Dr. John Doe**  
 Lic # C1-1234567

123 Main Street, Suite 0  
 Somecity, Delaware 10101  
 (302) 999-9999

DEA# \_\_\_\_\_

---

Name \_\_\_\_\_ D.O.B. \_\_\_\_\_

Address \_\_\_\_\_ Date \_\_\_\_\_

**Rx**

Refill NR 1 2 3 4 5

\_\_\_\_\_  
 Substitution Permissible

\_\_\_\_\_  
 In order for a brand name product to be dispensed, the prescriber must hand write "Brand Necessary" or "Brand Medically Necessary" in the space provided.

**SECURITY FEATURES LISTED ON BACK**



# Expiration of Prescription

Uniform Controlled Substance Regulation 4 requires that:

- Prescriptions for Schedules II and III controlled substances are void unless dispensed within seven (7) days of the original date of the prescription.



# Dosage Form/Day Supply Limits

Schedule II and Schedule III prescriptions cannot be written for more than 100 dosage units or 31 day supply, whichever is greater.



# Dosage Form/Day Supply Example #1

Prescription written for 1 tablet daily. The dosage unit is one tablet, the patient may receive 100 tablets.

Doctors of Delaware Dr. John Doe Lic # C1-1234567		999999
123 Main Street, Suite 0 Somecity, Delaware 10101 (302) 999-9999		DEA# AD5167123
Name <u>John Smith</u>	D.O.B. _____	
Address <u>3 Circle Road Somecity, DE</u>	Date <u>1/1/15</u>	
Rx	<u>Oxycodone 30 mg</u>	<b>Good Prescription</b>
	<u>1 qd</u>	<b>1 (dosage unit) X</b>
	<u>#100 One Hundred</u>	<b>100 equals 100</b>
Refill <input checked="" type="radio"/> NR 1 2 3 4 5		
<u>John Doe</u> Substitution Permissible		In order for a brand name product to be dispensed, the prescriber must hand write "Brand Necessary" or "Brand Medically Necessary" in the space provided.
SECURITY FEATURES LISTED ON BACK		



# Dosage Form/Day Supply Example #2

Prescription written for 2 tablets daily. The dosage unit is two tablets, the patient may receive 200 tablets.

Doctors of Delaware Dr. John Doe Lic # C1-1234567		999999
123 Main Street, Suite 0 Somecity, Delaware 10101 (302) 999-9999		DEA# <u>AD5167123</u>
Name <u>John Smith</u>	D.O.B. _____	
Address <u>3 Circle Road Somecity, DE</u>	Date <u>1/1/15</u>	
Rx	<u>Oxycodone 30 mg</u>	<b>Good Prescription</b>
	<u>tt qd</u>	<b>2 (dosage units) X</b>
	<u>#200 Two Hundred</u>	<b>100 equals 200</b>
Refill <input checked="" type="radio"/> NR	1 2 3 4 5	
<u>John Doe</u> Substitution Permissible		In order for a brand name product to be dispensed, the prescriber must hand write "Brand Necessary" or "Brand Medically Necessary" in the space provided.
SECURITY FEATURES LISTED ON BACK		



# Dosage Form/Day Supply Example #3

Prescription written for 1 tablet five times daily. The patient may receive the greater amount of a 31 day supply of 155 tablets.

<b>Doctors of Delaware</b> <b>Dr. John Doe</b> Lic # C1-1234567		999999
123 Main Street, Suite 0 Somecity, Delaware 10101 (302) 999-9999		DEA# <u>AD5167123</u>
Name <u>John Smith</u>	D.O.B. _____	
Address <u>3 Circle Road Somecity, DE</u>	Date <u>1/1/15</u>	
<b>Rx</b> <u>Oxycodone 30 mg</u> <u>1 tablet five times daily</u> <u>#155 One Hundred</u>		<b>Good Prescription</b>  <b>5 tablets a day X 31 days equal 155 tablets</b>
Refill <input checked="" type="checkbox"/> NR 1 2 3 4 5		
<u>John Doe</u> <small>Substitution Permissible</small>		<small>In order for a brand name product to be dispensed, the prescriber must hand write "Brand Necessary" or "Brand Medically Necessary" in the space provided.</small>
SECURITY FEATURES LISTED ON BACK		



# Dosage Form/Day Supply Example #4

Doctors of Delaware 999999  
**Dr. John Doe**  
 Lic # C1-1234567

123 Main Street, Suite 0  
 Somecity, Delaware 10101  
 (302) 999-9999 DEA# AD5167123

---

Name John Smith D.O.B. \_\_\_\_\_  
 Address 3 Circle Road Somecity, DE Date 1/1/15

**Rx** Oxycodone 30 mg **Invalid Prescription**

t qd

#200 Two Hundred

Refill  NR 1 2 3 4 5

John Doe  
Substitution Permissible

In order for a brand name product to be dispensed, the prescriber must hand write "Brand Necessary" or "Brand Medically Necessary" in the space provided.

**SECURITY FEATURES LISTED ON BACK**





# Dosage Form/Day Supply Example #4 Explanation

Example 4 was not a valid prescription because it prescribes more than the 100 dosage unit or 31-day supply permitted.

- The prescription was written for a quantity of 200 tablets with directions to take one tablet daily.
- The dosage unit from the directions is one. One times 100 provides for a maximum quantity of 100 tablets that can be prescribed and dispensed.



# Prescribing Multiple Schedule II Prescriptions

Under 21 CFR 1306.12, a practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance, provided the following conditions are met:

- each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice



# Prescribing Multiple Schedule II Prescriptions (cont'd)

- the practitioner provides written instructions on each prescription indicating the earliest date on which a pharmacy may fill each prescription
- the individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse



# Prescribing Multiple Schedule II Prescriptions (Cont'd)

- the issuance of multiple prescriptions as described in this section is permissible under the applicable state laws
- the individual practitioner complies fully with all other applicable requirements under the Act and these regulations as well as any additional requirements under state law.



# Prescribing Multiple Schedule II Prescriptions Example #1

**Doctors of Delaware** 999999  
**Dr. John Doe**  
 Lic # C1-1234567

123 Main Street, Suite 0  
 Somecity, Delaware 10101  
 (302) 999-9999

DEA# AD5167123

---

Name John Smith D.O.B. \_\_\_\_\_  
 Address 3 Circle Road Somecity, DE Date 1/1/15

**Rx** Adderall 5 mg

t qd

#30 Thirty

Refill NR 1 2 3 4 5

John Doe  
Substitution Permissible

In order for a brand name product to be dispensed, the prescriber must hand write "Brand Necessary" or "Brand Medically Necessary" in the space provided.

**SECURITY FEATURES LISTED ON BACK**



# Prescribing Multiple Schedule II Prescriptions Example #2

Doctors of Delaware 999999  
**Dr. John Doe**  
Lic # C1-1234567  
123 Main Street, Suite 0  
Somecity, Delaware 10101  
(302) 999-9999  
DEA# AD5167123

---

Name John Smith D.O.B. \_\_\_\_\_  
Address 3 Circle Road Somecity, DE Date 1/1/15

**Rx** Adderall 5 mg Do not dispense until 2/1/15  
t qd  
#30 Thirty

Refill (NR) 1 2 3 4 5

John Doe  
Substitution Permissible

In order for a brand name product to be dispensed, the prescriber must hand write "Brand Necessary" or "Brand Medically Necessary" in the space provided.

SECURITY FEATURES LISTED ON BACK



# Prescribing Multiple Schedule II Prescriptions Example #3

**Doctors of Delaware** 999999  
**Dr. John Doe**  
 Lic # C1-1234567

123 Main Street, Suite 0  
 Somecity, Delaware 10101  
 (302) 999-9999

---

DEA# AD5167123

---

Name John Smith D.O.B. \_\_\_\_\_  
 Address 3 Circle Road Somecity, DE Date 1/1/15

**R** Adderall 5 mg Do not dispense  
t qd until 5/1/15

#30 Thirty

Refill NR 1 2 3 4 5

John Doe  
Substitution Permissible

In order for a brand name product to be dispensed, the prescriber must hand write "Brand Necessary" or "Brand Medically Necessary" in the space provided.

**SECURITY FEATURES LISTED ON BACK**

**Not Valid  
Prescription- past  
90 day allowance**



# E-Prescribing

21 CFR §1300, 1304, 1306, and 1311 permits:

- the option of signing and transmitting prescriptions for controlled substances electronically
- pharmacies to receive, dispense and archive electronic prescriptions of schedule II-V controlled substances
  - Pharmacies may only process electronic controlled substance prescriptions using applications determined to meet DEA's requirements.
  - Electronic transmissions of controlled substance prescriptions requires security protocols to be established.





# Electronically Transmitted Prescriptions

Under the Uniform Controlled Substance Regulation 4 prescriptions for controlled substances may be transmitted electronically or via facsimile transmission by a practitioner or by the practitioner's authorized agent to a pharmacy.



# Administration vs. Dispensing Definitions

“Administer” or “administration” means:

the direct application of a drug to the body of a patient by injection, inhalation, ingestion or any other means.

“Dispense” or “dispensing” means:

the interpretation, evaluation, and implementation of a prescription, including the preparation and delivery of a drug to a patient or patient’s agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.



# Dispensing of Controlled Substances

- Practitioners are prohibited from dispensing controlled substances beyond a 72-hour supply (16 Del. C. §4739A).
- Practitioners who dispense a 72-hour supply must report the dispensing to the Delaware Prescription Monitoring Program (DE PMP).
- Samples that practitioners provide are not included in the 72-hour limit.



# Labeling

Practitioners who dispense drugs, including samples, shall affix a label to every container (24 Del. C. §2522).



# Labeling of Samples

Practitioner-dispensed samples shall be labeled with:

- date the drug is originally dispensed to the patient
- patient's full name
- practitioner's name
- practitioner's directions to the patient for use



# Labeling Dispensed Medication (not samples)

Practitioner-dispensed medication shall be labeled with:

- date the drug is originally dispensed to the patient
- patient's full name
- brand name and strength of the drug
- practitioner's directions to the patient for use
- practitioner's name
- address of the practitioner



# Security and Storage

Uniform Controlled Substance Regulation 7 requires:

- a burglar-resistant type safe or GSA Class 5 grade steel cabinet for storage of greater than 400 total dosage units of Schedule II substances
  - a safe weighing less than 750 pounds must be bolted, cemented, or secured to the wall or floor



## Security and Storage (Cont'd)

Uniform Controlled Substance Regulation 7 requires:

- Safes, cabinets or drawers containing controlled substances must only be accessible to authorized, licensed personnel
- Motion detector and camera surveillance are required unless otherwise approved by OCS

Schedules III, IV and V may be stored in a securely locked, substantially constructed cabinet.





# Theft and Loss

Registered practitioners must:

- complete DEA Form 106 and notify the OCS and DEA of any theft or significant loss of controlled substances
- notify the OCS of an loss or theft of Delaware Tamper Resistant Prescription Paper



# Practitioner Disposal of Controlled Substances

- Registered practitioners MAY NOT accept the return of dispensed controlled substances from their patients.
- Practitioner-stored controlled substances, including samples, must be disposed of through a reverse distributor.
  - (“reverse distributors” are firms registered by DEA to acquire and dispose of outdated and/or damaged controlled substances)



# Patient Disposal of Controlled Substances

Patients may dispose of their controlled substances by any of the following methods:

- according to FDA Drug Disposal Guidelines\*
- “take back” events authorized by the DEA/OCS
- envelope mailing to reverse distributors authorized by the DEA/OCS
- disposal in DEA/OCS authorized receptacles

\*<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm>



# Delaware Prescription Monitoring Program

The Delaware Prescription Monitoring Program (PMP) is a system that collects information daily on all controlled substance (schedules II-V) prescriptions.

Prescribers and dispensers can obtain immediate access to an online report to review a patient's controlled substance prescription history in order to better manage patient care and promote improved professional practice.



# Delaware Prescription Monitoring Program (cont'd)

Registration to access the Delaware PMP is limited to the following:

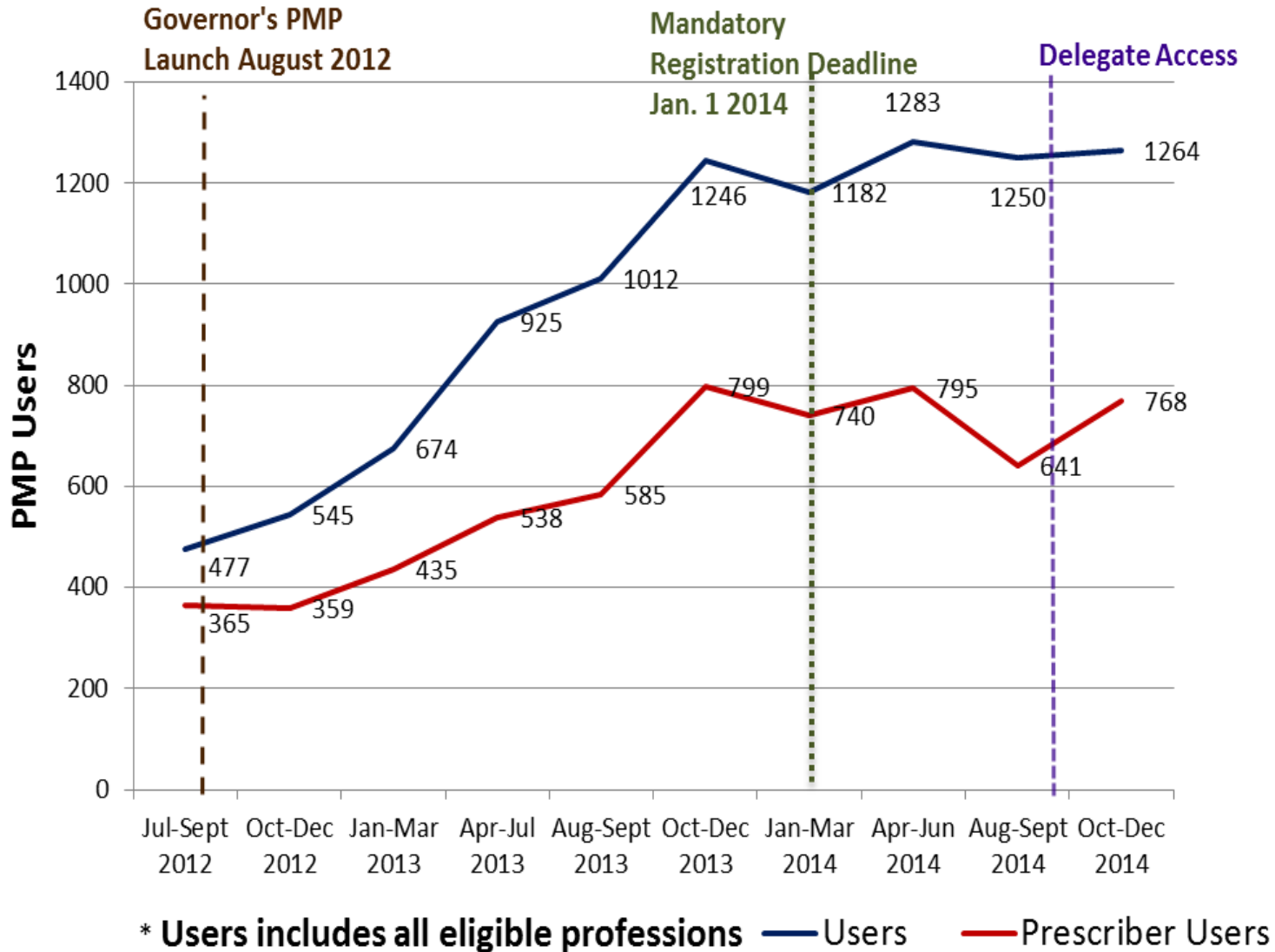
- practitioners (other than veterinarians) who hold a valid Delaware controlled substance registration
- delegates who are authorized by a Delaware-registered practitioner to access the PMP on the practitioner's behalf
- Delaware-licensed professional counselors of mental health and chemical dependency professionals
- Delaware-licensed pharmacists



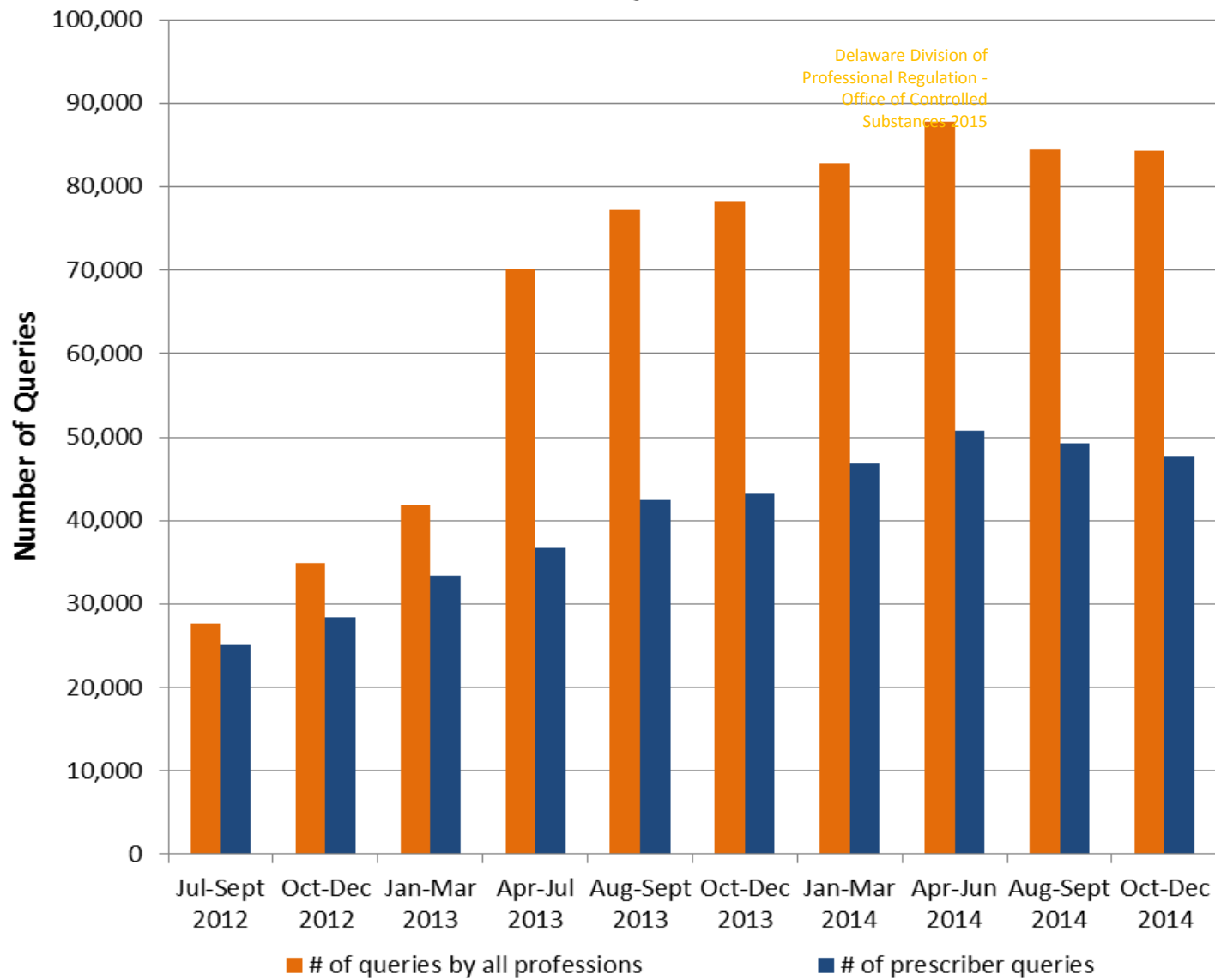
# Mandatory Registration

All practitioners who hold an active Delaware Controlled Substance Registration (with the exception of veterinarians) are required, by Delaware law, to register with the PMP.

# Delaware PMP Users Before and After Mandatory Registration



# Delaware PMP Queries 2012-2014



Source: Delaware Prescription Monitoring Program (DE PMP)





# Prescription Behavioral Surveillance System

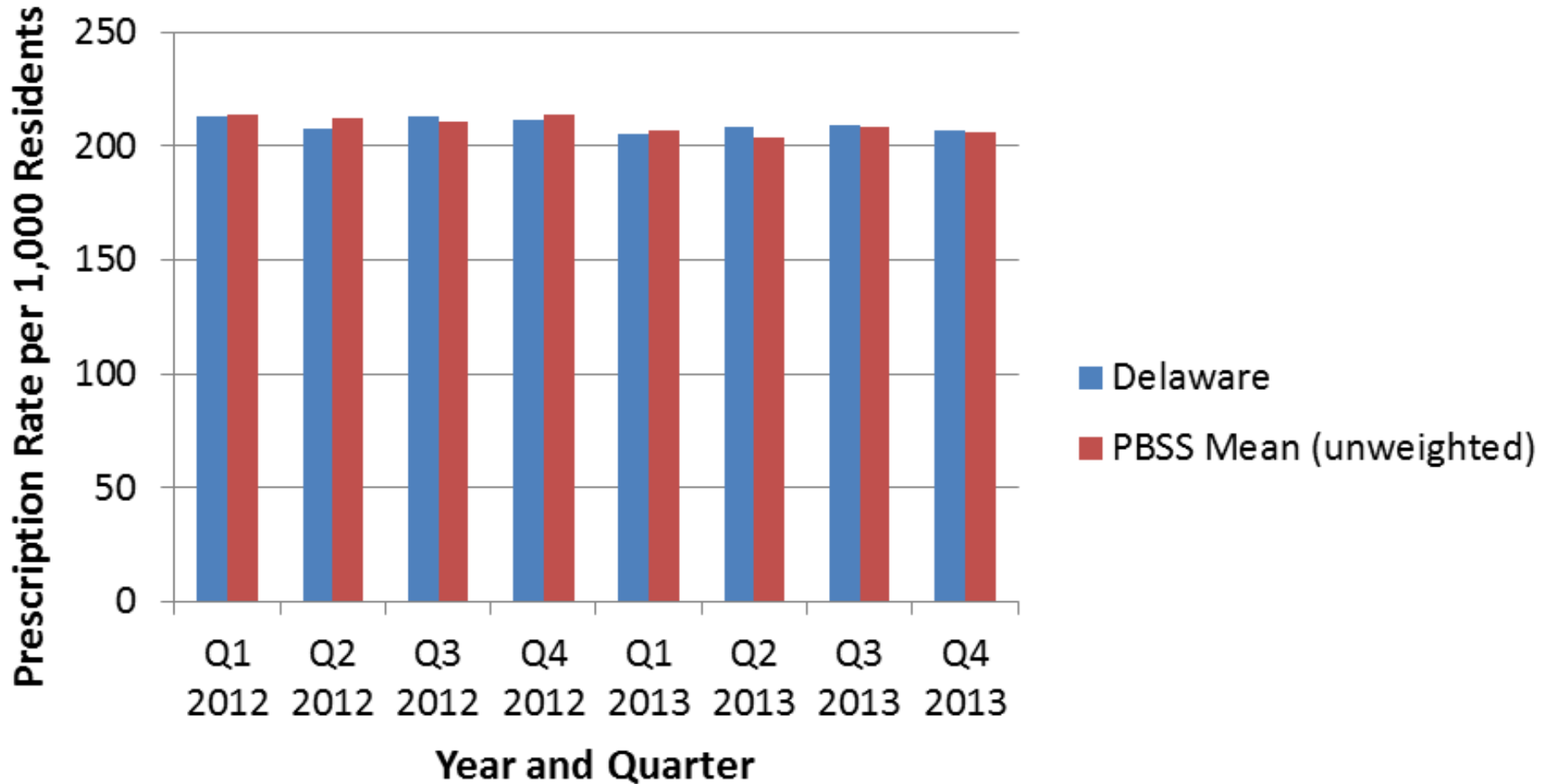
- The Division of Professional Regulation is contracted with the Brandeis Prescription Drug Monitoring Program (PDMP) Center of Excellence.
- Brandeis created the Prescription Behavior Surveillance System (PBSS) to analyze PMP data at a state and multi-state level.



# Quarterly Opioid Prescription Rates for Delaware

In 2012 and 2013, quarterly prescription rates for opioids in Delaware were similar to the mean rates for eight PBSS states (shown as rate per 1,000 residents). The 2013 annual prescription rates for Delaware compared to the PBSS states' mean rates were similar for opioids, 830 and 825, respectively. *(See next slide)*

## Delaware: Quarterly Opioid Prescription Rates for Delaware and PBSS States' Mean Rates (unweighted), 2012 - 2013



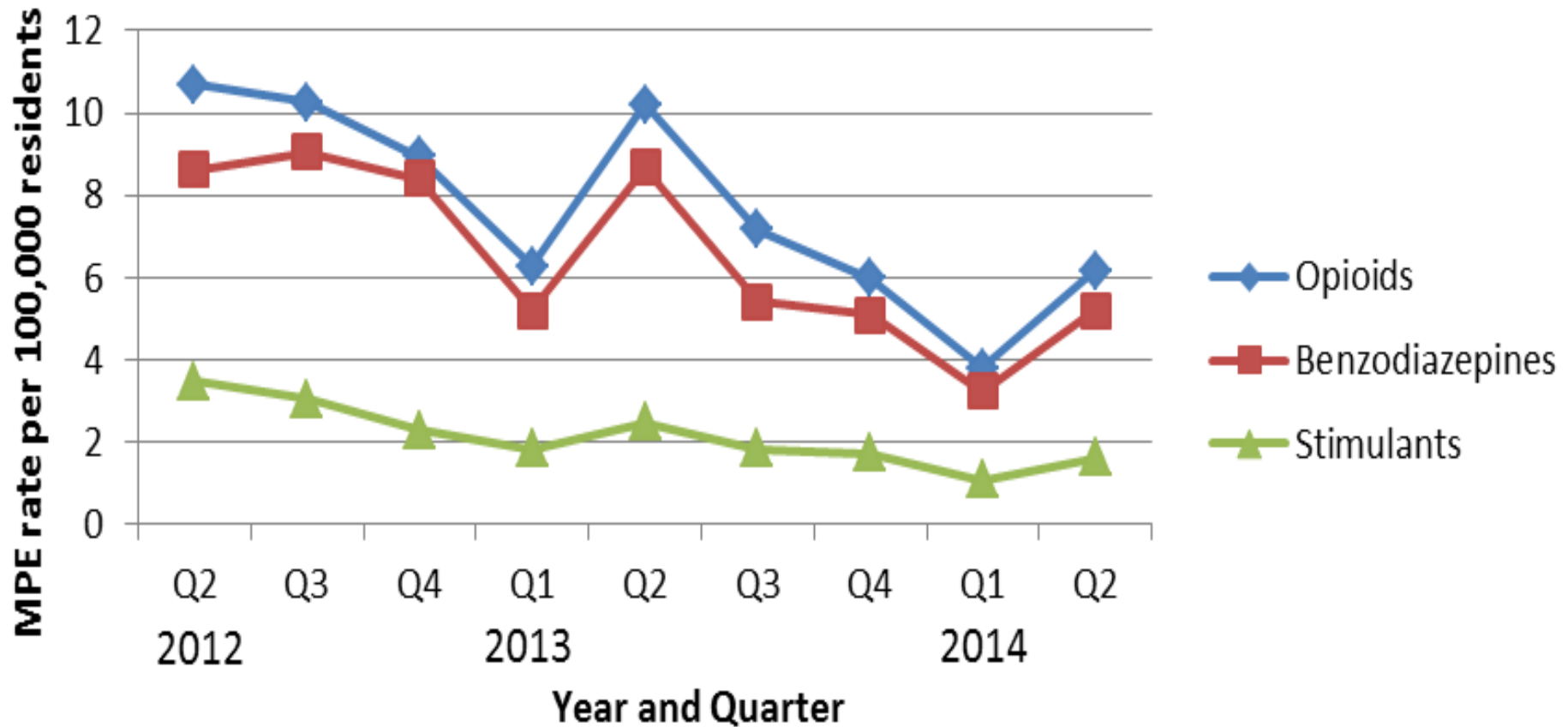
- PBSS states included are CA, DE, FL, ID, LA, ME, OH, and WV.



# Delaware: Multiple Provider Episode Rates for Opioids, Benzodiazepines and Stimulants

- Multiple Provider Episode (MPE) rate, a measure of risk for drug misuse, abuse and overdose, is defined as use of 5 or more prescribers and 5 or more pharmacies within 3 months based on the current 3 months.
- Rates of multiple provider episodes showed significant decreases from the second quarter of 2012 to the second quarter of 2014. (*See next slide*)

## Delaware: Multiple Provider Episode Rates for Opioids, Benzodiazepines and Stimulants, 2012 (Q2) to 2014 (Q2)



For the period from Q2 of 2012 to Q2 of 2014, multiple provider episode rates in Delaware showed significant decreases for opioids (42%), benzodiazepines (39%) and stimulants (53%). Rates are calculated by drug class for those receiving a prescription in the drug class.



# Model Policy for the Use of Controlled Substances for the Treatment of Pain

- June 2009 Board of Medical Licensure and Discipline (BMLD) adopted the Federation of State Medical Board's "Model Policy for the Use of Controlled Substance for the Treatment of Pain" as a "policy."
- February 2012 BMLD incorporated the Federation of State Medical Board's "Model Policy for the Use of Controlled Substance for the Treatment of Pain" as Regulation 18.



# BMLD Regulation 18.0 Use of Controlled Substances for the Treatment of Pain

## Purpose:

- to define specific requirements applicable to pain control, particularly related to the use of controlled substances
- to encourage better pain management
- to minimize practices that deviate from the appropriate standard of care that leads to abuse and diversion



# BMLD Regulation 18.0 Use of Controlled Substances for the Treatment of Pain

18.1 Evaluation of the Patient

18.2 Treatment Plan

18.3 Informed Consent

18.4 Agreement for Treatment

18.5 Periodic Review

18.6 Consultation





## 18.1 Evaluation of the Patient

A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The evaluation must document:

- **18.1.1.1** etiology, the nature and intensity of the pain, current and past treatments for pain
- **18.1.1.2** underlying or coexisting diseases or conditions
- **18.1.1.3** the effect of the pain on physical and psychological function, and history of substance abuse
- **18.1.1.4** the presence of one or more recognized medical indications for the use of a controlled substance

It further mandates that licensed physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances



## 18.2 Treatment Plan

A written treatment plan is required and must:

- state goals and objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned
- address whether treatment modalities or a rehabilitation program are necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment



## 18.2 Treatment Plan (cont'd)

After treatment begins, the physician must adjust drug therapy to the individual medical needs of each patient.



## 18.3 Informed Consent

The physician must discuss the risks and benefits of the use of controlled substances with:

- the patient
- persons designated by the patient; or
- the patient's surrogate or guardian, if the patient is without medical decision-making capacity



## 18.4 Agreement for Treatment

If the patient is at high risk for medication abuse or has a history of substance abuse, the physician must use a written agreement between the physician and patient outlining patient responsibilities that includes:

- **18.4.1** urine/serum medication levels screening when requested
- **18.4.2** number and frequency of all prescription refills
- **18.4.3** reasons for which drug therapy may be discontinued (e.g., violation of agreement)
- **18.4.4** a requirement that the patient receive prescriptions from one licensed physician and one pharmacy where possible



## 18.5 Periodic Review

The licensed physician shall periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health.

Periodic review shall include, at a minimum, evaluation of the following:

- **18.5.1** continuation or modification of controlled substances for pain management therapy, depending on the physician's evaluation of the patient's progress toward treatment goals and objectives.



## 18.5 Periodic Review (cont'd)

- **18.5.2** satisfactory response to treatment, as indicated by the patient's decreased pain, increased level of function, or improved quality of life.
  - Objective evidence of improved or diminished function must be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment.



## 18.5 Periodic Review (cont'd)

- **18.5.3** the physician shall assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities, if the patient's progress is unsatisfactory.





## 18.6 Consultation

The physician shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives.

- Special attention must be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a co-morbid psychiatric disorder requires extra care, monitoring, documentation and may require consultation with or referral to an expert in the management of such patients.
- At a minimum, physicians who regularly treat patients for chronic pain must educate themselves about the current standards of care applicable to those patients.



# BMLD Regulation 18 Summary

Regulations mandate that licensed physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Violation of BMLD Regulation 18 may result in disciplinary action against a licensed physician for deviating from these regulations.



# Document of Completion

- You have now met the one-hour educational requirement on Delaware law, regulation and programs.
  - If you now hold a Delaware Controlled Substance Registration (CSR), you must attest to completing this course during the online 2015 CSR renewal.
  - If you are applying for a new Delaware CSR, you must attest to completing this course on the application form.
- You may print this document for your files.
- Completion of this one-hour course does NOT provide continuing education credits approved by any authority, agency or organization other than the Delaware Secretary of State.

*I have completed this required course on \_\_\_\_\_, 20\_\_.*

*Signature:* \_\_\_\_\_