

Internet System for Tracking Over Prescribing of Controlled Substances

(I Stop Legislation)

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Objectives

- List the various elements of NYS's iSTOP legislation and its impact on the practice of pharmacy
- List the patient data that **MUST** be electronically reported under iSTOP
- Identify who has a duty to consult the PMP database and who is exempt
- List the pharmacist protections when reporting to the PMP database.
- Describe the changes under C-II, IV & Vs in NYS

Chapter 447 of the Laws of 2012.

Signed into law by Governor Cuomo on Monday,
August 27, 2012.

This bill would promote the safe and effective use of prescription drugs and curb the diversion and abuse of such drugs.

I-STOP LEGISLATION

PART A: Creating the Prescription Monitoring Program Registry

PART B: Requiring the use of Electroning Prescribing

PART C: Rescheduling Certain Controlled Substances

PART D: Prescription Pain Medication Awareness Workgroup and Continuing Education

PART E: Safe Disposal of Control Substances

Part A

- Creating the Prescription Monitoring Program registry

Section 3 of Part A of the bill would amend PHL
§ 3333 (4) to require that pharmacies file prescription
information with DOH by electronic means on a
real time basis pursuant to DOH regulations,

Required Information to be *Transmitted* by Pharmacies to the PMP database

- (I) **Patient Name;**
- (II) **Patient's Residential Address;**
- (III) **Patient's Date of Birth;**
- (IV) **Patient's Gender;**
- (V) **Date the Rx was issued;**
- (VI) **Date the Rx was dispensed;**
- (VII) **Metric Quantity of Controlled Substance Dispensed;**
- (VIII) **Number of Days Supply of the Control Dispensed;**
- (IX) **Name of the Prescriber;**
- (X) **Prescriber DEA ID Number;**
- (XI) **Name or NDC Number of Drug Dispensed;**
- (XII) **Method of Payment**

Section 4 of Part A would permit DOH to disclose relevant information about controlled substance activity to pharmacists.

Section 4 also would permit DOH to disclose information to the Attorney General's Medicaid Fraud Control Unit, in furtherance of an investigation of fraud, waste or abuse of the Medicaid program and pursuant to an agreement with DOH.

Section 4 also would permit DOH to provide individuals with their controlled substance histories maintained in the Registry.

Section 5 of Part A of the bill would add a new provision to provide that **the Registry may be accessed by practitioners and pharmacists** as set forth in new PHL § 3343-a, under terms and conditions established by DOH as necessary to maintain the security and confidentiality of the information contained in the Registry.

Section 5 also would provide that if it appears that a crime related to the diversion of controlled substances has been committed, DOH may notify the appropriate law enforcement agency and provide such information about the suspected criminal activity as reasonably appears to be necessary.

Pharmacists Authority to Consult the PMP

- **iSTOP provides authority for a pharmacist, pharmacy interns or his/or her designee (which includes another pharmacist, pharmacy intern or other individual) as may be permitted by the Commissioner of DOH;**
- **Designee MUST be EMPLOYED by the same pharmacy; or**
- **Under Contract with the pharmacy**
- **Pharmacist Consultation is *NOT MANDATORY!***

Immunity for Practitioners and Pharmacists

- I STOP provides *immunity* to practitioners, pharmacists, or persons acting on their behalf in good faith from any recourse (**civil liabilities**) arising from any *false, incomplete* or *inaccurate information* submitted to or reported to the PMP;
- *Requires* the Commissioner's of DOH and Education to provide *guidance* to practitioners, pharmacists and pharmacies on the *purposes and uses* of the PMP registry;
- Authorizes '*individuals*' or their *legal guardians* access to their '*own*' personal controlled substance records history from the PMP

Section 7 of Part A of the bill provides that Part A would take effect one year after enactment, (8/27/2013) except that the Commissioner of Health and the Commissioner of Education would be authorized to promulgate rules and regulations and take other action necessary to implement Part A on its effective date.

PART B

Electronic Prescribing

Requires the Commissioner of Health to promulgate regulations on or before December 31, 2012, establishing standards for electronic prescriptions for controlled substances that are feasible and lawful under federal law.

New PHL § 281 (3) would further provide that all prescriptions made in this State **on or after two years from that determination** must be made by electronic transmission from practitioners to pharmacists, with certain specified exceptions.

Section 3 of Part B of the bill would amend Education Law § 6810 to similarly require electronic prescribing for non-controlled substances.

DEFINITION OF ELECTRONIC PRESCRIPTION

An electronic prescription is created, recorded or stored by electronic means; issued and validated with an electronic signature; and transmitted by electronic means directly from the prescriber to a pharmacist.

Prescribers and pharmacists must have a secure (encrypted or encoded) system for electronic transmission from computer to computer. Any equipment used for electronic transmission of prescriptions should be so located to ensure the security and confidentiality of the transmission.

Procedures for electronic transmission of prescriptions should be documented.

Electronically transmitted prescriptions must:

- a. Contain the electronic signature of the prescriber
- b. Shall be electronically encrypted to prevent unauthorized access, alteration or use
- c. Have the signature or initials of the pharmacist or pharmacy intern entered into the pharmacy's records to indicate acceptance of the prescription by the pharmacy.

- An electronic prescription reduced to a fax is NOT a valid instrument.
- Only 2 acceptable documents can be accepted as a valid instrument via fax to a pharmacy;
 - A “fax back” refill authorization request
 - A manually signed NYS serialized blank

The information retained electronically should be capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of data.

All records required under laws, rules and regulations administered by the Education Department may be maintained in an electronic format. At this time, certain records for controlled substances and for certain programs such as Medicare may have additional, hard-copy requirements.

PART C

Controlled Substance Schedules

Section 1 of Part C of the bill specify that **hydrocodone**, already listed, may also be known as dihydrocodeinone, and to update the classification of oripavine.

Section 2 of Part C of the bill would add to Schedule II those formulations of hydrocodone that currently appear on Schedule III. (**effective 2/27/2013**)

Section 3 of Part C of the bill would require the Commissioner of Health to establish minimum standards for the storage, reporting, ordering and record keeping of the hydrocodone formulations added to new Schedule II

Section 5 of Part C of the bill would add a new Schedule II(c)(28) to list tapentadol, which is an opiate, as a Schedule II substance.

Section 6 of the Part C of the bill would amend the opening paragraph of Schedule II (d) to clarify that the inclusion of salts and isomers applies whenever such salts or isomers are possible within the specific chemical designation of a substance.

Section 7 of Part C of the bill would add a new Schedule II(g)(3) to provide the chemical designation of a precursor to fentanyl.

Section 12 of Part C of the bill would amend Schedule IV(c) to add fospropofol and carisoprodol to Schedule IV (effective 11/27/2012)

Section 14 of Part C of the bill would add new Schedule IV (f)(3) to tramadol to Schedule IV. (effective 2/27/2013)

Section 16 of Part C of the bill would amend Schedule V(d) to add two additional substances, ezogabine and lacosamide, which are depressants, to Schedule V. (11/27/2012)

PART D

Prescription Pain Medication Awareness Workgroup and Continuing Education

Part D- Prescription Pain Medication Awareness Program

Requires DOH to establish a workgroup to make recommendations in the implementation of the Prescription Pain Medication Awareness Program enacted in the 2012-13 budget, to expand its functions.

Under the bill, the workgroup will be responsible for making recommendations on

- continuing education for practitioners and pharmacists on pain management issues;
- protection and promotion of access of patients with a legitimate need for controlled substances;
- the implementation of the Prescription Monitoring Program provisions; and
- the inclusion of certain Schedule V substances in the consultation requirements of the Prescription Monitoring Program.

Continuing Education Requirements

- Requires a report of the DOH Commissioner (with Work Group recommendations) regarding the development of **recommendations and model courses** for **Continuing Medical Education** for health care professionals in the appropriate use of pain medications.
- Provides for **CE requirements** appropriate to address *prescription pain medication awareness* among health care professionals;
- Provides for **CE requirements** for **pharmacists** as it relates to *pain medication awareness*;
- Provides for **CE in Palliative Care** as it relates to *pain medication management*.

Section 2 also would require the Commissioner of Health to include additional stakeholders on the workgroup, including but not limited to consumer advocacy organizations, health care practitioners and providers, pharmacists and pharmacies, and law enforcement agencies.

Section 3 of Part D of the bill provides that Part D would take effect immediately.

PART E

SAFE DISPOSAL OF CONTROLLED SUBSTANCES

Section 1 of Part E of the bill would require DOH to establish a program for the safe disposal of unused controlled substances by consumers.

Provides *'immunity'* for those individuals bringing in **controlled substances** as it relates to state laws *on the possession and transport of controlled substances*. Voluntary for law enforcement agencies to participate

Section 2 of Part E of the bill provides that Part E would take effect immediately

Troop A – Batavia 4525 West Saile Drive Batavia, NY 14020	Troop B – Ray Brook 1097 State Route 6 Ray Brook, NY 12977
Troop C- Sidney 823 State Route 7 Unadilla, NY 13489	Troop D Route 5 Oneida, NY 13421
Troop E- Canandaigua 1569 Rochester Rd Canandaigua, NY 14425	Troop F- Middletown 55 Crystal Run Road, Middletown, NY 10941
Troop G – Latham 760 Troy-Schenectady Rd Latham NY 12110	Troop K – Poughkeepsie 2541 Rte 44 Salt Point, NY 12578
Troop L – Farmingdale 7140 Republic Airport East Farmingdale, NY 11735	



Thank you for time and attention

- Reference: Gov. Cuomo Press Release 8/27/12