**Massachusetts Chain Pharmacy Council**

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March 14, 2024

Mr. William Anderson

Office of the General Counsel

Massachusetts Department of Public Health

250 Washington Street

Boston, MA 02108 – 5183

Re: 105 CMR 222 – Massachusetts Immunization Information System

Dear Mr. Anderson:

I am writing on behalf of the members of the Massachusetts Chain Pharmacy Council to offer our comments on the proposed regulations at 105 CMR 222. We respectfully ask the Department to consider the following suggested changes to these proposed regulations.

**Pharmacy Data Reporting Period**

Section 105 CMR 222.100 would require all health care providers to report all new immunizations within 72 hours of the immunization administration. This reporting period has been reduced from the current reporting period of 7 days.

Immunizations are administered at retail pharmacies continuously throughout the business day. The 72-hour reporting deadline will therefore differ for each individual immunization, depending on the time of administration, and could therefore result in multiple reports being filed on a daily basis. We believe it would be more convenient for the providers, and we believe for the MIIS, if this language were amended to require the reporting of all immunizations administered within 72 hours of the end of each business day. This proposed language mirrors a similar provision that is contained in the Prescription Monitoring Program at 105 CMR 700.012 (A) (5).

**Required Data Collection from Recipients**

Section 105 CMR 222.100 would require health care providers to collect additional personal data from the immunization recipient, including their sex, gender, race, ethnicity and preferred language. Our member pharmacists know through experience that many consumers may object to providing some or all of this information. As currently written, the refusal to comply with the request for this data could result in a health care provider refusing to provide the vaccination. We would ask the Department to establish procedures for health care providers to follow in those cases where a consumer refuses to provide this required personal information.

The terms “sex” and “gender” are often considered to be interchangeable and the difference between the two terms is often misunderstood by consumers and medical providers. We would recommend the Department add separate definitions for both of these terms in order to alleviate any confusion and to provide guidance to the provider when requesting this information. The selection of the appropriate definitions should not be left to the opinion of the provider but instead should be based on the definitions included in the regulations. In order to avoid confusion, we would also request that the Department provide a set of options in the program field for these two terms to ensure uniformity of reporting.

**Reporting of Recipient’s Personal Information**

Section 105 CMR 222.105 would require a health care provider to fax an individual’s objection form to the Department within 24 hours of receipt. The provider is also required to change the data sharing status in the GUI in order to ensure the objection or withdrawal of objection is implemented within the MIIS. Our members question why a separate fax notification is required if the information must also be changed with the GUI. The proposed language appears to require a duplication of efforts for recording this information.

The requirement that the information be faxed limits the manner of transmission to a technology that is becoming increasingly outdated. Retail pharmacies would prefer language that does not limit the transfer of information by way of fax and would recommend the Department also allow for the transmission of this form through the Department’s graphic user interface.

**Conversion of Data Collection Systems**

The data systems used by pharmacies to report data to the MIIS are in most instances operated by third party providers. These providers will need to reprogram their systems in order to add the required new personal information fields. We would therefore urge the Department to engage with those system providers to ensure they can implement the necessary program changes within the time frame contemplated by the Department.

Thank you for your consideration of our views on these proposed regulations. I am available at your convenience if you need any further information regarding these issues.

Sincerely,

**Patrick J. Huntington**

Patrick Huntington

Legislative Counsel

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