State of New Jersey
OFFICE OF THE ATTORNEY GENERAL
DEPARTMENT OF LAW AND PUBLIC SAFETY
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CHRIS CHRISTIE
Governor

KIM GUADAGNO
Lt. Governor

CHRISTOPHER S. PORRINO
Attorney General

Andy Horowitz, Chief Executive Officer
Enclara Pharmacia
1601 Cherry Street
Suite 1700
Philadelphia, Pennsylvania 19102

January 24, 2017

Dear Mr. Horowitz:

I read with bewilderment your statement to the media calling to exempt from the five-day initial prescription limitation hospice patients and those in palliative care. Your support for the Governor's proposal is commendable, but your cautionary request is unnecessary: The rule proposal will limit initial prescriptions to a five-day supply for treatment of acute pain, and will not apply to treatment of patients who are currently in active treatment for cancer, receiving hospice care or are residents of long term care facilities. My letter dated January 18, 2016 made this plain, and was released to the media and reported on publicly. That letter is attached for your reference. Further, our expectation is that any legislation to codify the Governor's recommendations will also reflect these exemptions. I trust that, with this knowledge, you will be able to state publicly your unequivocal support for this initiative. Thank you for your consideration of and support for this critically important public health measure.

Very truly yours,

Christopher S. Porrino
Attorney General

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CHRISTOPHER S. PORRINO
Attorney General

January 18, 2017

Members of the State Board of Medical Examiners
c/o William V. Roeder, Executive Director
140 East Front Street
Trenton, New Jersey 08625

Re: Opioid Prescribing Emergency Regulations

Dear Board Members:

I am sure that the members of this Board are as deeply distressed as Governor Christie and I are about the tragic consequences of the prescription opioid and heroin epidemic presently affecting New Jersey citizens. As the Governor noted in last week's State of the State address, he has directed me to pursue a regulatory initiative to address this crisis.

The Scope of the Problem

The CDC Guideline for Prescribing Opioids for Chronic Pain, published in March of 2016, dramatically identifies the public health emergency that we face. Salient facts include:

- Nationally, an estimated 20 percent of patients presenting to prescriber offices with non-cancer pain symptoms, pain-related diagnoses, or acute and chronic pain reportedly receive an opioid prescription.
- In 2013, an estimated 1.9 million persons abused or were dependent on opioid pain medication.
- Having a history of a prescription for an opioid pain medication increases the risk for overdose and opioid use disorder.

- In the past decade, death rates associated with opioid pain medication have increased markedly.
- A long term (13 year) study concluded that, of the patients receiving opioids for chronic non-cancer pain, one in 550 patients died from an opioid-related overdose at a median of 2.6 years from their first opioid prescription, and one in 32 patients who escalated to opioid dosages of more than 200 morphine milligram equivalents died from opioid-related overdose.
- Most fatal overdoses could be identified retrospectively on the basis of 2 pieces of information: multiple prescribers and high total daily dosages.

Of particular concern, is the prevalence and consequence of opioid prescribing to young people:

- Research has shown significant increases in opioid prescribing for pediatric populations and a large number of adolescents are commonly prescribed opioid pain medications for conditions such as headache and sports injuries.
- An estimated 20% of adolescents with currently prescribed opioid medications report using them intentionally to get high or increase the effects of alcohol or other drugs.
- Misuse of opioid pain medications in adolescence strongly predicts later onset of heroin use.

Alarmingly, the 2016 American Society of Addiction Medicine (ASAM) Facts and Figures notes that "four in five new heroin users started out misusing prescription painkillers."

In New Jersey, we are witnessing the opioid epidemic first hand. In 2014, there were 1,306 drug-related deaths; in 2015, that number had risen to 1,587. Naloxone administrations in 2014 numbered 5174, in 2015, 7222. In 2016, we had 10,000 Narcan deployments. With the continued expansion of programs for first responders, we fully expect that number to be exceeded this year. According to the New Jersey Division of Mental Health and Addiction Services, in 2014, there were 28,653 patients in treatment for opioids; by 2015 that number had risen to 35,529. These statistics demonstrate that it is vitally important to change the culture and curtail prescribing practices at the outset of treatment in the outpatient setting for acute pain to minimize the risks of developing addictions. The CDC Guideline includes the following recommendation:

> Experts agreed that when opioids are needed for acute pain, clinicians should prescribe opioids at the lowest effective dose and for no longer than the expected duration of pain severe enough to require opioids to minimize unintentional initiation of long-term opioid use. . . Clinicians should not prescribe additional opioids to patients "just in case" pain continues longer than expected. Clinicians should re-evaluate the subset of patients who experience severe acute pain that continues longer than the expected duration to confirm or revise the initial diagnosis and to adjust management accordingly.

The Role for Regulatory Boards

I know that this Board has embraced the role that licensing boards can play in addressing the opioid epidemic. A review of enforcement actions undertaken by the Board of Medical Examiners over the last several years highlights both the prevalence of the problem and the commitment of the Board to protect the public. Enforcement efforts have grown both as to the number of Board actions entered - 5 in 2012, 7 in 2013, 23 in 2014 and 21 in 2015 - and the alacrity with which the State has moved for either a bar on further CDS prescribing, before the Director or the Board, or full practice suspension pending the hearing on charges. Since January 1, 2016, there have been 40 cases in which indiscriminate prescribing was at issue that have been pursued, or resolved, resulting in temporary suspensions or final orders of discipline against licensees. The Prescription Monitoring Program (PMP) has been an important tool, both in initial investigation of complaints, and in scrutinizing compliance going forward. Still, as the description above highlights, there is so much more to do to stop the prescribing that you have recognized as deserving of discipline before it even starts.

Proposed Reforms

Seizing on the CDC recommendation cited above, several states have enacted reforms that specifically limit the prescribing of opioids at the outset of treatment for acute pain. Starting on January 1, 2017, Maine will limit initial prescriptions for acute pain to 7 days, and New York limits the prescriber on an initial consultation or treatment for acute pain to a 7-day supply, with an ability to issue a 30-day supply after a subsequent consultation. In Massachusetts and Connecticut there is a 7-day limit, but if the prescriber, in the exercise of professional judgment, determines there is a need, and documents that there are no alternatives, more can be provided. All these constructs have exemptions for active cancer care, hospice, end-of-life and palliative care.

Several bills now pending before the New Jersey Legislature propose to amend N.J.S.A. 45:9-22.19 which currently authorizes physicians to issue prescriptions "in any quantity which does not exceed a 30-day supply." Pending legislation also addresses the need for prescribers to discuss risks, benefits and alternatives, especially with minors and to provide patients at risk of addiction and possible overdose with information about the availability of naloxone and substance abuse resources. Other bills presently under consideration would amend all prescriber practice acts to require continuing education in responsible opioid prescribing.

The challenge before us is too great, and the consequences too dire, to wait and see if legislation passes. The Governor and I are looking for your support in pursuit of a comprehensive regulatory approach that can be launched as soon as possible to achieve meaningful reforms quickly.

By this notice, I am advising of my intent to proceed under N.J.S.A. 45:1-17(b) to amend the rules of the boards that regulate prescribers, focused on codifying rigorous standards for the prescribing of opioids for acute pain and meaningful monitoring practices in the management of patients suffering from chronic pain not associated with cancer, palliative or end of life care. Failure to adhere to the standards set forth in the attached rule proposal will provide basis to seek emergent action to suspend or limit licenses pending a plenary hearing, pursuant to N.J.S.A. 45:1-22 and/or for disciplinary sanctions pursuant to N.J.S.A. 45:1-21.

I am advising that I will move to amend existing rule N.J.A.C. 13:35-7.6 to better align with the recommendations in the March, 2016 CDC Guideline which expressly includes the following:

- Long-term opioid use often begins with treatment of acute pain.

- The clinical evidence review found that opioid use for acute pain (i.e., pain with abrupt onset and caused by an injury or other process that is not ongoing) is associated with long-term opioid use, and that a greater amount of early opioid exposure is associated with greater risk for long-term use.

- Experts noted that more than a few days of exposure to opioids significantly increases hazards, that each day of unnecessary opioids use increases likelihood of physical dependence without adding benefit, and that prescription with fewer days' supply will minimize the number of pills available for unintentional or intentional diversion.

- Some experts thought that because some types of acute pain might require more than 3 days of opioid treatment, it would be appropriate to recommend a range of ≤3-5 days or ≤3-7 days when opioids are needed. Some experts thought that a range including 7 days was too long given the expected course of severe acute pain for most acute pain syndromes seen in primary care.

- Clinicians should not prescribe additional opioids to patients "just in case" pain continues longer than expected. Clinicians should re-evaluate the subset of patients who experience severe acute pain that continues longer than the expected duration to confirm or revise the initial diagnosis and to adjust management accordingly.

The amendments I am advancing would, consistent with N.J.S.A. 45:9-22.19, authorize the prescribers to issue an initial 5-day prescription for acute pain. A subsequent prescription could only be issued after a prescriber's supplemental consultation with the patient, either in person or by telephone or other means of direct communication. It is my expectation that this will substantially reduce the risk of addiction and the accumulation of opioids in household medicine cabinets across the State, stockpiles that are ripe for diversion. In addition, as specifically recommended by the CDC, those engaged in the long term prescribing of opioids for chronic pain should utilize pain management contracts, periodic urine screens and referrals to specialists. Provisions requiring discussions with patients concerning the risks, benefits and alternatives to opioid prescribing would also be incorporated.

Moving under N.J.S.A. 45:1-17(b) will enable us to achieve uniformity amongst the boards' regulating prescribers. I believe it is imperative that we achieve this remedy as soon as possible, and will seek to implement this rule initiative as an emergency adoption, to be effective upon filing at the OAL. In furtherance of this approach, I have prepared an Agency Statement of Imminent Peril, with which Governor Christie has concurred. As soon as you can, but not later than February 16, 2017, I ask for your support and assent to this initiative. A concurrent proposal will also be filed, on which members of the public and the regulated community may comment.

In addition, Division of Consumer Affairs Director Lee will also be proposing a rule establishing standards that those with CDS registrations must meet upon application and on annual renewal of their registration, in the exercise of his authority to ensure that registrants' have the capacity to "maintain effective controls against diversion." In addition to confirming that registrants adhere to security standards, the rule proposal would establish a

requirement to take continuing education coursework. Consistent with the CDC Guideline, the coursework should address when to initiate or continue opioids for chronic pain; opioid selection, dosage, duration, follow-up, and discontinuation; and assessing risk and addressing harms of opioid use. Understanding the scope of the opioid problem and the ways to responsibly prescribe are key to thwarting diversion. We would expect that the boards regulating prescribers will accept the 2 credits earned annually in satisfaction of the credits already mandated, so that no additional burden would be imposed, and this would only be required of those licensees who actually have a CDS registration.

Of course we do recognize that chronic pain (defined as any pain lasting three or more months) is a fact of life for many of our citizens. There is no doubt that patients suffering from chronic pain should receive appropriate and compassionate pain treatment based on a careful consideration of the benefits and risks of the treatment options. But, as reflected in the CDC Guideline, while evidence supports short-term efficacy of opioids for reducing pain and improving function in non-cancer patients, studies also show that opioid pain medication use also presents serious risks, including overdose and opioid use disorder. Professional licensing boards that regulate those with prescribing authority have a key role to play in implementing the CDC Guideline to improve patient safety, educate patients about the risks and benefits of opioid use as a pain management treatment, and reverse the cycle of opioid pain medication misuse that is contributing to the opioid overdose epidemic in New Jersey. While a public awareness campaign is of great value, the adoption of regulations intended to establish evidence-based prescribing standards and improve communication between health care providers and their patients will serve to immediately protect the public health and safety.

I am available at your January 18, 2017 meeting to consult with your members concerning the need to amend N.J.A.C. 13:35-7.6. I have appended the rule amendments I am intending to propose, as well as the rule that Director Lee is proposing. Please advise no later than thirty (30) days of receipt of this letter (and preferably sooner) as to whether your Board will stand with me to pursue these administrative reforms, consistent with the Governor's recognition of the imminent peril threatening the health and safety of the public.

Very truly yours,

By: _____
Christopher S. Porrino
Attorney General of New Jersey