



Amendments to 105 CMR 700.000

*Chapter 244 of the Acts of 2012: An Act
Relative to Prescription Drug Diversion,
Abuse and Addiction*

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Massachusetts Prescription Monitoring Program (MA PMP)

- Background
 - History
 - Required statutory change in regulation
- Proposed Regulations
 - Affected sections of DPH regulations
 - Definitions and Proposed Regulation Summaries
 - Practical Implications of New Regulations
- Summary and Next Steps

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Background

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Massachusetts Prescription Monitoring Program (MA PMP)

Purpose: Help promote safe prescribing and dispensing while contributing to deterrence and prevention of drug diversion and abuse

**Prescription
data collected
from:**

- MA Community Pharmacies
- Clinic/outpatient Pharmacies
- Out-of-state mail order pharmacies serving MA residents



MA PMP

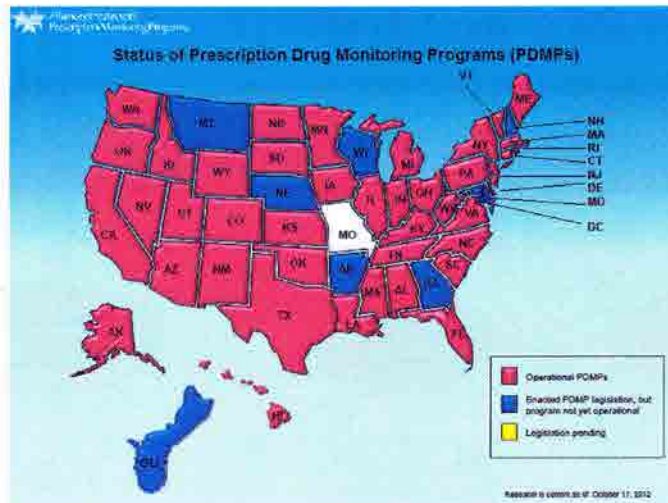
- Analyze for trends and respond to requests
- Consult with Medical Review Group and Advisory Council
- Data used as a clinical tool for prescribers, dispensers, and law enforcement



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Prescription Monitoring Programs in the U.S.



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History MA PMP

MA Prescription Monitoring Program (MA PMP)



¹ An Act Adding Safeguards to the Prescription Monitoring Program and Furthering Substance Abuse Education and Prevention

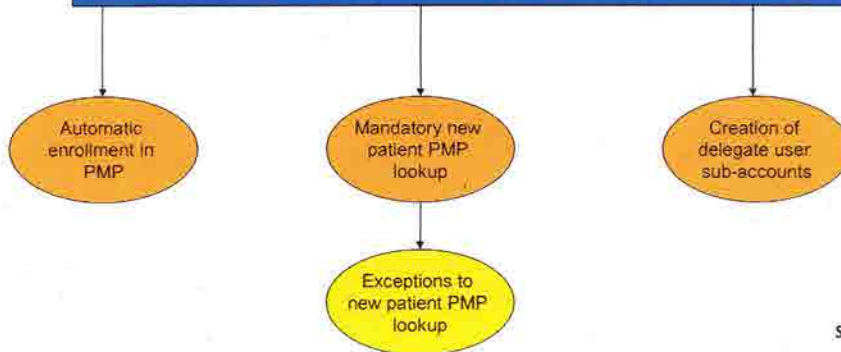
² An Act Relative to Prescription Drug Diversion, Abuse and Addiction

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Chapter 244 of the Acts of 2012

An Act Relative to Prescription Drug Diversion, Abuse and Addiction



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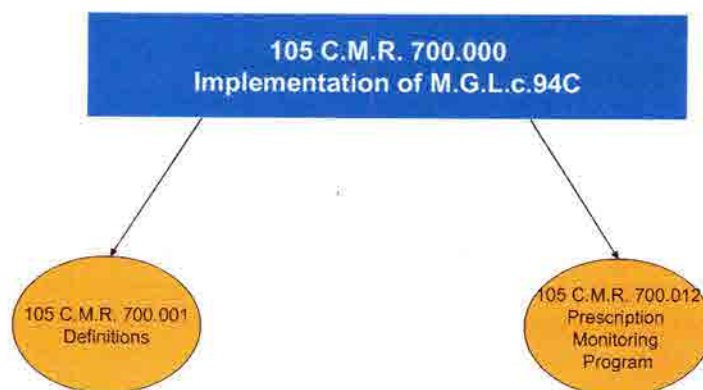


Proposed Regulations

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Affected DPH Regulations



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Definitions

105 C.M.R. 700.001

New patient means an individual person who has not received any professional services from the participant within the previous twelve months.

Participant means a registered individual practitioner or other person who is duly authorized to prescribe or dispense a controlled substance by a Massachusetts Board of Registration and is authorized by the Department to utilize the Prescription Monitoring Program.

Utilize means to access (directly or through a delegate) and review a patient's prescription history within the Prescription Monitoring Program.

Delegate means an authorized support staff member who may utilize the Prescription Monitoring Program on behalf of a participant.

Primary account holder means a participant who remains responsible for ensuring that utilization of the Prescription Monitoring Program by a delegate is limited to authorized purposes.

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105 C.M.R. 700.012 (G)

Applies to: physicians, dentists and podiatrists

- (1) **Effective January 1, 2013**, every practitioner, except a veterinarian and optometrist, who holds a valid Massachusetts Controlled Substance Registration will automatically, in a manner and schedule determined by the Department, be granted authority to utilize the prescription monitoring program, as established pursuant to 105 CMR 700.012(F).
- (2) To complete a Massachusetts Controlled Substance Registration, a practitioner must accept the Terms and Conditions of use for the prescription monitoring program.

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105 C.M.R. 700.012 (H)

- Applies to individuals who have not received any professional services from the participant within the previous 12 months.
- **Exceptions:**
 - Optometrists
 - Participants who are restricted to Schedule VI controlled substances or granted a waiver by the Department
 - Instances where PMP utilization is unfeasible or would result in a delay causing patient harm
 - Participants, other than attending physicians, providing care in hospitals or other inpatient facilities
 - Other exceptions as defined in guidance by the Department

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105 C.M.R. 700.012 (J)

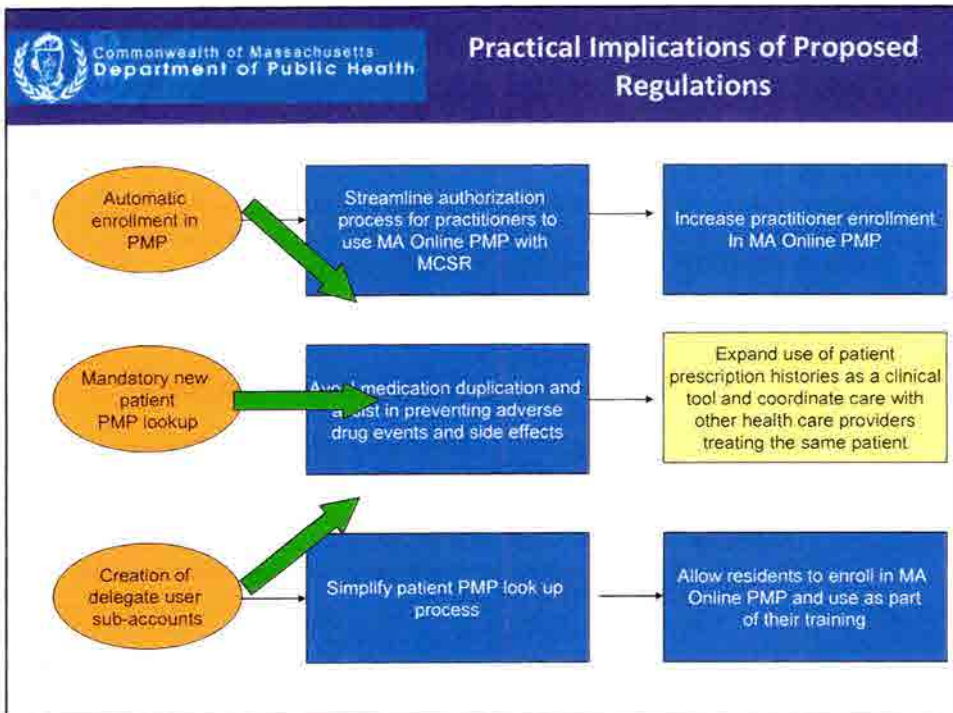
- Applies to primary account holders who seek to authorize up to 2 delegate users to utilize the Prescription Monitoring Program and will remain responsible for all delegate use of the program.
- Requirements:
 - Primary account holder must submit a written request to the Department to create a delegate user sub-account.
 - All requests submitted must be accompanied by an attestation that the primary account holder will:
 - ✓ Ensure that delegates comply with the prescription monitoring program Sub-Account User Terms and Conditions;
 - ✓ Monitor delegate use of the prescription monitoring program and inform the Department when a delegate has violated the Sub-Account User Terms and Conditions or is no longer authorized by the participant to be a delegate; and
 - ✓ Take reasonable steps to ensure that the delegate is sufficiently competent in the use of the prescription monitoring program.

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Practical Implications of Proposed Regulations

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Commonwealth of Massachusetts Department of Public Health

Automatic Enrollment Process

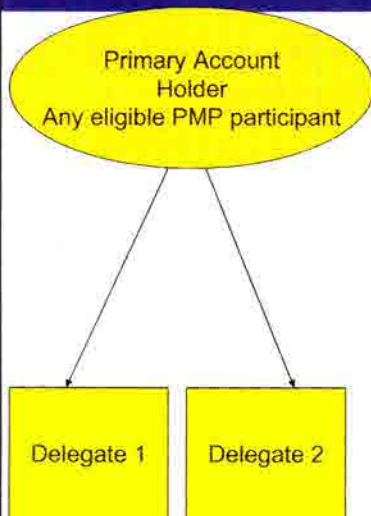
Changes to MCSR Application Process

Comparison table for Automatic Enrollment	Before new regulations	With amendments
PMP Enrollment	Voluntary	Automatic with MCSR
Identity by Notarization	Required	Not required
MA Online PMP Terms and Conditions	Signed when enrolled	One signature for MCSR and Terms and Conditions

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Delegate User Sub-accounts



Steps:

- 1) Primary Account Holder designates up to 2 delegate users (more available by waiver from the Department)
- 2) Primary Account Holder submits request for subaccounts to Drug Control Program (DCP)
- 3) Primary Account Holder agrees to be held responsible for delegate user access to PMP and ensure appropriate use
- 4) Primary Account Holder to notify DCP when delegate user subaccount should be inactivated

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Summary

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- Regulations required by the Chapter 244 of the Acts of 2012 *An Act Relative to Prescription Drug Diversion, Abuse and Addiction*
- Key features of new regulations:
 - ✓ Automatic enrollment of prescribers in the Prescription Monitoring Program (PMP)
 - ✓ Mandatory new patient PMP lookups, including exclusions
 - ✓ Creation of delegate user subaccounts on the MA Online PMP

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- Public Hearing to be held in March 2013
- Return to Council for Final Promulgation

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