



January 22, 2019

Sue Mears  
Iowa Board of Pharmacy  
400 SW 8th St. Suite E  
Des Moines, IA 50309-4686

RE: ARC 4205C – Notice of Intended Action: Proposing rule making related to prescription monitoring program and providing an opportunity for public comment

*Submitted electronically via [sue.mears@iowa.gov](mailto:sue.mears@iowa.gov)*

To the Iowa Board of Pharmacy,

UnityPoint Health (UPH) is submitting comments on the notice of intended action to Chapter 37, Iowa Prescription Monitoring Program. The development of these proposed rules was instigated by the passage of HF 2377, and UPH appreciates the time and effort of the Iowa Board of Pharmacy and the PMP Advisory Council in this endeavor. Except as described in this letter, UPH supports the chapter rewrite as proposed, and we generally encourage efforts to collaboratively address the recent rise in opioid-related deaths and undertake proactive responses aimed at opioid abuse/addiction prevention and treatment. We particularly applaud the Board for retaining an exemption from PMP reporting for licensed hospital pharmacies for purposes of inpatient hospital care. That said, **UPH has operational concerns with the proposed changes to PMP reporting for hospitals**. We respectfully detail our concerns below and request your action.

### **PMP REPORTING BY HOSPITAL PHARMACIES**

Background: Currently, 657 IAC 37.3(1) provides an exemption for hospital pharmacies upon request:

- a. A licensed hospital pharmacy shall not be required to report the dispensing of a controlled substance for the purposes of inpatient hospital care, the dispensing of a prescription for a starter supply of a controlled substance at the time of a patient's discharge from such a facility, or the dispensing of a prescription for a controlled substance in a quantity adequate to treat the patient for a maximum of 72 hours.

Based on this rule, UnityPoint Health hospital pharmacies have applied for and received waivers from the Board of Pharmacy to be exempt from PMP reporting. As such, UPH hospital pharmacies do not presently report dispensing activities to the PMP nor have we invested in training or infrastructure to support such reporting duties.

As proposed in ARC 4205C, new section 37.7(1) on exempted dispensing and administration reads:

The dispensing or administration of a controlled substance as described in this subrule shall not be considered a reportable prescription. A pharmacy engaged in the distribution of controlled substances solely pursuant to one or more of the practices identified in this subrule shall notify the PMP administrator of the exempted practice, and the pharmacy shall not be required to report to the PMP.

- a. The dispensing by a licensed hospital pharmacy for the purposes of inpatient hospital care.
- b. The dispensing by a licensed pharmacy for a patient residing in a long-term care or inpatient hospice facility.
- c. The administration by a prescriber of a controlled substance for the purposes of outpatient procedures.

This rewritten subrule specifically links the pharmacy PMP reporting exemption to “one or more of the practices identified in this subrule,” in apparent reference to subparts (a) through (c). Hospital pharmacies are still exempt from PMP reporting for inpatient hospital care in subpart (a), although language referencing the dispensing of starter supplies at discharge and 72-hour take-home quantities has been removed. Pharmacies are still exempt from PMP reporting for patients in long-term care or inpatient hospice. Pharmacies are also exempt from PMP reporting when prescribers administered a controlled substance for outpatient procedures. In addition, the Board has revised the definition of “reportable prescription” in section 37.2 to specifically include a non-exclusive list of dispensing and administration activities:

1. The dispensing of a controlled substance to an emergency department patient;
2. The administration of a controlled substance to an emergency department patient at the discretion of the treating practitioner;
3. The administration or dispensing of an opioid antagonist to an emergency department patient;
4. The dispensing of a controlled substance sample; and
5. The dispensing of a controlled substance or opioid antagonist to a patient upon discharge from a hospital or care facility.

For hospital pharmacies, this laundry list seemingly includes some instances in which PMP reporting may be triggered – dispensing to ED patients and dispensing upon discharge. Presumably, there may be other unspecified instances that also require PMP reporting, although criteria are not detailed.

Scope of PMP Reporting: We are unclear of the extent to which hospital pharmacies are responsible for outpatient reporting as it is never explicitly stated. As proposed, pharmacies dispensing controlled substances pursuant to section 37.7(1)(a), (b) or (c) are exempt from PMP reporting. While subparts (a) and (b) relate to well defined settings, the reference to “outpatient procedures” in subpart (c) raises questions. While the term in the current rule is “outpatient care,” the proposed rule provides no guidance as to whether “outpatient procedures” has a different

interpretation. Without definition, we are uncertain as to whether this connotes a greater or equivalent scope of services or instead is a lesser subset of outpatient care.

We also seek clarification as to the relationship between the “outpatient procedures” exemption in section 37.7(1)(c) and the “reportable prescription” definition in section 37.2. Since pharmacies do not have PMP reporting duties for certain “outpatient procedures,” it is reasonable to interpret that some emergency department prescriptions listed in items 1 and 2 under “reportable prescription” and other prescriptions listed in items 4 and 5 may fall under the outpatient procedures exemption and may avoid reporting obligations. For instance, if a controlled substance is dispensed for a patient in the emergency department while the patient is having a procedure to set a broken bone, the controlled substance reporting may be exempt under section 37.7(1)(c), even though it is included within the definition of “reportable prescription.”

In addition, the use of a non-exclusive five-item list within the definition of “reportable prescription” is problematic by itself as there is no lead-in language to suggest to practitioners the criteria used to establish this list. This non-exclusive list, even when read in conjunction with section 37.7, does not provide sufficient notice to practitioners of what activities are reportable. In current law, the hospital pharmacy exemption with its inclusion of starter supplies and the 72-hour take-home supplies is clear and sets forth bright-line standards. As proposed, the vague definitional language in section 37.2 will result in inconsistent reporting and may place some hospital pharmacies in a situation where they could potentially over-report to assure compliance.

Outpatient Reporting Burden: Imposing PMP reporting duties on hospital pharmacies will be associated with increased costs and administrative burdens.

- HIPAA Disclosure: HIPAA requires logging of disclosures of information for purposes of treatment or patient authorization. Each PMP entry is considered a release of protected health information that is classified as an accountable disclosure. As such, hospital pharmacies will be required to separately log each PMP entry in EPIC as a HIPAA disclosure. This separate tracking will require additional time and effort and associated compliance costs.
- Decision Support Costs (Chart reviews and/or EPIC builds): Since the vast majority of controlled substances dispensed by hospital pharmacies are related to inpatient care, hospital pharmacies will need to identify those prescriptions which are subject to PMP reporting and do not qualify under the outpatient procedure exemption. UPH will need to employ decision support framework to assure reporting compliance. While there are several framework options, each requires time, training and costs.

The best-case scenario would be to embed this framework within our EPIC record. Currently, UnityPoint Health’s EPIC record does not have the capability to make this determination, which would require a costly report build as well as the associated time needed for development, training, testing and go-live. We do not want to invest in this EHR infrastructure until there are clear reporting directives.

In the short term, this reporting determination would require our hospitals to manually review patient charts to identify outpatient services deemed to be reportable prescriptions. Not only will this manual process be resource intensive, but it is likely to divert efforts from direct patient care. As a result, we anticipate that our hospitals may choose to report all controlled substances that do not squarely fall within the inpatient care exemption, instead of targeting our reporting by performing time-consuming chart reviews.

- PMP Reporting Interface: Since hospital pharmacies have been exempt from PMP reporting, we have not yet established an interface for PMP reporting as authorized under section 37.17. We believe that this interface is a must for our providers, pharmacists and others to stay productive and focused on the true concern, the patient, without diverting excess time to complying with data capture. We intend to work forthrightly with the Board to understand interface requirements so that we can understand if our EHR contains the data elements needed for capture and the effort needed to begin interface development. This process will take time and effort related to development, training, testing and go live and is likely to require contracted work from IT vendors to accomplish. There are costs associated with these efforts.

Potential Adverse Implications: In the absence of clearly defined reporting triggers, we are concerned that reporting will be inconsistent. For those pharmacies who over-report prescriptions outside the definition of reportable prescription, extraneous records may significantly add to the volume in the PMP database making it difficult for end users to arrive at the best conclusion when consulting the PMP. Healthcare professionals will be confronted with a larger number of providers and medications reported under a patient's PMP record. As a result, patient records may appear more robust and prescriber and dispenser practices may appear as outliers. This could negatively affect patients if healthcare professionals mistakenly conclude a patient is doctor shopping or drug seeking. Similarly, prescribers or dispensers could be unduly targeted for disciplinary review.

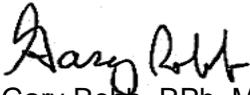
Request: UnityPoint Health encourages the Board of Pharmacy to revise the proposed PMP reporting requirements for hospital pharmacies. As written, the PMP reporting duties are unclear and will result in inconsistent reporting and increased implementation costs unless clarified.

- (1) Retain the Exemption in the Current Rule. We would suggest that the proposed rule retain the current exemption for inpatient hospital care, which also exempts dispensing of starter supplies at discharge and 72-hour take-home supplies. This will provide exemption status to hospital pharmacies and compliance certainty while we work with the Board to craft language that clearly delineates PMP reportable prescriptions and exemptions and mitigates administrative burdens and the risk of adverse implications.
- (2) Revise the Proposed Rule to Define Outpatient Procedure. We urge that outpatient procedure be included as a defined term within section 37.2. As the Board is crafting this definition, we would encourage that stakeholder input be solicited. In addition to outpatient procedure definition, this request would also entail harmonizing the definition of "reportable prescription" to avoid conflicting interpretations.

- (3) Additional Implementation Time: We would request additional time to implement training, workflow changes and operationalize a decision support tool. Ideally, we would request a delayed effective date of at least six months or, alternatively, a six-month delay in imposing any penalties for hospital pharmacy non-compliance.

We are pleased to provide comments to the proposed rule and its impact on our patients and integrated healthcare system. To discuss our comments or for additional information on any of the addressed topics, please contact Gary Robb or Ben Cappaert.

Sincerely,



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