**MEMORANDUM**

TO: Jennifer Baader, Assistant Counsel, House Tech Review

FROM: Illinois Academy of Family Physicians, Illinois Pharmacists Association, Illinois Academy of Physician Assistants, Illinois Retail Merchants Association, Illinois College of Emergency Physicians, Illinois Society of Advanced Practice Nurses, Illinois Council of Health System Pharmacies, Illinois Society of Eye Physicians and Surgeons, Illinois Hospital Association, Illinois Society of Anesthesiologists, Illinois Optometric Association, Illinois State Ambulance Association, Illinois Osteopathic Society, Illinois State Dental Society, Illinois State Medical Society

RE: Proposed Alternative to House Amendment #1 to House Bill 1

DATE: April 27, 2015

Attached to this memorandum is an LRB version of our proposed amendment to House Bill 1. In light of some drafting errors in the amendment we presented during our meeting with Leader Lang on Monday, April 20 and as a result of some of our conversations with Leader Lang during that meeting, we have prepared a new LRB draft amendment for your review (34732a). In Part I of this memorandum is a summary of these provisions of the draft amendment. In Part II of this memorandum is a list of both provisions from House Amendment 1 to House Bill 1 which were not included in the attached amendment and also those provisions from House Amendment 1 that are not substantively changed in the attached amendment.

**Part I**

Changes to the Open Meetings Act

* The Open Meetings Act is amended to specifically allow for a closed meeting of the Prescription Monitoring Program (PMP) Advisory Committee and a new subset of this Advisory Committee called the Peer Review Subcommittee.

Improved Drug Overdose Prevention Program

* The amendment makes several improvements to an existing report by the Department of Human Services (DHS) on statewide drug overdose trends. The report must be made on annual basis and include an analysis of drug overdose information, both reported overdoses and overdose deaths, which is a new reporting requirement set forth in House Amendment 1.
* By using both existing and new overdose data in a meaningful way, State entities, such as local law enforcement agencies and other organizations which provide substance abuse care, can allocate their resources to the areas where action is needed to address opioid and heroin overdose.
* The report must also include a description of efforts undertaken for prescription drug disposal in Illinois. This change is vital because the federal rules have only been recently promulgated and their effectiveness is yet unknown. By studying this issue, Illinois can be a leader in terms of seeing how the expansion of drug disposal can be made more effective or can be improved. Trends in drug disposal can also be examined alongside drug overdose data.

Expanded Access to Opioid Antagonists

* The amendment updates current provisions which establish a program for the distribution for opioid antagonists like Naloxone.
* These provisions have a more extensive and scientifically accurate definition of an opioid antagonist. The amendment also updates the word “antidote” in an effort to prevent the potential misuse of this prescription drug and instead reinforces that drugs like Naloxone are a means to address overdose, in the same way AED’s and epi-pens address cardiac arrest and allergic reactions.
* The amendment adds criminal immunity for health care professionals who prescribe or dispense an opioid antagonist, directly or by standing order, except for willful and wanton misconduct. Current law only provides for professional immunity for health care professionals.
* For lay persons who administer an opioid antagonist, immunity is also expanded to criminal prosecution and civil immunity.
* The definition of “health care professional” is updated to more accurately reflect the collaborative agreements of physician assistants and advanced practice nurses. The definition is also expanded to include pharmacists.
* The amendment authorizes the Medical Director of the Department of Public Health to write a standing order for opioid antagonists for pharmacies. In order to ensure the most participation in this program, the amendment provides for immunity for pharmacists who dispense opioid antagonists by changing the language in the Good Samaritan Act to include the cost of the drug product, dispensing and administration fees, except for willful and wanton misconduct.

Medication Take Back Program

* The amendment requires DHS to develop by rule a medication take-back program by January 1, 2017. This program must include drop-off sites and mail-back options. The program must be published on the Department’s website.
* The amendment also expands the current Prescription Pill and Drug Disposal Fund. Besides allowing law enforcement agencies to receive grants from the Fund, the amendment expands eligibility for these grants to any municipality or organization that establishes containers designated for the collection and disposal of unused controlled substances or conducts mail-back programs and for the publication or advertising of collection events or mail-back programs conducted by municipalities or organizations.
* During the Coalition’s meeting with Leader Lang, we had offered language which would have doubled the existing fee which supports the Prescription Pill and Drug Disposal Fund, from $20 to $40. This fee is assessed against certain drug offenses and is collected by Circuit Clerks following convictions for these offenses. Leader Lang had asked us to make the fee increased by rule. We have encountered the following issues in making this fee from a statutory provision to a rule:
* As the fee already exists in the Unified Code of Corrections and is currently being assessed by the 102 circuit clerks around the State, transitioning an existing fee to rule, as opposed to establishing a new fee from rule, would entail a very difficult and precise transition period in light of the time it would take to promulgate the rule and implement this change around the State.
* There are a variety of fees assessed by circuit clerks on certain offenses for deposit in specific funds, such as the Trauma Center Fund, DUI Equipment Fund, and the Spinal Cord Injury Paralysis Cure Research Trust Fund. A change which would move a fee from the Unified Code of Corrections to the administrative rules of the Illinois Criminal Justice Information Authority will likely be opposed by circuit clerks and the Administrative Office of the Illinois Courts.
* Legislation establishing mandatory fees on criminal offenses has been recently called into question in an Illinois Bar Journal article, The Mandatory Criminal Fines Conundrum.
* In light of these complications, we have not included the fee increase in this draft. As of April 26, the balance of this Fund is $109,291.77.
* Finally, the amendment requires the Illinois Criminal Justice Information Authority to promulgate rules regarding the distribution of monies from this Fund by July 1, 2016. These rules have not been adopted since the Fund’s inception in January 1, 2012, despite a legislative mandate to do so.

Administration of Opioid Antagonists in Schools

* The amendment preserves all of the provisions of House Amendment 1, but updates existing provisions of existing law to more accurately reflect the collaborative agreements of physician assistants and advanced practice nurses. The amendment also updates references to “opioid antidote” to “opioid antagonist” and the substantive definition of “opioid antagonist”.

Opioid Overdose Report Requirement

* The amendment requires health care professionals, hospital administrators, or their designees to report incidences of overdose to the Department of Public Health when treatment is provided in the hospital emergency department. Reporting must be done within 48 hours of the confirmed diagnosis of the overdose.
* The identity of the person reporting shall not be disclosed to the subject of the report, and those reporting shall not be held criminally, civilly, or professionally liable for reporting, except for willful and wanton misconduct. Maintaining the confidentiality of the reporter and ensuring that they are not held liable for the reporting is necessary to protect against a potential backlash by the subject of the report and is consistent with other mandatory reporting laws, such as the medical provider reporting requirements in Section 8.1 of the FOID Act (430 ILCS 65/8.1).
* The Department is required to provide a semiannual report to the General Assembly summarizing the reported data and post data on its website.

Mental Health Parity

* In addition to including all of the substantive changes set forth in House Amendment 1 to the mental health parity provisions of the Insurance Code, the amendment expands the Department of Insurance working group set forth in House Amendment 1 to include the discussion of the treatment and insurance coverage of mental health issues and also to include specific representation in this group by mental health physician groups. In House Amendment 1, this working is focused entirely on examining the treatment and coverage of substance abuse disorders.

Medicaid Coverage

* The amendment ensures that prescriptions for naltrexone, methadone, and opioid antagonists issued by all prescribers, including physicians, advanced practice nurses, and physician assistants, will be included as covered benefits under the Medicaid program.

Addressing the Frequency of Prescribing

* The physician is required to document in the medical record of the patient the medical necessity for the amount and duration of the 3 sequential 30-day prescriptions for Schedule II narcotics. Under current law, no such documentation is required to be made by physicians.
* In light of our discussion with Leader Lang on April 20, the term “Schedule II narcotics” was chosen over previous draft language which had used the term “Schedule II opioid analgesics,” as the analgesic term would not include specific medications that can be abused, like Fentanyl, in the physician documentation requirement.
* Overall, this change is intended to make the physician prescriber specifically consider the circumstances when the 3 sequential prescriptions are written for patients.
* The amendment also requires a pharmacy to maintain a policy regarding the type of identification necessary, if any, to receive a prescription in accordance with State and federal law. This information must be posted where prescriptions are filled.

Efforts to Reduce Doctor Shopping

* The amendment decreases the threshold when the PMP will send unsolicited reports to prescribers to alert them of potential medication shopping. When a person has been identified as having 3 or more prescribers or 3 or more pharmacies, or both, that do not utilize a common electronic file in the course of a continuous 30-day period, an alert may be sent to the prescriber by the PMP.
* In order to protect prescribers who may fear the impact of negative feedback or complaints from patients who are “doctor shopping,” the amendment provides protection for providers and their clinical decision not to prescribe. Specifically, the amendment provides that any patient feedback, including grades, ratings, or written or verbal statements in opposition to a clinical decision that the prescription of a controlled substance is not medically necessary shall not be the basis of any adverse action, evaluation, or any other type of negative credentialing, contracting, licensure, or employment action taken against a prescriber or dispenser.

Improvement of PMP information

* The amendment increases the speed of information transmitted to the PMP to require pharmacies to report prescription data by the end of the next business day, as opposed to the current seven day requirement.
* The amendment adds information which must be transmitted to the PMP. Under the amendment, the date of birth and gender of the person obtaining the prescription and the days supply which is represented by the prescription will now be reported to the PMP.
* These changes will have a significant impact on the PMP, promoting its use as a clinical tool for providers and dispensers. Adding the date of birth will allow DHS to improve the search function on the PMP, which now can take up to 15 minutes to query a single name because of the commonality of names on the system. Adding the days supply will help in efforts to distinguish medically appropriate from suspect prescribing.
* Ultimately, increasing the speed of data transmission to the PMP will eliminate the current seven day window which allows those who are seeking to obtain prescription drugs for misuse the ability to “doctor shop” without detection for entire week.

Integration of Prescription Monitoring Program Data into Electronic Health Records

* The amendment requires DHS to create rules within one year of the effective date of the legislation that establish a pilot initiatives within hospital to integrate electronic health records (EHR) with the PMP on or before January 1, 2019.
* In collaboration with the PMP Advisory Committee, DHS shall identify funding sources to support these pilot projects.
* The rules promulgated by DHS must also ensure that the Department continues to monitor updates in EHR technology and how other states have integrated their prescription monitoring databases with EHR systems.

Expanded Prescription Monitoring Program

* The amendment updates and expands the PMP to make this program a more effective and comprehensive resource for prescribers and dispensers in order to prevent the potential misuse of prescription drugs at the initial point of prescribing.
* The PMP will be required to create a log-in for all prescribers and dispensers in conjunction with the renewal or obtaining of an Illinois controlled substance license. Under current law, enrollment in the PMP is voluntary, but with the amendment, there will be a seamless process to automatically enroll in the PMP all those who prescribe and dispense controlled substances in Illinois.
* In addition to all prescribers and dispensers now being enrolled in the PMP, the amendment also authorizes designees of prescribers and dispensers to view PMP information. These designees must meet four requirements in order to ensure the safety and confidentiality of PMP information:

(1) the designee is employed by the same hospital or health care system; is employed by the same professional practice; or is under contract with such practice, hospital, or health care system, as the prescriber or dispenser;

(2) the prescriber or dispenser takes reasonable steps to ensure that such designee is sufficiently competent in the use of the PMP;

(3) the prescriber or dispenser remains responsible for ensuring that access to the PMP by the designee is limited to authorized purposes and occurs in a manner that protects the confidentiality of PMP information, and remains responsible for any breach of confidentiality; and

(4) the ultimate decision as to whether or not to prescribe or dispense a controlled substance remains with the prescriber or dispenser.

* In response to our meeting with Leader Lang on April 20, we have also specifically provided that the designees shall receive information from the PMP on how to log-on and use the system.
* As the PMP is a separate system that must be checked by a prescriber or dispenser independent of a patient’s medical records, allowing designees to view the PMP will give prescribers and dispensers the flexibility to more effectively integrate the PMP into their clinical workflows to avoid delays in providing medical care.

Ensuring that Prescribers and Dispensers have Instant Access to Resources

* With an enrollment that will now represent all prescribers and dispensers who have a controlled substance license in Illinois, the PMP will be able use this network of contacts to provide an unprecedented level of information and access to continuing education specifically focused upon the prescribing of opioids.
* The amendment requires all prescribers to designate their fields of medical specialty when they are enrolled with the PMP. With this information, the PMP will now be able to send targeted and relevant information to prescribers and dispensers.
* Prescribers and dispensers will now receive notices about continuing education opportunities relevant to prescribing in four different ways: (1) upon their enrollment with the PMP, (2) from periodic updates sent out by the PMP via email, (3) through the PMP website, which is now required to be updated through the input of PMP Advisory Committee, and (4) when they have been identified by the Peer Review Subcommittee as potentially prescribing outside of accepted medical standards.
* The PMP is specifically required to maintain a website with mandated information, including current clinical guidelines developed by health care professional organizations on the prescribing of opioids or other controlled substances, programs or information developed by health care professional organizations that may be used to assess patients or help ensure compliance with prescriptions, relevant medical studies, and other publications which involve the prescription of controlled substances.

PMP Advisory Committee

* With this amendment, the existing PMP Advisory Committee will now have specifically qualified members chosen by the Clinical Director of the PMP.
* The composition of the Advisory Committee will be as follows: 4 physicians, one advanced practice nurse, one physician assistant, one optometrist, one dentist, one podiatric physician, and 3 pharmacists. The Clinical Director has the ability to appoint a representative of an organization representing a profession required to be appointed to the Committee. This is to ensure that the Committee is fully appointed at all times.
* The Advisory Committee will also have defined duties that must be accomplished in specific timeframes established in the amendment, such as the quarterly review of the PMP website to ensure that this information is up-to-date and relevant to prescribers and dispensers. The PMP Advisory Committee also shall review grant opportunities to improve the operation of the PMP and integrate its data into Electronic Health Records.

Efforts to Detect, Prevent, and Rectify Overprescribing

* The amendment transforms the review of PMP information in an effort to detect negative prescribing or dispensing behavior that may otherwise go unreported to the Department of Financial and Professional Regulation (IDFPR).
* Under the amendment, review of PMP information will now be performed by a team of qualified practitioners as a Peer Review Subcommittee. This Subcommittee, composed of 3 physicians and 2 pharmacists from the PMP Advisory Committee, are required to periodically review the data contained within the PMP to identify those prescribers or dispensers who may be prescribing or dispensing outside the currently accepted standards in the course of their professional practice.
* If the Subcommittee identifies a prescriber or dispenser who has potentially deviated from medically accepted prescribing or dispensing practice, the Subcommittee is authorized to send a “Request for Information” to the prescriber or dispenser. This Request for Information must be sent by certified mail. A prescriber or dispenser has 30 days to respond.
* A prescriber or dispenser will be referred to the IDFPR for investigation if the Peer Review Subcommittee makes any of the following determinations:
* If a prescriber or dispenser does not respond to three successive requests for information;
* In the opinion of a majority of members of the Peer Review Subcommittee, the prescriber or dispenser does not have a satisfactory explanation for the practices identified by the peer review subcommittee in its request for information; or
* Following communications with the Peer Review Subcommittee, the prescriber or dispenser does not sufficiently rectify the practices identified in the request for information in the opinion of a majority of the members of the Peer Review Subcommittee.
* IDFPR may initiate an investigation and discipline in accordance with current laws and rules for any prescriber or dispenser referred by the Peer Review Subcommittee.
* To protect the confidentiality of patient information, the deliberations, information and communications of the Peer Review Subcommittee are privileged and confidential and shall not be disclosed in any manner except in accordance with current law.
* In response to our meeting with Leader Lang on April 20, we have added an annual report requirement which is specific to the activities of the Peer Review Subcommittee. This report must detail the work of the Peer Review Subcommittee, such as the number of prescribers and dispensers reviewed and referred to IDFPR, in a way as to protect the identity of patients, prescribers, or dispensers. The report must be prepared each year by the Peer Review Subcommittee and submitted to DHS and the General Assembly.

Criminal Sanctions

* Adds the attempt to obtain controlled substances by misrepresentation, fraud, forgery, or subterfuge to the list of violations under the Illinois Controlled Substances Act.
* The amendment creates a new offense, to knowingly withhold information requested from a practitioner, with the intent to obtain a controlled substance that has not been prescribed by misrepresentation, fraud, forgery, deception, subterfuge, or concealment of a material fact.

**Part II**

The attached amendment includes several provisions of House Amendment 1 to House Bill 1 that have no changes at all, save for technical changes, such as updating the term “opioid antidote” to “opioid antagonist”. Those provisions are as follows:

* Requiring law enforcement and other entities to develop a Drug Overdose Response Policy.
* Requiring DHS to develop educational materials and programs regarding the dangers of gaining access to opioids and the Good Samaritan Overdose Law.
* Requiring DHS to conduct or approve a training program for State Police officers in the administration of opioid antagonists.
* The creation of the Parity Education Fund.
* Training requirements for opioid antagonists for the probationary police officers, police officers, firefighters, EMT and EMR personnel, and other law enforcement personnel.
* Overdose death reporting requirements for coroners.
* Application of insurance mandate for mental and emotional disorders to the Counties Code, Municipal Code, and Medicaid, and also the substantive changes to this mandate that add coverage for clinical stabilization services and acute treatment services, external independent review provisions, and reporting on mental health services loss ratios.
* Addition of opioid antagonists to the provisions of the School Code authorizing administration of asthma medication and epi-pens.
* Creation of a heroin and opioid prevention pilot program by the State Board of Education and DHS.
* Insurance mandate for the coverage of opioid antagonists.
* Changes to the mental health parity provisions of the Insurance Code, including educational efforts to promote knowledge of these provisions.
* Changes to the Health Carrier External Review Act which ensure proper criteria for a review of coverage determinations involving substance use disorders.
* Provisions authorizing the purchase of opioid antagonists with the proceeds of criminal and civil forfeiture funds and additional substantive requirements for the exercise of civil and criminal forfeiture.
* Expansion of existing Drug Court programs.

The following provisions of House Amendment 1 to House Bill 1 are not included in the attached LRB Draft:

* Registration and licensing of Pain Clinics by the Illinois Department of Financial and Professional Regulation (IDFPR).
* Limiting Schedule II controlled substances to a 10-day supply, unless indicated as medically necessary by the prescriber.
* A required “patient assessment” prior to prescribing and dispensing an Schedule II controlled substance which must be reflected on the prescription.
* Requiring the acknowledgement of the unsolicited reports from the PMP.
* Allowing IDFPR to access PMP information and monitor the activities of prescribers.
* Three new violations of the Controlled Substances Act.