TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

Economic Impact Statement

LSA Document #18-282

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses Description of the Rule

The Indiana State Department of Health (ISDH) is authorized by IC 16-19-10-8 to collect data relating to symptoms and health syndromes from outbreaks or suspected outbreaks of diseases that may be a danger to public health. The Electronic Reporting of Emergency Department Visit Abstract Data by Hospitals rule (currently in 410 IAC 1-2.4) defines who must submit data, what data they must submit, and how they must submit data to satisfy syndromic surveillance reporting in Indiana. The current rule, promulgated in 2005, is outdated regarding all data elements that must be submitted per federal mandate.

The proposed rule does the following:

- Amends the definition of Health Level 7 (HL7) to include language that the hospitals must use the criteria for electronic submission set by the Centers for Medicare and Medicaid Services (CMS) to replace language that referred to outdated versions of the system.
- Adds seven new variables to the data reporting requirements (discharge diagnosis, date and time of discharge, discharge disposition, patient race, patient ethnicity, triage notes, and patient care location name or unique identifier).
- Adds a one-week required notice of when hospitals need to inform ISDH they will be updating their syndromic surveillance feed to prepare and minimize downtime.
- Repeals the incorporation by reference section to remove outdated references to the old versions of HL7. The proposed rule modifies reporting requirements based on CMS Meaningful Use (MU) recommendations.

This proposed change to the rule is intended to keep Indiana's law aligned with the most up-to-date federal guidelines while also increasing data quality to the ISDH to help determine if an outbreak needs to be investigated and ensure facilities are reporting based on 410 IAC 1-2.4. The proposed rule will create a standard length of time needed to inform ISDH prior to updating a syndromic surveillance feed to minimize, if not eliminate, any downtime of their system. The number of businesses affected by this proposed rule change is limited to all hospitals that have an emergency department as well as the potential to affect all Hoosiers who engage in the healthcare system.

Economic Impact on Small Businesses

1. Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule.

Health care facilities with emergency departments will be subject to the proposed rule. The ISDH estimates more than 120 health care facilities with emergency departments will be affected due to the number of health care facilities with emergency departments. This rule will not have significant economic impact on the health care facilities with emergency departments that meet the definition of small business as the syndromic surveillance reporting requirements and reporting mechanisms are well established and have been practiced by many of these health care facilities with emergency departments for many years.

2. Estimate of the average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rule.

The proposed rule does not add any additional annual reporting, record keeping, or other administrative costs for small businesses to comply with the proposed rule. Though additional data fields are being collected, most facilities purge their data after a few weeks and would not add to record keeping or administrative costs.

3. Estimate of the total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rule.

The proposed rule does not increase the economic impact on small businesses for complying with the proposed rule.

4. Statement justifying any requirement or cost that is imposed on small businesses by the rule; and not expressly required by the statute authorizing the agency to adopt the rule; or any other state or federal law

The proposed rule does not impose any costs on small businesses. The proposed rule provides an updated definition of already required reporting information to the ISDH. There is a small requirement for small businesses to provide ample prior warning to when a system is being upgraded to avoid downtime of syndromic surveillance reporting.

Date: May 14,2024 1:11:07AM EDT DIN: 20181017-IR-410180282EIA Page 1

5. Regulatory Flexibility Analysis

Other factors considered:

A. Establishment of less stringent compliance or reporting requirements for small businesses.

The proposed rule provides an updated definition of already required reporting information to the ISDH.

Less stringent requirements could have devastating effects, resulting in the inability to identify a possible public health emergency or any necessary follow-up information.

B. Establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

The proposed rule has reporting timeframes that are recommended by the CMS Meaningful Use Guidelines.

- **C.** Consolidation or simplification of compliance or reporting requirements for small businesses. The proposed rule does not consolidate or simplify reporting requirements for small businesses.
- D. Establishment of performance standards for small businesses instead of design or operational standards imposed on other regulated entities by the rule.

The proposed rule does not establish different performance standards for small businesses. The proposed rule provides an updated definition of already required reporting information to the ISDH.

E. Exemption of small businesses from part or all of the requirements or costs imposed by the rule. The proposed rule does not exempt small businesses from part or all of the requirements imposed by the rule.

Conclusion

The proposed rule provides an updated definition of already required reporting information to the ISDH by the CMS. Less stringent requirements could have devastating effects, resulting in the inability to identify a possible public health emergency or any necessary follow-up information.

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