

Presented at

CBI Conference: e-Rx and EHR

March 22, 2016
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**New York I-STOP Mandate —
Will this Be a Trend Across Additional States
and Impact the ePrescribing Landscape?**

Agenda

- **Background**
 - Prescription Drug Abuse
 - ePrescribing of Controlled Substances
 - Prescription Drug Monitoring Program
- **I-STOP Overview & Drivers**
 - Metrics to Watch
- **The Impact for Pharma**
 - Challenges for Pharma Reps
 - Actions to Consider

Learning Objectives

- **Understand** the components of I-STOP so that manufacturers can prepare for fully electronic prescribing in New York
- **Assess if additional states will follow New York's lead** on mandated ePrescribing and what metrics from New York will be assessed in determining the success of implementation
- **Identify tactics that have been utilized** for successful HCP onboarding with mandated ePrescribing and what challenges still exist with this process

Background



Houston, We Have a Problem



7
MILLION
ED visits were
related to
**PRESCRIPTION
DRUG
MISUSE/ABUSE**
in 2011*



259
MILLION
PRESCRIPTIONS
written in 2012
for opioids**

18,893

PEOPLE
died in 2014
due to
prescription
painkiller
overdoses**



1.9
MILLION
AMERICANS
(age 12 or older)
abused prescription
pain relievers
in 2014**

*www.cdc.gov/drugoverdose/data/overdose.html

**www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf

Prescription Drug Monitoring Programs

Preventing deaths from prescription drug overdose is high profile issue at state and federal level

- **49** States have PDMP and allow/encourage prescribers to check it before prescribing controlled substances.
- **10** states have established **rules on the books requiring prescribers to check PDMP** before prescribing, for **most or all** Controlled Substance prescriptions (e.g., NY)
- **5** require it for **limited** circumstances (e.g., if abuse suspected, or for certain drugs only)
- **9** new states have **proposed legislation** this year to require prescribers to check PDMP.
- **3** have proposed legislation to require the State to **make access available to prescriber systems (EHRs)**

EHRs will begin to integrate PDMP access into the ePrescribing workflow

Source: *Point-of-Care Partners ePrescribing State Law Review*

DEA Removes Final Barrier to ePrescribing

THE DEA REQUIRES THE FOLLOWING TO LEGALLY EPREScribe CONTROLLED SUBSTANCES*:

- Use of certified applications by prescribers and pharmacists (Part 1311 audit)
- Identity proofing (prescribers)
- Two-factor authentication (prescribers)
- Access controls to limit unauthorized use
- Certain state-specific rules
 - New York state's I-STOP legislation requires registration with the state's Bureau of Narcotic Enforcement (BNE)

The DEA's Interim Final Rule (IFR) allowing EPCS became effective on June 1, 2010**

*Note: Individual states may set more stringent requirements

**<http://www.deadiversion.usdoj.gov/21cfr/cfr/2111cfrt.htm>. Accessed January 23, 2015

ePrescribing: The Infrastructure is in place



80%

Physicians

Nearly 80% of
physicians
ePrescribe today



700

**EHRs
Enabled**

Approximately 700
EHRs enabled for
ePrescribing



100%

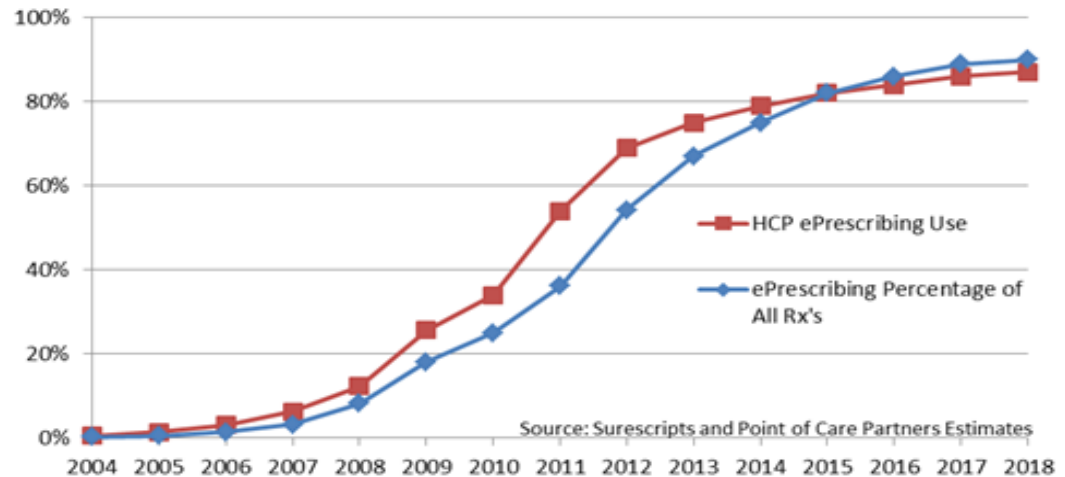
Retail Pharmacies

Nearly 100%
retail
pharmacies

EHR Adoption Growth Impacts ePrescribing

- **Majority of HCPs are using EHRs**
- **Factors influencing growth of EHR use:**
 - Government incentives
 - Transformation of payment model to outcomes-based reimbursement
 - Practice consolidation required EHR use
- **New adoption is no longer as important as optimization of existing EHRs in practices**
 - Quality improvement
 - Resolving gaps-in-care
 - Standardizing treatment
 - Increasing practice efficiency

Electronic Prescription Utilization and Adoption



*EHRs are now the **primary method** of writing prescriptions including EHR printed prescriptions in addition to electronically transmitted*

I-STOP Overview & Drivers



What is I-STOP?

I-STOP LAW

The Internet System for Tracking Over-Prescribing Act (I-STOP) was signed by NY Governor Andrew M. Cuomo in June 2012. This act, implemented to curb prescription drug related abuse, created a number of laws that impact prescribers, pharmacies and EHR/ePrescribing vendors operating in New York State.

New York State's Solution: I-STOP

FIVE KEY COMPONENTS

- Prescription Monitoring Program Registry
- Electronic Prescribing Mandate
- Controlled Substance Schedule Update
- Prescription Pain Medication Awareness Program
- Safe Disposal of Prescription Drugs



3.27.16



Signed into law on August 27, 2012



Goals of I-STOP

- **Decrease in overdose deaths**
- **Elimination of stolen/forged prescription blanks**
- **Reduction in patients who “doctor shop”**
- **Identification and shut-down of “pill mills”**
- **If these results are positive, expect more states to follow suit**
 - Massachusetts legislature is working on Bill H1935 to mandate ePrescribing

All eyes are on NYS to see impact of I-STOP EPCS and PDMP mandates

I-STOP March 27, 2016 ePrescribing mandate

Requires all prescriptions issued in in New York to be transmitted electronically (with limited exceptions).

Controlled and non-controlled substances and medical devices/syringes dispensed at a pharmacy

Potential Penalties:

- Fines and/or jail
- License revocation or suspension

Applies to:

- Physicians
- Dentists
- Podiatrists
- Physician Assistants
- Nurse Practitioners
- Mid-wives
- Optometrists

Prescribers are still required to check the New York State prescription monitoring program registry before prescribing a controlled substance in compliance with earlier I-STOP regulations.

Exemptions to March 27th Mandate

Veterinarians

ePrescribing not available due to temporary electrical or technological failure

Prescription will be dispensed at a pharmacy outside of New York State

Prescriber has a waiver*

eRx cannot be issued timely and delay would adversely affect patient's medical condition

Rx for controlled substance cannot exceed 5 day supply

*The Commissioner of Health may grant a waiver, not to exceed 1-year, for economic hardship, technological limitation or other exceptional circumstance.

http://www.health.ny.gov/professionals/narcotic/electronic_prescribing/waiver.htm

ePrescribing Adoption in New York

As of February 29, 2016

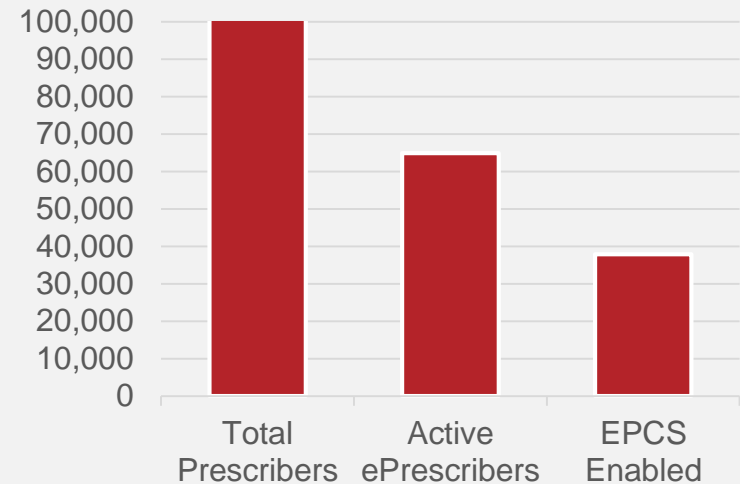
New York is leading the nation in the enablement of electronic prescribing of controlled substances (EPCS).

- 63% of prescribers are active ePrescribers
- 37% of prescribers are enabled for EPCS
- 98% of pharmacies engaged in ePrescribing are capable of receiving EPCS prescriptions

Impact of I-STOP:

- At the end of 2015, New York prescriber enablement for EPCS outpaced the national average of 5.8% by five times
- EPCS adoption increased from < 2% in February 2015 to 37% in February 2016
- Software vendors serving 96% of New York prescribers are certified for EPCS

NY Prescriber Adoption
As of 2/29/2016



Source: Surescripts

Last Minute Changes

- **NY Assembly Bill A09335**, introduced on March 9, 2016 makes minor technical changes to I-STOP:
 - Exempts prescribers who write no more than 25 prescriptions a year from the e-prescribing/EPCS mandate:
 - Prescriber must apply for a waiver yearly and make a notation in the patient's record each time the exemption is utilized and terminate the certification if he/she exceeds 25 prescriptions
 - This bill does **NOT** further delay the ePrescribing/EPCS mandate. All prescriptions for both non-controlled and controlled substances must be electronically prescribed on March 27, 2016.

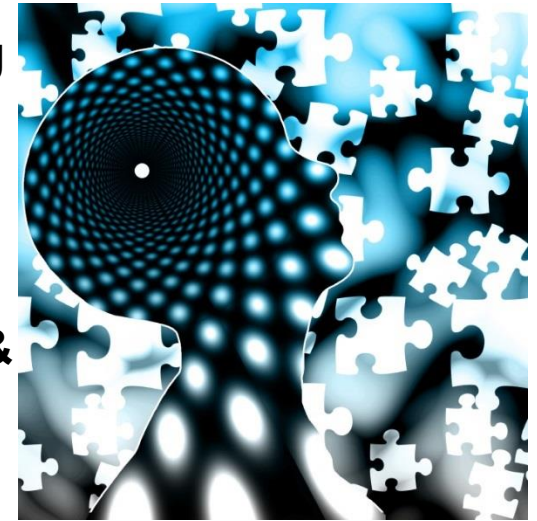


Impact of I-STOP for Pharmaceutical Manufacturers



ePrescribing Challenges: Today's Pharma Rep

- **Potentially frustrated customers** trying to understand current systems and regulations governing their patients and the way they practice medicine
- For some non-tablet products, **ePrescriptions can be confusing**
- **Requires interaction with practice administrators & IT specialists** not typically part of the total office call
- **Limited time** for product discussions
- Technological hurdles to overcome, including ePrescribing nuances for specialty medications and prior authorization



Expect Questions from Practices New to ePrescribing

HCPs who have newly adopted ePrescribing as a result of I-STOP may have questions about how to ePrescribe your products

Choices for

- Quantity
- Unit of Measure
- Patient Instructions (aka SIG)

may not be intuitive

The image shows a screenshot of a 'Prescribe New Medication' form. The form is titled 'Prescribe New Medication' and contains several sections for data entry:

- * Drug Name**: A text input field.
- Indication**: A text input field.
- * Dosage**: A text input field.
- * Sig**: A text input field.
- Duration**: A dropdown menu followed by a text input field and a '#' symbol, with 'Day' as a label.
- * Dispense**: A dropdown menu followed by a text input field and a '#' symbol.
- * Refills**: A dropdown menu followed by a text input field and a '#' symbol.
- Options**: A checkbox for 'Maintenance Drug' and a checkbox for 'Brand Name Necessary'.
- Comment**: A text input field with a note 'For office use only'.
- * Prescriber**: A text input field.
- Pharmacy Note**: A text input field.
- Effective Date**: A text input field with a note 'For office use only'.
- * Package**: A text input field.
- Written Date**: A text input field.
- Special Instructions**: A text input field.
- Samples Given**: A checkbox.

At the bottom of the form, there are buttons for 'Add to Favorites', 'Add Another', 'OK', and 'Cancel'.

Actions to Consider

There are a number of actions to consider to ensure new prescribers can easily ePrescribe your products

Ensure that your products are available for selection in the EHR

Assist the HCP in understanding how to correctly prescribe your products, especially Patient Instructions (SIG), Quantity and Unit of Measure

Encourage use of Favorites to foster easy selection of standardized prescriptions

Promote regularly scheduled database updates to ensure most current drug, drug interaction and formulary information

“I-STOP will be a national model for smart, coordinated communication between healthcare providers and law enforcement to better serve patients, stop prescription drug trafficking, and provide treatment to those who need help.”

New York State Attorney General Eric Schneiderman



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