

Regulatory Analysis

I. Description of the Rule **History and Background of the Rule**

The origin for the proposed civil penalty schedule is in response to the adoption of 410 IAC 7-26 and the amendment of 410 IAC 7-23 to effectuate that adoption. This rule was originally adopted on December 4, 2003, and amended on March 19, 2025. Out of compliance items based on 410 IAC 7-26 are classified in a tiered violation system, and classified as either: Priority (P), Priority Foundation (Pf) or CORE. These designations replaced the previous “Critical and Non-Critical” designation approach. The new risk-based system categorizes violations based on their risk to contribute to foodborne illness or injury.

Priority: Directly Contributes to Foodborne Illness

Priority Foundation: Supports or enables a violation to become a “Priority”

CORE: General Sanitation and Operational Control Violations that pose minimal risk to health hazards. Implementing a three-tier violation classification system better identifies risk-based controls within Retail Food Establishments, minimizes the physical and financial burden on industry, the consumer and regulatory partners. The implementation of the civil penalty rule empowers retail food establishments to reduce repeat violations, reduces follow-up inspection requirements from local health departments, and leads to more efficient and cost-effective environments for all parties.

a. Scope of the Rule- The proposed rule will establish a revised civil penalty schedule for retail food establishments in violation of rule provisions in 410 IAC 7-26. This rule was amended in LSA #24-375 as part of the 410 IAC 7-26 adoption. However, civil penalties for provisions of 410 IAC 7-26 that did not previously exist in 410 IAC 7-24 were not included in that rulemaking as part of the Indiana Department of Health’s commitment to education retail food establishments on new sanitary standards before enforcement actions occurred.

The rule amendment includes factors the department will consider when determining penalties to be assessed within ranges established within the penalty schedule. The proposed rule explicitly provides violation designations (Priority, Priority Foundation and CORE) that constitute the severity of identified health hazards for purposes of the Indiana Department of Health to sustain compliance from retail food establishments under IC 16-42-5.

b. Statement of Need-

As a longstanding policy of the department, the proposed rule ensures fair and business-focused enforcement of Indiana's public health laws by ensuring that retail food establishments are afforded an opportunity to correct violations of 410 IAC 7-26 before civil penalties are imposed. Civil penalties are in place to continue to ensure regulated retail food establishments are compliant with state law to further our mission to promote, protect and improve the health and safety of all Hoosiers. The civil penalty rule was updated in March 2025 to reclassify violation risk categories into the new categories set forth in 410 IAC 7-26 (Priority, Priority Foundation and CORE). With the adoption of this rule, establishments with a history of noncompliance will be issued penalties in an amount based on the inherent risk of the violation itself.

This amendment requires the regulatory authority to offer RFEs the opportunity to enter corrective plans before imposing civil penalties. This requirement mirrors obligations the state has under Indiana Code.

c. Statutory Authority for the Proposed Rule-

This amendment requires regulatory authorities, such as the local health departments, to offer RFE the opportunity to enter corrective plans before imposing civil penalties. This requirement mirrors obligations that the state has under Indiana Code and creates an industry safeguard from excessive penalties

d. Fees, Fines, and Civil Penalties-

This rule complies with IC 4-22-2-19.6(b)(3) because this rule sets a range of potential dollar amounts for civil penalties imposed and sets forth the factors that will be considered to determine the penalty imposed within the range.

II. Fiscal Impact Analysis

a. Anticipated Effective Date of the Rule-

The proposed rule will follow an approval schedule based on the Office of Budget Management and Budget Committee meeting schedules.

Anticipated Dates

OMB Submission: 7/9/2025

Budget Committee Presentation: 8/20/2025

The Notice of First Public Comment Period: 9/3/2025

Public Comment Deadline: 10/03/2025
Public Hearing Date: 10/08/2025
IDOH Executive Board Meeting: Date TBD
Submission to Attorney General's Office: 11/03/2025
Proposed effective date of rule: 02/18/2026

b. Estimated Fiscal Impact on State and Local Government-

The Indiana Department of Health does not anticipate an impact on state revenue. The department has no data to further assess previous civil penalty enforcement cases pursued by local health departments. However, this amendment should not affect local revenue because this rule merely creates an enforcement mechanism for provisions of 410 IAC 7-26 and does not create independent requirements on local governments who were already expected to offer food establishments an opportunity to correct before imposing civil penalties.

c. Sources of Expenditures or Revenues Affected by the Rule-

All civil penalties assessed under this proposed rule would be deposited into either the local or state general fund per IC 16-42-5-28.

III. Impacted Parties

While this rule applies to both retail food establishments and wholesale food establishments, this amendment will only apply to retail food establishments. The Indiana Department of Health does not have the total estimated number of registered retail food establishments spread across all 95 counties. However, all facilities (excluding home-based vendors) that sell, store, package, repackage, serve, or vend food for human consumption are required by IC 16-42-1-6 to register with their local regulatory authority.

As subordinates of the Indiana Department of Health on food safety matters, local health department food inspectors may carry out food inspection/investigation responsibilities per IC 16-42-5-24 under the guidance concerning the interpretation of food regulations across the state, so the enforcement of state laws and rules are uniformly executed.

IV. Changes in Proposed Rule

This proposed amendment allows regulatory authorities to substantively enforce provisions of 410 IAC 7-26 that did not have comparable provisions in the now repealed 410 IAC 7-24. The rules identified with 410 IAC 7-26 "*Indiana Retail Food Establishment Sanitation Requirements*" are required by the United States Food and Drug Administration (FDA) as a recipient of federal funding. The Indiana Department of

Health is annually audited by the FDA on multiple components of our code to ensure an adequate level of federal sanitation standards are met within Indiana sanitation requirements. The proposed tiered civil penalty fee schedule has been modified to associate a fee to the violations likeliness to contribute to foodborne illness or injury based on recommendations from the FDA. The fee schedule is classified as follows:

\$0-\$100: CORE Violations. Violations cited under this category present minimal risk to foodborne illness or injury.

\$100-\$150: Core/Priority Foundations. Violations cited under this category present an increased risk to foodborne illness or injury.

\$150-\$250: Priority/Priority Foundation. Violations cited under this category pose indirect or immediate risks to foodborne illness or injury.

\$250-\$500: Priority Foundation: Imminent Health Hazards

Additionally, a corrective action requirement has been proposed within the body of the 410 IAC 7-23 to ensure industry is provided adequate notice of violation and opportunity to correct prior to civil penalties levied upon their business in a manner similar to IC 4-21.5-2.5. The timeline for correction before civil penalties are imposed is set by 410 IAC 7-26-475 and 476.

V. Benefit Analysis

a- Estimate of Primary and Direct Benefits of the Rule

The primary benefit of this rule is to address retail food establishments' history of noncompliance with food safety requirements, minimize the likeness of foodborne illness, and prioritizing employee training while increasing the facilities overall sanitation. The proposed corrective action requirement will allow local health departments to balance the need to protect public health with Indiana's commitment to supporting small businesses. To prevent levying penalties upon retail food establishments, local health departments are encouraged to work collaboratively with the establishment by creating a supportive prevention-focused model that prioritizes public health to maintain compliance with 410 IAC 7-26.

b- Estimate of Secondary or Indirect Benefits of the Rule

To ensure minimal disruption to the retail food establishments business model, an indirect benefit of the rule is the reimbursement of the local health departments time spent at the facility obtaining compliance through continued coaching and training to further promote the health of Hoosiers that consumer product within regulated establishments.

c- Estimate of Any Costs Savings to Regulated Industries

There are currently no direct cost savings for regulated industries. However, by complying with 410 IAC 7-26, these industries avoid penalties associated with noncompliance under 410 IAC 7-23. Therefore, any cost savings resulting from this rule stem from retail food establishments maintaining sanitation compliance in accordance with 410 IAC 7-26.

Regulated entities subject to compliance with sanitation requirements under the authority of the Indiana Department of Health have received comprehensive training and resources from IDOH, Local Health Departments, and the Indiana Restaurant & Lodging Association several months prior to the enforcement of 410 IAC 7-26 and the proposed civil penalty rule. Allotted time for industry adjustment to the new code was essential prior to issuing penalties for non-compliance.

VI. Cost Analysis

a. Estimate of Compliance Costs for Regulated Entities

The proposed rule does not increase compliance costs for retail food establishments because this rule only creates civil penalties for provisions of 410 IAC 7-26 that did not exist in 410 IAC 7-24. Therefore, this rule only creates an enforcement mechanism for 410 IAC 7-26 and does not create its own compliance costs. The rule does not require establishments to alter their business or staff training to comply, nor does it require establishments to take additional action. The proposed rule only impacts an establishment with a history of noncompliance after violations during the correction action plan period are not brought into compliance.

b. Estimate of Administrative Expenses Imposed by the Rules

The rule amendment does not increase administrative expenses for the Indiana Department of Health, the local health departments or regulated entities. The amendments to this rule will be implemented by the local health departments but they were already ensuring compliance with 410 IAC 7-26 and collecting civil penalties under this rule. Retail food establishments subject to this rule will not face additional administrative expenses because (1) this rule only applies to those establishments determined to be noncompliance with 410 IAC 7-26 and (2) because the proposed corrective action requirement can be fulfilled by an inspection checking for compliance with 410 IAC 7-26.

c. The fees, fines, and civil penalties analysis required by IC 4-22-2-19.6

This rule complies with IC 4-22-2-19.6(b)(3) as it sets the potential dollar range for imposed civil penalties and considers the factors which present food safety risks to human health to determine the penalty imposed within an applicable range.

VII. Sources of Information

a. Independent Verifications or Studies

The Indiana Department of Health did not independently verify this data or rely on any studies. However, the Indiana Department of Health regularly interacts with local health officers and environmental health specialists subordinate to the state department under IC 16-42-5-24 to provide guidelines to uniformly interpret state regulations, food safety trends, and noncompliance concerns. Feedback from local health departments did not result in IDOH determination that an increase or decrease in funds would be generated from the proposed civil penalty rule.

b. Sources Relied Upon in Determining and Calculating Costs and Benefits

No other sources were relied on when determining and calculating the costs and benefits of this rule.

VIII. Regulatory Analysis

This proposed rule does not increase compliance costs for regulated entities. This rule will help to drive more competitive business models and ensure overall consumer protection regarding food safety.

Consumers are more likely to shop and consume in clean retail stores, less risks associated with foodborne illnesses will lower the costs of loss of business, loss of products, and other contributing factors hindering businesses due to non-compliance with state and federal regulations.

The overall conclusion resulting from this rule is that the benefits to industry will exceed any associated industry costs.

IX. Contact Information of Staff to Answer Substantive Questions

Kian Hoss
Staff Attorney
Indiana Department of Health
2 N Meridian St.
Indianapolis, IN 46204
kihoss@health.in.gov