Wisconsin Medical Society

WISCONSIN HOSPITAL ASSOCIATION, INC.

May 12, 2017

Sharon Henes
Administrative Rules Coordinator
Department of Safety and Professional Services
Division of Policy Development
1400 East Washington Avenue, Room 151
P.O. Box 8366
Madison, WI 53708-8366

Re: Comments on CR 17-028 and EmR1706 from the Wisconsin Hospital Association and Wisconsin Medical Society regarding CSB 4

Dear Ms. Henes:

The Wisconsin Hospital Association and the Wisconsin Medical Society appreciate the opportunity to provide comment on CR 17-028 and EmR1706, which make changes to Wis. Admin Code § CSB 4 governing the operation of Wisconsin's Prescription Drug Monitoring Program (PDMP). Physicians, advanced practice nurse prescribers, physician assistants, dentists and other prescribers rely upon the dispensing data collected by the PDMP to help them provide efficient, high quality care to their patients. The ability to access and use statewide dispensing data is welcomed and embraced by physicians and health systems as a key infrastructure that helps prevent the abuse of opioids and other prescription drugs.

Since the implementation of the ePDMP earlier this year, health care providers have been identifying ways that the ePDMP can be improved to enable more efficient high quality care while maintaining or improving the usefulness of the PDMP in their efforts to help prevent the abuse of opioids and other prescription drugs. Achieving a maximally functioning PDMP system is particularly important for physicians and their health systems as they are under significant pressure to provide health care in the most efficient and cost-effective manner possible.

Those and other pressures are also contributing to ever increasing rates of physician burnout which ultimately impacts access to physician care in Wisconsin. Thus, it is important that regulations and processes are carefully tailored to balance and recognize impacts on care delivery efficiency, clinical

efficacy and quality of care, and the professional medical judgement of physicians and other prescribers.

With that desire to achieve a maximally functioning PDMP system that balances those shared policy goals and impacts, we recommend several changes to CSB 4 that are attached to this comment letter. In summary, those changes are the following:

1) **Recognition of medical delegation and agency.** To reduce regulatory compliance complexity and enable a better incorporation of PDMP data into physician and prescriber clinical workflows, we propose a change that explicitly recognizes that existing medical principles of agency and delegation apply to the review required under this chapter.

Practitioners operate in a team environment and regularly delegate medical acts to others. Under law, practitioners that delegate medical acts to their agents remain fully responsible for the care provided pursuant to the delegation. This clarifying change aligns with existing principles of medical delegation and any inappropriate delegation can be addressed by the practitioner's licensing board.

2) **Provide specificity on what is required to be reviewed.** We propose greater regulatory clarity to mandated practitioners and their electronic health record (EHR) vendors by providing specificity regarding what data elements must be contained in a record that will satisfy the practitioner's review obligation. This clarity will also help DSPS facilitate efforts to integrate PDMP data with prescribers' EHRs by providing regulatory certainty as to what information must be built into an EHR integration in order for a practitioner to meet his or her regulatory obligation.

Section 961.385(2)(b) states: "The board shall establish by rule a program for monitoring the dispensing of monitored prescription drugs. The program shall do all of the following…(b) Identify specific data elements to be contained in a record documenting the dispensing of a monitored prescription drug, including the method of payment and, subject to sub. (2m), the name recorded under s. 450.11 (1b) (bm)." The proposed list of data elements in the PDMP dispensing record that physicians and practitioners will be required to review are the data elements currently listed by the ePDMP and are contained in the existing list defined in CSB 4.04(2).

3) **Vendor summaries.** We propose maintaining the CSB's prohibition on a vendor simply providing a summary of PDMP data or a snapshot of PDMP data as a means to enable physicians and practitioners to meet the review mandate.

We understand the Board's intent to prohibit vendors from showing only a summary of PDMP data as a means to fulfill the practitioner mandate. But we are concerned that as written, the language in the emergency rule is creating barriers to PDMP-EHR integration efforts that would not simply show a summary of PDMP data. We propose that CSB 4.015 (2) be amended to more precisely address the CSB's intent of prohibiting a vendor from simply showing a summary of the mandated PDMP data to a practitioner.

4) **Require registration with ePDMP to address push notifications and law enforcement alerts.** Subject to flexibility granted to a practitioner by the Board, we propose making it clear that all mandated practitioners must register with the web-based ePDMP and maintain current contact

information so that the PDMP system can contact and alert a practitioner when the ePDMP receives a law enforcement alert.

This clarification recognizes that a practitioner could utilize a PDMP-EHR integration best designed for routine, day-to-day practice and utilize the ePDMP functionality to receive and read special "push" notifications for law enforcement alerts. By adding this clarification, practitioners and their EHR vendors will have additional and potentially less costly options for creating PDMP-EHR integration options focused on addressing routine, day-to-day utilization of PDMP data.

5) **Access to PDMP data and the Department's role.** We propose adding new language recognizing that upon request the Department shall make PDMP records, law enforcement agency alert information, and other information generated by the PDMP system indicating misuse or diversion of controlled substances available to a practitioner's vendor, provided the vendor enters into a data use agreement approved by the Department. This provision makes more explicit that the Department, and not just the department's data vendor, has a role in determining the terms upon which PDMP data gathered under this state program are made available to requesting health care providers.

6) **Address referrals to law enforcement.** It is our understanding that the Department recognizes that the current language regarding referrals to law enforcement in CSB 4.105(3) is inconsistent with the statute and we agree with that reading of the rule and statute. We also understand that the Department is working to make clear that mere non-compliance with the review mandate cannot be referred to law enforcement and we agree that changes need to be made to CSB 4.105(3). We are not offering specific language to amend CSB 4.0105(3) to the Department to address this issue at this time, but look forward to working with the Department as it revises CSB 4.105(3).

The Wisconsin Medical Society, the Wisconsin Hospital Association, and our members thank you for the opportunity to comment on CR 17-028 and EmR1706. If you have any additional questions, please contact either Mark Grapentine, Wisconsin Medical Society Senior Vice President Government Affairs and Legal Affairs at mark.grapentine@wismed.org or 866.442.3800, or Matthew Stanford, Wisconsin Hospital Association General Counsel at mstanford@wha.org or 608-274-1820.

PROPOSED CHANGES TO THE EMERGENCY RULE

Create CSB 4.02(6m) as follows:

CSB 4.02(6m) "PDMP dispensing record" means for each patient, a record comprised of the following data elements compiled by the PDMP system that are listed under CSB 4.04(2):

(a) The dispenser's full name.
(c) The date dispensed.
(d) The prescription number.
(e) The name and strength of the monitored prescription drug.
(f) The quantity dispensed.
(g) The estimated number of days of drug therapy.
(ge) Payment type.
(gm) The number of refills authorized by the prescriber.
(gs) The refill number of the prescription.
(h) The practitioner's full name.
(j) The date prescribed.
(L) The patient's full name or if the patient is an animal, the animal's name and the owner's last name.
(m) The patient's address, or if the patient is an animal, patient's owner's address, including street address, city, state, and ZIP code.
(n) The patient's date of birth, or if the patient is an animal, patient's owner's date of birth.
(o) The patient's gender.
(p) The name recorded under s. 450.11 (1b) (bm), Stats.

Modify CSB 4.105(1) and (2) as follows:

CSB 4.105 Practitioners' requirement to review PDMP dispensing records.

(1) The PDMP dispensing record about a patient shall be reviewed before the practitioner issues a prescription order for the patient. The required review may be performed by the practitioner or by the practitioner's agent in accordance with applicable standards of practice. The requirement that the PDMP dispensing record be reviewed does not apply if any of the following is true:

(a) The patient is receiving hospice care, as defined in s. 50.94 (1) (a).
(b) The prescription order is for a number of doses that is intended to last the patient 3 days or less and is not subject to refill.
(c) The monitored prescription drug is lawfully administered to the patient.
(d) Due to emergency, it is not possible to review the patient's PDMP dispensing record before the practitioner issues a prescription order for the patient.

(e) The patient's PDMP dispensing record cannot be reviewed because the PDMP system is not operational or due to other technological failure if that failure is reported to the board.

(2) A review of a summary of a PDMP dispensing record does not satisfy the requirement to review the patient's PDMP dispensing record under sub. (1). Except as otherwise provided by the Board:

(a) Any practitioner required to review the patient's PDMP dispensing record under sub. (1), shall register with the PDMP system and maintain current contact information.

(b) The PDMP system shall contact a registered practitioner upon receiving information from a law enforcement agency pursuant to s. 961.37(3) with instructions to access the PDMP system to view the law enforcement agency information.

(2m) Upon request, the PDMP dispensing records maintained by the PDMP system, information received by the PDMP system from a law enforcement agency pursuant to s. 961.37(3), and other information generated by the PDMP system indicating misuse or diversion of controlled substances shall be made available to a contractor of a health care provider to enable practitioners to access such information for patient care purposes if the contractor agrees to a data use agreement defining terms of use and access approved by the Department that are in accordance with this chapter. This subsection does not prohibit the Department or its vendor from releasing information without such data use agreement.