

PROGRAM BILL # 39 1

PROGRAM BILL SUBMITTED BY THE GOVERNOR AND THE ATTORNEY GENERAL

2012

MEMORANDUM

AN ACT to amend the public health law, in relation to enacting the internet system for tracking over-prescribing (I-STOP) act and creating a prescription monitoring program registry (Part A); to amend the public health law and the education law, in relative to prescription drug forms, electronic prescribing and language assistance; and to repeal section 21 of the public health law, relating thereto (Part B); to amend the public health law and the penal law, in relation to schedules of controlled substances; and to repeal certain provisions of the public health law relating thereto (Part C); to amend the public health law, in relation to continuing education for practitioners and pharmacists in prescription pain medication awareness and the duties of the prescription pain management awareness workgroup (Part D); and to amend the public health law, in relation to the safe disposal of controlled substances (Part E)

Purpose:

This bill would promote the safe and effective use of prescription drugs and curb the diversion and abuse of such drugs by: (1) modernizing the state's Prescription Monitoring Program and enacting the Internet System for Tracking Over-Prescribing Act; (2) requiring all prescriptions to be transmitted by electronic means; (3) updating the State's controlled substance schedules; (4) expanding the duties of the workgroup established under the Prescription Pain Medication Awareness Program with respect to continuing education for practitioners and pharmacists; and (5) requiring the Department of Health (DOH) to establish a safe disposal program to facilitate consumer disposal of unused medications.

Summary of Provisions:

Section 1 of the bill sets forth the legislative intent and findings explaining the measures taken by the bill to address diversion and abuse of controlled substances.

Section 2 of the bill provides that each part is a separate component of the bill with its own effective date.

Section 3 of the bill, which appears after Part E, sets forth a severability provision.

Section 4 sets forth an overall effective date for the bill.

A. The “Internet System for Tracking Over-Prescribing” (I-STOP) Act (Part A)

Section 1 of Part A of the bill provides that the bill would enact the “Internet System for Tracking Over-Prescribing” (I-STOP) Act.

Section 2 of Part A of the bill would add new Public Health Law (PHL) § 3343-a. New PHL § 3343-a(1) would require the Commissioner of Health to update the State’s existing Prescription Monitoring Program by establishing and maintaining a system for collecting, monitoring and reporting data concerning the prescribing and dispensing of controlled substances. Known as the Prescription Monitoring Program Registry (PMP Registry or Registry), the Registry would be secure, easily accessible by practitioners and pharmacists, and compatible with the electronic transmission of prescriptions for controlled substances required under Part B of the bill.

New PHL § 3343-a(2) would require health care practitioners or their authorized designees to consult the Registry before prescribing or dispensing any controlled substance listed on Schedule II, III or IV of PHL § 3306, with certain exceptions.

New PHL § 3343-a(3) would permit pharmacists or their authorized designees to consult the Registry before dispensing a controlled substance.

New PHL § 3343-a(4) would provide practitioners, pharmacists or their designees who act reasonably and in good faith immunity from civil liability arising from any false, incomplete or inaccurate information submitted to or reported by the Registry or for any resulting failure of the system to accurately or timely report such information.

New PHL § 3343-a(5) would require the Commissioner of Health to provide guidance to practitioners and, in consultation with the Commissioner of Education, to pharmacists and pharmacies, regarding the purposes and uses of the Registry established by this section.

New PHL § 3343-a(6) would permit individuals to request copies of their controlled substance history maintained in the Registry and to seek correction of erroneous information.

New PHL § 3343-a(7) would require DOH to periodically analyze data contained in the Registry and provide information about potential violations of law or breaches of professional standards to the appropriate entities.

New PHL § 3343-a(8) would require DOH to seek funding, as appropriate, from the federal government or other entities to support operation of the Registry, and to prohibit DOH

from specifically imposing fees for such operation on practitioners, pharmacists, designees or patients.

New PHL § 3343-a(9) would require the Commissioner of Health to promulgate rules and regulations necessary to effectuate the provisions of new PHL § 3343-a.

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, and to authorize DOH to waive the real time requirement if and to the extent that the Commissioner of Health finds it warranted, in his or her discretion, due to a pharmacy's demonstration of economic hardship or other exceptional circumstance.

Section 4 of Part A of the bill would amend PHL § 3371(1)(d), which currently permits DOH to disclose controlled substances information to a central registry, to refer instead to the Registry.

Section 4 also would amend PHL § 3371(1)(e), which currently permits DOH to disclose information about dispensed controlled substances to a practitioner under limited circumstances, so that DOH also could provide notifications of relevant controlled substance activity and allow practitioners to consult the Registry as required by new PHL § 3343-a.

Section 4 also would add new PHL § 3371(1)(f) to permit DOH to disclose relevant information about controlled substance activity to pharmacists, including as permitted by new PHL § 3343-a.

Section 4 also would add new PHL § 3371(1)(g) to 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 add new PHL § 3371(1)(h) to permit DOH to disclose information to local health departments for purposes of public research and education pursuant to an agreement with DOH.

Section 4 also would add new PHL § 3371(1)(i) to permit DOH to disclose information to medical examiners and coroners.

Section 4 also would add new PHL § 3371(1)(j) to permit DOH to provide individuals with their controlled substance histories maintained in the Registry, as permitted by new PHL § 3343-a(6).

Section 5 of Part A of the bill would renumber PHL § 3371(2) and 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 add a new PHL § 3371(3) to 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.

Section 6 of Part of A of the bill would add new PHL § 3302(41) to define the Registry.

Section 7 of Part A of the bill provides that Part A would take effect one year after enactment, 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

Section 1 of Part B of the bill would revise PHL Article 2-A to create a new Title I, which would incorporate existing PHL §§ 270 through 276 and section 277.

Section 1-a of Part B of the bill would renumber PHL §§ 276-a and 276-b as §§ 278 and 279 respectively, and designate such sections and § 280 as a new Title II.

Section 2 of Part B of the bill would amend PHL Article 2-A to add a new Title III, consisting of new PHL § 281.

New PHL § 281 would incorporate the provisions of existing PHL § 21 into subdivisions (1) and (2) and include a subdivision (3) requiring 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.

Section 4 of Part B of the bill would repeal PHL § 21.

Section 5 of Part B of the bill provides that Part B would take effect immediately.

Part C. Controlled Substance Schedules

Section 1 of Part C of the bill would amend Schedule II(b)(1) of PHL § 3306 to 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 new Schedule II(b)(1) to PHL § 3306 to add to Schedule II those formulations of hydrocodone that currently appear on Schedule III.

Section 3 of Part C of the bill would add new PHL § 3307(5) to 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(b)(1) as if they were set forth in Schedule III.

Section 4 of Part C of the bill would repeal Schedule II(b)(6), which lists oripavine.

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 8 of Part C of the bill would amend Schedule II(h), pertaining to anabolic steroids, to eliminate language describing the purposes of such substances. The section would also add boldione, desoxymethyltestosterone, and 19-nor-4,9(10)-androstadienedione to Schedule II and correct typographical errors in the chemical designation of some of the other listed substances.

Section 9 of Part C of the bill would amend the opening paragraph of Schedule III(c), 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 10 of Part C of the bill would amend Schedule III(e) to remove references to hydrocodone (dihydrocodeinone).

Section 11 of Part C of the bill would amend Schedule III(f) to clarify the description of dronabinol.

Section 12 of Part C of the bill would amend Schedule IV(c) to add fospropofol and carisoprodol to Schedule IV.

Section 13 of Part C of the bill would amend Schedule IV(e)(11) correct a typographical error.

Section 14 of Part C of the bill would add new Schedule IV(f)(3) to tramadol to Schedule IV.

Section 15 of Part C of the bill would amend Schedule V(b) correct a typographical error.

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.

Section 17 of Part C of the bill would make a technical change to PHL § 3331(7), correcting a reference to a drug that had been moved from one place on the controlled substances schedules to another.

Section 18 of Part C of the bill would amend Penal Law § 220.00(8) to classify hydrocodone, as added to Schedule II(b-1), as a “narcotic preparation.”

Section 21 of Part C of the bill provides that Part C would take effect 90 days after enactment, except that sections 2, 3, 10, 14 and 18 would take effect 180 days after enactment and sections 15 and 17 would take effect immediately.

Part D. Prescription Pain Medication Awareness Program

Sections 1 and 2 of Part D of the bill would amend PHL § 3309-a, which 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: (1) continuing education for practitioners and pharmacists on pain management issues; (2) protection and promotion of access of patients with a legitimate need for controlled substances; (3) the implementation of the Prescription Monitoring Program provisions; and (4) the inclusion of certain Schedule V substances in the consultation requirements of the Prescription Monitoring Program.

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

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.

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

Legislative History:

This is a new bill, although certain of its components have been included in various legislative proposals.

Statement in Support:

Illicit use of prescription medicine has become the nation’s “fastest-growing drug problem,” according to R. Gil Kerlikowske, Director of the White House Office of National Drug Control Policy. According to the federal Centers for Disease Control and Prevention

(CDC), nearly 15,000 people die every year of overdoses due to prescription painkillers. In 2010, 1 in 20 people in the United States over the age of 11 reported using prescription painkillers for nonmedical reasons in the past year. During the period 1999 through 2008, overdose death rates, sales, and substance abuse treatment admissions related to prescription painkillers all increased substantially. Sales of opioid painkillers quadrupled between 1999 and 2010. Enough opioid painkillers were prescribed in 2010 to medicate every American adult with 5 mg of hydrocodone every four hours for a month. Moreover, an estimated 70 percent of people who abuse prescription painkillers obtained them from friends or relatives who originally received the medication from a prescription. The problem is of particular concern with respect to young adults and teens.

Criminal diversion and abuse of prescription drugs results in addiction, adverse drug events, accidental death due to overdose, violent or self-injurious behavior, family conflicts, and increased costs to businesses and the health care system. As a result, many individuals who suffer from prescription drug abuse – as well as their families – have paid heavy costs from this epidemic. This bill, together with other initiatives that will be implemented by DOH, sets forth a new strategy to address the growth of prescription drug abuse in New York. This approach seeks to minimize opportunities for addiction, abuse and criminal diversion while protecting the ability of patients to access needed medications on a timely basis.

Part A. Creating a Modernized and Improved Prescription Monitoring Program (I-STOP)

This legislation will require updating and modernization of DOH's Prescription Monitoring Program (PMP) Registry – making it one of the best systems in the nation to monitor prescription drug abuse and to help the medical community provide better care. The PMP Registry will be secure and easily accessible by practitioners and pharmacists, allowing them to view their patients' controlled substance histories.

The new system will substantially decrease opportunities for “doctor shoppers” to illegally obtain prescriptions from multiple practitioners. The legislation will include information about dispensed controlled substances reported by pharmacies on a “real time” basis—as determined through a regulatory process, to effectively stop doctor shopping and combat the circulation of illegally-obtained prescription drugs. The “real time” approach in this legislation was modeled on the system recently implemented in Oklahoma. Currently in New York, pharmacists are required to report each controlled substance they dispense by no later than the 15th day of the next month following the month in which the substance was dispensed, which essentially means between 15 and 45 days after dispensing.

In addition, practitioners will be required to consult the PMP before prescribing or dispensing controlled substances listed on Schedule II, III or IV of PHL § 3306 for the purpose of reviewing a patient's controlled substance prescription history to help the practitioner assess whether such prescription is necessary. Although this legislation requires health care practitioners to consult the PMP Registry before prescribing or dispensing the controlled substances that are most prone to abuse and diversion, it strikes the right balance by exempting practitioners from consulting in specific situations in order to protect patient access to needed medications.

To help minimize administrative burdens on practitioners, the bill will permit a practitioner to designate another person employed by or under contract with the practitioner's practice to access the information on behalf of the practitioner.

Moreover, pharmacists, for the first time, will now be able to consult the PMP Registry before dispensing a controlled substance. Currently, pharmacists do not have access to the PMP, meaning that they cannot check to see if a person who presents a prescription has a history that suggests abuse or diversion of controlled substances. Many times a patient who is attempting to obtain drugs for illegitimate purposes presents a prescription where the prescribing practitioner is not from the local area; the patient is unfamiliar to the pharmacist or is from out of town; or the patient is picking up a prescription for someone else. Access to a patient's recent controlled substance history that is otherwise not available would provide additional information to pharmacists that may have concerns of the legitimacy of a prescription or potential diversion.

Part B. Requiring Electronic Prescribing

New York will become a national leader by being one of the first states to move from paper prescriptions to a system mandating the electronic prescribing (e-prescribing) for all controlled substances. E-prescribing is critical to help eliminate diversion that results from the alteration, forgery, or theft of prescription paper.

Under this bill, e-prescribing would be mandatory for essentially all prescriptions within approximately three years, with limited exceptions. E-prescribing is a secure method of transmitting prescriptions from practitioners to pharmacists. Since an e-prescription cannot be physically altered, forged, or stolen by individuals attempting to divert controlled substances for addiction and illegal sale, it curtails prescription fraud.

In addition, electronic prescribing enhances patient care by minimizing medication errors due to misinterpretations of handwriting on written prescriptions. It is estimated that 20 percent of the approximately 7,000 annual deaths caused by medication errors are attributable to misinterpretations of written prescriptions. Moreover, medication errors are estimated to cost the nation's health care system over \$70 billion each year. In New York, adverse drug events due to errors in written and oral prescriptions carry an annual cost to the health care system of approximately \$130 million.

E-prescribing should also improve the efficiency of practitioners and pharmacies; it has been estimated that approximately 30 percent of prescriptions require pharmacists to call physicians due to poor handwriting on prescription forms. Additionally, e-prescribing is also more convenient for consumers, who would otherwise need to either wait at the pharmacy for a prescription to be filled or make separate trips to drop off the prescription form and then pick up the medication.

Part C. Updating Controlled Substance Schedules

There are five controlled substance schedules. Schedule I controlled substances may not be prescribed, dispensed, possessed, distributed or administered except for research purposes with the approval of DOH. Substances listed on Schedules II, III, IV and V may be prescribed

only by authorized practitioners. Schedule II controlled substances have a high potential for abuse and addiction and are more difficult to divert since a prescriber must issue a new prescription for each dispensing. By regulation, Schedule II substances can be prescribed or dispensed in supplies that do not exceed 30 days. However, to protect access to those patients who need it the most, practitioners can prescribe a supply of up to 90 days if he or she indicates, on the face of the prescription, that the patient has one of several enumerated conditions, including chronic pain.

Entries on the State schedules are not identical to those on the five federal schedules of controlled substances (21 U.S.C. § 801). Drug-seeking individuals often exploit the fact that certain drugs classified as controlled substances under federal law are not controlled substances under New York law and are more easily diverted. It is therefore important, whenever appropriate, to add substances scheduled under federal law to the State schedules. At the same time, the State should not wait for federal action when it appears that a substance is dangerous and should be scheduled. This bill would add several additional substances, including some which have yet to be federally scheduled but warrant inclusion in the State drug schedule, and move others from one schedule to another, as specified below.

First, the bill would remove hydrocodone from Schedule III, where it is listed for small quantities, meaning that hydrocodone would appear only on Schedule II. Hydrocodone is among the most abused and diverted prescription medications. Nationally, according to the 2010 *Monitoring the Future* report by the University of Michigan, eight percent of all high school seniors used hydrocodone for non-medical purpose. In 2009 alone, there were over 86,000 emergency room visits resulting from the non-medical use of hydrocodone.

Second, the bill would add tramadol, a painkiller that has been shown to be prone to abuse. Accordingly, the bill would add tramadol as a Schedule IV substance.

Third, the bill would add carisoprodol to the schedules. Carisoprodol is a skeletal muscle relaxant that acts directly on the central nervous system and whose action in the body is similar to meprobamate, a Schedule IV controlled substance. Excessive use of meprobamate can result in psychological and physical dependence. Carisoprodol, when abused, is typically combined with other controlled substances or alcohol. Abusers who combine carisoprodol with hydrocodone claim that this combination produces effects similar to those of heroin. On January 11, 2012, the DEA placed carisoprodol in Schedule IV of the federal Controlled Substance Act. In New York, the 2009 New York State Police Toxicology Drug Statistics indicated that almost 200 of the 2,269 cases of driving while ability-impaired (DWAI) related to drug use in that year were due to carisoprodol use – an incidence that was higher than other controlled substances such as stimulants, methadone and zolpidem. This bill would add the substance to Schedule IV.

Fourth, the bill would add fospropofol to the State's controlled substance Schedule IV. Fospropofol is currently used in sedation of adult patients undergoing monitored anesthesia care sedation for diagnostic or therapeutic procedures. On November 11, 2009, fospropofol was added by the DEA to Schedule IV of the federal Controlled Substance Act. The DEA cited abuse among medical professionals as well as the potential use of fospropofol as a "date-rape" drug in support of the decision to schedule fospropofol.

Fifth, the bill would appropriately schedule oripavine, in conformance with current DEA scheduling, under the category of opium and opiates and any salt, compound, derivative or preparation of opium or opiates. The DEA placed oripavine in Schedule II of the federal Controlled Substance Schedule in 2007. Oripavine is a derivative of thebaine, a natural constituent of opium.

Part D. Enhancing the Prescription Pain Medication Awareness Program

According to the CDC, a significant proportion – 17.3 percent – of abused medications are prescribed to the person that abuses them. This indicates a need for increased efforts to educate prescribers about the dangers of overprescribing controlled substances, particularly opioids.

This bill therefore would enhance the Prescription Pain Medication Awareness Program established by PHL § 3309-a, which requires DOH to establish a workgroup to educate the public and health care practitioners about the risks associated with prescribing and taking controlled substance pain medications. The workgroup will be expanded 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. Moreover, under the bill, the workgroup would be charged with making recommendations related to continuing education for practitioners and pharmacists and to provide guidance in the implementation of the Prescription Monitoring Program.

Part E. Establishing a Safe Disposal Program

An estimated 70 percent of people who abuse prescription painkillers obtained them from friends or relatives. Therefore, it is critical to provide consumers with a means of safely disposing of prescriptions. Part D of this bill would require DOH to institute a program for the safe disposal of unused controlled substances by consumers. DOH would work with local police departments to establish secure disposal sites for controlled substances on the premises of police stations. At these sites, individuals would be able to voluntarily surrender unwanted and unused controlled substances.

Under present law, individuals can only safely dispose of controlled substances during an approved “take back” event. Various methods of self-disposal are either burdensome or harmful to the environment. Moreover, current federal regulations prohibit patients from returning unused controlled substances to pharmacists and doctors. This program would help alleviate this problem by providing a continual safe disposal option to New Yorkers.

Budget Implications:

The bill is not expected to have a fiscal impact, as initial investments can be covered within existing budgeted resources. In future years, funds needed to support a contract to enhance and ultimately replace the existing Registry will be substantially if not totally offset by a decrease in costs associated with the State’s obligation to provide official forge-proof paper prescription forms to prescribers.

Effective Date:

The bill would take effect upon enactment, except that Part A would take effect one year after enactment, although necessary regulations could be promulgated before such time. In addition, Part C would take effect 90 days after enactment, except that sections 2, 3, 10, 14 and 18 would take effect 180 days after enactment and sections 15 and 17 would take effect immediately.