Legislative Summary Memo
A.10623/Committee on Rules
*I**nternet S**ystem for T**racking O**ver P**rescribing*
iSTOP – Chapter 447 of the L. 2012 (Aug. 27, 2012)

PART A

Section 1:
Establishes the iSTOP ACT

§2 (A). Amends Public Health Law by adding a new section 3343-a that establishes a 'real time' (not defined in statute) Prescription Drug Monitoring Program (PMP) and defines 'who' and 'what' information shall be included on this registry. Requires a minimum of 6 months patient records but no more than 5 years for the PMP database. ***Effective date: 8/27/13.***

(B) Required information to be reported by pharmacies includes:

(I) Patient's Name;
(II) Patient's residential address;
(III) Patient's date of birth;
(IV) Patient's gender;
(V) Date Rx issued;
(VI) Date Rx dispensed;
(VII) Metric quantity of controlled substance dispensed;
(VIII) Number of days supply of the Control dispensed;
(IX) Name of prescriber;
(X) Prescriber's DEA number;
(XI) Name of NDC of drug dispensed; and
(XII) Method of payment

(C) Requires that the registry be secure, easily accessible by practitioners and pharmacists, compatible with e-prescribing of controls and any regulations promulgated to the extent practicable, streamline prescriber consultation of the PMP database with similar registries operated by state or federal agencies***. Effective date: 8/27/13.***

(D) Requires DOH to establish protocols necessary to protect information contained in the PMP.

Section 2:

Duty to Consult: Requires every practitioner (or their designee) to consult the PMP prior to prescribing or dispensing any controlled substance listed as a Schedule II, III, or IV for the purpose of 'reviewing a patient's controlled substance history' with a few exemptions:

Exemptions from Mandatory Consult of PMP:

(I) Veterinarians;
(II) A practitioner dispensing under subdivision 3, §3351 of this article (prescribers in i.e. Methadone Clinics);
(III) A practitioner administering a controlled substance;
(IV) A practitioner prescribing or ordering a control for use on the premises of an institutional dispenser as defined under §3342 of this title.
(V) A practitioner prescribing in an Emergency Department of a general hospital so long as the Rx does not exceed a 5 day supply and only if control were used in accordance with the directions for use;
(VI) A practitioner prescribing a control to a patient under the care of Hospice, as defined by §4002 of this chapter;
(VII) A practitioner when:
  a. It is not reasonably possible for the practitioner to access the registry in a timely manner;
  b. No other practitioner or designee authorized to access the PMP is reasonable available;
  c. The quantity of the control substance does not exceed a five (5) day supply and were used in accordance with the directions for use;

(VIII) A practitioner acting in compliance with regulations that may be promulgated by the Commissioner of DOH as to circumstances under which consultation of the PMP registry would result in a patient's inability to obtain a prescription in a timely manner, thereby adversely impacting the medical condition of such patient;
(IX) A situation where the registry is not operational as determined by the DOH due to technological or electrical failure;
(X) A practitioner who has been granted a 'waiver' by the Commissioner of DOH due to technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstances demonstrated by the practitioner pursuant to a process established by the Commissioner of DOH.

(B) – This section authorizes a practitioner to authorize a designee to consult the PMP registry on behalf of the practitioner. Practitioner assumes all liability from that authorization and requires the Commissioner of DOH to establish regulations with reasonable parameters with regard to a practitioner's authority to authorize a designee. ***Effective date: 8/27/13.***

Section 2, paragraph 3 – Pharmacists authority to Access PMP registry.

(3) This section provides authority for a **pharmacist, pharmacist intern or his/her designee** (which includes another pharmacists, pharmacist intern or other individual as may be permitted by the Commissioner of the DOH) to access the PMP registry. The designee **MUST** be employed by the same pharmacy or is under contract with the pharmacy. **Pharmacist Consultation IS NOT MANDATORY**. ***Effective date: 8/27/13.***

Section 2, paragraph (4): Immunity for Practitioners and Pharmacists:

(4) Provides immunity to practitioners, pharmacists or persons acting on their behalf in good faith from any recourse (civil liability) arising from any false, incomplete or inaccurate information submitted to or reported to the PMP registry.

(5) Requires the Commissioner of DOH in consultation with the Commissioner of Education to provide guidance to practitioners and pharmacists and pharmacies regarding the purposes and uses of the PMP registry including educational information available to them.

(6) Authorizes 'individuals' access to their personal controlled substance records history. If the patient lacks capacity to make health care decisions, then the person who has legal authority to make health care decisions may have access. The department shall provide for Public Awareness of this option and 'how' the PMP registry will be used. (i.e. DOH website).

(7) Requires the DOH to analyze PMP data periodically to determine if any information indicates that a violation of law or breach of professional standards may have occurred and if necessary, notify appropriate entities as permitted under this article.

(8) **Funding:** This section requires the Commissioner to apply for monies available from the federal government and other institutions to the extent deemed appropriate and to use these monies to supplement the PMP registry.

(B) States that the PMP registry **SHALL NOT** be funded in whole or in part by any fees imposed on practitioners, pharmacists, designees or patients.

(9) Requires Commissioner of DOH, in consultation with the Work Group, to promulgate regulation necessary to implement this program.

Section 3, subdivision 4 of §3333 of the PHL as amended by Chap. 178, 2010. – Filing of controlled information electronically

(4) Added to section of the law: Requires the "REAL TIME" filing of controlled substance prescription information to the PMP registry. Real Time to be determined by the Commissioner of Health in consultation with the Commissioner of Education via regulations provided that the Commissioner may grant a waiver allowing a pharmacy to make such filings within a longer period of time if and to the extent that the commissioner finds it warranted due to economic hardship, technological limitations which are not necessarily in the control of the pharmacy. Also provides for regulations that ***'shall specify'*** the manner in which such requirements shall apply to the delivery of controlled substances to individuals in this state by means of mail or licensed express delivery services.

Section 4, paragraphs (d) and (e), subdivision 1 of §3371 of the PHL:

This section covering paragraphs (d), (e), and new paragraphs (F), (G), (H), (I), and (J) spells out 'who' has access to the PMP registry and 'authorizes' DOH staff to release this data to those

authorized and under what conditions. This includes notifications of a patient seeing another doctor.

This authorization is repeated in the next Section 5.

Section 5, paragraph 3 authorizes DOH to notify authorities if they reasonably believe that the crime of 'diversion' of controlled substances has been committed and provide relevant information to law enforcement agencies.

Section 6. paragraph (41) of §3302 of the PHL ***defines*** "Registry" or "Prescription Monitoring Program Registry" as that established pursuant to §3343-A of this Article. A lot more to come with regulations.

PART B - Prescription Drugs, Various Provisions

Section 2, Article 2-A of the PHL is amended to add a new Title III:

Title III

Prescription Forms, Electronic Prescribing and Language Assistance Section 281. Official New York Prescription Forms.

§281 (1). As amended, it authorizes the Commissioner of DOH, in consultation with the Commissioner of Education to promulgate Emergency Regulations for the e-prescribing of prescriptions from prescribers to pharmacists or for ordering and filling requirements of prescription drugs for recipients eligible for Medical assistance under Title 11 of Article Five of the Social Services Law (Medicaid); EPIC and all controlled substances (Under Article 33 of this chapter.

(2) Requires Commissioner (DOH) with consultation from Commissioner of Education to promulgate regulations requiring prescription forms and e-prescriptions to include a section wherein a prescriber may indicate whether the patient is a Limited English Proficiency (LEP) and a line where he/she may specify the preferred language of the patient. Paper Rx forms must have the LEP line on them by ***March 30, 2013***. Affects pharmacies with an ownership interest in 8 or more outlets.

(3) **Mandatory E-Prescribing of ALL Prescriptions:** On or before **March, 2013**, the Commissioner, in consultation with Commissioner of Education shall promulgate regulations for 'standards' for e-prescribing, effective two years **(March 30, 2015)** from that date. After that date, all prescriptions will have to be in electronic form with **SOME** exceptions as listed under Mandatory Consultant requirements above. That would be Veterinarians and for practitioners if not available because of technological limitations, temporary failure of technology or electrical access or issued by those practitioners who received a 'waiver' form the Commissioner, not to exceed one year, certain due to economic hardship, or other exceptional circumstances demonstrated by the practitioner such as a delay would adversely impact a patient if it is impractical for the patient to obtain substances prescribed via e-prescription, or issued by a practitioner to be dispensed by a pharmacy outside NYS.

(4) Requires a practitioner who does not use e-prescribing to file information with DOH as soon a practical. Each exception requires filing information on controls with state.

Part C

Section 1. Paragraph 1, subdivision (b) of Schedule II of Section 3306.

(10) Adds **Hydrocodone** (Also known as **Dihydrocodeinone**) and **Oripavine** to **Schedule II**. ***(180-days) – Effective date: 2/23/13.***

§5, subdivision (c) of Schedule II of Sec. 3306 of the PHL adds a new paragraph (28) which adds **Tapentadol – *(90-days - Effective date: 11/25/12.***

§7, subdivision (9) of Schedule II of Sec. 3306 adds a new paragraph (3) which adds **Immediate Precursor to Fentanyl** and subparagraph (I) **4- Anilino-N-Phenethyl – 4 – Piperidine (ANPP). *(90-days) – Effective date: 11/25/12.***

§12, subdivision (c) of Schedule IV of Sec. 3306 of the PHL adds a new paragraphs (52) and (53) which adds (52) **Fospropofol** and (53) **Carisoprodol. *(90-days) – Effective date: 11/25/12.***

§13 , Paragraph 11 of subdivision (e) of Schedule IV, Sec. 3306 of the PHL as added by Chapter 457, Laws of 2006, removes [Modafanil} and adds **Modafinil. *(90-days) – Effective date: 11/25/12.***

§14. Subdivision (f) of **Schedule IV** of Sec. 3306 of the PHL adds a new paragraph (3) which adds **Tramadol in any quantities. *(180-days) – Effective date: 2/23/13.***

§16. Subdivision (d) of Schedule V of Sec. 3306 of the PHL, as added by Chap. 178 of the L. 2010 is amended under subparagraph (d) to include **Isomers, and Salts of Isomers** and under subparagraph (d) (1) adds **Ezogabine {N-2-Amino-4-(4-Fluorobenzylamino} – Carbamic Acid Ethyl Ester) and subparagraph (2) adds Lacosamide {(R) – 2 –Acetoamido-N-Benzyl-3-Methoxy-Propionamide)} *(90-days) – Effective date: 11/25/12.***

Part D

Section 1. Continuing Education Requirements: Requires a report of the DOH Commissioner (with Work Group participation) regarding the development of recommendations and model courses of continuing medical education and other training materials for licensed health care professionals in the appropriate use of pain mediations. Such training materials should include:

1). Educational and continuing medical **education requirements** for practitioners appropriate to address prescription pain medication awareness among health care professionals;

2.) Provides for continuing education requirements for pharmacists related to prescription pain medication awareness; and

3.) continuing education in palliative care as it relates to pain management.

Requires outreach and assistance to health care professional organizations to encourage and facilitate continuing medical education training programs from their members regarding appropriate prescribing practices for the best patient care. by Jan., 2013 from the DOH.

Section 2: Report of the Commissioner of Health to Governor and Legislature of the iSTOP Implementation Advisory Work Group.

§3. Requires a report on or before **September 1, 2012** by the Commissioner of Health, in consultation with the Commissioner of the Office of Alcoholism and Substance Abuse Services, the Commissioner of Education and the Executive Secretary of the Board of Pharmacy shall name Work Group members to provide guidance in furtherance of the implementation of the iSTOP Act. The advisory work group should include: consumer advisory organizations, health care practitioners and providers, oncologists, addiction treatment providers, practitioners with experience in pain management, pharmacists and pharmacies and representatives of law enforcement. **This section of the legislation takes effect immediately.**

Part E

Section 1. – Establishes a DOH **'Take Back" Safe Disposal program** for controlled substances. Must be done through law enforcement agencies. Provides immunity for those individuals bringing in controlled substances as it relates to state laws on the possession and transport of controlled substances. **This section takes effect immediately**.

CRITICAL ENACTMENT DATES for iSTOP:

The main enactment dates for the purposes of the iSTOP legislation reads as follows:

PART A – Pages 1 - 9 of the legislation shall take effect one year from the effective date of this Act. **August 27, 2013. Chapter 447, Laws of 2012.**

PART B – Pages 9 – 11 of the legislation shall take effect immediately ***EXCEPT*** subdivision 2 of Section 281 which shall take effect by **March 30, 2013** (regulations filed) and electronic prescribing two years subsequent to the final regulations published as it relates to e-prescribing.

PART C – Pages 12-18. Section 19 of the legislation. **(Controls Schedule Changes)** This act shall take effect on the **90th day** after it shall have become law **(11/24/12);** provided that sections **2, 3, 10, 14 and 18** (of this act) shall take effect **180 days (02/24/13)**. after it shall have become law (signed by Governor). You can use those section number references to determine which parts of the law will become law when. This entire section covers controlled drugs being added to, removed or moved within control classifications CII-C-V.

PART D – Pages 18-19 of the legislation. This act shall take effect Immediately. – This section of the law establishes a state workgroup of experts to provide guidance in implementing the iSTOP Act. Workgroup findings report due is **March 1, 2013**.

PART E – pages 19-20 – This act shall take effect IMMEDIATELY – Establishes a Controlled Substance Safe Disposal program for consumers.

Pre-iSTOP 2012-2013 Budget Changes:

§3309-a – Creates the Prescription Pain Medication Awareness Program: Establishes a Prescription Pain Medication Awareness program within the Health Department to educate the public and health care practitioners about the risks associated with prescribing and taking controlled substance pain medication. Provides for:

1.) The Commissioner of Health, in consultation with the Commissioner of the Office of Alcoholism and Substance Abuse Services shall:
    a. Develop and conduct a public health education media campaign designed to alert youth, parents and the general population about the risks associated with prescription pain medications and the need to properly dispose of any unused medication;
    b. Create a 'Workgroup' no late than June 1, 2012 consisting of experts from the fields of palliative and chronic care pain management and addiction medicine;
    c. The workgroup shall report to the Commissioner regarding the development of recommendations and model courses for continuing medical education, refresher courses and other training materials for licensed health care professionals on the appropriate use of prescription pain medication.
    d. Once submitted to the Commissioner of Health, these programs shall be made available for the use in medical education, residency programs, fellowship programs, and for use in continuing education programs no later than January 2013.
    e. No later than January 1, 2013, the DOH shall provide outreach and assistance to health care professional organizations to encourage and facilitate continuing medical education training programs for their members regarding the appropriate prescribing practices and the risks associated with prescription pain medications;
    f. The Workgroup shall provide information to the Commissioner of DOH for use in the development and continued update of the public awareness campaign, including information, resources, and active web links that should be included on the website. **Note: Pharmacies should have already received a letter from the DOH and samples of bag stuffers that can be ordered free of charge for use in prescription bags.**