NEW YORK CITY BAR

COMMITTEE ON BIOETHICAL ISSUES

WENDY J. LUFTIG
CHAIR
ONE PARK AVENUE
SIXTH FLOOR, RM 6-349
MANHATTAN, NY 10016
Phone: (646) 754-4593
Wendy.Luftig@nyumc.org

CARMEN JULE
SECRETARY
180 WATER STREET
ROOM 1852
NEW YORK, NY 10038-3562
Phone: (212) 331-5889
cejule@gmail.com

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Katherine Ceroalo
New York State Department of Health
Bureau of House Counsel
Reg. Affairs Unit, Rm. 2438
ESP Tower Building
Albany, NY 12237

RE: Comments and Recommendations for the Internet System for Tracking Over-Prescribing Act ("I-STOP") Proposed Regulations, Part 80 of Title 10 NYCRR

Dear Ms. Ceroalo:

The Bioethical Issues Committee of the New York City Bar Association (the "Committee") [1] submits these comments and recommendations on proposed regulations to the Internet System for Tracking Over-Prescribing Act ("I-STOP"), Part 80 of Title 10 NYCRR, pursuant to recent amendments to Article 33 of the New York Public Health Law (Chapter 447 of the Laws of 2012), published in the New York State Register, June 19, 2013. [2]

A. BACKGROUND

The Bioethical Issues Committee has actively monitored drug control policy at federal, state and local levels and its impact on access to pain care and management, as well as relevant research activity and reports.

In the fall of 2011, the Institute of Medicine (IOM) released its groundbreaking report, *Relieving Pain in America* (2011),[3] highlighting the prevalence of pain among Americans from diverse backgrounds. The report also revealed that vulnerable populations, including racial and ethnic minorities, women, older adults and veterans, may be at particular risk for inadequate pain assessment and treatment (IOM, 2011).[4] Given mounting evidence of an alarming increase in nationwide prescription drug abuse,

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[1] The drafting subcommittee members were Mary Beth Morrissey (Chair), Karen Cahn, Adira Hulkower, Fanette Pollack, Ronald Thomas, and Lauren Zaccagnino. Mary Beth Morrissey was the primary author. This commentary does not necessarily represent the views of any individual members of the Committee on Bioethical Issues or their respective law firms or employer organizations.

[2] NY Reg, June 19, 2013 at 9. Proposed Amendment of Part 80 of Title 10 of NYCRR, ID-No-HLT-25-13-00017-P; New York Public Health Law Sections 3333, 3343-a, 3371.

[3] Institute of Medicine. (2011). *Relieving pain in America: A blueprint for transforming prevention, care, education and research.* Washington DC: National Academies Press.

[4] *Ibid.*

misuse and diversion, the U.S. Food and Drug Administration (FDA) in July 2012 approved a Risk Evaluation and Mitigation Strategy for extended-release and long-acting opioid analgesics.[5]

B. ACTIVITY IN NEW YORK STATE

In New York, legislation to strengthen the effectiveness of New York's existing Prescription Monitoring Program ("PMP") and to increase detection of prescription fraud and drug diversion was introduced in 2010. The Internet System for Tracking Over-Prescribing ("I-STOP") legislation was developed, in large part, to address prescription pain medication misuse, as documented in the Attorney General's report, "A Proposal Addressing New York's Prescription Drug Abuse and Drug Diversion Epidemic."[6]

Like most other states, New York State has had an existing PMP in place, but consultation of the PMP registry has not been required until now. The proposed I-STOP regulations delineate how the new consultation mandate will be implemented, and will require "real time" reporting for prescribing and dispensing of certain controlled substances by practitioners and pharmacists. The legislative objectives of the proposed I-STOP regulations include (a) helping practitioners make informed decisions about prescribing controlled substances, (b) promoting the safe and effective medical use of prescription drugs, and (c) reducing diversion.[7]

In addition to the statewide mandates under I-STOP, on the local level the New York City Department of Health and Mental Hygiene recently issued new guidance governing the prescribing of opioids in the emergency rooms of public hospitals ("Preventing Misuse of Prescription Opioid Drugs," December, 2011).[8] The City Health Information Bulletin includes information, *inter alia*, on the burden of death and injury resulting from use of prescription opioids; approaches to pain management; and guidance for prudent prescribing of opioids for pain management.[9]

C. ACTIVITY OF THE BIOETHICAL ISSUES COMMITTEE, SUBCOMMITTEE ON PALLIATIVE CARE

On April 1, 2013, the Committee held a program to address issues related to I-STOP and its implementation. Program panelists included Terence O'Leary of the Bureau of Narcotics Enforcement (BNE), New York State Department of Health (DOH), which is charged with overseeing the implementation of I-STOP; Joseph Lowy, MD, Director of Palliative Care Services, NYU Langone Medical Center; Christopher Comfort, MD, Medical Director, Calvary Hospital; Eric Legome, MD, Chief, Emergency Medicine, Kings County Hospital, Health and Hospitals Corporation; and Mary Beth Morrissey, PhD, MPH, JD, Fellow and Health Care Management Certificate Program Faculty Director, Fordham University Global Healthcare Innovation Management Center, and Chair of the Committee's Subcommittee on Palliative Care.

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5 U.S. Food & Drug Administration (2012). *Risk Evaluation and Mitigation Strategy for extended release and long-acting opioids*.

6 New York State Attorney General (2010). "A Proposal Addressing New York's Prescription Drug Abuse and Drug Diversion Epidemic."

7 *See* n 2, *supra* at 10.

8 New York City Dept. of Health & Mental Hygiene, *Preventing Misuse of Prescription Opioid Drugs*, City Health Information, Vol. 30(4), 25 (Dec. 2011).

9 *Ibid,* 24-28.

The following comments on the proposed regulations have been developed as a follow-up to the April 1st program, and take into consideration recommendations issued on June 19, 2013 by the DOH Prescriber and Pharmacist Workgroup.[10]

D. PRINCIPLE OF BALANCE IN DRUG CONTROL POLICY

The Committee position is that drug control policy and its implementation should be consistent with the "Principle of Balance" established by the United Nations' Single Convention on Narcotic Drugs of 1961 (Single Convention, 1961), to which the U.S. is a party.[11] The Single Convention promotes the dual goals of public health and public safety (Gilson, 2010).[12] As such, the Committee supports an approach which embodies both public safety and public health strategies that are designed to (a) maximize use of existing drug control programs, and implement interventions that target the sources of non-medical prescription drug abuse and diversion (Pain & Policy Studies Group, 2009)[13]; and (b) address the underlying social determinants of the non-medical prescription drug use problem and support treatment for individuals struggling with addiction (Pugh et al., 2013).[14]

E. COMMENTS ON THE I-STOP REGULATIONS

In our comments below, we identify areas of the proposed regulations that may be overly broad or require further specification to make the implementation of the I-STOP law more feasible and more likely to lead to positive outcomes for intended beneficiaries. Our comments address five areas: 1) scope of the proposed regulations; 2) clinical guidance; 3) appointment and qualifications of designees; 4) privacy and confidentiality; and 5) education and training.

1. Scope of Proposed Regulations

Two issues of scope may make implementation of the proposed regulations unwieldy. First, the I-STOP statute provides legal authority for pharmacists to consult the PMP registry before filling a prescription. Although pharmacy consultation is not mandatory, this new grant of authority may act as a mandate. Other than a broad reference to preventing "doctor-shopping," the regulations do not delineate the pharmacist's responsibilities after consulting the PMP. This expansion of the "duty to consult," with its concomitant responsibilities, may cause inefficiencies and may lead to conflicts in patient care.

The second issue that relates to scope involves the targeted beneficiaries of the proposed regulations. Specifically, the amendments fail to distinguish between high- and low-risk types of

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[10] Prescriber & Pharmacist Education Workgroup, *Education and Certification Standards of Prescibers and Pharmacists for Scheduled Drugs* (June 19, 2013).

[11] United Nations. *Single convention on narcotic drugs (1961) as amended by the 1972 protocol amending the single convention on narcotic drugs* (1961) (1972). Geneva, Switzerland: United Nations.

[12] United Nations. *Single convention on narcotic drugs (1961) as amended by the 1972 protocol amending the single convention on narcotic drugs* (1961) (1972). Geneva, Switzerland: United Nations; Gilson, A. M. (2010). Laws and policies involving pain management. In J. C. Ballentyne, J. P. Rathmell, S. M. Fishman (Eds.), Bonica's Management of Pain (4th ed.) (pp. 166-182). Philadelphia, PA: Lippincott, Williams & Wilkins.

[13] Pain & Policy Studies Group, WHO Collaborating Center for Policy and Communications in Cancer Care, FDA Comment Letter, 2009.

[14] Pugh, T. et al. (2013). Blueprint for Public Health and Safety Approach to Drug Policy. Joint publication of The New York Academy of Medicine and Drug Policy Alliance.

prescription drug use. Should a patient who has a chronic or incurable medical condition with excruciating and intractable pain be relegated to the same class as a patient undergoing minor surgery requiring several weeks of pain killers during convalescence? The ability of a practitioner to exercise professional judgment about prescribing appropriate pain medications is undermined by this indiscriminate regulatory scheme. Although the amendments do not mandate prescription practices or establish any explicit presumption of illegality, the unintended outcome may be a chilling effect on the prescribing and dispensing of necessary pain medication for patients genuinely in need of such care.

2. Clinical Guidance

The statutory scheme creates an environment that is ripe for the development of clinical guidance. Per the regulatory impact statement annexed to the regulations, the "proposed amendments promote the safe and effective use of prescription drugs while attempting to curb the diversion of such drugs;" the ultimate goal of these amendments is that of "enhanced patient care and safety." [15]

Needless to say, developing a system designed to avert the overprescribing or overuse and abuse of addictive narcotics has merit. However, the regulations alone fail to address the multivariate and complex issues that may arise when prescribing scheduled medications in the clinical setting. A system that merely alerts clinicians to the possibility of drug overuse, but provides no accompanying clinical guidance will likely fail to achieve the goal of enhanced patient care and safety.

Clinical guidance is in order regarding the implementation and possible repercussions of I-STOP. Placing mandatory consultation and real-time reporting within the substantive, rather than procedural, context of the clinical encounter is vital in order to successfully achieve the directive of the Principle of Balance – the promotion of both public health and public safety – while at the same time, meeting the needs of patients who require scheduled medications for effective pain management and preventing diversion. This goal can be achieved through the educational recommendations set forth by the Prescriber and Pharmacist Workgroup enumerated below, as well as through peer reviewed recommendations crafted by palliative care and pain management practitioners. Such guidelines should become mandatory educational components. (See Item 5 below.)

3. Appointment of Designees and Their Responsibilities

The regulations provide that a practitioner may authorize a designee to consult the PMP registry on her/his behalf, "provided that the ultimate decision on whether or not to prescribe a controlled substance remains with the practitioner."[16] This provision was enacted to free practitioners from the burden of performing PMP searches themselves.

The practitioner can appoint any designee(s) to access the system provided that the designee is located in New York State, is employed by the same professional practice or under contract with such practice, and is aware of and conforms to all state and federal privacy statutes. The responsibility for ensuring that the designee maintains the privacy of the records rests with the practitioner, who must take "reasonable steps to ensure or has actual knowledge that such designee is sufficiently competent in the use of the PMP and that such designee is aware of and conforms to all relevant federal and state privacy statutes."[17] The practitioner also has responsibility for "ensuring that access to the PMP by the designee is

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[15] *See* n 2, *supra* at 10.

[16] *See* n 2, *supra* at 9.

[17] *Ibid.*

limited to authorized purposes and occurs in a manner that protects the confidentiality of the information obtained from the PMP, and remains responsible for any breach of confidentiality."[18] Moreover, the practitioner must select and maintain all active designees authorized to access the PMP, and upon termination of employment or termination of the designee's authorization, the practitioner must immediately notify DOH of the revocation of authorization.[19]

Based on the above, designees are granted authority to access confidential medical prescription records of all patients in the medical practice. No qualifications are set for the designees' appointment; nor are there specified guidelines to ensure that designees use the system properly and ensure patient confidentiality. Additionally, an unreasonable and unrealistic burden is placed upon the practitioner for training, monitoring, auditing, and policing the system. It may be preferable to develop a more secure system which would include an automatic alert when similar prescriptions by another physician are generated for the same patient. As a result, the Committee's specific critiques with respect to the use of designees include:

- No required qualifications for designees are enumerated;
- No standards for training designees or ensuring confidentiality are specified;
- The procedures for designee access may result in breaches of confidentiality;
- The practitioner is subject to unreasonable monitoring duties;
- A disgruntled employee may commit confidentiality breaches that cannot be remedied; and
- Costs may be passed on to patients.

4. Privacy and Confidentiality

The use of a designee creates a particular vulnerability to the privacy of a patient's medical records. In addition, data may be disclosed by individuals seeking to demonstrate that the database is not secure or to expose some information they feel should be publicized, such as a politician's use of particular drugs or a practitioner's tendency to prescribe certain drugs. Other motivations, either economic or ideological, can provide a black market for the data. Moreover, the media on which data reside are vulnerable to theft or loss. In 2012, a California Child Support Services DR test lost cartridges of data that included names, addresses, Social Security numbers, health care, and other information.[20]

The I-STOP law addresses immunity for practitioners from liability for false or inaccurate information[21] but is silent on protections to patients from accidental or intentional disclosure of personal data. Such protections should be included in the I-STOP regulations[22] in the following manner. For

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[18] *Ibid.*

[19] *Ibid.*

[20] Associated Press, "Lost Data May Have Exposed 800,000 Individuals in CA," available at http://www.programbusiness.com/News/Lost-Data-May-Have-Exposed-800000-Individuals-in-CA (last viewed July 12, 2013).

[21] §7637(4).

[22] In the case of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), such

example, designees should be licensed professionals, thereby ensuring competence and compliance, and allowing for the potential revocation of the designee's license for either accidental or intentional disclosure. In addition, patients whose information is inadvertently disclosed should be able to pursue sanctions and possibly legal action, particularly in instances in which the patient suffers damage, such as loss of employment. Third, protection against discrimination that is a result of unauthorized disclosure should be included.

Needless to say, complete privacy cannot be guaranteed. However, breaches of privacy and mitigation of damages should be addressed as I-STOP is implemented. The most equitable solution may be to include within the proposed regulations requirements and sanctions that are not overly burdensome to health care practitioners, but at the same time provide patients with recourse in instances of breach.

5. Education and Training

The DOH Prescriber and Pharmacist Education Workgroup appointed pursuant to the provisions of the I-STOP law has made recommendations relating to education and training which are contained in, "Education and Certification Standards of Prescribers and Pharmacists for Scheduled Drugs, June 19, 2013."[23] The Committee endorses all of the I-STOP Workgroup recommendations, both in scope and content, and expresses especially strong support for mandated education and training recommendations, as well as the recommended content areas, listed below:

Regulatory Recommendations

1. Initial education and subsequent recertification should be mandatory for all prescribers and pharmacists.

2. Initial education for those already licensed should commence with re-registration.

3. Education should address all scheduled drugs and can be targeted to practice or specialty.

4. Online education should be available.

5. All education vendors should demonstrate to the consumer that they comply with current content standards established by the state rather than the state approving each curriculum.

6. All prescribers and pharmacists should maintain records of completed education.

7. Requirements specific to dentists: Both the 2 and 8 hour continuing education tracks should be incorporated into the existing 60 hours of continuing education for dentists.

8. Requirements specific to pharmacists: As a requirement for re-licensure, pharmacists must take 45 hours of continuing education of which 23 hours must be live each three-year cycle.

9. Within 2 years of the commencement of the I-STOP software, access to I-STOP should be conditional on attestation of having completed appropriate education and then upon recertification going forward. The 2-year grace period will allow for the development and acquisition of education.

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enforcement was deferred to the regulations. *See* CFR 45 Part 164.

[23] *See* n. 10.

10. The Office of the Professions with the New York State DOH should establish a seven member or larger panel of prescribers and pharmacist to approve education program standards.

11. The Office of the Professions of the New York State DOH, with representative stakeholders, should establish outcome measures to determine the success, as well as, unintended outcomes of the I-STOP initiative. (Education and Certification Standards of Prescribers and Pharmacists for Scheduled Drugs, June 19, 2013.)

Recommended Content Areas

1. Overview of DEA requirements
2. Pharmacology of scheduled drugs
3. Managing acute pain
4. Managing chronic non-cancer pain
5. Managing addiction
6. Non-opioid pain management
7. Pain, mental health and substance use disorders
8. Dosing and monitoring
9. Patient management
10. Prescribing guidelines
11. Referral to specialty care for pain, mental health and substance use disorders
12. Clinical application of the PDMR
13. Resources for prescribers and pharmacists (Education and Certification Standards of Prescribers and Pharmacists for Scheduled Drugs, June 19, 2013.)

The Committee would add to the above mandatory education content areas specific guidance and instruction on the privacy and confidentiality of patient records containing personal health information.

F. CONCLUSION

For the foregoing reasons, the Committee expresses overall support for the proposed regulations, and requests consideration of the additional recommendations in the areas of Scope, Clinical Guidance, Appointment and Responsibilities of Designees, Privacy and Confidentiality, and Education and Training expressed above.

Respectfully submitted,

Wendy Luftig

Wendy Luftig, Chair

THE ASSOCIATION OF THE BAR OF THE CITY OF NEW YORK
Committee on Bioethical Issues

Wendy Luftig, Chair
Carmen Jule, Secretary

Subcommittee on Palliative Care
Mary Beth Morrissey
Karen Cahn
Adira Hulkower
Fanette Pollack
Ronald Thomas
Lauren Zaccagnino

Other Committee Members
John Costa
Stephen Elliott
Wendy Goldstein
Grace Healy*
Kyle Jacobi
Joan Perryman
Jenny Shum
Phoebe Stone
Flora Tartakovsky*
David Zabell*

*These members of the Committee remain neutral on this submission.