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MAINE BOARD OF LICENSURE IN MEDICINE BOLIM

In this issue:

Prescription Drug Abuse in the U.S. and Maine

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Background

In 1999 approximately 4000 people in the United States died as a result of overdosing on prescription painkillers.*1* A year later Maine U.S. Attorney Jay P. McCloskey sent letters to Maine prescribers concerning the increasingly major problem of the ?diversion of opioid analgesics from legitimate to illegitimate use.? As a result, the Board issued a ?Special Edition Summer 2000? newsletter that highlighted this concern and the Board?s recent adoption of rules designed to address this issue. The relevant features of the new rule included:

- A full evaluation of the patient, including a complete history, physical and diagnostic assessment.
- A treatment plan for the patient?s specific issue.
- Consideration of treatment modalities other than or in addition to controlled substances.

- Documenting the reason/basis for prescribing the controlled substance.

Over the years, the Board?s newsletters have included articles and information related to prescribing opioids. The Board?s Winter 2003 newsletter included an article entitled ?Safe Prescribing,? which included ?a study of drug deaths completed by the Department of Attorney General and the Office of the Chief Medical Examiner? that was focused ?on the growing problem with drug [opioid] misuse in the state.? The newsletter also advised that the Board could provide pain management guidelines and sample pain management agreements upon request. The Board?s Fall 2005 newsletter included an example of a case of inappropriate prescribing of opioids for a patient with a history of substance misuse. The deficiencies noted by the Board, which were intended to educate licensees, included:

- Lack of continuity or follow-up plan from visit to visit.
- Poor charting of the prescriptions in the patient?s medical record.
- Failure to address a pain specialist?s recommendation to reduce the amount of opiates.
- Lack of written pain management agreement.

The Board?s Fall 2010 newsletter included an article on the Board?s updated rule (Chapter 21 ? ?Use of Controlled Substances for Treatment of Pain?) and the Prescription Monitoring Program (PMP) as a useful tool to prevent and detect prescription misuse. The Board urged all physicians to use the PMP, and identified the following deficiencies in medical records it had reviewed as part of its complaint investigations:

- Multiple early refills.
- Infrequent or no urine testing.
- Infrequent or no pill counts.
- Documentation of failed urine testing with no follow-up.
- Documentation of failed pill counts with no follow-up.
- Concerns regarding diversion from other physicians, legal authorities, or family members with no follow-up.
- Failure to use the PMP when concerns arise.

In November 2011, the U.S. Centers for Disease Control and Prevention reported that:*2*

- In 2010 nearly 15,000 people died of prescription painkiller overdoses (this is almost 4 times the number who died in 1999).
- In 2010 about 1 in 20 people (age 12 or older) reported using prescription painkillers for nonmedical reasons.
- In 2010 enough prescription painkillers were prescribed to medicate every adult in the U.S. around-the-clock for a month.

- In 2009 nearly half a million emergency room visits were due to people misusing or abusing prescription painkillers.
- Nonmedical use of prescription painkillers costs health insurers up to $72.5 billion annually in direct health care costs.

To address these issues, the CDC at that time recommended that prescribers:

- Follow guidelines for responsible prescribing, including:
    - Screening and monitoring for substance abuse and mental health problems.
    - Prescribing painkillers only when other treatments have not been effective for pain.
    - Prescribing only the quantity of painkillers needed based on the expected length of pain.
    - Using patient-provider agreements combined with urine drug tests for people using prescription painkillers long term.
    - Talking with patients about safely using, storing, and disposing of prescription painkillers.
- Use PDMPs [Prescription Drug Monitoring Programs] to identify patients who are improperly using prescription painkillers.

<u>Current Reports</u>

In October 2015, the Maine State Epidemiological Outcomes Workgroup (SEOW) issued a special report on heroin, opioids, and other drugs in Maine.*3* The executive summary of that report included:

- Prescription drugs continue to represent a serious public health concern.
- Prescription drug misuse continues to have a large impact on treatment, mortality/morbidity, and crime in Maine.
- **Pharmaceutical drugs contribute to the majority of drug overdose deaths.**
- **As the availability of prescription narcotics has leveled off, heroin use and the consequences thereof have been on the rise.**
- **Availability and accessibility of opioids continues to be a problem.**

According to the SEOW report, from 2009 to 2014 drug-related overdose deaths went up each year. In 2014, there were **208** drug-related overdose deaths compared to **131** motor vehicle related deaths. Of the **208** drug-related deaths, **186** (89%) involved pharmaceutical drugs. According to the Maine Attorney General?s Office, in 2015 there were **272** drug-related overdose deaths in Maine ? an increase of 31% over 2014.*4* The increase was attributed to heroin or fentanyl or a combination of the two drugs. In addition, overdose

deaths (157) caused by illegal drugs like heroin exceeded overdose deaths (111) caused by pharmaceutical opioids.

In December 2015, the CDC issued a new report*5* on opioid overdose deaths in the U.S., which concluded that:

- There is an epidemic of drug overdose (poisoning) deaths in the United States.
- Since 2000, the rate of deaths from drug overdoses has increased 137%, including a 200% increase in the rate of overdose deaths involving opioids (opioid pain relievers and heroin).
- In 2014 there were 47,055 drug overdose deaths in the United States.
- **The opioid epidemic is worsening.**
- **Maine** was one of 14 states with statistically significant increases in the rate of drug overdose deaths from 2013-2014.
- **Opioids ? primarily prescription pain relievers and heroin - are the main drugs associated with overdose deaths.**
- Natural and semisynthetic opioids ? which include the most commonly prescribed opioid pain relievers oxycodone and hydrocodone ? continue to be involved in more overdose deaths than any other opioid type.
- **Heroin drug overdoses tripled in 4 years ? and is closely tied to opioid pain reliever misuse and dependence.**
- **Reversing this epidemic of opioid drug overdose deaths requires intensive efforts to improve safer prescribing of opioids.**

Current Responses to the Epidemic

1. The CDC

To address this worsening epidemic, in January 2016, the CDC issued draft guidelines for prescribing opioids for chronic pain and took public comments regarding them.*6* On March 16, 2016, the CDC issued the final guidelines for prescribing opioids for chronic pain,*7*which are available at the following website: http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1er.htm?s_cid=rr6501e1er_w

Those draft guidelines are as follows:

Determining When to Initiate or Continue Opioids for Chronic Pain

- Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should opioid therapy only if expected benefits for both pain

and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy, as appropriate.

- Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
- Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

- When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.
- When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to > 50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to > 90 MME/day or carefully justify a decision to titrate dosage to > 90 MME/day.
- Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.
- Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

Assessing Risk and Addressing Harms of Opioid Use

- Before staring and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (> 50 MME), or concurrent benzodiazepine use, are present.

- Clinicians should review the patient?s history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.
- When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
- Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.
- Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

2. Maine State Legislation

In March 2016, two bills were introduced in Maine to respond to this epidemic:

- LD 1646 ? ?An Act To Prevent Opiate Abuse by Strengthening the Controlled Substances Prescription Monitoring Program? (GOVERNOR?S BILL). This bill proposes to:
    - Require prescribers to check the PMP upon initial prescription of a benzodiazepine or opioid and every 90 days as long as the prescription is renewed.
    - Require dispensers to check the PMP prior to dispensing a benzodiazepine or opioid.
    - Require prescribers to complete a training course on prescribing opioids that is approved by the Department of Health and Human Services. The course must be completed by December 31, 2017 and every 5 years thereafter.
    - Prohibit prescribing more than 100 morphine milligram equivalents of an opioid per day to any one patient.
    - Prohibit prescribing more than a 15-day supply of an opioid to any one patient for the treatment of chronic pain.
    - Prohibit prescribing more than a 3-day supply of an opioid for the treatment of acute pain.
    - Effective January 1, 2018, require electronic prescriptions for all opioid medications.

- LD 1648 ?An Act To Amend the Laws Governing the Controlled Substances Prescription Monitoring Program and To Review Limits on the Prescription of Controlled Substances?. This bill proposes to:
    - Permit the sharing of PMP information with a Canadian province.
    - Require licensing boards to examine the circumstances in which prescribers and dispensers would be required to check the PMP, and enact joint rules regarding those circumstances.
    - Require licensing boards to examine the MaineCare limits on prescribing controlled substances and determine whether those limits should apply to all patients, and enact joint rules regarding those limits.
    - Require DHHS to amend its rules by January 1, 2017, to require the registration of pharmacists with the PMP as data requesters.

The Joint Standing Committee on Health and Human Services held a public hearing and two work sessions regarding these two bills, and on March 23, 2016 voted 11-1 ?ought to pass? LD 1646 as amended. The amendments included raising the limits for prescribing opiates for acute (7- day supply) and chronic (30-day supply) pain, and exceptions to the PMP check and dosage limits. The amendment to LD 1646 will be presented to the House and Senate for review and action in April.

3. Board Initiative ? Update Chapter 21

The Board?s staff is in the process of drafting an update to the current rule regarding prescribing controlled substances. Those draft changes may include:

- Requiring prescribers to use ?universal precautions? when prescribing controlled drugs, such as:
    - Evaluation of the patient, including a complete history and risk assessment to determine if the potential benefits of prescribing controlled drugs outweighs the risk to the patient.
    - Informed consent, including the benefits and risks of controlled drugs.*8*
    - Querying, assessing, and documenting PMP information.
    - Utilizing Written Treatment Agreements.
    - Urine drugs screens and random pills counts.
- Establishing treatment requirements, such as:
    - Conditions regarding initiating or continuing opioid therapy.
    - Establishing and documenting a treatment plan.
    - Periodic review of treatment efficacy and risks of patient harm.
    - Consultation or referral.
    - Discontinuing opioid therapy.
    - Medical Record Keeping.

- Continuing Medical Education.

All of these current efforts focus on reducing the amount of opioids being prescribed and dispensed to patients in order to save lives. Educational material and resources regarding controlled substance prescribing are available on the Board?s website: http://www.maine.gov/md/resources/prescribing.html.

1. CDC. Prescription Painkiller Overdoses in the U.S. November 2011. http://www.cdc.gov/VitalSigns/Painkiller Overdoses.
2. Ibid.
3. Maine Department of Human Services, Office of Substance Abuse. SEOW Special Report: Heroin, Opioids, and Other Drugs in Maine. October 2015. http://www.maine.gov/dhhs/samhs/osa/data/cesn/Mental_Health_in_Maine_SEOW.pdf
4. Gagnon, Dawn. ?Overdose Deaths Hit Record High in Maine.? Bangor Daily News. Mar. 8, 2016, p. A1.
5. ?Increases in Drug and Opioid Overdose Deaths ? United States 2000-2014.? U.S. Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report, Early Release/Vol. 64, December 18, 2015.
6. CDC. ?CDC Guideline for Prescribing Opioids for Chronic Pain ? United States, 2016.?
7. ?CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016.? U.S. Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report, Early Release/Vol. 65, March 15, 2016.
8. The Maine PMP webpage has a link to www.searchandrescuemaine.org - a prescriber education initiative designed to help identify high risk patients.

New Medical Director, Margaret (Peg) Duhamel, MD

Peg was born in southern New Hampshire and earned her medical degree at Dartmouth Medical School. She did an internal medicine residency at Maine Medical Center, then settled in the Mid Coast area.

She worked briefly at the Togas VA before joining Mid Coast Medical Group in Bath. She later stopped clinical practice to raise her children, but continued to work part time for the

group as practice manager after they became a department of Mid Coast Hospital. During that time she was also involved in several community volunteer programs.

In 2005, Dr. Duhamel helped develop the hospitalist service and an outpatient weight loss program for Mid Coast Hospital. She also wrote grant proposals that started the funding for the Community Assistance Prescription Program at the Oasis Free Clinic. In 2009, she returned to clinical practice with Mid Coast Medical Group where she also served as director of the bone density service.

She lives in Woolwich with her husband and enjoys cooking, traveling, biking, and cross-country skiing.

New Board Member, Brad Waddell, MD

Brad Waddell, MD is board certified in General Surgery and completed fellowship training in surgical oncology at Roswell Park Cancer Institute in Buffalo, NY. Prior to moving to Maine in 2009, Dr. Waddell was on active duty in the US Army for more than 20 years. He achieved the rank of Colonel in the Army Medical Corps and was deployed to Iraq and Afghanistan on multiple occasions. His last assignment in the Army was as Chief of Surgery at William Beaumont Army Medical Center in El Paso, TX. Dr. Waddell also served as a member of the Army Medical Command Special Review Panel, which is a peer-review board of specialty experts that advises the Army Surgeon General on medico-legal matters involving providers within the Army Medical Department.

Dr. Waddell specializes in General Surgery and Surgical Oncology at Eastern Maine Medical Center in Bangor. He is a member of the American College of Surgeons Commission on Cancer.

Dr. Waddell is a native of South Carolina. He is married to Deanna Dorsey, MD, who is a Maine native and works as an anesthesiologist at Eastern Maine Medical Center. They have 2 teenage daughters.

New Public Member, Lee Corbin

Lee has lived all of her life in Connecticut and Maine, with a brief detour to Colorado for law school. Lee was initially a trained cartographer, working for a municipality in Connecticut where she also opened her own graphic design business. After raising her son and daughter as a single mom, she returned to school at Yale University, majoring in Geology and Environmental Studies. With a science degree, she moved to Colorado to obtain her law degree with an eye toward practicing Natural Resource law. As fate would have it though, she practiced family law and estate planning (with a large dose of real estate law attached). For the last 7 years she worked for the Department of State, involved in (legal) citizenship and identity issues. Lee retired from the Federal Government in mid-2014 and now resides in West Boothbay Harbor, in the dream home her son built for her. She works part-time at the Coastal Maine Botanical Gardens, rides horses (dressage and jumping), plays tennis, and plays with her yellow lab, Cailey, and her Maine Coon Cat, Jake ? she is an animal lover.

Adverse Actions

Reinaldo O. de los Heros, MD License #MD17206 (Date of action 2/29/2016) On February 29, 2016 the Board entered into a consent agreement with Dr. de los Heros based upon the Board concluding that Dr. de los Heros engaged in unprofessional conduct relating to his medical recordkeeping and treatment of a patient who committed suicide after ingesting both prescribed and non-prescribed substances. The Consent Agreement requires that Dr. de los Heros be subject to a license probation for at least six (6) months during which he is required to have a practice monitor who will make reports to the Board, including his compliance with specified medical recordkeeping requirements.

Whitney Houghton, MD License #MD10913 (February 17, 2016) On February 17, 2016, the Board entered into a consent agreement with Dr. Houghton imposing discipline for unprofessional conduct relating to issues involving medication prescribing and medical recordkeeping. The Board imposed a one (1) year license probation with conditions including but not limited to a requirement that Dr. Houghton take a medical recordkeeping/charting course.

Marc D. Christensen, MD License #MD162385 (February 12, 2016) On February 12, 2016, the Board entered into a consent agreement with Dr. Christensen imposing disciplinary action for unprofessional conduct, engaging in conduct that evidences a lack of ability or fitness to discharge the duty owed to a patient or the general public, and misuse of alcohol that has resulted or may result in the licensee performing services in a manner that endangers the health and safety of patients. This action was taken following his self-report of involvement in a motor vehicle accident and arrest for operating under the influence, and a subsequent report by another entity that he was on call at the time of the incident for the treatment of patients. The Board imposed a reprimand, a $1,000 civil penalty, reimbursement of costs of investigation, and a seven (7) year license probation with conditions.

Aasim Shaheen Sehbai, MD License #MD20425 (December 8, 2015) On December 8, 2015, the Board issued a Decision and Order. The Board imposed a reprimand, a $1,000 fine, and a condition of probation that commences upon the practice of medicine in Maine and requires that Dr. Sehbai inform the Board of his employer. The Board?s action was based upon finding that Dr. Sehbai: 1) engaged in the practice of fraud, deceit, and misrepresentation in obtaining a license by misrepresenting the facts of a prior disciplinary action taken against him by the Delaware Medical Board, as well as failing to disclose allegations pending in Delaware at the time of his Maine application that ultimately resulted in a second disciplinary action by the Delaware Medical Board; and 2) that he was the subject of disciplinary action in Delaware for conduct that would, if committed in the State of Maine, constitute grounds for discipline, specifically unprofessional conduct for drafting two fraudulent letters of recommendation and asking a patient to sign a letter that he drafted in his own defense.

Bruce G. Manley, PA-C License #PA599 (November 10, 2015) On November 10, 2015, the Board entered into a consent agreement with Mr. Manley following his admission that he ingested morphine that was not prescribed to him, and receipt of a report that he came to work with the substance in his system. The Board imposed a reprimand, a $1,000 civil penalty, and a five (5) year probation with conditions for misuse of alcohol, drugs, or other substances that has resulted or may result in the licensee performing services in a manner than endangers the health or safety of patients.

Carl T. Folkemer, MD License #MD18400 (November 10, 2015) On November 10, 2015 the Board issued a decision and order denying Dr. Folkemer?s application for renewal of his license. The Board?s action was based upon its findings that Dr. Folkemer: 1) engaged in practices of deceit, fraud and misrepresentation in attempting to obtain a change in his conditions of licensure and to renew his license to practice medicine in the State of Maine; 2) demonstrated incompetence by failing to remember his history of prescription writing that was in violation of his limited license in the State of Maryland as well as prescribing medications that he was not authorized to prescribe in order to alleviate his financial

situation; 3) engaged in unprofessional conduct by violating his 2010 Consent Order with the State of Maryland; and was the subject of disciplinary action in Maryland for conduct that would, if committed in the State of Maine, constitute grounds for discipline, including incompetence, unprofessional conduct, engaging in activity requiring a license under the governing law of the Board that was beyond the scope of acts authorized by the license, and noncompliance with an order or consent agreement of the Board.

Adedipe, Olugbenga, MD License #19992 (July 13, 2015) On May 12, 2015, the Board voted to preliminarily deny the Licensee?s application for permanent medical licensure due to fraud, deceit or misrepresentation in obtaining his emergency medical license by certifying that he met all requirements for licensure, including successfully completing Step 3 of the USMLE within 3 attempts. In lieu of the denial of licensure, the Board also voted to offer the applicant a Consent Agreement. On July 13, 2015, the Licensee entered into a Consent Agreement with the Board. As discipline for this conduct, the Licensee agreed to pay a civil penalty in the amount of one thousand dollars ($1000.00). Upon payment of the civil penalty, the Board issued the Licensee a permanent medical license.

2015 Annual Statistics

Below is a snapshot of the Board?s activities in complaints and licensure for 2015.

2015 Complaint Statistics	
Number of Complaints carried forward from 2014	83
Number of Complaints filed in 2015	136
Number of Complaints dismissed in 2015	132
Number of Complaints dismissed with a Letter of Guidance	15
Number of Complaints resulting in Discipline	14
Number of Complaints carried forward to 2016	58

2015 New Licenses Granted	
Administrative	2
Camp Licenses	47
Educational Certificates	96
Emergency License	38
MD Permanent License	523
MD Temporary	177
PA Permanent License	84

Total	967

2015 License Renewals	
Paper Renewals	88

Electronic Renewals	2299
total	2387

2015 Permanent Licenses Expired and Not Renewed	
Administrative	1
MD Permanent	578
PA Permanent	53

Total	632

Recent Developments at the Board

1. Collaborative Drug Therapy Management

This is a new joint rule (Chapter 5 for the Medical Board) with the Board of Pharmacy, which has finally completed the rule making process. The rule sets out the requirements for collaborative drug therapy for patients by medical practitioners and pharmacists. Requirements include continuing education for pharmacists, a collaborative practice agreement (with specific content requirements), a treatment protocol (with specific content requirements), and standards for notifications and record-keeping. The new rule will allow medical practitioners to work collaboratively with pharmacists in out-patient settings to manage chronic medical conditions such as asthma, diabetes, dyslipidemia, hyperlipidemia, hypertension, infectious disease, cancer, thyroid disorders and coagulation disorders. The new rule is available on the Board?s website.

2. Consultative Telemedicine Registration is now available

The Board has developed an application process for this new category of licensure (even though it is called a ?registration?). Physicians may now apply for this registration. The registration allows physicians not located or practicing within Maine and not providing direct care to Maine patients to provide expert consultation on a regular basis at the request of a Maine physician, physician assistant, or advanced practice registered nurse. The registration does not permit the physician to open an office in Maine, meet with patients in Maine, or receive calls in Maine from patients. In addition, the physician, physician assistant, or advanced practice registered nurse who requests the consultation retains ultimate responsibility over the care, diagnosis and treatment of the patient. Applications for Consultative Telemedicine Registration can be found on our webiste under Apply for MD Licensure.

Online Renewal Notification Option

To E or not to E?

The Board is considering changing the way it notifies its licensees it is time to renew their licenses. As shown in the 2015 Annual statistics, 96% of licensees are renewing their licenses online. Currently the Board sends those notifications through the mail. Each year hundreds of these notices are returned because licensees have not updated their addresses, as required by 32 MRS ?3300-A. This amounts to a waste of both staff resources and money.

Based on this information, the Board is considering notifying its licensees of renewal by e-mail. When there is no record of an e-mail address the notification would be sent by US mail.

The Board is seeking comments from its licensees prior to making a decision. If you have comments, please e-mail them to the Board?s Executive Director, Dennis Smith, at Dennis.E.Smith@maine.gov

We look forward to hearing your opinion.

Editor-in-Chief David Nyberg, Ph.D. ? Graphic Design Ann Casady