

This Special Edition of Dateline was prepared in response to the recently-implemented Internet System for Tracking Over-Prescribing law, which affects how most New York State practitioners prescribe controlled substances. If you are a MLMIC insured and have any questions not covered in the following article, please do not hesitate to contact the attorneys at Fager & Amsler LLP, by calling the office nearest you, or by utilizing the Contact Us feature on MLMIC.com.

1-877-426-9555 – Syracuse · 1-877-777-3560 – Long Island · 1-800-635-0666 – Latham

Complying With I-STOP: The New York State Prescription Monitoring Program

*Marilyn Schatz, Esq., Fager & Amsler LLP
Counsel to Medical Liability Mutual Insurance Company*

In an effort to reduce the overwhelming increase in the misuse, diversion and overdose of prescription controlled substances, and to try to decrease the associated violence and deaths which result, the New York State legislature unanimously enacted the Internet System for Tracking Over-Prescribing (I-STOP) law. This legislation became effective August 27, 2013. Compliance with the law and regulations is mandatory. They apply to physicians, dentists, and other licensed practitioners who prescribe or dispense controlled substances. When practitioners prescribe or dispense any Schedule II, III, or IV controlled substance in New York State, they must first consult the new Department of Health (DOH) Prescription Monitoring Program (PMP) registry. The registry can be accessed 24 hours a day, seven days a week, but the data cannot be printed on Saturdays and Sundays.

If a practitioner chooses to do so, the registry may be consulted prior to prescribing or dispensing any controlled substance from Schedules II – V. Please note that hydrocodone

has become a Schedule II substance (which may not be refilled automatically)¹, and Tramadol has been moved to Schedule IV.²

Practitioners' Obligations

New York State practitioners must:

1. ***consult*** the registry **no more than 24 hours prior to prescribing or dispensing** any controlled substance listed in Schedule II, III, or IV; **and**
2. ***document*** in the patient's medical record that the registry was consulted (or, if the registry was not consulted, include required details of any of the six specific exceptions listed on page 2).³

Documentation of registry consultation can be a printout from the registry, which the practitioner initials and dates, a brief note by the practitioner that the registry was accessed,

1. Public Health Law § 3306, Schedule II (b)(1)(10).
2. Public Health Law § 3306, Schedule IV (f)(3).
3. 10 NYCRR § 80.63 (c)(1).

continued on page 2

www.mlmic.com

Dateline is published under the auspices of MLMIC's Patient Safety & Education Committee, Donald J. Pinals, M.D., Chairperson.

Editorial Staff

John Scott, Editor

Frances Ciardullo, Esq.

Matthew Lamb, Esq.

Robert Pedrazzi

Donnaline Richman, Esq.

Daniela Stallone

Linda J. Trentini, CIC

Michael Zeffiro, Esq.

or a checkmark placed by the practitioner in a pre-printed box in an electronic health record (EHR).

No controlled substance may be prescribed prior to a practitioner's examination of the patient unless an exception below applies.⁴ After the initial examination, there is no requirement that a patient be seen every time a prescription is issued or refilled. The frequency and need for future examinations prior to prescribing remains within the practitioner's reasonable professional judgment.⁵

If an initial prescriber is unavailable, a practitioner may continue therapy and prescribe a controlled substance if the practitioner had:

1. access to the patient's records which justify the prescription; or
2. direct and sufficient consultation with the initial prescriber who assures the practitioner of the need for continuing therapy, and the practitioner concurs.⁶

Practitioners must document the activity in their own record if the patient's record is not available, and submit the prescription information to the initial prescriber, who must add it to the patient's record.⁷

If a patient's record contains results of an examination performed by a consulting physician or hospital staff member, a practitioner may prescribe a controlled substance.⁸

A practitioner may prescribe a controlled substance prior to performing an examination of a patient with a new condition if:

1. the practitioner has a pre-existing professional relationship with the patient; **and**
2. an "emergency" exists (immediate administration of the drug is neces-

sary, and no alternative treatment is available); **and**

3. the prescription is no more than a five-day supply if used as directed.⁹

Exceptions to the Duty to Consult

The duty to consult the registry does not apply to:

1. veterinarians;
2. practitioners who
 - a. dispense or administer methadone to an addict on a waiting list for admission to a maintenance program,
 - b. administer controlled substances,
 - c. prescribe or order a controlled substance for an in-patient of a hospital, clinic, nursing home, or similar Article 28 facility, or for a patient being transferred from such facility on an emergency basis,
 - d. prescribe a controlled substance in the emergency department of a general hospital, only if the prescribed quantity is no more than a five-day supply if used as directed (practitioners working at an independent urgent care facility are not exempt from the duty to consult), or
 - e. prescribe for a patient under hospice care;
3. a practitioner when
 - a. timely access to the registry is not reasonably possible, **and**
 - b. no other practitioner or authorized designee is reasonably available, **and**
 - c. the prescribed quantity is no more than a five-day supply if used as directed;
4. a practitioner, when consulting the registry would

- a. result in a patient's inability to obtain a prescription in a timely manner, **and**
- b. the delay would have an adverse impact on the patient's medical condition, **and**
- c. the prescribed quantity is no more than a five-day supply if used as directed;

5. circumstances when the registry is either not operational, or cannot be accessed by the practitioner due to a temporary technological or electrical failure; or
6. a practitioner who has obtained a waiver from the DOH because the practitioner's ability to consult the registry is unduly burdensome due to either technological limitations not within the practitioner's control, or other exceptional circumstances.¹⁰

If any of the limited exceptions above are applicable, the reason must be carefully documented in the patient's medical record.

If a practitioner relies on exception 3 for not consulting the registry, documentation must also include: conditions, occurrences, or circumstances as to why timely consultation was unreasonable; a description of the barrier to accessing the registry; **and** the practitioner's efforts to contact designees.¹¹

If a practitioner relies on exception 4, documentation must also include: a description of the circumstances leading to the conclusion that registry consultation would have an adverse impact on the patient's ability to timely obtain a prescription; **and** the relationship between that delay and the patient's medical condition.¹²

To obtain an application for a **waiver** of the duty to consult the registry, a practitioner may call or send an e-mail to the

4. 10 NYCRR § 80.63 (d)(1).

5. 10 NYCRR § 80.63 (d)(2).

6. 10 NYCRR § 80.63 (d)(3).

7. 10 NYCRR § 80.63 (d)(3).

8. 10 NYCRR § 80.63 (d)(4).

9. 10 NYCRR § 80.63 (d)(5).

10. 10 NYCRR § 80.63 (c)(2)(x).

11. 10 NYCRR § 80.63 (c)(1)(i).

12. 10 NYCRR § 80.63 (c)(1)(ii).

DOH Bureau of Narcotic Enforcement (BNE) to request waiver information. (See “Resources” on pages 7-8.) An e-mail request to the BNE will be expedited if “Request for Information on Waiver of Duty to Consult” is entered in the subject line.

A waiver of the duty to consult the registry may be granted for up to a maximum of one year. However, a practitioner who gains the ability to consult during the approved waiver period must provide written notification to the DOH within five business days. The DOH will then provide the practitioner with a reasonable time to begin consulting the registry.¹³

Practitioners’ Initial Access to the Registry

Licensed practitioners must first establish an individual Health Commerce System (HCS) account to obtain access to the registry. Instructions are available at <https://hcsteamwork1.health.state.ny.us/pub/top.html>. Click on “Apply for an HCS Medical Professions account.”

Application documents will be e-mailed to practitioners. These documents must be printed, signed, notarized, and returned to the DOH in order to receive a user identification and password that are required to access the registry. Passwords will have to be changed every 90 days. Practitioners must not share their HCS password or DEA number. Doing so may result in licensure or criminal sanctions, or HCS account revocation.

There has been a serious delay in processing HCS accounts due to the enormous volume of practitioners submitting requests in anticipation of the August 27, 2013 effective date of the duty to consult the registry. The DOH has advised:



“During this transition period, practitioners who are making a good faith effort to apply but are unable to establish HCS accounts, should continue to provide treatment to their patients in the same manner as they currently do, including the prescribing of controlled substances without accessing PMP Registry. We expect this transition period to last through October.”¹⁴

Appointing a Designee

The law provides specific criteria that allow practitioners to appoint a designee to consult the registry on their behalf. Practitioners may delegate their duty to consult the registry to one or more designees, including another practitioner. An individual may be the

designee for multiple practitioners. The designee may be a member of the practitioner’s administrative staff. However, the prescribing or dispensing practitioner is ultimately responsible for determining whether to prescribe or dispense a controlled substance based upon an examination of the patient and after reviewing the patient’s drug history in the registry.

To appoint a designee, the following criteria must be met:

1. the designee is in New York State when the registry is accessed;
2. the designee is employed by, or has contracted with, the same professional practice (including, but not limited to, an institutional dispenser where the practitioner is employed, under contract, or has privileges or authority to practice);
3. the practitioner either knows or acts reasonably to ensure that a designee is competent to use the registry, and the

14. New York State Department of Health Statement, accessed at http://www.health.ny.gov/professionals/narcotic/prescription_monitoring/?utm_source=doh&utm_medium=ci-link&utm_campaign=istop on August 29, 2013.

13. 10 NYCRR § 80.63 (c)(2)(x)(b).

continued on page 4

- designee is familiar and complies with federal and state privacy statutes;
- the practitioner is ultimately responsible for a breach of confidentiality by the designee and must be certain that the designee accesses the registry solely for an authorized purpose and that access occurs in a manner that protects the confidentiality of registry data; **and**
 - the practitioner selects and maintains all active designees authorized to access the registry. If a designee's authority to access the registry is terminated for any reason, the practitioner must immediately inform the DOH of revocation of the designee's authority to access the registry.¹⁵

Designees' Initial Access to the Registry

Since HCS accounts may not be shared, prescribing practitioners must create an account for each individual who will act as a designee on their behalf. A practitioner with an established HCS account, or a facility administrator, must log in to: <https://commerce.health.state.ny.us>. Application documents must be printed, completed, signed, and provided to the intended user/designee.

The intended designee must:

- sign the document in front of a notary;
- maintain a copy; and
- send the original to the address provided on the document within 60 days or the practitioner's request will be purged from the system.

A letter containing a personal identification number and account activation instructions will be mailed to the designee. Activation must be accomplished within two weeks from the date on the letter. **To activate an account**, designees must enter their full name, PIN,

and temporary access word at <https://hcsteamwork1.health.state.ny.us/pub/cgi-bin/applinks/pubforms/olaa/activate>. Once the account is activated, the password should be changed.

Fulfilling the Duty to Consult the Registry

Within 24 hours prior to a practitioner prescribing or dispensing a controlled substance, the practitioner or designee must log in to their individual established HCS account at <https://commerce.health.state.ny.us> using the identification number and password provided by the DOH, then click on the "NYS PMP" logo to conduct a Patient Search. The registry contains at least six months, but no more than five years, of patient controlled substance information from practitioners' dispensing data and pharmacists' dispensed and reported data.



Up to thirty searches may be accomplished with each log-in to the registry. The date and time of each search will automatically be entered into the registry and become a permanent part of the practitioner's consulting data. Search results are available for "My Prescriptions" and "Others' Prescriptions." There are page breaks between each patient's information so that the data may easily be printed and filed in the medical record. If errors or inconsistencies are found in the data, a practitioner may notify the pharmacy, if applicable, to correct the data, or call or e-mail the BNE. (See "Resources" on pages 7-8.)

Documentation of registry consultation to verify every patient's narcotic prescription history is mandatory. (See "Practitioners' Obligations" on page 1 for documentation methods.)

A "Drug Listing" option is available

at the top of the registry website that details brand and generic drug names, the specific schedule into which the drug falls, and whether refills are permissible. The duty to consult the registry also applies to refills of any controlled substance.

The "Extended" option on the registry site reveals both the patient's payment method and the names of dispensers. The data may be indicative of doctor-shopping or a breach of a pain management contract. This is crucial information for a practitioner to review and consider when prescribing and dispensing.

If a Patient Search leads the practitioner to conclude there is suspicious activity which would reasonably indicate an addiction or habituation to controlled substances, the practitioner must report this information to the BNE.¹⁶ (See "Resources" on pages 7-8 for the telephone number of an area BNE investigator.)

To refer an addicted patient for professional treatment, a practitioner may call the Addictions Helpline of the State Office of Alcoholism and Substance Abuse Services (OASAS), or contact a local opioid addiction counselor at the Substance Abuse and Mental Health Services Administration (SAMHSA). (See "Resources" on page 8 for contact information.)

Dispensing Controlled Substances

Practitioners and pharmacists must electronically file prescription **dispensing** information with the BNE on a real-time basis within 24 hours prior to dispensing a Schedule II, III, or IV controlled substance. Pharmacists have no obligation to consult the registry prior to dispensing such drugs. A waiver to allow for a longer filing period (up to the 15th day of the month after the month the substance was dispensed) may be provided by the DOH if the practitioner can show exceptional

15. 10 NYCRR § 80.63 (c)(3).

16. Public Health Law § 3372.

circumstances such as economic hardship, or technological limitations beyond the practitioner's control.¹⁷

To obtain an application for a **waiver of the duty to submit dispensing information**, a practitioner may send an e-mail to the BNE and enter "Request for Information on Waiver of Reporting Dispensed Controlled Substances" in the subject line, or call the BNE. (See "Resources" on pages 7-8 for contact information.) The application must include a sworn statement describing detailed circumstances in support of a waiver. A practitioner who gains the ability to submit dispensing information during the approved waiver period must provide written notification to the DOH within five business days. The DOH will provide the practitioner with a reasonable time to begin submitting dispensed information.¹⁸

If a practitioner does not dispense any controlled substances during the relevant period of time, the practitioner must file a **zero report** with the BNE, or apply for a waiver of this requirement. This report must be submitted to the DOH within 14 days after the previously reported dispensing of a controlled substance, or the submission of a zero report, or the termination of a waiver of the duty to file a zero report.¹⁹

A practitioner may apply for up to a two year **waiver of the duty to file a zero report** if the practitioner does not dispense controlled substances in New York State. The practitioner may send an e-mail to the BNE and enter "Request for Information on Waiver of Filing Zero Report" in the subject line, or call the BNE (See "Resources" on pages 7-8). The application must include a sworn statement of facts detailing the circumstances in support of a waiver. The practitioner must submit written notification to



the DOH within five business days of circumstances that would result in the possible dispensing of a controlled substance, thereby terminating the waiver as of the date of notification.²⁰

Additional Permitted Disclosures

I-STOP inherently permits the disclosure of patient health information to the DOH. In addition, practitioners may disclose patient controlled substance information to:

1. a pharmacist;
2. the Medicaid fraud control unit;
3. a local health department to conduct public health research or education;
4. a medical examiner or coroner;
5. patients to obtain his/her own controlled substance history; and
6. law enforcement agencies when there is reason to believe a crime involving the diversion of controlled substances has been committed.²¹

Oral Prescriptions for Schedule II Controlled Substances

A practitioner may orally prescribe Schedule II (and certain other controlled substances such as Clonazepam) *in an emergency* if:

1. the immediate administration of the drug is necessary for proper treatment; **and**
2. no alternative treatment is available; **and**
3. it is not possible for the practitioner to provide a written or electronic prescription for the drug at the time.²²

A practitioner must send a written or electronic prescription to the pharmacist within 72 hours after submitting an emergency oral prescription. The prescription must include the words "*Authorization for emergency dispensing.*" The pharmacist must

17. 10 NYCRR § 80.71 (e).

18. 10 NYCRR § 80.63 (c)(2)(x).

19. 10 NYCRR § 80.73 (f)(2)(i).

20. 10 NYCRR § 80.73 (f)(2)(ii).

21. 10 NYCRR § 80.107.

22. 10 NYCRR § 80.68 (e).

continued on page 6



provide written or electronic notice to the DOH within seven days of dispensing if the practitioner fails to deliver the prescription.²³

Upon receipt of an emergency oral prescription, a pharmacist must:

1. simultaneously reduce the prescription to a written or electronic format; **and**
2. dispense the substance in conformity with labeling requirements; **and**
3. make a good faith effort to verify the identity of both the practitioner and the patient.²⁴

Schedule II controlled substances may not be refilled.²⁵ No greater than a 30-day supply and no additional pre-

scriptions may be issued within the next 30 days unless no more than a seven-day supply remains.²⁶

A practitioner or an authorized individual may transmit by **facsimile** a New York State or out-of-state prescription for a hospice patient or a patient residing in a Residential Health Care Facility (RHCF). The hospice program or facility must be licensed or approved by the DOH, and the dispensing pharmacy must have a written agreement or contract with the program or RHCF to dispense to such a patient. The practitioner must write "*hospice patient*" or "*RHCF patient*" on the prescription and, within 72 hours, transmit the original New York State or original out-of-state prescription, attached to any prescription transmitted

by facsimile, to the pharmacist. Within seven days from the date on the prescription, the pharmacist must report to the DOH any failure to receive a prescription from the practitioner.²⁷

If a New York State or out-of-state prescription is **incomplete**, the practitioner may orally provide additional information to the pharmacist, who may then add it to the prescription. The pharmacist may **not** add: the practitioner's signature; the date; the name and/or quantity of the controlled substance; or the patient's name. The patient's address, sex, or age **may** be added by a pharmacist without prior practitioner authorization if there is a good faith effort to obtain the information.²⁸

A practitioner may orally authorize a pharmacist to **change** a New York State or out-of-state prescription, but **not** if the change applies to the practitioner's signature, the date it was written, or the name of the drug or patient.²⁹

Oral Prescriptions for Schedule III, IV, and V Controlled Substances

A practitioner may orally prescribe a Schedule III, IV, or V controlled substance even if an emergency does not exist. An oral prescription will be filled for up to a five-day supply, or for the lesser of a 30-day or 100 dosage units for a Schedule IV substance, if used as directed.³⁰

A practitioner must send a written or electronic prescription to the pharmacist within 72 hours after submitting an oral prescription. The prescription must include the words "*Follow-up prescription to oral order.*" If applicable, the pharmacist must record "*Follow-up prescription not received.*"³¹

23. 10 NYCRR § 80.68 (c).

24. 10 NYCRR § 80.68 (a).

25. 10 NYCRR § 80.67 (a).

26. 10 NYCRR § 80.67 (c).

27. 10 NYCRR § 80.67 (e).

28. 10 NYCRR § 80.67 (g).

29. 10 NYCRR § 80.68 (h).

30. 10 NYCRR § 80.70 (b).

31. 10 NYCRR § 80.70 (c).

Immunity

As long as practitioners, designees, and pharmacists act in good faith and with reasonable care, they will be immune from civil liability arising from: false, incomplete, or inaccurate information submitted to or reported by the registry; or failure of the system to accurately or timely report such information.³²

Penalties

The DOH will periodically monitor and analyze registry data to determine whether a violation of law or a breach of professional standards has occurred.³³ Failure to comply with the duty to consult the registry in a timely fashion is considered to be willful misconduct. This can lead to the imposition of a fine up to \$2,000, criminal sanctions of up to one year of imprisonment, and/or charges of professional misconduct, possibly resulting in permanent revocation of the practitioner's license.³⁴

Risk Management Recommendations

Office procedures should be developed and instituted to incorporate consultation of the registry into daily office practice. We recommend reviewing all patient appointments anticipated for the following day to determine whether a Schedule II, III, or IV controlled substance might be prescribed or dispensed, then consulting the registry within 24 hours prior to the patient's appointment.

We also suggest that the registry's Patient Search information be printed and scanned or placed into the patient's medical record so that it is available for the practitioner to review, initial, and date during the patient's examination. Practitioners must continue to exercise their professional judgment in assessing the patient for potentially adverse drug interactions, and identifying red flags

which are indicative of doctor-shopping or misuse of controlled substances.

In summary, the obligations of practitioners subject to the I-STOP law are not optional. **Strict compliance is mandatory** in order to prevent prescription fraud, forgery, doctor-shopping and drug diversion. This process will help to both prevent adverse drug interactions and identify patients who exhibit addictive behavior. Use of the registry is crucial to avoid significant monetary, criminal, and/or professional disciplinary penalties.

RESOURCES

For Assistance with the Prescription Monitoring Program

The DOH Commerce Accounts Management Unit (CAMU) may be contacted at 866-529-1890 for assistance in activating, creating, or utilizing any HCS account. Press:

- **option 1** if you have an HCS account and need help logging in, activating a locked account, changing an expired password, or obtaining an account status;
- **option 2** if you need help creating an HCS account; or
- **option 3** if you have questions about the PMP registry.

Continuing Education

A continuing education webinar entitled "I-STOP Implementation" is available at <http://www.mssny.org>

Bureau of Narcotic Enforcement (BNE)

Riverview Center/Central Office
150 Broadway
Albany, New York 12204
866-811-7957, or 866-772-4683
Fax: 518-402-0709
narcotic@health.state.ny.us
www.health.ny.gov/professionals/narcotic/prescription_drug_abuse_awareness

32. Public Health Law § 3343-a (4).

33. Public Health Law § 3343-a (7).

34. Public Health Law §§ 12-b (2), 3396.

continued on page 8

MLMIC Offices

2 Park Avenue
New York, NY 10016
(800) 275-6564

2 Clinton Square
Syracuse, NY 13202
(800) 356-4056

90 Merrick Avenue
East Meadow, NY 11554
(877) 777-3560

8 British American Boulevard
Latham, NY 12110
(800) 635-0666



Fager & Amsler's attorneys are available during normal business hours to assist MLMIC insureds with a wide range of legal services, including, but not limited to, advisory opinions concerning liability issues, liability litigation activities, lecture programs, consulting services, and legal audits and assessments.

Healthcare law, regulations, and practices are continually evolving. The information presented in Dateline is accurate when published. Before relying upon the content of a Dateline article, you should always verify that it reflects the most up-to-date information available.



Medical Liability Mutual Insurance Company
 2 Park Avenue
 New York, NY 10016

PRESORT STANDARD
 U.S. POSTAGE
 PAID
 PERMIT #1174
 NEW YORK, NY



I-STOP continued from page 7

Regional Offices

New York City: 212-417-4103
 Buffalo: 716-847-4532
 Syracuse: 315-477-8459
 Rochester: 585-423-8098

**Patient Education Posters
 (available free of charge
 from the BNE)**

- *Sharing Prescription Drugs is Dangerous and Dumb*
- *HIGH Isn't the Only Thing You'll Get. Arrested...*
- *Seek Help Now. It Could Save Your Life*

- *Tell Your Doctor ... It's the Law*
- *We ID... It's the Law*
- *Do you or a family member have a problem with prescription drugs?*

Drug Enforcement Administration

877-883-5789
www.deadiversion.usdoj.gov/index.html

**New York State Office of
 Alcoholism and Substance
 Abuse Services (OASAS)**

877-8-HOPE-NY (877-846-7369)
addictionmedicine@oasas.ny.gov
www.oasas.ny.gov

**Substance Abuse and Mental
 Health Services Administration
 (SAMHSA)**

877-SAMHSA (877-726-4727)
info@buprenorphine.samhsa.gov
www.samhsa.gov

**New York State Education
 Department/Board of Pharmacy**

518-474-3817, Ext. 130
www.op.nysed.gov