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REPORT ON LEGISLATION BY THE BIOETHICAL ISSUES COMMITTEE

A.355-A **M. of A. Rosenthal**
S.4348-A **Sen. Hannon**

AN ACT to amend the public health law, in relation to the prescription pain medication awareness program and providing for the repeal of such provisions upon expiration thereof

THIS BILL IS APPROVED

The Bioethical Issues Committee of the New York City Bar Association (the "Committee")[1] submits these comments in support of A.355-A/S.4348-A, which would require every health care professional licensed, registered or certified under Title Eight of the Education Law to treat humans and registered under the Federal Controlled Substances Act and in possession of a registration number from the federal Drug Enforcement Administration to complete three hours of Continuing Medical Education (CME) course work on pain management, palliative care and addiction prior to renewal of registration to practice. These hours would be deemed to count toward the professional's obligation for board certification. In addition, any health care practitioner would be able to request an exemption from the applicable requirements if he or she demonstrated that there would be no need for him or her to complete such course work or training because of the nature, area or specialty of his or her practice, or that he or she had completed course work or training deemed by the Commissioner to be equivalent to the standards spelled out under the law.

BACKGROUND

Through the work of its Subcommittee on Palliative Care, the Committee has actively monitored drug control policy at federal, state and local levels, and the impact of such policies on access to pain care and management, as well as relevant research activity and reports.

[1] This report was prepared by the Subcommittee on Palliative Care of the Bioethical Issues Committee of the New York City Bar Association. Mary Beth Morrissey, Chair of the Subcommittee, was the primary author. The report was then reviewed and approved by the entire Bioethical Issues Committee and represents the consensus opinion of the Committee. The opinions expressed in this letter do not necessarily represent the views of any individual member of the Bioethical Issues Committee or any member's respective law firm or employer organization.

In the fall of 2011, the Institute of Medicine (IOM) released its groundbreaking report, *Relieving Pain in America* (2011),[2] highlighting the prevalence of pain among Americans of diverse backgrounds. The report 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).[3] The IOM also found that pain is a neglected area of content in all phases of medical education. Responding to the IOM's recommendations, the U.S. Department of Health and Human Services created the NIH Interagency Pain Research Coordinating Committee to oversee the development of a national strategy to improve pain care.[4]

At the federal administrative agency level, in July 2012, the U.S. Food and Drug Administration (FDA) approved a Risk Evaluation and Mitigation Strategy ("REMS") for extended-release and long-acting opioid analgesics, which included a "Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics."[5] These recommendations provide a beginning ground for developing a comprehensive state-mandated education program that should address appropriate prescribing practices including patient assessment and counseling, as well as effective strategies for communicating with patients about their life goals.

ACTIVITY IN NEW YORK STATE

In June 2012, a joint Attorney General-Governor program bill to strengthen the effectiveness of New York's existing Prescription Monitoring Program ("PMP") and to increase detection of prescription fraud and drug diversion was enacted.[6] The Internet System for Tracking Over-Prescribing ("I-STOP") legislation was developed, in large part, to address prescription pain medication misuse, as documented in Attorney General Schneiderman's January 2012 report, "A Proposal Addressing New York's Prescription Drug Abuse and Drug Diversion Epidemic."[7]

Like most other states, New York State has had an existing PMP in place, but consultation of the PMP Registry was not required until enactment of I-STOP. The I-STOP regulations require "real time" reporting for prescribing and dispensing of certain controlled substances by practitioners and pharmacists. The legislative objectives of the I-STOP regulations include: (a) helping practitioners make informed decisions about prescribing

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

[3] Ibid.

[4] Public Law 111-148 ("Patient Protection and Affordable Care Act"), Title IV, Subtitle D, § 4305, as it amends Part B of Title IV of the Public Health Service Act (42 U.S.C. 284 et seq.).

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

[6] 2012 N.Y. Laws Ch. 447.

[7] N.Y.S. Office of the Attorney General, A Proposal Addressing New York's Prescription Drug Abuse and Drug Diversion Epidemic [hereinafter "A.G. Report"] (Jan. 10, 2012), *available at* http://www.ag.ny.gov/sites/default/files/press-releases/2012/ISTOP%20REPORT%20FINAL%201.10.12.pdf (last visited Feb. 6, 2015).

controlled substances, (b) promoting the safe and effective medical use of prescription drugs, and (c) reducing diversion.[8]

ACTIVITY OF THE BIOETHICAL ISSUES COMMITTEE, SUBCOMMITTEE ON PALLIATIVE CARE

On August 5, 2013, the Committee submitted comments to the New York State Department of Health on the proposed I-STOP regulations.[9] The following points from the Committee's 2013 comments are relevant to the provisions of the pending bill and strengthen the rationale for mandated education and training for all health care professionals:

- A balanced approach to drug control policy and its implementation is needed that takes into account public safety and public health concerns, consistent with the well-established principle of balance in drug control policy.[10] 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 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.

- Mandated education and training are consistent with advancing the goals of generalist-level and primary care workforce development, changing practice patterns,[11] and increasing equitable access to adequate care and appropriate prescribing practices for all individuals from diverse backgrounds.

- Most pain management is currently provided by non-specialists who have not been adequately trained in pain management and palliative care.

- Mandated education should include content on the privacy and confidentiality of patient records containing personal health information.

STRENGTHS OF THE PROPOSED LEGISLATION

The provisions of A.355-A/S.4348-A address the urgent need for mandated education for health care professionals, and make measureable progress toward achieving the goals of balance

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[8] NY Reg, June 19, 2013 at 10. 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.

[9] August 2013 Bioethical Issues Committee Comments I-STOP, Proposed Amendments of Part 80, Title 10 NYCRR, *available at* http://www2.nycbar.org/pdf/report/uploads/20072554-CommentsRecommendationsforI-STOP.pdf.

[10] 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.

[11] Leong, L,Ninnis, J, Slatkin, N, Rhiner, M, Schroeder, L, Pritt, B, Kagan, M, Ball, T & Morgan, R. (2010). Evaluating the impact of pain management education on physician practice patterns – A continuing medical education outcomes study. *J Canc Edu*, 25, 224-228.

that the Committee has identified for improving public safety and health. The mandate that would be imposed by the proposed legislation and made applicable to all health care professionals with DEA registration numbers, who would be required to access and complete a minimum number of hours of CME course work prior to renewal of registration to practice, would help build the generalist-level workforce and eliminate health disparities. The course work would address issues of prescribing controlled substances, pain management, managing acute pain, palliative medicine, end of life care, addiction, as well as the state required I-STOP and federal DEA requirements. This content would give health care professionals needed guidance in areas that have presented significant challenges for those who do not have specialized training in pain management. The proposal would also allow those who have competence in these areas to apply for an exemption. Existing curricula, including those developed by a nationally recognized health care professional, specialty, or provider association, would be considered in implementing the proposal, reducing burdens and costs. The Committee would encourage the inclusion of provisions on privacy and confidentiality protections applicable to personal health information in any such curricula.

Finally, the Committee believes that mandated pain management and palliative care education and training would be instrumental in assuring meaningful implementation of the New York Palliative Care Access Act and Palliative Care Information Act.[12]

CONCLUSION

For the foregoing reasons, the Committee supports enactment of A.355-A/S.4348-A.

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[12] New York Palliative Care Information Act (Public Health Law 2997-c) and New York Palliative Care Access Act (Public Health Law 2997-d).