TITLE 410 INDIANA DEPARTMENT OF HEALTH

Readoption Reviews

LSA Document #24-588

410 IAC 1-1, IMMUNIZATION OF SCHOOL CHILDREN

I. Statement Whether the Subject Matter Covered by the Rule Remains Carried out by the Agency

The statutory requirement for school immunizations is still effective so the rule continues to be needed. Schools must still document student compliance with the requirements and must report to IDOH so IDOH can perform necessary work with the reported information.

II. Rationale for the Continued Need for the Rule

Under IC 20-34-4-2(e), IDOH is obligated to have rules setting out required immunizations for children and method of documenting proof of immunity. This rule sets forth how to meet the documentation requirements in the statute, when student immunization records must be provided, and how schools are to report to IDOH. It is needed so schools understand what they must do to comply with student immunization requirements.

III. Analysis of fees, fines, and civil penalties under IC 4-22-2-19.6

There are no fees, fines or civil penalties imposed under this rule.

IV. Cost-Benefit, Economic Impact, Fiscal Impact, or Regulatory Burden Statements

No previously published cost-benefit, economic impact, fiscal impact, or regulatory burden statements are available from the Indiana Register. A copy of a regulatory burden statement that meets the requirements of IC 4-22-2-22.7 follows:

1. Description of Rule

   a. History and Background of the Rule – This rule, 410 IAC 1-1, has been in place since 1976 and ensures that school children in Indiana are properly immunized. It was last updated in 2009.

   b. Scope of the Rule - The scope of this rule is to allow IDOH to expand or modify the list of immunizations required by IC 20-34-4-2. This rule also sets the notification requirements for immunizations, so that IDOH can maintain the Children & Hoosiers Immunization Registry Program.

   c. Statement of Need - This rule is required by IC 20-34-4-2(e).

   d. Statutory Authority for the Proposed Rule - IC 20-34-4-2

   e. Fees, Fines, and Civil Penalties – There are no fees, fines, or civil penalties.

2. Fiscal Impact Analysis

   a. Anticipated Effective Date – January 1, 2026

   b. Estimated Fiscal Impact on State and Local Government – This rule does not fiscally impact state or local government. This rule requires schools to report immunization data to IDOH, but this reporting requirement was set by IC 20-34-4-6(a). The CHIRP registry is free for use so schools do not have a cost associated with the reporting method required by IDOH.

   c. Sources of Expenditures or Revenues Affected by the Rule - This rule does not impact the revenue of state or local government.

3. Impacted Parties - The impacted parties of this rule are the individual children who must receive immunizations, the healthcare providers who must submit immunization data to IDOH, the schools who must obtain immunization data

from parents, and IDOH, who maintains the immunization database. For data on the number and percentage of Indiana students vaccinated annually, please see https://www.in.gov/health/immunization/school-immunization-data/. Indiana has approximately 2,460 elementary schools, 1,500 middle schools, and 850 high schools.

4. Changes in Proposed Rule - None

5. Benefits Analysis

a. Estimate of Primary and Direct Benefits of the Rule - The benefit of this rule is to ensure that school children do not miss school from illness. Further, this rule protects the public by reducing the possibility of disease by ensuring immunity. The benefit of prevention is difficult to quantify and IDOH is unaware of any studies evaluating the cost and benefit of immunization in Indiana, but it is significant. However, the cost imposed by this rule itself is minimal because it operationalizes requirements from statute and imposes minimal costs of its own. Therefore, while the benefits of disease prevention are difficult to quantify, the low regulatory burden shows that the benefits of this rule outweigh any costs. The clarity this rule provides benefits those who must implement the immunization requirements because they understand what they need to do to comply with documentation and reporting requirements.

b. Estimate of Secondary or Indirect Benefits of the Rule - An indirect benefit of this rule to the public is economic productivity because families will not have to miss work to care for ill children and will not have to spend money for treatment. IDOH approximates that there are 1.6 million children under 18 in Indiana who would be impacted by this rule, but IDOH cannot quantify the number of families that would be impacted by this rule because families can have multiple children. Further, IDOH cannot quantify the lost productivity from failure to be immunized because IDOH is not aware of studies specific to this topic.

c. Estimate of Any Cost Savings to Regulated Industries - There are minimal cost savings to this rule. The immunization requirements in rule currently matches the immunization requirements in Indiana Code. Therefore, any cost savings are from the fact that hospitals and schools can report vaccination status electronically to the IDOH immunization registry, CHIRP, authorized under IC 16-38-5-1. 410 IAC 1-1-3 also creates cost savings to comply with IC 20-34-4-5(a) by setting the documentation sufficient to constitute an immunization record.

6. Cost Analysis

a. Estimate of Compliance Costs for Regulated Entities - There are no compliance costs specifically from this rule because IC 20-34-4-6(a) creates the reporting requirements set by this rule.

b. Estimate of Administrative Expenses Imposed by the Rule - There are no administrative expenses imposed by this rule.

c. The fees, fines, and civil penalties analysis required by IC 4-22-2-19.6 - There are no implementation costs to this rule because this rule matches Indiana Code.

d. If the implementation costs of the proposed rule are expected to exceed the threshold set in IC 4-22-2-22.7(c)(6) – There are no implementation costs because this is a readoption.

7. Sources of Information

a. Independent Verifications or Studies - IDOH did not independently verify the information in this analysis or rely on any studies.

b. Sources Relied Upon in Determining and Calculating Costs and Benefits - IDOH did not use any outside sources to determine the costs and benefits of this rule and did not consult with industry groups.

8. Regulatory Analysis – This rule only imposes minimal costs to children being immunized and their families, and providers who must report to IDOH because the vaccination requirements and reporting requirements already exist in Indiana Code. Because this rule mimics statute, there is low to no burden on regulated entities or individuals that is set specifically by this rule. While the benefits of this rule are unquantifiable, the low burden shows that the benefits outweigh any costs. The clarifications of documentary and reporting requirements do not add cost to the requirement of the immunization in the statute.

V. Alternative Methods of Achieving the Purpose of the Rule

IDOH is obligated under IC 20-34-4-2(e) to adopt rules concerning (1) required immunizations; (2) a child's age for administering each vaccine; (3) adequately immunizing doses; and (4) method of documentation of proof of immunity. If this rule and IC 20-34-4-2(e) were both repealed, the alternative method for achieving the purpose of the rule would be for IC 20-34-4 to either list these standards specifically or to adopt standards set by organizations like the Centers for Disease Control and Prevention or the United States Public Health Service Advisory Committee on Immunization Practices.

VI. Complaints and Comments

The only complaint received is from schools raising concerns that FERPA and parental consent prohibit them from providing data to the state’s system. The department has been working with schools to reduce manual data entry and hopes to eliminate any manual reporting for schools using a school information system with HL7 capacity by the end of 2025.

VII. Difficulties Encountered

The department is using grant funds to develop and publish a HL7 message segment to allow schools and providers to report immunization information directly to the state system rather than rely on manual data entry. FERPA is a barrier for schools and reporting of immunizations to the state as it requires parental consent.

VIII. Changes in Technology, Economic Conditions, or Other Factors

Improvements in technology have reduced the need for manual data reporting to IDOH and IDOH continues to work with regulated entities to minimize reporting burdens.

IX. Other State or Federal Requirements

Indiana requires immunization against (1) diphtheria; (2) pertussis (whooping cough); (3) tetanus; (4) measles; (5) rubella; (6) poliomyelitis; (7) mumps; (8) varicella; (9) hepatitis A; (10) hepatitis B; and (11) meningitis pursuant to IC 20-34-4-2. Indiana includes these immunizations in 410 IAC 1-1-1 and includes any additional immunizations recommended by IDOH and the CDC.

Indiana’s immunization requirements match Ohio, South Dakota, Kentucky and Idaho. Michigan and Illinois do not require Hepatitis A vaccinations but otherwise share the vaccination requirements. While Indiana’s Hepatitis A vaccination requirement is a more stringent standard than Illinois’s requirements or Michigan’s requirements, there have been several Hepatitis outbreaks in Indiana since 2017 and vaccination against Hepatitis A is critical to prevent the spread of Hepatitis. As noted below, Indiana’s standard is less stringent than Ohio (which requires influenza, pneumococcal disease and rotavirus) and states like Illinois and South Dakota (which place stricter requirements on the type of immunization documentation.

Illinois requires the same immunizations as Indiana in 77 Ill. Adm. Code 665.230 and 240 except that Illinois does not require Hepatitis A. Illinois requires proof of immunity under 77 Ill. Adm. Code 665.250 that is more strict than Indiana’s standard in 410 IAC 1-1-3 because Illinois requires laboratory evidence of immunity for varicella, hepatitis B, measles after July 1, 2022, and mumps if a physician does not verify the date of illness.

South Dakota requires the same immunizations as Indiana in SD Codified Law 13-28-7.1 but unlike 410 IAC 1-1-3, only accepts certification from a physician that the child received or is receiving the vaccination or certification from a physician that immunization would endanger the child's life or a written statement from a parent that immunization would be contrary to their religious doctrine.

Ohio, in ORC Ann. 5104.014, requires the same immunizations as Indiana but also requires immunization against influenza, pneumococcal disease, and rotavirus. Proof of immunization must be written evidence satisfactory to the person in charge of admission to the school.

Kentucky, in 902 KAR 2:060, requires the same immunizations as Indiana though the immunization requirements are listed in a schedule based on age. Kentucky also requires certificates of immunization signed by a physician; an advanced practice registered nurse; a physician assistant; a pharmacist; the local health department administrator; or a registered nurse or licensed practical nurse designee of a physician, local health department administrator, or other licensed healthcare facility.

Michigan, in Mich. Admin. Code R 325.176, requires the same immunizations as Indiana except for Hepatitis A. Michigan only allows a certificate of immunity to be certified by a health professional or local health department.

Idaho, in IDAPA 16.02.15.100, requires the same immunizations as Indiana. Under IDAPA 16.02.15.105, students are not required to obtain the required immunizations if the student has laboratory proof of immunity or a disease diagnosis from a healthcare professional.

X. Previous Amendments

This rule has not been amended since its adoption in 2009.

XI. Integration into Indiana Code

The substantive content in this rule could be integrated into Indiana Code because the list of immunizations in 410 IAC 1-1-1 mirrors IC 20-34-4-2. The immunization record requirement in 410 IAC 1-1-2 matches the requirements in IC 20-34-4-5 and the reporting requirement in 410 IAC 1-1-4 matches the requirements in IC 20-34-4-6. The only difference is that 410 IAC 1-1-3 documentation of immunization can come from a healthcare professional, from the state immunization registry, or from the school corporation. IC 20-34-4-5(a) only allows documentation to come from the healthcare professional that administered the immunization or from the state immunization registry.

XII. Contact Information of Staff to Answer Substantive Questions

Ann Z. Knotek, Staff Attorney, Indiana Department of Health. (317) 233-7874; aknotek@health.in.gov

410 IAC 1-2.5, DISEASE REPORTING AND CONTROL

I. Statement Whether the Subject Matter Covered by the Rule Remains Carried out by the Agency

IC 16-41-2-1 gives IDOH the authority to pass administrative rules that establish reporting, monitoring, and preventative procedures for communicable disease reporting and control. 410 IAC 1-2.5 is the latest version of the rule first adopted on November 25, 2015, and readopted on November 12, 2021. The subject matter of 410 IAC 1-2.5 comprises a fundamental function of IDOH as the public health authority. IDOH is further required by IC 16-41-2-1 to publish a list of reportable communicable diseases; other diseases or conditions that pose a serious health risk; and control measures for each disease/condition on the IDOH website.

II. Rationale for the Continued Need for the Rule

There is a continued need for 410 IAC 1-2.5. Along with definitions and a list of individual diseases and conditions, the rule gives specific directions for local health officers to implement, including timelines for reporting, disease-specific precautions, and treatment protocols. The rule allows for expedited reporting of diseases to protect the citizens of Indiana without the delay of the legislative process.

Readoption of 410 IAC 1-2.5 will have an unchanged impact on regulated entities, e.g., the physicians, hospitals, and laboratories who are mandated reporters. The rule does not have a direct impact on persons who pay taxes or fees for government services or for the consumers of products and services affected by the rule.

410 IAC 1-2.5 achieves the regulatory goal of administering the list of communicable diseases and other diseases/conditions and their control in the least restrictive manner while incorporating best practices as referenced by the statute, namely the United States Centers for Disease Control and Prevention (CDC) and the Counsil of State and Territorial Epidemiologists referenced in IC 16-41-2-1.

410 IAC 1-2.5 is written for ease of comprehension to the greatest extent possible in that it defines terms, provides general guidance to reporters, then follows up with disease/condition-specific guidelines for practitioners and local health officers.

410 IAC 1-2.5 does not contain any fees, fines, or civil penalties for mandatory reporters.

III. Analysis of fees, fines, and civil penalties under IC 4-22-2-19.6

There are no fees, fines, or civil penalties for reports to IDOH pursuant to this rule.

IV. Cost-Benefit, Economic Impact, Fiscal Impact, or Regulatory Burden Statements

The following Economic Impact Statement was published in the Indiana Register on June 10, 2015, to which no revisions are necessary: 20150610-IR-410150039EIA

V. Alternative Methods of Achieving the Purpose of the Rule

IC 16-41-2-1 requires IDOH to publish a list of reportable communicable diseases, other diseases or conditions that pose a serious health risk based upon the characteristics of the disease or condition, and control measures for the diseases and conditions on the IDOH website. Additionally, IDOH "may adopt rules under IC 4-22-2 that establish reporting, monitoring, and preventive procedures for communicable diseases." 410 IAC 1-2.5 is a long administrative rule. Successive versions of the rule have been filed and repealed since the rule was first promulgated in 1976. The rule takes a "belt and suspenders" approach to communicable disease reporting in that the list of reportable diseases is published both on the IDOH website and included in the administrative rule. IDOH continually evaluates the requirements of the rule to ensure it meets current standards and has removed diseases/conditions to be reported when appropriate to lessen the burden on mandatory reporters, e.g., medical providers, health care facilities, and laboratories.

VI. Complaints and Comments

IDOH receives occasional complaints from health care providers who are mandatory reporters. When complaints are received, IDOH works with the providers to understand the burden placed on them by the rule. Then, IDOH clarifies the situation and works to decrease the burden on reporters while still obtaining the information necessary to protect public health.

VII. Difficulties Encountered

IDOH does not have difficulty administering the rule as administration of the rule is a routine function of the department and there is a multi-disciplinary group within IDOH with responsibility for the rule.

VIII. Changes in Technology, Economic Conditions, or Other Factors

Updates may be needed to clarify reporting requirements in consideration of updated technology. IDOH is unaware of any way in which economic conditions or other factors have affected the rule.

IX. Other State or Federal Requirements

All the states reviewed have detailed statutory and regulatory schemes for the reporting and control of communicable and other reportable diseases and conditions. Most are similar to Indiana in that they include a lengthy administrative rule. Illinois' administrative scheme is more complex than Indiana's in that it involves multiple reporting steps. Other states involve broader reporting groups; for example, Kentucky requires "heads of household" to report, Michigan and Idaho require schools to report, Ohio requires poison control centers and pharmacies to report, and Idaho also requires day care and food service facilities to report. South Dakota's rule is less detailed than Indiana's in that it does not include detailed prevention and treatment measures for each communicable or reportable disease.

Federal Regulations –N/A.

Illinois – Authority for the Notifiable Diseases and Conditions Code is found in 77 Ill. Adm. Code 690 and references three statutes: 745 ILCS 45 (reports are confidential and reporters are granted immunity), 20 ILCS 2305 (Illinois Department of Public Health to investigate the causes of dangerously contagious or infectious diseases, especially epidemics, and restrict/suppress such; state department can act for local authorities where they fail/refuse to act), and 20 ILCS 2310. Notifiable diseases and conditions are to be reported to local health authorities, who in turn report to the state department of health pursuant to 77 Ill. Adm. Code 690. Pursuant to § 690.10, there are three classes of reportable diseases, with the most important class reportable within three hours, the second class within twenty-four hours, and the third class within three days. 77 Ill. Adm. Code 690.110 references diseases/conditions that were reportable in the past but are no longer so, as well as diseases/conditions reportable but contained in different sections of the code. Other sections cover reporting; detailed control procedures for individual diseases/conditions; sexually transmitted diseases; death where the decedent had a known or suspected communicable disease; isolation, quarantine, and closure; and registries. Illinois divides its communicable diseases into three categories with different lengths of time windows for reporting. Illinois' reporting system is more complex than Indiana's, involving multiple steps of reporting.

Kentucky – KRS §214.010 requires medical professionals and "every head of family" to report all designated diseases to the local health board pursuant to administrative rule. Kentucky's administrative rule on communicable diseases is found at 902 KAR 2 and is divided into chapters on reportable disease surveillance (comparable to Indiana's rule); inspections and control procedures; surveillance and screening of carriers and selected groups; immunization; rabies control; sexually transmitted diseases; tuberculosis detection, prevention, and control; and HIV test counseling. Kentucky's provision that every "head of family" is responsible for reporting communicable diseases greatly broadens who is a potential reporter of communicable diseases in Kentucky.

Michigan – The Michigan statute on communicable diseases is found at MCLS § 333.5115 and gives the Michigan Department of Health authority to establish minimum procedures and standards for administration and enforcement of communicable disease and infection laws. Administrative rules on communicable disease and infection are found at Michigan Administrative Code Rule 325.171. The rule is divided into sections on definitions; disease reporting; reporting and surveillance requirements; investigations; procedures for physicians, local health officers, and schools for disease and infection control; immunizations, venereal disease, and pregnancy care; tuberculosis; specimen submission;

rabies/rabid animals; confidentiality; and newborn eye prophylaxis. Michigan includes schools as mandatory reporters within its program and is therefore broader than Indiana's reporting program.

Ohio – The authority of the Ohio Department of Health to quarantine and isolate individuals and for disease control and prevention is found in the statute establishing the power of the department, ORC §3701.13. The administrative rule on communicable diseases is found at Chapter 3701-3 of the Ohio Administrative Code. This rule consists of sections on definitions; a list of diseases to be reported; reporting of occupational diseases; air/blood-borne diseases; notification; laboratory result reporting; HIV tests and reporting; isolation; reporting by poison control centers and other health-related entities; reporting requirements for pharmacies; drug overdose reporting; animal bites; and reports of rabid mammals. In Ohio, poison control centers and pharmacies are mandated reporters, broadening the number of mandatory reporters over that of Indiana's program.

Idaho – The first section of the Idaho Administrative Code containing the various sections on reportable diseases references the legal authority for the rule, citing to several statutes. IDAPA 16.02.00. The sections of IDAPA 16.02.10 cover: documents incorporated by reference; disclosure of information; definitions (two sections); persons required to report reportable diseases; conditions, and school closures; access to medical records; penalty provisions; delegation of powers and duties; where to report reportable diseases; report contents and method of reporting; reportable or restrictable diseases, conditions and reporting requirements; testing for certain reportable diseases when informed consent is not possible; investigation and control of reportable diseases; preventing spread of health hazards from dead human bodies; special disease investigations; and sections for reporting and control measures for daycare facilities, food service facilities, and schools. Idaho has a detailed and extensive administrative rule for communicable diseases, with daycares, schools, and food service facilities also included as reporters and participants in the program; Idaho's list of mandatory reporters is broader than Indiana's.

South Dakota – South Dakota's statute for its communicable disease program is found at S.D. Codified Law § 34-22-1. Much of the program is contained in statute, of which a number of sections have been repealed. §34-22-9 establishes that the South Dakota Department of Health shall direct the state-wide system for communicable disease prevention, control, and treatment, including the promulgation of administrative rules to: (1) Conduct communicable disease surveillance which includes detection, assessment, and analysis; (2) Prescribe criteria for communicable disease case definitions; (3) Prescribe procedures for communicable disease case and contact notification, referral, and management; (4) Prescribe methods and procedures for the prevention and control of communicable disease; (5) Prescribe methods and procedures for the control of communicable disease patients and carriers, including the monitoring, quarantine, and isolation of any patient or carrier; (6) Prescribe medical and posttreatment supervision measures for communicable disease patients and carriers; (7) Prescribe methods and procedures for the prevention and control of occupationally-related communicable diseases; and (8) Prescribe procedures for infection prevention measures for communicable disease control and prevention. Rules on these topics are found in Article 20, Chapters 1-3 of South Dakota's administrative code. The rules cover definitions and reportable diseases and conditions; reporting and surveillance; and control measures.

X. Previous Amendments

There have been several versions of the communicable disease rule since 1976. The current rule, 410 IAC 1-2.5 was adopted on November 25, 2015.

XI. Integration into Indiana Code

It would be difficult to shift the entirety of the subject matter contained in this rule to statute due to its large scope, particularity, and need for periodic updating (the first and second versions of the rule were in effect for twelve years, the third for fifteen years, and the most recent for ten to date). IDOH is in the process of updating this rule and can evaluate what may be able to be in statute rather than rule.

XII. Contact Information of Staff to Answer Substantive Questions

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410 IAC 1-3, INFECTIOUS WASTE

I. Statement Whether the Subject Matter Covered by the Rule Remains Carried out by the Agency

Prior to March 24, 2025, 410 IAC 1-3 Infectious Waste was housed with the Infectious Disease Epidemiology and Prevention Division (IDEPD). It has been transferred to the Consumer Services and Healthcare Regulation (CSHCR) commission. While under IDEPD, there have been approximately two investigations since 2016 in which Indiana Department of Health (IDOH) personnel were highly engaged in investigation related to non-adherence to State rule requirements.

Eighty Indiana counties have trained staff and implemented systems to address conducting environmental inspections based on the requirements of this rule.

II. Rationale for the Continued Need for the Rule

Yes, the problem this rule was intended to address still exists. There is still a need for uniform requirements for handling infectious waste in Indiana. The State department is required by IC 16-41-16-8 to adopt rules after considering multiple federal guidelines such as the EPA, CDC, OSHA, DOL, and Environmental Management. The Rule has not changed since 1998, so it may be out of date.

Counties have enacted ordinances and have their own investigators. The Rule is the least restrictive as possible. The Rule is easy to comprehend. Counties are using HFI funds to fund inspectors and inspections. The statute allows the state to designate agents to inspect and investigate. So, if funding is stable, the Rule has practicable enforcement because counties are willing to do the work.

III. Analysis of fees, fines, and civil penalties under IC 4-22-2-19.6

The civil penalties are set forth in IC 16-41-16-10 though IDOH will need to update its rules to set the factors for determining what amount of penalty is issued or address it through statutory transfer.

IV. Cost-Benefit, Economic Impact, Fiscal Impact, or Regulatory Burden Statements

No previously published cost-benefit, economic impact, fiscal impact, or regulatory burden statements are available from the Indiana Register. A copy of a regulatory burden statement that meets the requirements of IC 4-22-2-22.7 follows:

1. Description of Rule

   a. History and Background of the Rule - This Rule minimizes expenses to regulated entities as much as possible while keeping Indiana residents safe. Some local health departments have separate ordinances that authorize them to enforce these requirements. However, with the recent Health First Indiana (HFI) budget reduction it is unclear if the local health departments will be able to continue this work. This rule was promulgated in 1989. It was amended in 1998.

   b. Scope of the Rule - The Rule applies to all entities that generate infectious waste. IDOH does not keep data on the number of entities that handle infectious waste.

c. Statement of Need - There is still a need for uniform requirements for handling infectious waste in Indiana to protect residents from health risks that arise from improper disposal of waste that can spread infectious diseases. The State department is required by IC 16-41-16-8 to adopt rules after considering multiple federal guidelines such as the EPA, CDC, OSHA, DOL, and Environmental Management. Some of this rule is duplicative of the statute but needs to be readopted at this time to keep the regulatory scheme in place while IDOH evaluates transfer of the rule to the Indiana Code.

d. Statutory Authority for the Proposed Rule - IC 16-41-16-8

e. Fees, Fines, and Civil Penalties - penalties for violating this Rule are set forth in IC 16-41-16-10, though IDOH will need to update its rule to set the factors for determining the fine.

2. Fiscal Impact Analysis

a. Anticipated Effective Date – January 1, 2026

b. Estimated Fiscal Impact on State and Local Government - The costs for state government associated with this Rule are created by the statute, not the Rule. Any local costs are adopted at the local level if they choose to enforce these requirements.

c. Sources of Expenditures or Revenues Affected by the Rule - No revenue is affected by the rule because any cost is due to the requirements of the statute and not the rule.

3. Impacted Parties - (1) Approximately 130 Hospitals.

(2) Ambulatory surgical facilities.

(3) Medical laboratories.

(4) Diagnostic laboratories.

(5) Blood centers.

(6) Pharmaceutical companies.

(7) Academic research laboratories.

(8) Industrial research laboratories.

(9) Health facilities.

(10) Offices of health care providers.

(11) Diet or health care clinics.

(12) Offices of veterinarians.

(13) Veterinary hospitals.

(14) Approximately greater than 800 emergency medical services providers.

(15) Mortuaries, and

(16) Persons involved in infectious waste activities.

IDOH does not have an estimate of the number of impacted parties.

4. Changes in Proposed Rule – There are no changes because this is a readoption.

5. Benefits Analysis

a. Estimate of Primary and Direct Benefits of the Rule - The benefits of regulating infectious waste cannot be quantified but are significant. There is no way to determine how many people would suffer health related problems from untreated infectious waste and the costs of such problems. The benefit of not contracting a communicable

disease from infectious waste is significant. This rule clarifies methods of compliance with the statutory requirements and labelling requirements for transport.

b. Estimate of Secondary or Indirect Benefits of the Rule – There are no secondary or indirect benefits.

c. Estimate of Any Cost Savings to Regulated Industries – There are no cost savings to regulated industries based on this rule.

6. Cost Analysis

a. Estimate of Compliance Costs for Regulated Entities - The cost of infectious waste disposal is due to the requirements in IC 16-41-16 and other regulations outside of IDOH's jurisdiction, such as federal regulation. This rule is clarifications of the requirements in the statute so there is no cost from the rule itself.

b. Estimate of Administrative Expenses Imposed by the Rule - Administrative costs of this rule are due to the statutory requirements in IC 16-41-16 and other regulation including federal regulation.

c. The fees, fines, and civil penalties analysis required by IC 4-22-2-19.6 – The civil penalties in this rule need to be updated to comply with IC 4-22-2-19.6.

d. If the implementation costs of the proposed rule are expected to exceed the threshold set in IC 4-22-2-22.7(c)(6) – There are no implementation costs associated with this rule because this is a readoption.

7. Sources of Information

a. Independent Verifications or Studies – IDOH did not rely on any independent verifications or studies for this regulatory analysis.

b. Sources Relied Upon in Determining and Calculating Costs and Benefits – IDOH compared the state law with the current rule to determine the costs of the rule.

8. Regulatory Analysis – The rule helps to protect the public against communicable diseases. The costs of this rule stem from the statute itself rather than the rule. Accordingly, IDOH has determined that the benefits of the rule outweigh its costs.

V. Alternative Methods of Achieving the Purpose of the Rule

It would be less costly to have local designees conduct inspections and investigations.

VI. Complaints and Comments

None.

VII. Difficulties Encountered

The Commission has difficulty administering the Rule from the agency level with agency employees. Most of the difficulties are related to delegating responsibilities to the local health departments in a uniform manner. The Indiana Code allows IDOH to delegate inspection and investigation authority, but IDOH has to handle the civil penalties process. Most counties were already doing this work on their own. Now, all 92 counties have opted in to HFI funding, and a stipulation of receiving the funding is that the local health departments must use HFI funding on a system to handle infectious waste enforcement.

VIII. Changes in Technology, Economic Conditions, or Other Factors

Since the last time the rule was adopted, counties in Indiana have received additional funding appropriated through Health First Indiana. With that funding, counties have increased resources to respond to and address infectious waste concerns.

IX. Other State or Federal Requirements

While Indiana's rule may be more restrictive than some states below because more facility types are subject to the rule, the statute establishes the applicable facilities, so it is not because of the rule itself.

Illinois is **more restrictive** than Indiana. Illinois regulates medical/infectious waste by incorporating the following into their Rule:

i. "An Ounce of Prevention: Waste Reduction Strategies for Health Care Facilities," American Society for Healthcare Environmental Services, 840 North Lake Shore Drive, Chicago, Illinois 60611 (1993).

ii. "Revised Statistical Definitions for Metropolitan Areas," OMB Bulletin No. 93-17, Office of Management and Budget, Washington, D.C. (June 30, 1993). Office of Management and Budget, National Technical Information Services, 5285 Port Royal Road, Springfield, VA 22161. (703) 487-4600.

iii. 40 CFR 60.8.

iv. 40 CFR 60, appendix A, Methods 1, 2, 3, 3A, 5, 9, 10, 10B, 23, 26, 26A, 29.

v. 40 CFR 60, appendices B and F.

vi. 40 CFR appendix A, Methods 3B, 6, 6C, 7, 7E, 22 (2010).

vii. 40 CFR 60, subpart Ce and Ec (2010).

viii. ANSI/ASME PTC19.10-1981, Flue and Gas Analyses [Part 10, Instruments and Apparatus]. American National Standards Institute (ANSI), Attn: Customer Service Department, 25 West 43rd Street, 4th Floor, New York, NY 10036. (212) 642-4980.

ix. ASTM D6784-02, Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury in Flue Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method). American Society for Testing and Materials (ASTM), 100 Barr Harbor Drive, PO Box C70, West Conshohocken, PA 19428-2959. (610) 832-9585.

x. "Fabric Filter Bag Leak Detection Guidance", U.S. Environmental Protection Agency. (EPA-454/R-98-015, September 1997). Superintendent of Documents, U.S. Government Printing Office (GPO), P979050, St. Louis, MO 63197-9000.

xi. Ill. Admin. Code tit. 35, § 229.104 (Lexis Advance through February 28, 2025).

Kentucky is the **same** as Indiana. In Kentucky medical/infectious waste management is governed by specific regulations, including those related to air quality for medical waste incinerators. (401 KAR 59:020 and 401 KAR 61:010), and hospital/nursing facility operations (902 KAR 20:016 and 902 KAR 20:300).

"In Kentucky, there are no specific regulations pertaining to medical waste and there is no one agency with jurisdiction over medical waste. There are, however, regulations that reference the characterization, treatment, handling, labeling, storage, transport and disposal of this type of waste. These state regulations overlap between environmental, public health, labor and transportation agencies. They are intended to protect personnel, the public and the environment from exposure, injury or contamination of potentially infectious wastes." https://eec.ky.gov/Environmental-Protection/Waste/recycling-and-local-assistance/Pages/medical-waste.aspx

c. Michigan is the **same** as Indiana. In Michigan, medical waste regulations are under the purview of the Department of Environmental Quality. The statutes and Rule cover facility registration, medical waste management plans, employee safety and record of training, packaging and storage, and shipping.

i. Medical waste: Medical Waste Regulatory Act (MWRA)

ii. Michigan Compiled Laws and Regulations (MCL) 333.13801 to 333.13831

iii. Michigan Administrative Cose (MAC)r.325.1541 to 325.1549

d. Ohio is **more restrictive** than Indiana. Ohio EPA regulates the generation and treatment of infectious waste, as authorized by Chapter 3734 of the Ohio Revised Code. Businesses generating more than fifty (50) pounds of infectious waste in any calendar month are required to register with Ohio EPA and, among other requirements, ensure all

infectious waste is treated prior to ultimate disposal. Approved treatment technologies may be used onsite, or infectious wastes may be sent to a commercial treatment facility.

Ohio's infectious waste regulations contain approved treatment methods. Most commonly, autoclave and incineration technologies are used to treat infectious waste prior to disposal. Additional approved treatment methods include chemical treatment utilizing a sodium hypochlorite solution (bleach) for stocks and cultures; applied heat encapsulation for sharps; and chemical treatment utilizing peracetic acid and grinding. A business may submit a request for site-specific or statewide approval of an alternative treatment technology.

Transportation of infectious waste (hazardous material) is regulated by the Public Utilities Commission of Ohio (PUCO). For more information regarding the transportation of infectious waste, please contact PUCO by telephone at 800.686.PUCO (7826).

e. Idaho is **slightly less** restrictive than Indiana**.** Idaho law only provides requirements relating to medical waste to facilities that meet the definition of a hospital, and the Idaho Department of Health and Welfare oversees compliance. The US Department of Transportation and the Occupational Safety and Health Administration also have relevant regulations. Idaho's Department of Environmental Quality's Regulated Medical Waste Management and Disposal Guidance was developed to assist healthcare facilities in locating pertinent regulations and identifying best practices.

f. South Dakota is the **same** as Indiana. South Dakota does not have a statute but has administrative rules regulating infectious waste disposal and off-site disposal at ARSD 74:27 and 74:36.

Indiana's Rule regulates more sources of infectious waste because IC 16-41-16-1 establishes which facilities are subject to this regulation. It covers:

(1) Hospitals.

(2) Ambulatory surgical facilities.

(3) Medical laboratories.

(4) Diagnostic laboratories.

(5) Blood centers.

(6) Pharmaceutical companies.

(7) Academic research laboratories.

(8) Industrial research laboratories.

(9) Health facilities.

(10) Offices of health care providers.

(11) Diet or health care clinics.

(12) Offices of veterinarians.

(13) Veterinary hospitals.

(14) Emergency medical services providers.

(15) Mortuaries, and

(16) Persons involved in infectious waste activities.

X. Previous Amendments

None.

XI. Integration into Indiana Code

This rule could be transferred to the Indiana Code, but it will need to be evaluated for overlap with existing statutes and federal requirements.

XII. Contact Information of Staff to Answer Substantive Questions

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410 IAC 1-4, UNIVERSAL PRECAUTIONS

I. Statement Whether the Subject Matter Covered by the Rule Remains Carried out by the Agency

a. IDOH continues to carry out the program responsible for universal precautions in workplaces where blood and other body fluids are handled. IC 16-41-11-9 gives IDOH the authority to pass administrative rules to carry out the chapter on training in health precautions for communicable diseases. This chapter focuses on employers in healthcare and other fields regarding the management and training of employees to apply universal precautions, *see* IC 16-41-11. 410 IAC 1-4 was first adopted on November 22, 1993, and has been readopted periodically since then.

II. Rationale for the Continued Need for the Rule

a. There is a continued need for 410 IAC 1-4 as IDOH is mandated by statute to oversee the use of universal precautions by healthcare workers as part of its communicable disease oversight program. The administrative rule includes sections on definitions, provides for a detailed program which includes training and oversight for the employers of health care workers, establishes an expert advisory review panel over workers positive for HIV and HPB, and details a process to address workplace violations of the rule.

b. Readoption of 410 IAC 1-4 will continue to have the same impact on regulated entities, e.g., facilities where employees are required to use universal precautions when handling blood and other body fluids to avoid the spread of communicable diseases. The rule does not have a direct impact on persons who pay taxes or fees for government services. Consumers of products and services affected by the rule, such as people being treated or otherwise served in a facility where blood or other body fluids are handled, are not the direct focus of the rule but could be adversely impacted if universal precautions are not utilized.

c. 410 IAC 1-4 achieves the regulatory goal of containing the spread of communicable disease in the least restrictive manner possible while making clear to employers their responsibility for the training and use of universal precautions in applicable workplaces.

d. 410 IAC 1-4 is written for ease of comprehension in that it communicates specific practices to employers to follow in facilities where employees handle blood and other body fluids.

e. 410 IAC 1-4 does not contain any fees, fines, or civil penalties.

III. Analysis of fees, fines, and civil penalties under IC 4-22-2-19.6

a. There are no fees, fines, or civil penalties for reports to IDOH pursuant to this rule.

IV. Cost-Benefit, Economic Impact, Fiscal Impact, or Regulatory Burden Statements

a. No previously published cost-benefit, economic impact, fiscal impact, or regulatory burden statements are available from the Indiana Register. A copy of a regulatory burden statement that meets the requirements of IC 4-22-2-22.7 follows:

1. Description of Rule

a. History and Background of the Rule – 410 IAC 1-4 was first adopted on November 22, 1993. It was readopted on July 11, 2001, May 22, 2007, September 11, 2013, and November 13, 2019.

b. Scope of the Rule – 410 IAC 1-4 regulates facilities that reasonably anticipate dealing with potentially infectious materials in the course of work. The rule includes sections on definitions, facility operator responsibilities, facility operator policies, minimum training and certification requirements for individuals who must use universal precautions, precautions to be taken, an expert review panel to advise where there is an HIV or HPB positive employee, and process to address complaints of rule violations.

c. Statement of Need – The rule is needed to implement an employer-managed program to train and manage employees on a universal precautions program for facilities where blood and other body fluids are handled.

d. Statutory Authority for the Proposed Rule – Authority for 410 IAC 1-4 is established by IC 16-41-11.

e. Fees, Fines, and Civil Penalties – 410 IAC 1-4 does not add or increase any fees, fines, or civil penalties.

2. Fiscal Impact Analysis

a. Anticipated Effective Date of the Rule -- January 1, 2026.

b. Estimated Fiscal Impact on State and Local Government – 410 IAC 1-4 focuses on a small portion of the workplace safety practices regulated by IOSHA, specifically the handling of bloodborne pathogens and other potentially infectious materials regulated by OHSA at 20 CFR 1910.1030. IDOH's main responsibilities fall under two areas: 1. Approving Expert Review Panels (ERPs) pursuant to 410 IAC 1-4-8.1 and 2. Responding to complaints of violations. Unresolved cases against health care workers are forwarded to the Attorney General's consumer protection division and IOSHA violations are referred to the Indiana Department of Labor. Thus, the main impact on IDOH fiscally is in staff time devoted to these two areas of responsibility.

c. Sources of Expenditures or Revenues Affected by the Rule – Sources of expenditures or revenues are not expected to be affected by the rule.

3. Impacted Parties

i. Facility operators, managers, and staff throughout the state where blood and other body fluids are handled.

ii. Types and estimated numbers of such facilities in Indiana include:

iii. Facility	Est. Number in IN
iv. Hospitals	130
v. Clinics	122
vi. Community Health Centers	35
vii. EMS Providers	> 800
viii. Tattoo Parlors	unknown; hundreds and increasing
ix. Dialysis Centers	> 300
x. Funeral Homes	> 500

4. Changes in Proposed Rule

i. There are no changes being proposed to the rule.

5. Benefit Analysis

i. The main benefit provided by the readoption of the Universal Precautions rule is the continued protection of both healthcare workers and patients from exposure to infectious diseases where blood and other body fluids are handled. The value of this benefit cannot be quantified because the Department does not know how many healthcare workers

would contract an infectious disease, or the severity of their illness, in the absence of the rule. The benefit is significant, however, especially to potentially affected healthcare workers.

6. Cost Analysis

i. There is limited to no cost imposed by this rule because the costs are imposed by the statute requiring universal precautions and federal occupational safety regulation.

7. Estimate of Compliance Costs for Regulated Entities – There are no additional costs imposed upon regulated entities due to the adoption of this rule as the use of employer-provided protective equipment in the observation of Universal Precautions is already required by Occupational Safety and Health Administration (OSHA) at 29 CRF 1910.1030, and the Indiana Occupational Safety and Health Administration (IOSHA).

8. Estimate of Administrative Expenses Imposed by the Rules – There are no additional administrative expenses imposed by the adoption of this rule as the administrative costs are already imposed by the Universal Precautions statute, see IC 16-41-11.

9. The fees, fines, and civil penalties analysis required by IC 4-22-2-19.6 – There are no fees, fines, or civil penalties associated with this rule.

10. If the implementation costs of the proposed rule are expected to exceed the threshold set in IC 4-22-2-22.7(c)(6) – N/A.

11. Sources of Information

a. Independent Verifications or Studies – None.

b. Sources Relied Upon in Determining and Calculating Costs and Benefits – None

12. Regulatory Analysis

i. This rule itself does not impose additional costs for compliance with universal precautions requirements, but the continued implementation of universal precautions significantly outweighs the cost of protective equipment for health workers, because universal precautions significantly decrease the incidence of healthcare-associated infections (HAIs) through prevention.

V. Alternative Methods of Achieving the Purpose of the Rule

a. 410 IAC 1-4 creates an industry standard to protect Hoosiers from the spread of infectious disease by exposure to bodily fluids. The rule only applies to facilities where exposure to blood or potentially infectious material may occur. Some states regulate universal precautions through the occupational safety side or professional licensing instead of through their public health authority.

VI. Complaints and Comments

a. IDOH has not received any complaints or comments regarding this rule.

VII. Difficulties Encountered

a. IDOH does not encounter difficulties administering the rule and its policies are reinforced through the ongoing work of agency staff.

VIII. Changes in Technology, Economic Conditions, or Other Factors

a. IDOH is not aware of any changes regarding technology, economic conditions, or other factors that have occurred since the last time the rule was readopted.

IX. Other State or Federal Requirements

a. All of the jurisdictions surveyed have provisions for infection control, but they are found in different areas of code/regulation. For example, Illinois' rule is dispersed throughout its administrative code based on what types of facilities are involved, as is Idaho's. Michigan's is found in its occupational safety section and Ohio's is found in its professional licensing section.

i. Federal Regulations – 29 CFR 1910.1030 establishes the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard, which all states must follow.

ii. Illinois – References to universal precautions are found in individual chapters of the Illinois Administrative Code by types of facilities, such as birth centers (77 IAC §262.2000), hospitals (77 IAC §265.2000), community care programs (89 IAC §240.1535), adult day service centers (89 IAC §240.1555) and so on. There is no specific statute referring to universal precautions in Illinois code. The provisions of Illinois' administrative code contain less detail than are found in Indiana rule.

iii. Kentucky – Universal precautions are referred to in several health care related sections of the Kentucky administrative code. There is a reference to universal precautions, including a definition of the term at 201 KAR 25:080, on HIV/HPV infection control for podiatrists. Universal precautions also are referenced at 902 KAR 20:275 concerning freestanding or mobile technology. There are several references to universal precautions pertaining to dental services, as well as in 201 KAR 15:125 regarding permits for surface transportation of dead bodies. Regulation pertaining to hospitals is found at 902 KAR 20:016. Kentucky does not have a statute on universal precautions, and Kentucky's administrative code provisions contain less detail than Indiana's administrative rule.

iv. Michigan – Regulations on universal precautions are found in Michigan's administrative code (revised) in Part 554, Sections 70001 through 70016 of the Department of Labor and Economic Opportunity under the heading of the Director's Office, General Industry Safety and Health Standard. The regulation covers scope, application, and referenced standards; definitions; exposure; engineering controls; PPE; various industry specific sections; and training. The focus of the rule is on employer requirements. There is no specific statute covering universal precautions in the Michigan code. The scope of Indiana and Michigan's treatment of universal precautions is similar, with Michigan's rule located in the section on occupational safety and Indiana's under public health authority.

v. Ohio – The Ohio's administrative code on universal precautions is found in the portion of the code for the State Medical Board at Chapter 13 under "Exposure-Prone Invasive Procedure Precautions." The chapter includes sections on definitions, a breakdown of the four applications covered by universal precautions (hand washing, disinfection and sterilization of equipment, handling/disposal of needles and other sharp instruments, and wearing/disposal of gloves and other PPE), and violations. Ohio Revised Code Title 47, Chapter 4731 provides for the state medical board to adopt administrative rules for universal precautions. Ohio statute also includes provisions for universal precautions in the statutes covering various medical professionals, certain service settings, tattooing/body piercing, and solid and hazardous waste. Ohio's approach to universal precautions is like Indiana's but is found under the State Medical Board rather than public health.

vi. Idaho – Idaho does not have a statute for universal precautions. Administrative rules for universal precautions in Idaho are dispersed throughout the administrative code. A reference to universal precautions in children's residential care facilities is found at IDAPA 16.04.18.150. Universal precautions must be part of training for juvenile corrections facilities in IDAPA 05.02.01.124. Mention of universal precautions is also found in administrative rules for direct service

staff at residential habilitation agencies and assisted living facilities. Treatment of universal precautions in Idaho is facility-specific and not part of a program managed by the Idaho Department of Health and Welfare.

vii. South Dakota – South Dakota's statute on universal precautions is found at S.D. Codified Laws § 34-22-9(8), where the term 'universal precautions' has been replaced with the term 'infection prevention measures.' For example, infection prevention and control with reference to Ambulatory Surgery Center Facilities is found at ARSD 44:76:02:10. The administrative rule on communicable disease control incorporates control measures but South Dakota does not have a separate program for infection prevention measures.

X. Previous Amendments

a. The rule on universal precautions was first adopted in 1989, then expanded in 1993. The rule has been readopted regularly since then, most recently in 2019.

XI. Integration into Indiana Code

a. This statutory requirement should be evaluated to determine what overlap exists with IOSHA and transfer of the rule into the Indiana Code based on that evaluation. Furthermore, Indiana's adoption of OSHA standards provides that IOSHA cannot require an occupational health or safety regulation that is stricter than OSHA's pursuant to IC 22-8-1.1-17.5. IOSHA incorporates OSHA standards at 610 IAC 9-2-8. Indiana employers would still be required to follow the bloodborne pathogens standard of OSHA regardless of if it is referenced in Title 16 specifically or the general requirements of Title 22 of the Indiana Code.

XII. Contact Information of Staff to Answer Substantive Questions

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TITLE 410 IAC 3.2, Children with Special Health Care Needs

I. Statement Whether the Subject Matter Covered by the Rule Remains Carried out by the Agency

The Indiana Code and the Social Security Act (42 USC 701 et seq.) require this rule. The program pays healthcare expenses for children with special healthcare needs as a payor of last resort.

II. Rationale for the Continued Need for the Rule

The program is still required by code. *IC 16-35-2-2*.

This rule does not regulate any entities—it allows families to apply for healthcare funding as a payor of last resort. The federal government provides a set budget per year. IDOH plans to amend the Rule to address budget concerns. This rule does not have any expenses for its consumers/recipients. The costs/responsibilities for the recipients are applying to the program to determine eligibility. The rule is not restrictive and uses already established income limits to determine eligibility. The rule does not duplicate other laws. It is not complex and is not difficult to understand. The program can operate the program, but the rule needs to be amended to address budget shortfalls.

III. Analysis of fees, fines, and civil penalties under IC 4-22-2-19.6

There are no fees, fines, or civil penalties.

IV. Cost-Benefit, Economic Impact, Fiscal Impact, or Regulatory Burden Statements

No previously published cost-benefit, economic impact, fiscal impact, or regulatory burden statements are available from the Indiana Register. A copy of a regulatory burden statement that meets the requirements of IC 4-22-2-22.7 follows:

1. Description of Rule

a. History and Background of the Rule - The Indiana Code requires IDOH to administer federal funds provided for services to children under the federal Social Security Act (42 USC 701 et seq.). There has not been a major update to the Rule. IDOH plans to update the Rule. The Rule was originally promulgated in 1993. It was last amended in 2010. The amendment added 410 IAC 3.2-1-1.5 to add a new definition. It amended 410 IAC 3.2-1-33 to update a definition. It also amended 410 3.2-6-2 and 410 IAC 3.2-7-3 concerning medical eligibility and limited health services included in the health care service package and amended 410 IAC 3.2-9-1 concerning travel reimbursement.

b. Scope of the Rule – The Rule is in place to comply with Indiana Code and disburse funds for children with special healthcare needs.

c. Statement of Need – This Rule addresses a state and federal statutory responsibility.

d. Statutory Authority for the Proposed Rule - *IC 16-35-2-2* & Social Security Act (42 USC 701 et seq.)

e. There are no fees, fines, or civil penalties.

2. Fiscal Impact Analysis –

a. Anticipated Effective Date of the Rule – January 1, 2026.

b. Estimated Fiscal Impact on State and Local Government – The program relies on federal funding and approximately $14 million in state funding per year. The program utilizes approximately $2 million Title V and matching state funding for staff. These costs are not created by the Rule. IC 16-35-2-2 requires that IDOH administer the money provided for services to children under the federal Social Security Act.

c. Sources of Expenditures or Revenues Affected by the Rule – Federal, State, and Title V.

3. Impacted Parties

Indiana children (and at least one adult) with special healthcare needs and their families who use the program. There are currently 853 people who utilize the program. Health care providers receive compensation for services. The program is a payor of last resort, so it is likely that the payments would not otherwise be made, and children may not receive care.

4. No proposed changes – The program plans to propose the following changes after the Rule is readopted: (1) require a primary insurance, and (2) serve only ages 0-21.

5. Benefit Analysis –

a. a. Estimate of Primary and Direct Benefits of the Rule – Children with special healthcare needs can get the healthcare they need. IDOH cannot monetize or quantify the benefits because the lack of life saving medications and care can vary from person to person. Health care providers also benefit by being paid for services rendered.

Another benefit of the rule is that the benefits program is run properly. This allows the intended beneficiaries of the program to participate while the State and Federal resources are used as they are intended to be.

b. b. Estimate of Secondary or Indirect Benefits of the Rule – The Rule directly helps children receive lifesaving medications and care, but this program also has a positive impact on Indiana families as a whole by acting as a safety net. The cost for children and youth with special health care needs not financially sustainable for families.

c. Estimate of Any Cost Savings to Regulated Industries – There are no regulated entities.

6. Cost Analysis –

a. Estimate of Compliance Costs for Regulated Entities – The only costs to families using the program are applying and providing information to make sure that the family meets the program’s eligibility recruitments. It is difficult to put a cost on the application process, but families can determine if the benefit of being on the program is worth it to them.

b. Estimate of Administrative Expenses Imposed by the Rules – The administrative expense of this rule is for families applying to participate in the program.

c. The fees, fines, and civil penalties analysis required by IC 4-22-2-19.6 - there are no fees, fines, or civil penalties.

d. If the implementation costs of the proposed rule are expected to exceed the threshold set in IC 4-22-2-22.7(c)(6) - costs are not expected to exceed $1,000,000 as this is a readoption.

7. Sources of information – Program staff knowledge from administering the program.

8. Regulatory Analysis – Costs are agency/program staff and budget shortfalls that are not covered by the funds allocated to the program and arise from the need to have a program rather than how it is implemented in the rule. The program serves our most vulnerable population by providing lifesaving medications and care. The benefits of the program outweigh the costs because the implementation of the program requires proper administration of the program benefits.

V. Alternative Methods of Achieving the Purpose of the Rule

The program plans to amend the rule to lower the costs so that the program can operate within its budget.

VI. Complaints and Comments

None.

VII. Difficulties Encountered

A. Agency in administering the Rule: The current rule is outdated.

B. Small businesses or other regulated parties: None

VIII. Changes in Technology, Economic Conditions, or Other Factors

People over 21 with Cystic Fibrosis were grandfathered into the program due to their life expectancy. Due to new treatments, their life expectancy has increased. There is currently a 50-year-old on the program which will contribute to the funding shortage.

IX. Other State or Federal Requirements

Illinois does not have a rule. Illinois has an eleven-office agency that is in charge of administering the federal funds. The Division of Specialized Care for Children (DSCC).

Kentucky has a rule to administer the funds in section 911 of Chapter one of the Kentucky Administrative Regulations.

Michigan has a statute and a rule to administer the funds. MCL 333.5815 / Rule: 722.601

Ohio has a statute and rule to administer the funds. ORC 3701.023 / Rule: 3701-43

Idaho has a statute and a rule to administer the funds. Idaho Code: 56-1003 / Rule: ISAPA 16.02.26

South Dakota has a statute and a rule to administer the funds. SDCL 34-1-21 / Rule: ARSD 44:06

X. Previous Amendments

There were no previous amendments.

XI. Integration into Indiana Code

This rule may be able to be moved to the Indiana Code, but it is not a direct transfer because updating is needed.

XII. Contact Information of Staff to Answer Substantive Questions

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410 IAC 5, RADIOLOGICAL HEALTH

I. Statement Whether the Subject Matter Covered by the Rule Remains Carried out by the Agency

IDOH continues to regulate medical use of radiology. However, IDOH no longer regulates radioactive materials, which is now regulated by the Indiana Department of Homeland Security.

II. Rationale for the Continued Need for the Rule

There is a continued need for this rule because this rule creates standards for use of ionizing radiation, including the use of x-ray machines. Without this rule, the public could be harmed by improper medical care.

III. Analysis of fees, fines, and civil penalties under IC 4-22-2-19.6

There are no fees, fines, or civil penalties under this rule.

IV. Cost-Benefit, Economic Impact, Fiscal Impact, or Regulatory Burden Statements

No previously published cost-benefit, economic impact, fiscal impact, or regulatory burden statements are available from the Indiana Register. A copy of a regulatory burden statement that meets the requirements of IC 4-22-2-22.7 follows:

1. Description of Rule

This rule sets standards for medical use of radiation and the standards to operate radiation for medical purposes.

a. History and Background of the Rule – This rule was originally adopted in 1978 based on authority in the now repealed IC 13-1-2-9 to regulate radioactive materials. This rule was adopted again in 1984. Provisions in rule 6.1 were adopted in 1993. This rule has not been amended since.

b. Scope of the Rule – This rule regulates medical radiological machines and its operators.

c. Statement of Need – Without this rule, there would not be any standards use of radiation in medical settings. Without this rule, patients can be harmed by receiving improper doses of radiation and therefore would be harmed by the health effects of radiation, such as cancer.

d. Statutory Authority for the Proposed Rule – IC 16-19-3-4, IC 16-41-35-26, IC 16-41-35-29.

e. Fees, Fines, and Civil Penalties – This rule does not add fees, fines or civil penalties. The provision in 410 IAC 5-3-12.5(f)(2) is a pre-IC 4-22-2-19.6 provision that sets the fee amount necessary to cover cost of surveillance of uranium or thorium mills. However, as noted above, IDOH no longer regulates uranium or thorium mills.

2. Fiscal Impact Analysis

a. Anticipated Effective Date of the Rule - January 1, 2026

b. Estimated Fiscal Impact on State and Local Government – There is no fiscal impact on state or local government.

c. Impacted Parties - The parties that impacted this rule are medical providers seeking to utilize radiation in medicine, such as utilizing x-ray machines. Other parties impacted are members of the public who receive services covered by this rule.

3. Impacted parties – those who operate radiation devices in medical settings and the patients who get medical tests by those devices.

4. Changes in Proposed Rule -There are no changes being proposed during this rule readoption.

5. Benefit Analysis

a. Estimate of Primary and Direct Benefits of the Rule – The direct benefit of this rule is that patients will not be exposed to unnecessary radiation in medical settings. Without this rule, there would not be any standards governing the use of radiation in medical settings. Patients might be harmed by receiving improper doses of which can cause cancer. However, according to a 2007 Milken Institute report on the economic burden of chronic disease, the avoidable treatment cost and output losses attributable to cancer by 2023 throughout the country were $410 billion.

Although this figure includes other preventable costs and losses from cancer, so that the specific benefit from preventing over-radiation cannot be quantified, it nonetheless shows the benefit is significant.

This rule also assures patients that x-rays are being performed properly, which allows patients to receive proper medical care. This benefit cannot be quantified, but is undoubtedly significant, particularly to patients.

b. Estimate of Secondary or Indirect Benefits of the Rule – Patients will be able to receive proper medical scans because of this rule. As a result, the health of the state will increase, and the economy will improve as a result.

c. Estimate of Any Cost Savings to Regulated Industries – This rule is not being amended and will not result in cost savings.

6. Cost Analysis

a. Estimate of Compliance Costs for Regulated Entities – The department estimates that 11,000 individuals and 5000 facilities within the state are subject to this article. The compliance cost for these individuals and facilities is the time cost to be inspected under 410 IAC 5-1-5 and the cost of licensing under 410 IAC 5-2. However, the obligation to be inspected is based on IC 16-41-35-29(d) and not this rule. The licensees' obligation to make their facility available to the Department, provide records and permit the Department to test their facility is an outgrowth of the Department's authority to inspect the facility. Similarly, the cost of licensing is by IC 16-41-35-29(c) and is not set specifically by this rule.

Rules 4 through 10.1 set protection and exposure standards for use of radiation. However, these standards mirror the recommendations set by the National Council on Radiation Protection and Measurements, which IDOH is required to be in general conformance with under IC 16-41-35-28. Therefore, there is no compliance cost set by those rules.

b. Estimate of Administrative Expenses Imposed by the Rules – Administrative expenses under this rule are the recordkeeping costs under 410 IAC 5-1-4 related to disposal of radioactive material. These costs are low because they either effectuate other sections of this article or Indiana Code. The requirements in 410 IAC 5-4-10 to keep records on an individual's radiation exposure match the National Council on Radiation Protection and Measurements standard and are consistent with a medical professional's record keeping requirement. The requirement to conduct surveys under 410 IAC 5-4-9, the monitoring requirements in 410 IAC 5-14-15 and the disposal requirements in 410 IAC 5-4-17, 18, and 19 also match the National Council on Radiation Protection and Measurements standards that IDOH's are expected to conform with. Therefore, any administrative burdens are not set by these rules but by the Indiana Code and the standards that IDOH must conform with.

c. The fees, fines, and civil penalties analysis required by IC 4-22-2-19.6 – The provision in 410 IAC 5-3-12.5(f)(2) is a pre-IC 4-22-2-19.6 provision that sets the fee amount necessary to cover cost of surveillance of uranium or thorium mills. This provision sets a specified amount to be paid. However, Homeland Security now regulates radioactive materials previously regulated under 410 IAC 5-3.

d. If the implementation costs of the proposed rule are expected to exceed the threshold set in IC 4-22-2-22.7(c)(6) – This rule is not being amended. Medical radiology providers have been complying with this rule since its promulgation and have been trained to comply. Therefore, there are minimal to no compliance costs under this rule.

7. Sources of Information

a. Independent Verifications or Studies – IDOH did not independently verify the information in this analysis or rely on any studies.

b. Sources Relied Upon in Determining and Calculating Costs and Benefits – IDOH utilized the 2007 Milken Institute report on the economic burden of chronic disease to estimate the cost of cancer within the US. The report can be found here. IDOH did not rely on any other sources.

8. Regulatory Analysis - Without this rule, there would not be any standards governing the use of radiation in medical settings. Patients can be harmed by receiving improper doses of radiation and therefore would be harmed by the health effects of radiation, such as cancer. However, according to a 2007 Milken Institute report on the economic burden of chronic disease, the avoidable treatment cost and output losses attributable to cancer by 2023 throughout the country were $410 billion. This estimate likely underestimates the costs attributable to cancer given higher than expected inflationary increases and increases in cancer rates. Therefore, while the benefits of cancer prevention are difficult to quantify, the low regulatory burden shows that the benefits of this rule outweigh any costs.

V. Alternative Methods of Achieving the Purpose of the Rule

No alternative methods exist because of the complexity of the rule and the risk to the public if radiation is used improperly.

VI. Complaints and Comments

IDOH has not received any complaints regarding this rule. If requested, IDOH will assist facilities in locating physicists or inspectors to meet the requirements, especially for machine inspections. Resources for the rule are available on the division website.

There have been comments received from the public regarding the fact that 410 IAC 5-6.1 does not address some of the latest technology such as PET/CAT scanning equipment. This will be addressed in a separate rulemaking to update the rule.

VII. Difficulties Encountered

IDOH has not experienced any difficulties enforcing this rule. IDOH will assist facilities complying with this rule.

VIII. Changes in Technology, Economic Conditions, or Other Factors

The last time the rule was amended was 1993. Since then, there have been technological changes that should be considered for updating the rule. Handheld dental x-ray units are relatively new and are manufactured to be handheld versus a wall mounted dental intraoral x-ray machine, which is not manufactured to be handheld. All technical parts of the rule should be reviewed for applicability and/or updating if necessary.

Further, there is no longer a physicist review committee to approve physicist or x-ray machine applicants. This function is done by staff employed by IDOH's Consumer Services and Healthcare Regulation Division of Radiology and Weights & Measures.

Note: 410 IAC 5-3 *Licensing of Radioactive Material*, can be transferred since radioactive material is regulated by the Indiana Department of Homeland Security now.

IX. Other State or Federal Requirements

There are no federal requirements regarding radiation health.

Illinois radiology requirements are set by 31 Ill. Adm. Code 335. That code is substantially similar to Indiana's because it also sets standards for radioactive material handling, radiation dosages, and calibration standards. Illinois also regulates mobile nuclear medical services in 32 Ill. Adm. Code 335.2120. Illinois is an agreement state, which means that it handles the Nuclear Regulatory Commission's duties in the state.

Idaho regulates medical radiology under IDAPA 16.02.27. It has similar licensing provisions for radiation machine facility but, similar to Indiana, Idaho is a non-agreement state. That means the Nuclear Regulatory Commission handles radioactive material licenses rather than the state of Idaho.

Michigan - MICH. ADMIN. CODE R 333.500 et seq regulates medical radiology in a manner substantively similar to Indiana. Michigan is a non-agreement state. Michigan's rule requires a radiation safety officer training course that substantively matches the requirement in 410 IAC 5-3-12.

Ohio statute ORC Ann. 3748.01 et seq, like Indiana, certifies radiation experts, facility inspections, and penalties for violations. Like Indiana, Ohio statute also sets disposal requirements.

Kentucky regulates medical radiology in KRS § 311B.010 et seq. Kentucky is an agreement state, which means that it handles Nuclear Regulatory Commission's duties in the state. The fact that Kentucky is an agreement state is the substantive difference between Kentucky's standards.

South Dakota – South Dakota regulates medical radiology under ARSD 44:03:01.01 et seq. Like Indiana, South Dakota is a non-agreement state. South Dakota's standards are substantially similar to Indiana's standards because it also regulates radiation experts, facility standards, and radiation dosage standards and requirements.

X. Previous Amendments

This rule has not been amended since 1993.

XI. Integration into Indiana Code

This rule is highly technical in nature and may not be well suited for integration into the Indiana Code. Further, this rule is meant to be updated based on changes in medical technology. If this rule were integrated into the Indiana Code, the Code could have to be updated multiple times to stay current with medical practice and industry standards. These concerns could be addressed by amending IC 16-41-35-28 to state that IDOH is adopting the recommendations of the National Council on Radiation Protection and Measurements. However, doing so would prevent IDOH from any deviation from those recommendations.

XII. Contact Information of Staff to Answer Substantive Questions

Ann Z. Knotek, Staff Attorney, Indiana Department of Health. (317) 233-7874; aknotek@health.in.gov

410 IAC 5.1, RADON

I. Statement Whether the Subject Matter Covered by the Rule Remains Carried out by the Agency

IDOH continues to certify radon testers and mitigators as required by IC 16-41-38-2.

II. **Rationale for the Continued Need for the Rule**

IDOH is required by statute to operate program that certifies radon testers and mitigators, so the rule continues to be necessary. It is important that testing and mitigation are properly performed because exposure to radon causes lung cancer. Those providing these services are required to be trained and certified by either the National Radon Proficiency Program (NRPP) or the National Radon Safey Board NRSB. IDOH's certification program is based on national standards because the EPA has already formulated a National Radon Action Plan that provides a framework for reducing radon exposure to acceptable levels.

IDOH has not been able to identify a less costly or intrusive alternative. Indiana's license cost is very competitive compared to adjoining states and IDOH has seen tremendous growth in the radon program. IDOH's rule is not intrusive to businesses. Should a complaint be filed against a professional, IDOH only advises on next steps. It is not a requirement they follow those recommendations to keep their license. The rule is written for ease of comprehension, and the enforcement is practicable. The requirements of the rule do not have any additional requirements than the existing federal guidelines

established by the EPA. IDOH is required to certify testers and mitigators by Indiana Code. IDOH did so by implementing the researched methods supplied by the EPA into this administrative Rule.

III. Analysis of fees, fines, and civil penalties under IC 4-22-2-19.6

The rule describes the circumstances for which IDOH will assess a civil penalty as a range of potential dollar amounts, stating the factors that IDOH will utilize to set a specific dollar amount in an individual case with sufficient certainty that a review of an agency action or comparable process can evaluate whether the amount was reasonable. Therefore, it complies with the requirements of IC 4-22-2-19.6.

Indiana's license is the lowest cost radon license compared to Ohio, Illinois, and Kentucky. Costs in these states range from $250 to $600. With Indiana's only costing $100, we are the most affordable in the Midwest. There are several licensees from other states acquiring Indiana licensures from the Chicagoland area, Cincinnati, and Louisville area. Indiana's costs do not limit financial growth in our state or others. Michigan does not require state registration.

IV. Cost-Benefit, Economic Impact, Fiscal Impact, or Regulatory Burden Statements

Fiscal Analysis - IDOH has reviewed the previously published Economic Impact Statement found here: 20210721-IR-410210023EIA, and no changes are necessary.

V. Alternative Methods of Achieving the Purpose of the Rule

There is no less costly or less intrusive alternative. IDOH's license cost is very competitive compared to adjoining states and IDOH has seen tremendous growth in the program.

VI. Complaints and Comments

Since summer of 2022, complaints received from the public concerning the implementation of the rule by the agency only occurred during a reporting transition period January through February 2023. Once IDOH completed an online database allowing licensed radon individuals to upload their reporting on their own, licensees had to learn how to access and upload that information. Complaints were limited to site functionality and a learning curve for the licensees. IDOH has seen leaps in on time reporting since the 2023 reporting year. From 52% on time reporting in 2023 to 67% on time reporting, our ability to work with our licensees has seen great improvements. This year we have 96% compliance with reporting, our main requirement to keep their license. Inactive licenses are suspended and most often are not renewed.

VII. Difficulties Encountered

The rule is not intrusive to businesses. Should a complaint be filed against a professional, we only advise on next steps. It is not a requirement they follow those recommendations to keep their license.

Due to Illinois, Ohio, and Kentucky adopting similar rules on radon, IDOH has not been informed of any difficulties for small businesses or other regulated persons in complying with the rule. Due to radon testing and mitigation being such a niche profession, the small community understands the rules and regulations and is working towards a more uniform approach to testing and mitigation.

VIII. Changes in Technology, Economic Conditions, or Other Factors

There have been no changes to technology, economic conditions, or other factors that impact the rule. This rule does not directly affect technology, economic conditions, or other factors. This rule does not demand technological changes; it has not impacted business growth due to license fees or any other factors. It is flexible and changes with national standards as it references those standards within the rule. When national standards change, our rule automatically follows.

IX. Other State or Federal Requirements

Illinois has similar requirements to Indiana. 32Ill. Adm. Code 422

Kentucky has similar requirements to Indiana Radon Statutes**:**

KRS 211.9101: Definitions for KRS 211.9101-211.9135

KRS 211.9103: Creation of Kentucky Radon Program Advisory Committee – Qualifications of Members – Terms – Vacancies – Quorum – Officers

KRS 211.9105: Powers and Responsibilities of Radon Program Advisory Committee

KRS 211.9107: Prohibition Against Conduct of Radon Measurement, Mitigation, or Laboratory Analysis Without Certification – Exceptions

KRS 211.9109: Registration as Radon Measurement Contractor – Renewal of Registration Certificate – Duties of Measurement Contractor

KRS 211.9111: Registration as Mitigation Contractor – Renewal of Registration Certificate – Duties of Mitigation Contractor

KRS 211.9113: Insurance Policy Required for Mitigation and Measurement Contractors

KRS 211.9115: Registration as Radon Laboratory – Renewal of Registration Certificate – Requirements for Radon Laboratory

KRS 211.9119: When Business Entity May Engage in Radon Measurement, Mitigation, or Laboratory Analysis

KRS 211.9125: Sanctions for Misconduct – Cabinet's Powers – Appeals

KRS 211.9129: Cabinet's Powers to Examine, Inspect, and Test – Prohibition Upon Interfering with Inspection

KRS 211.9131: Duty to Report Noncompliance with KRS 211.9101 to 211.9135 – Location and Retention of Required Records

KRS 211.9133: Radon Mitigation and Control Fund

KRS 211.9135: Cabinet's Role as Radon Control Agency for Commonwealth

Radon Administrative Regulations:

902 KAR 95:040: Radon Contractor Certification Program

Michigan: The program has been transferred to the Department of Environmental Quality. There is no administrative rule or license requirement.

Ohio has similar regulations to Indiana. Ohio Administrative Code 3701-69 & Ohio Revised Code 3723.09.

Idaho does not have a license requirement for testers or administrative rule.

South Dakota: no license requirement for testers or administrative rule.

Michigan, Idaho, and South Dakota do not have license requirements. Indiana is stricter than only these three states as part of the required state review. From a public health standpoint, making sure the entities performing this type of work on Indiana residents' homes are certified protects Indiana residents' investments in their homes and health. Additionally, state law requires this program.

X. Previous Amendments

History and Background of the Rule - The Indiana Code requires that IDOH certify radon testers and mitigators. IDOH promulgated a rule based on federal framework from the EPA because the methods are researched. This provides a reliable certification system to protect the health of Indiana residents. The last major update was in 2021. The amendment amended 410 IAC 5.1-1-9, 410 IAC 5.1-1-10, 410 IAC 5.1-1-16, and 410 IAC 5.1-1-18 to revise definitions. The amendment also amended 410 IAC 5.1-1-22 through 410 IAC 5.1-1-29 to revise the certification and standards

requirements applicable to radon testing, radon mitigation, and laboratory analysis. The amendment amended 410 IAC 5.1-1-31 to revise the documents incorporated by reference as part of this rule. Lastly, it repealed 410 IAC 5.1-1-3.

XI. Integration into Indiana Code

The rule can be transferred to the Indiana Code.

XII. Contact Information of Staff to Answer Substantive Questions

Ann Z. Knotek, Staff Attorney, Indiana Department of Health. (317) 233-7874; aknotek@health.in.gov

410 IAC 6-2.1, PUBLIC AND SEMI-PUBLIC POOLS

I. Statement Whether the Subject Matter Covered by the Rule Remains Carried out by the Agency

IDOH still uses the Rule to provide standards for the safe and sanitary operation and maintenance of public and semi-public swimming pools.

II. Rationale for the Continued Need for the Rule

There is a continued need for the foundation this rule sets for public and semi-public pools. The program that covers this rule is still in use and local health departments use the rule to make sure pools are safe.

The rule is simple, concise, and the regulated industry has had many years to adapt to it. It has remained unchanged for 15 years. The current rule presents the lowest short-term cost for the regulated industry, while still providing the foundation for the aquatic venue safety and sanitation that the general public expects. Enforcement of the Rule is challenging for some local health departments with limited resources. IDOH cannot identify any ways to reduce costs or make the rule less restrictive for regulated entities.

III. Analysis of fees, fines, and civil penalties under IC 4-22-2-19.6

There are no fees, fines, or civil penalties.

IV. Cost-Benefit, Economic Impact, Fiscal Impact, or Regulatory Burden Statements

The previously published Economic Impact Statement has been reviewed, and no revisions are necessary. 20100127-IR-410090006EIA

V. Alternative Methods of Achieving the Purpose of the Rule

The current rule presents the lowest short-term cost for the regulated industry, while still providing the foundation for the aquatic venue safety and sanitation that the public needs and expects.

VI. Complaints and Comments

Overall, the rule has been well established with few complaints lodged since the last review in 2021.

Lifeguarding: There has been one recent (11/21/2024) formal complaint letter filed requesting a very specific exemption to the lifeguard expectation for age 55+ communities with pools larger than 2,000 square feet that don’t allow minors. Exemptions are not an option in the rule. They wanted an “exemption” because of the cost of hiring a lifeguard. It would seem unfair to the rest of the regulated community to provide for this specific exemption. Allowing such an exemption based on specific caveats would also be difficult for local health departments (LHD) to monitor and enforce.

Small cold plunges: Some small business owners as well as regulators have stated that they would prefer clear statements regarding the handling of small, one-patron cold-plunge spas in a commercial setting. The popularity of these small venues has increased considerably over the course of the past year. It has been possible to address these relatively new venues using the existing 410 IAC 6-2.1 and 675 IAC 20 (coordinating with partners at Indiana Department of Homeland Security).

The two key cold-plunge manufacturers (at this point) have been working with IDOH to develop products which are more appropriate for commercial sales/use.

VII. Difficulties Encountered

The greatest difficulty in administering the 410 IAC 6-2.1 rule has been the limitation of some local health departments to expend the necessary time of trained, qualified staff to effectively administer it. Public/semi-public swimming pool inspections have not historically been an expected/mandated requirement of LHDs. LHD administrators/managers know this and have often been forced to make hard decisions regarding which priorities to address using limited staff resources. Health First Indiana funds for additional LHD staff, as well as Core Services' expectations tied to said monies, are expected to address this limitation over time. It will, of course, take time to hire and train the necessary staff and get LHD pool inspection programs running effectively.

VIII. Changes in Technology, Economic Conditions, or Other Factors

Conditions are largely the same as they were in November 2021 when 410 IAC 6-2.1 was last reviewed. The rule is relatively concise, simple, and the regulated industry has had many years to adapt to it (over 15). The IDOH working with LHDs have been able to effectively interpret the 2010 rule to implement basic safety and sanitation expectations, even across the wider variety of modern aquatic venues. Thanks to a pool industry that has adapted to 410 IAC 6-2.1, some of the costs of compliance (particularly regarding disinfectant feed and control) have reduced considerably in recent years. Chemical feed technology has evolved to the point that it is considerably easier and more cost-effective to comply with 410 IAC 6-2.1-30 than it was at the time of the last readoption. There are now simple, easy-to-use chemical feeders that owner/operators can purchase, install, and maintain with options under $500. Most indoor operations required more complex, professionally installed/maintained systems in the past that carried initial price tags of roughly $3000 to as high as $10,000. For many outdoor seasonal aquatic venues, this same new disinfectant feeder technology has alleviated the need to drain and refill pools one or two times per season; such was often necessary while using the lower-cost disinfectant feeders available in the past.

New technologies involving on-site daily chemical testing have become available in recent years. These could make it easier to comply with the daily monitoring requirements of 410 IAC 6-21-30 at unstaffed facilities, although these technologies are still being perfected, are still costly, and are not yet widely used.

IX. Other State or Federal Requirements

Illinois has three statutes and a rule. It is slightly more regulated and includes beaches. https://dph.illinois.gov/topics-services/environmental-health-protection/swimming-facilities.html#laws-and-rules

Kentucky has two statutes and two rules which include beaches. It covers about the same except Kentucky includes penalties. https://www.chfs.ky.gov/agencies/dph/dphps/emb/Pages/pools.aspx

Michigan is the same as Indiana.
https://www.michigan.gov/egle/-/media/Project/Websites/egle/Documents/Forms/DWEHD/Public-Swimming-Pool/EQP2263-Public-Act-and-Rules-Governing-Public-Swimming-Pools.pdf?rev=ac420bf9af3d4929a0645b2d98f327bb

Ohio is the same as Indiana. 3749 Ohio Revised Code (ORC) & 3701-31 Ohio Administrative Code (OAC)

Idaho just passed House Bill 202 which removes state-level sanitation standards for public pools, giving authority to local jurisdictions. This change took effect on July 1, 2025. IDOH does not recommend taking this stance because this would risk the health and safety of Hoosiers for the reasons stated throughout this document.

South Dakota has an administrative rule. Pool operators must comply with the "Recommended Standards for Swimming Pool Design and Operation," 1996 edition, Great Lakes-Upper Mississippi River Board of State and Provincial Public Health and Environmental Managers. In addition, operators must take weekly samples and log them.

All of the States are more restrictive than Indiana except Idaho. Our local health departments already have limited resources and the uniform rule that is already established eliminates the need for each local health department to promulgate/research regulations.

X. Previous Amendments

In 2010, an amendment added 410 IAC 6-2.1-5.3, 410 IAC 6-2.1-5.6, 410 IAC 6-2.1-7.3, 410 IAC 6-2.1-7.5, , 410 IAC 6-2.1-17.5, 410 IAC 6-2.1-18.5, 410 IAC 6-2.1-19.3, 410 IAC 6-2.1-19.5, and 410 IAC 6-2.1-20.5 to add new definitions. It added 410 IAC 6-2.1-42.1 concerning tourist home pools and spas. It amended 410 IAC 6-2.1-44 to amend procedures concerning fecal accidents. It made numerous other changes concerning updating definitions, requirements for the operation of public and semi-public pools and spas, and reference information. It repealed 410 IAC 6-2.1-8.

XI. Integration into Indiana Code

This rule can be integrated into the Indiana Code, but any transfer should include updates to address new issues like cold plunges.

XII. Contact Information of Staff to Answer Substantive Questions

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410 IAC 6-6, MOBILE HOME COMMUNITY SANITATION AND SAFETY

I. Statement Whether the Subject Matter Covered by the Rule Remains Carried out by the Agency

IDOH still oversees mobile home community sanitation and safety.

II. Rationale for the Continued Need for the Rule

There is a continued need for the Rule. The Rule is still used to make sure mobile home communities meet the basic standards of sanitation and safety. There are no alternatives. The Rule is written for ease of comprehension, and the enforcement is practicable.

III. Analysis of fees, fines, and civil penalties under IC 4-22-2-19.6

The civil penalties in the Rule are to address noncompliance with the Rule. The factors for determining the seriousness of violations are found in 410 IAC 6-6-14.1 in compliance with the requirements of IC 4-22-2-19.6.

IV. Cost-Benefit, Economic Impact, Fiscal Impact, or Regulatory Burden Statements

A previous Economic Impact Statement was published, and no changes are needed. It can be found at 20061025-IR-410050328EIA.

V. Alternative Methods of Achieving the Purpose of the Rule

IDOH has not identified any less burdensome alternatives to the rule. The costs incurred by mobile home community owners would be for correcting violations observed during routine facility inspections to enforce minimum standards of the rule, and possible civil penalties for failure to comply with the rule.

VI. Complaints and Comments

IDOH has not received any complaints or comments concerning the rule or its implementation.

VII. Difficulties Encountered

There have been no difficulties encountered by IDOH in administering the rule. There should be no undue burden in complying with the rule, as it only establishes minimum health, safety, and construction requirements for mobile home communities.

VIII. Changes in Technology, Economic Conditions, or Other Factors

The increase in availability of municipal water and sewer has made it more cost effective for mobile home community owners to comply with these sections of the rule, in lieu of operating and maintaining private water wells and onsite sewer systems.

IX. Other State or Federal Requirements

Illinois's regulation is comparable. It has both a statute and a rule. Its rule covers more topics than ours. https://dph.illinois.gov/topics-services/environmental-health-protection/manufactured-modular-homes-mobile-structures.html#laws-and-rules

Kentucky's regulation is also comparable. It also has both a statute and a rule. KRS 219.370 & 815 KAR 20:170

Michigan's regulation is comparable, but includes slightly more protection for occupants The Mobile Home Commission Act 96 of 1987 https://www.legislature.mi.gov/Laws/MCL?objectName=mcl-Act-96-of-1987 & Regulated by the Department of Environmental Quality MAC section 125

Ohio's regulation is comparable and is found in both statute and rule, but enforcement is by the Ohio Manufactured Homes Commission, not the Health Department. Ohio Administrative Code 4781-12 & Ohio Revised Code 4781

Idaho does not have a state-level regulation but rather relies on local ordinances. IDOH does not recommend this option because a uniform rule across the state serves operators and residents in a more efficient manner. Also, some local health departments do not have the resources to regulate in this area.

South Dakota: None. IDOH does not recommend this approach because Indiana's population is over five times greater than South Dakota's. IDOH actively investigates sanitation violations that risk Indiana residents' health.

X. Previous Amendments

In 2007, IDOH promulgate an amendment that updated definitions, added to construction requirements, added water supply distribution system requirements, updated water disposal requirements, updated refuse disposal requirements, updated ground anchor requirements, and updated the resources that are incorporated by reference.

XI. Integration into Indiana Code

The Rule was first passed in 1981 and updated in 2007 and has been readopted twice since then. It provides much more detail than the current Indiana statute and gives details that help the regulated entities and IDOH staff understand the standards and risks of noncompliance with those standards. It may currently be too technical and will be more effectively updated by IDOH when necessary if it stays in administrative rule.

XII. Contact Information of Staff to Answer Substantive Questions

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410 IAC 6-9, AGRICULTURAL LABOR CAMP SANITATION AND SAFETY

I. Statement Whether the Subject Matter Covered by the Rule Remains Carried out by the Agency

IDOH inspects, licenses, and reviews construction or alteration plans for the approximately 121 licensed Agriculture Labor Camps in Indiana. A roster of current labor camps can be found here.

II. Rationale for the Continued Need for the Rule

The rule needs to be readopted because IDOH is required to regulate Agricultural Labor Camps. There are no alternative or less intrusive methods to achieve this purpose. The rule sets forth the minimum requirements to maintain safe agricultural camps to minimize the risk of illness. The rule includes some standards that go into more detail than the federal standards. To do that, the rule needs to state or duplicate the federal requirement. The rule has practicable enforcement via routine inspections. The rule is written for ease of comprehension.

III. Analysis of fees, fines, and civil penalties under IC 4-22-2-19.6

The civil penalties in the rule punish noncompliance. The civil penalties in the rule are based on the seriousness of the violation. The violations have the potential to impact the health, safety, or welfare of a person or animal. The number of previous violations/histories of noncompliance is considered when determining the civil penalty amount.

IV. Cost-Benefit, Economic Impact, Fiscal Impact, or Regulatory Burden Statements

No previously published cost-benefit, economic impact, fiscal impact, or regulatory burden statements are available from the Indiana Register. A copy of a regulatory burden statement that meets the requirements of IC 4-22-2-22.7 follows:

1. Description of Rule

a. History and Background of the Rule - The rule was promulgated in 1981 and amended in 2007.

b. Scope of the Rule - This rule addresses the inspection, licensing, and plan approval for construction or alteration of agricultural labor camps in order to ensure safe facilities, proper water supply, and proper sewage disposal.

c. Statement of Need - IC 16-41-26-8 requires a state-wide rule to regulate agricultural labor camps.

d. Statutory Authority for the Proposed Rule - IC 16-41-26, IC 16-19-5-1.

e. Fees, Fines, and Civil Penalties - The Rule imposes civil penalties per the chart below:

		Range of
Violation		Penalty
Construction notice; permit	410 IAC 6-9-2	$50 to $100
Camp facilities	410 IAC 6-9-3	$50 to $500
Operation and sanitation: safety requirements	410 IAC 6-9-4	$50 to $500
Health or safety hazards; reporting communicable diseases	410 IAC 6-9-5	$50 to $500
Interference with agent	410 IAC 6-9-5.5	$100 to $500

2. Fiscal Impact Analysis

a. Anticipated Effective Date – January 1, 2026.

b. Estimated Fiscal Impact on State and Local Government - The cost of having to issue permits to operate camps is required pursuant to IC 16-41-26-3. The requirement and associated costs of inspections are not a result of the rule; they are required pursuant to IC 16-41-26-6. Therefore, the costs are a result of statute and not the rule itself.

c. Sources of Expenditures or Revenues Affected by the Rule - There are no expenditures affected by this rule because the costs come from the statute and not the rule.

3. Impacted Parties - Owners and people who live in agricultural labor camps. Annually, there are approximately 121 licensed agricultural labor camps in the state.

4. Changes in Proposed Rule – There are no changes to this rule because it is a readoption.

5. Benefits Analysis

a. Estimate of Primary and Direct Benefits of the Rule - The benefits include worker safety, a healthy agricultural workforce due to less risk of disease and illness spread, and Indiana can attract more agricultural laborers by going above federal standards. Indiana's rule is slightly more strict than federal standards because past inspections revealed terrible conditions for migrant seasonal farm workers. The federal requirements do not work well with larger labor camp operations because the regulations can allow for overcrowding. The value of these benefits cannot be quantified without data on safety and illness results that would prevail in the absence of the rule, but the IDOH believes they are significant.

b. Estimate of Secondary or Indirect Benefits of the Rule - The Rule focuses on sanitation and that helps reduce the amount of disease and illness. That indirectly prevents burdening surrounding health care systems and compromising food production on farms.

c. Estimate of Any Cost Savings to Regulated Industries - IDOH is not aware of any cost savings to regulated industries. A healthier and cleaner environment may provide long-term cost savings.

6. Cost Analysis

a. Estimate of Compliance Costs for Regulated Entities - Costs for compliance are difficult to quantify because there are many ways to satisfy the requirements of the rule. For example, they can choose to house workers in manufactured homes, hotels, or onsite buildings constructed for the purpose of housing agricultural laborers. All of these costs will vary based on the size of the operation. Further, IDOH does not have access to this data. While the variety of compliance options makes it difficult to estimate costs, it allows regulated entities to decide which option works best for them. IDOH does not currently charge for permits.

b. Estimate of Administrative Expenses Imposed by the Rule - There are limited administrative expenses that result from this rule because it sets the standards for the camps themselves rather than setting administrative requirements such as record keeping or documentation.

c. The fees, fines, and civil penalties analysis required by IC 4-22-2-19.6 – The civil penalties provision of this rule contains the factors used to determine the penalty and complies with IC 4-22-2-19.6.

d. If the implementation costs of the proposed rule are expected to exceed the threshold set in IC 4-22-2-22.7(c)(6) – There are no implementation costs for this rule because it is a readoption.

7. Sources of Information

a. Independent Verifications or Studies - IDOH did not rely on any independent studies or outside sources of information. Rather, it relied on program personnel's knowledge and experience of reviewing applications, conducting investigations, and issuing penalties.

b. Sources Relied Upon in Determining and Calculating Costs and Benefits – The program relied on the program personnel's knowledge and experience of reviewing applications, conducting investigations, and issuing penalties.

8. Regulatory Analysis – There are no new requirements. Costs are agency/program staff of approximately $132,215.00 for IDOH and arise from the statute and the need to comply with it, not from the rule itself. Costs for the regulated entities cannot be quantified because there are too many variables for compliance and IDOH does not have access to the data. Benefits of the Rule are safe and sanitary living quarters and all of the benefits stated above. From a public health standpoint, those outweigh the costs to meet the minimum requirements imposed by the rule.

V. Alternative Methods of Achieving the Purpose of the Rule

There are no known less burdensome alternatives to the rule. Conducting inspections is the only way to verify that safety and housing requirements are met. The costs incurred by agricultural labor camp operators would be for correcting violations observed during routine facility inspections to ensure the minimum standards of the rule are met.

VI. Complaints and Comments

Since residents in agricultural labor camps are provided with this type of housing by the farm they work at, this rule provides a mechanism for them to have such facilities constructed and operated in a safe and sanitary manner. Most complaints are from tenants and neighbors that are experiencing a problem that the property owner or manager has not addressed, so the complaints are not about the rule itself, but rather violations of the rule.

VII. Difficulties Encountered

This rule is not complex. The agency has not encountered any difficulties administering it and small businesses have not had difficulties complying with it. There should be no undue burden in complying with the rule, as it only establishes minimum health, safety, and construction requirements for agricultural labor camps.

VIII. Changes in Technology, Economic Conditions, or Other Factors

The rule was last reviewed in 2000, and factors have not changed since that time.

IX. Other State or Federal Requirements

Illinois: Illinois has a statute and a rule that are similar to Indiana's rule. 210 ILCS 110 & Public Act 098-1034. Illinois requires a permit only for camps that have over 10 workers or more than four families. Indiana's rule is more specific, but Illinois' rule references other laws and rules. For example, Illinois' rule adds water testing, sewage compliance, and construction approvals that are based on other state codes. Indiana's rule is more specific regarding exact ratios, square footage, and facility requirements.

Kentucky: Pursuant to 803 KAR 2:600 and a state plan approved by the US Department of Labor, OSHA, Occupational Safety and Health (Kentucky's agency) standards for Agriculture, all employers, employees, and places of employment engaged in agricultural operations must comply with the federal rule, 29 CFR Part 1928. IDOH does not recommend leaving this rule to federal control. The conditions witnessed during inspections show that this rule and state inspections are necessary to protect the health and safety of Indiana residents.

Kentucky has relinquished jurisdiction for the issues related to Field Sanitation (29 CFR 1928.110) and Temporary Labor Camps (29 CFR 1910.142) in agriculture except for agricultural temporary labor camps associated with egg, poultry or red meat production, or the post-harvest processing of agricultural or horticultural commodities. In Kentucky, the Employment Standards Administration, U.S. Department of Labor, has assumed responsibility for the enforcement of these OSHA standards.

Michigan: Michigan's regulations are the same as Indiana. Michigan Administrative Code R 325.3601 to R 325.3612 and MCL 333.12421. Both states aim to protect agricultural and the surrounding area through comprehensive regulations, with Indiana focusing on the facility and Michigan emphasizing broader compliance and enforcement mechanisms. For example, Michigan charges $1,000 per day for operating without a license, and operators must provide evidence of worker's employment upon request.

Ohio: Ohio has a statute and rule. Ohio's rule is more robust than Indiana's. Ohio Administrative Code 3701-33 and Ohio Revised Code 519.01. Ohio's equivalent of what would be the Indiana Department of Homeland Security also regulates portions of labor camps. Their multi-agency approach allows for broader oversight of labor camps. Ohio's rule also provides

more procedural avenues for enforcement, including the ability to act before a camp operates, and formal recourse through hearings and legal action.

Idaho: Idaho repealed its agriculture labor law, so they rely on federal law.

South Dakota: South Dakota does not have a statute or rule on this issue and relies on the federal law.

Federal: The Migrant and Seasonal Agricultural Worker Protection Act (MSPA) protects migrant and seasonal agricultural workers by establishing employment standards related to wages, housing, transportation, disclosures, and recordkeeping. Some of the requirements in the Indiana Rule are in the MSPA. Some of the regulations in the Indiana Rule go further MSPA regulations. For example, where there are shared toiled facilities, separate rooms are needed for each sex under the MSPA. In Indiana, separate rooms must have floor-to-ceiling solid walls.

The IDOH rule is stricter than federal regulations because those provisions require additional sanitation benefits that are necessary based on IDOH's history of inspection of the facilities. The federal rule is best suited for smaller agricultural labor camps and Indiana has many larger camps that require additional regulation. IDOH already receives complaints from the public who are near agricultural labor camps that the camps are not sanitary. Any further lessening of these regulatory requirements would produce less sanitary conditions. As noted above, IDOH has not received complaints from the regulated community about the stringency of the rule.

X. Previous Amendments

No substantive changes since 2000.

XI. Integration into Indiana Code

IDOH recommends moving this rule into code after readoption.

XII. Contact Information of Staff to Answer Substantive Questions

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410 IAC 7-15.5, SANITATION OF BED AND BREAKFAST ESTABLISHMENTS

I. Statement Whether the Subject Matter Covered by the Rule Remains Carried out by the Agency

This rule must be readopted because IDOH continues to set food safety standards for food establishments and specifically bed and breakfast establishments.

II. Rationale for the Continued Need for the Rule

There is a continued need for this rule because the Food Protection Division is obligated to issue rules under IC 16-41-31-5. This rule does not impose a cost on taxpayers because there are no government services affected by this rule. However, this rule could impose a cost on businesses that must meet the standards set by this rule. Since this rule has not been substantively changed since adoption, there should only be minimal costs for businesses complying with this rule.

III. Analysis of fees, fines, and civil penalties under IC 4-22-2-19.6

There are no fees, fines or civil penalties under this rule.

IV. Cost-Benefit, Economic Impact, Fiscal Impact, or Regulatory Burden Statements

No previously published cost-benefit, economic impact, fiscal impact, or regulatory burden statements are available from the Indiana Register. A copy of a regulatory burden statement that meets the requirements of IC 4-22-2-22.7 follows:

1. Description of Rule

a. History and Background of the Rule - This rule was promulgated in 1992 based on industry input. This rule has not been updated since.

b. Scope of the Rule - The rule is intended to provide health and safety standards for bed and breakfast establishments. IDOH has provided a rule that outlines standards required for food safety, utilities, bedding, and physical plant. The rule is intended to provide confidence in visitors to these establishments that they are going to have a high standard of care for their stay.

c. Statement of Need - This rule is required by IC 16-41-31-5. Without this rule, bed and breakfast establishments would not be held to any cleanliness or food safety standards.

d. Statutory Authority for the Proposed Rule - IC 16-19-3-4(b); IC 16-41-31-5; IC 16-41-32-14.

e. Fees, Fines, and Civil Penalties - This rule does not impose fees, fines, or civil penalties.

2. Fiscal Impact Analysis

a. Anticipated Effective Date – January 1, 2026.

b. Estimated Fiscal Impact on State and Local Government - There is no impact to state or local governments from this rule, though local health departments do charge inspection fees to inspect bed and breakfast establishments' compliance with this rule.

c. Sources of Expenditures or Revenues Affected by the Rule - Because this rule does not affect revenue of state government, it does not impact any sources of revenue or expenditures.

3. Impacted Parties - The approximately 50 bed and breakfast establishments in the state are the regulated parties. Any patron of those establishments is also an impacted party. Local health departments are impacted by this rule because they inspect the bed and breakfast establishments.

4. Changes in Proposed Rule – There are no changes to the rule because it is a readoption.

5. Benefits Analysis

a. Estimate of Primary and Direct Benefits of the Rule - The primary benefit of this rule is the prevention of foodborne illness and the assurance that bed and breakfasts are sanitary. Foodborne illness in Indiana, according to a 2015 study by Robert L. Scharff, has an estimated annual cost exceeding $1.6 billion. That estimate has likely increased in the last ten years. However, that study evaluated all sources of foodborne illness and was not limited to bed and breakfast establishments. Therefore, the cost of foodborne illness and the benefit of prevention cannot be quantified because it is impossible to determine the amount of illness, foodborne or otherwise, that is prevented due to maintaining proper sanitary conditions at bed and breakfast establishments.

b. Estimate of Secondary or Indirect Benefits of the Rule - An indirect benefit of this rule is increased tourism and preservation of the service industry. Bed and breakfast establishments are frequented by tourists, but an establishment is unlikely to have patrons if the establishment has a reputation for illness.

c. Estimate of Any Cost Savings to Regulated Industries - Any cost savings to industry or the public will be from the prevention of illnesses and therefore the corresponding loss of business.

6. Cost Analysis

a. Estimate of Compliance Costs for Regulated Entities - This rule implements and clarifies the requirements of IC 16-41-29, IC 16-41-30, and IC 16-41-32 and does not create separate requirements. Therefore, the only compliance cost under this rule is to comply with the food preparation and handling requirements promulgated under IC 16-41-31-5. These food preparation and handling requirements pose limited costs to regulated entities because the rule is written in terms of outcomes rather than specific processes. For example, 410 IAC 7-15.5-29 merely requires that food be

protected from contamination and refrigerated. This rule's focus on outcomes rather than processes, if permitted by Indiana Code, reduces the compliance cost on regulated entities.

This rule imposes both one-time costs and ongoing costs on bed and breakfasts. These one-time costs include water supply requirements under section 39, plumbing requirements under section 41, toilet requirements under section 42, and walling and flooring requirements under sections 46 and 47. The cost to comply with sections 41 and 42 should be minimal because they require compliance with the plumbing code promulgated by IDHS. The costs to comply with sections 39, 46, and 47 are unquantifiable because bed and breakfasts operate out of an individual's home, and the costs to ensure that the home complies with this rule will depend on the home being used.

As stated above, most of the costs associated with this rule are specifically related to food safety, but these costs are difficult to quantify because this rule is outcome driven rather than process driven. Therefore, there is no singular way that a bed and breakfast can ensure compliance with this rule. Bed and breakfasts can ensure compliance with this rule by either working with their local health department to ensure compliance or voluntarily comply with ServSafe standards which are more stringent than this rule.

b. Estimate of Administrative Expenses Imposed by the Rule - The only administrative cost from this rule is the obligation under section 53 to maintain a registry of individuals occupying the bed and breakfast. However, this section is both required by IC 16-41-29 and needed to verify that the establishment complies with the occupancy limitations on bed and breakfasts set by IC 16-41-31-1. Therefore, there is no administrative expense imposed by this rule.

c. The fees, fines, and civil penalties analysis required by IC 4-22-2-19.6 - There are no fees, fines, or civil penalties under this rule.

d. If the implementation costs of the proposed rule are expected to exceed the threshold set in IC 4-22-2-22.7(c)(6) – There are no implementation costs associated with this rule because it is a readoption.

7. Sources of Information

a. Independent Verifications or Studies - IDOH did not independently verify the information in this analysis or rely on any studies.

b. Sources Relied Upon in Determining and Calculating Costs and Benefits - IDOH did not use any outside sources to determine the costs and benefits of this rule and did not consult with industry groups.

8. Regulatory Analysis - The benefit of this rule is the prevention of foodborne illness, but that benefit is unquantifiable because it is impossible to quantify the cost of illness that is prevented or quantify the benefit of illness being prevented. For example, because this rule sets food safety standards, this rule reduces the risk of foodborne illnesses like salmonella. However, it is impossible to determine the benefit of reducing or stopping the spread of salmonella at a bed and breakfast without knowing how many people would be exposed to salmonella, the length of time the bacteria was spreading, visitors' susceptibility to salmonella and other factors. The number of variables makes quantifying the benefit of food safety difficult and imprecise. While the cost and benefit of the food safety provisions in rule 15.5 is difficult to quantify, the benefits outweigh the costs because the costs are expected to be low and the benefit of preventing foodborne illnesses is high because the communicability of foodborne illness.

V. Alternative Methods of Achieving the Purpose of the Rule

Industry self-regulation is possible but that raises the likelihood that patrons will eat food that was not prepared according to food safety standards or stay in rooms that are improperly cleaned and maintained.

VI. Complaints and Comments

This rule was promulgated by IDOH with industry support in 1992. This rule is enforced by the local health departments who act as IDOH's subordinates on food safety matters. The Food Protection Division has not received any complaints or comments regarding this rule from the local health departments or businesses. However, moving forward, it is important for the IDOH to connect with the Indiana Bed & Breakfast Association to discuss updating the rule to ensure it remains effective and meets industry needs.

VII. Difficulties Encountered

As noted above, this rule is enforced by the local health departments. IDOH has not been informed of any difficulties by local health departments in administering this rule or difficulties by industry complying with this rule.

VIII. Changes in Technology, Economic Conditions, or Other Factors

This rule was adopted in 1992. Since then, food safety standards have changed. Further, the need for this rule has changed due to businesses like Airbnb and Vrbo because there are fewer locations operating as bed and breakfasts and residences that are rented via Airbnb and Vrbo do not meet the definition of bed and breakfast establishment unless they provide breakfast to guests.

This rule was last readopted in 2019. Since then, Indiana has moved from the potentially hazardous food standard to the time/temperature control for safety food (TCS) standard in both IC 16-42 and the retail food code, 410 IAC 7-26. The TCS standard reflects current food safety standards issued by the US Food and Drug Administration.

IX. Other State or Federal Requirements

There are no federal standards on bed and breakfast establishments. Neither the surrounding states nor the states identified by OMB have less stringent standards than Indiana.

Illinois's Bed and Breakfast Act, located at 50 ILCS 820, is substantially the same as 410 IAC 7-15.5. Both Illinois' Act and this rule incorporate the "potentially hazardous food" standard that has been abandoned by the FDA and the food service industry in 2013.

Kentucky regulates food establishments, including bed and breakfasts, consistent with the 2013 FDA Model Food Code. This standard is stricter than Indiana's standard, which does not require compliance with a model food code.

Michigan's Food Law of 2000 as amended holds bed and breakfasts to the same standard as other food establishments. They must comply with the 2013 FDA Model Food Code. This standard is stricter than Indiana's standard, which does not require compliance with a model food code.

Ohio regulates food establishments, including bed and breakfasts, consistent with the 2013 FDA Model Food Code pursuant to ORC Ann. 3731.01.

South Dakota, in ARSD 44:02:06 has not adopted an FDA code. However, the standard adopted is substantially similar to Indiana's standard and also incorporates the potentially hazardous food standard.

Under IDAPA 16.02.19.002, Idaho adopts the 2013 model food code but Idaho Code § 39-1602 exempts bed and breakfasts from following the code. As a result, Idaho's standards are substantially similar to Indiana's standards because Indiana also exempts bed and breakfasts from food code standards.

X. Previous Amendments

This rule has not been substantively amended since its adoption in 1992. However, IDOH intends to amend this rule in the next eighteen (18) months because it incorporates outdated standards that are creating a burden on industry and food safety.

XI. Integration into Indiana Code

The substantive content in this rule is not appropriate for integration into the Indiana Code because it reflects food safety standards, and those standards change depending on market conditions and technology available. Several provisions of this rule are based on outdated versions of the FDA Model Food Code and are inconsistent with current provisions of IC 16-42-5. Instead of adopting this rule into the Indiana Code, IDOH will work to repeal this rule. At that time, IDOH will incorporate this rule into the newly adopted 410 IAC 7-26 and simultaneously update this incorporated language to reflect current standards. Despite this plan, IDOH does not have an estimated date that this repeal and incorporation into 410 IAC 7-26 will take place. Any amendment to 410 IAC 7-26 must be made in consultation with the Indiana Restaurant & Lodging Association to ensure that any edits being proposed adequately reflect business and food safety needs. Additionally, the statute separating bed and breakfast facilities should be repealed to support treating bed and breakfasts the same as all other retail food establishments.

XII. Contact Information of Staff to Answer Substantive Questions

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410 IAC 12-1, COMMERCIAL WEIGHING AND MEASURING DEVICES

I. Statement Whether the Subject Matter Covered by the Rule Remains Carried out by the Agency

IDOH's Weights and Measures division continues to set commercial weighing and measuring standards within the state.

II. Rationale for the Continued Need for the Rule

There is a continued need for this rule because this rule creates standards for weights used in many areas of commerce, such as weights of agricultural foods and petroleum products. Without these rules, there would not be a definitive standard, which allows for deceptive marketing practices.

III. Analysis of fees, fines, and civil penalties under IC 4-22-2-19.6

410 IAC 12-1-7 sets civil penalties for failure to comply with Indiana Code provisions related to weights and measures and this rule. Civil penalties are within a specified range with specific penalties set based on harm to public health, the extent of the deviation from statutory requirements, the motive for the deviation and any history of noncompliance. While these civil penalties predate IC 4-22-2-19.6, the method of determining a civil penalty is consistent with IC 4-22-2-19.6.

IV. Cost-Benefit, Economic Impact, Fiscal Impact, or Regulatory Burden Statements

No previously published cost-benefit, economic impact, fiscal impact, or regulatory burden statements are available from the Indiana Register. A copy of a regulatory burden statement that meets the requirements of IC 4-22-2-22.7 follows:

1. Description of Rule

a. History and Background of the Rule - This rule sets the standards for compliance with federal requirements for weighing and measuring devices used in commerce throughout the state. This rule was last amended in 2014.

b. Scope of the Rule - The scope of this rule is to incorporate National Institute of Standards and Technology (NIST) standards necessary to maintain uniform enforcement of weights and measuring devices consistency.

c. Statement of Need - This rule is required by IC 24-6-3-2. Further, without this rule, there would be no standards for weights and measures inspections.

d. Statutory Authority for the Proposed Rule - IC 24-6-3-2.

e. Fees, Fines, and Civil Penalties - 410 IAC 12-1-7 sets civil penalties for failure to comply with Indiana Code provisions related to weights and measures and this rule. Civil penalties are within a specified range with specific penalties set based on harm to public health, the extent of the deviation from statutory requirements, the motive for

the deviation and any history of noncompliance. While these civil penalties predate IC 4-22-2-19.6, the method of determining a civil penalty is consistent with IC 4-22-2-19.6.

2. Fiscal Impact Analysis

a. Anticipated Effective Date – January 1, 2026.

b. Estimated Fiscal Impact on State and Local Government - This rule does not directly impact local government, but Indiana code allows locals to utilize city and county inspectors.

c. Sources of Expenditures or Revenues Affected by the Rule - IDOH is already obligated by code to keep standard weights and ensure compliance with those weights. Civil penalties could be collected under this rule, but those penalties are expected to defray the cost of inspections and not be a source of revenue.

3. Impacted Parties - Impacted parties of this rule are businesses that sell goods via weight and any parties that purchase those goods. Examples include grocery stores and the transportation and shipping industries. Given the breadth of the impact of this rule, most businesses in Indiana could be affected.

4. Changes in Proposed Rule - This is a rule readoption process, and no changes are being proposed.

5. Benefits Analysis

a. Estimate of Primary and Direct Benefits of the Rule -The benefit of this rule is that Hoosiers can expect items purchased are weighted properly and can therefore be used for their intended purpose. The value of this benefit cannot be quantified, however, as there are too many items with widely different prices to be considered and consumers' expectations are subjective. The Department believes it is significant, however, for consumers to be able to rely on the accuracy of the weight of items they purchase.

b. Estimate of Secondary or Indirect Benefits of the Rule - An indirect benefit of this rule to the public is economic productivity because individuals can expect proper weights on items purchased, which helps facilitate commerce. This benefit also cannot be quantified because consumers' expectations are subjective but is also expected to be significant.

c. Estimate of Any Cost Savings to Regulated Industries - There are minimal cost savings to this rule because it requires compliance with NIST standards, which are industry standards.

6. Cost Analysis

a. Estimate of Compliance Costs for Regulated Entities - The compliance cost with this rule is ensuring that weights and measures comply with 2013 standards when NIST adopts yearly standards and is currently on the 2025 standard. This creates compliance costs for entities that operate in multiple states. This cost cannot be quantified because the Department doesn't know all the businesses that operate in multiple states or the costs incurred specifically from having to comply with multiple standards. The cost is not believed to be significant, however, as the results from applying various standards are not likely to differ significantly.

b. Estimate of Administrative Expenses Imposed by the Rule - There are no administrative expenses imposed by this rule.

c. The fees, fines, and civil penalties analysis required by IC 4-22-2-19.6 - There are no fees, fines or civil penalties under this rule.

d. If the implementation costs of the proposed rule are expected to exceed the threshold set in IC 4-22-2-22.7(c)(6) - There are no implementation costs to this rule because this rule matches Indiana Code.

7. Sources of Information

a. Independent Verifications or Studies - IDOH did not independently verify the information in this analysis or rely on any studies.

b. Sources Relied Upon in Determining and Calculating Costs and Benefits - IDOH did not use any outside sources to determine the costs and benefits of this rule and did not consult with industry groups.

8. Regulatory Analysis - This rule imposes some costs on regulated entities because it adopts an outdated NIST standard. Industry representatives have requested IDOH adopt the latest NIST standard. The only reason that IDOH has not adopted the 2025 standards is because of the Weights & Measures Division's impending transfer to Indiana Department of Homeland Security.

This rule applies to any business in Indiana that buys or sells a product or relies on weights to conduct business. It is impossible to calculate the number of businesses this rule applies to without an exact number of businesses operating in Indiana. While the Indiana Secretary of State contains a listing of all businesses registered with the State, this listing does not include businesses like sole proprietorships that do not have to register.

It is also impossible to quantify the costs to comply with this rule because of the varying standards that exist and because IDOH does not have information on whether businesses comply with more stringent standards than this rule.

The 2013 handbooks adopted by this rule are based on Class F field weights that are less precise than current weights.

V. Alternative Methods of Achieving the Purpose of the Rule

Other than more current NIST standards, no alternative methods exist because this rule relates to commercial weights and standards. Without a set standard, the public can be misled. A benefit to the government setting standards is that the consumers won't be at risk for ineffective devices because businesses are held to standards that are independent of profit. Ultimately this can ensure the efficacy of health-related goods, such as medicines.

VI. Complaints and Comments

There have been comments received from industry regarding the fact that this rule is out of date.

VII. Difficulties Encountered

IDOH has not experienced any difficulties enforcing this rule and regulated entities have not expressed any difficulties in complying with the rule.

VIII. Changes in Technology, Economic Conditions, or Other Factors

The only changes in technology, economic conditions or other factors relevant to this rule is the promulgation of the new NIST standards. Within these standards, the 2013 NIST handbook required the Class F field weights that have been discontinued because they did not have the precision needed and provided inconsistent weight measurements.

IX. Other State or Federal Requirements

There are no federal requirements.

Illinois statute 225 ILCS 470 adopts the same NIST handbooks as Indiana but also adopts subsequent publications – unlike Indiana which adopts the 2013 handbooks specifically.

Michigan statute MCLS § 290.628c adopts the same handbooks as Indiana but adopts the 2023 edition.

Ohio statute ORC Ann. 1327.49 adopts the NIST handbooks without reference to a specific year.

Kentucky statute KRS § 363.590 explicitly adopts the most recent NIST handbooks.

Idaho Administrative Code IDAPA 02.02.14.004 adopts the 2023 versions of the NIST handbooks used in Indiana.

South Dakota adopts the 2020 NIST handbooks in ARSD 20:01:02.

Indiana's standard is more restrictive than the comparison states because the NIST handbook 130 adopted doesn't reference e-commerce and biodiesel. It also has substantially fewer standards relevant to e-commerce. Further, because later standards are adopted by the surrounding states, Indiana keeping to the 2013 standard creates a burden on industry.

X. Previous Amendments

This rule has not been substantively amended since 2013. However, IDOH is working to update the rule to adopt the 2025 NIST handbooks.

XI. Integration into Indiana Code

This rule could be incorporated into the Indiana Code because IC 24-6-3-16 explicitly adopts the 1993 NIST Handbooks. If this rule were integrated into the Indiana Code, the chapter should be written to adopt the latest version of the NIST handbook to avoid the need for yearly amendments.

XII. Contact Information of Staff to Answer Substantive Questions

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410 IAC 12.1, MOTOR FUEL

I. Statement Whether the Subject Matter Covered by the Rule Remains Carried out by the Agency

IDOH's Weights and Measures division continues to set motor fuel standards within the state.

II. Rationale for the Continued Need for the Rule

There is a continued need for this rule because this rule creates motor fuel standards throughout the state. Without these rules, there would not be a definitive standard, which allows for deceptive marketing practices.

III. Analysis of fees, fines, and civil penalties under IC 4-22-2-19.6

410 IAC 12.1-2-5 sets out IDOH's authority to stop sales or act against motor fuel registration. However, there are no fees, fines, or civil penalties under IC 4-22-2-19.6 in this rule.

IV. Cost-Benefit, Economic Impact, Fiscal Impact, or Regulatory Burden Statements

No previously published cost-benefit, economic impact, fiscal impact, or regulatory burden statements are available from the Indiana Register. A copy of a regulatory burden statement that meets the requirements of IC 4-22-2-22.7 follows:

1. Description of Rule

a. History and Background of the Rule - This rule provides for the inspection of gasoline for octane rating and the proper labelling of gasoline and gasoline pumps by the Indiana Department of Health Division of Weights, Measures and Metrology (Weights and Measures). This rule was adopted in 1993 and was amended in 2013.

b. Scope of the Rule - The scope of this rule is to allow IDOH to set motor fuel standards and the inspection of motor fuel sold in Indiana.

c. Statement of Need - This rule is required by IC 16-44-3-5. Further, without this rule, there would be no methodology for inspection of motor fuel outlets and there is a likelihood of fuel being sold that does not comply with IC 16-44-3 and fuel that is mixed with water or other chemicals.

d. Statutory Authority for the Proposed Rule - IC 16-19-3-4(b); IC 16-44-3-5.

e. Fees, Fines, and Civil Penalties - 410 IAC 12.1-2-5 allows IDOH to stop the sale of noncompliant fuel, but this rule does not impose fees, fines or civil penalties.

2. Fiscal Impact Analysis

a. Anticipated Effective Date – January 1, 2026.

b. Estimated Fiscal Impact on State and Local Government - This rule does not fiscally impact local government. IDOH fuel inspectors are responsible for inspections under IC 16-44-3-5 and 410 IAC 12.1.

c. Sources of Expenditures or Revenues Affected by the Rule - This rule does not impact on the revenue of state because IDOH is already obligated to test motor fuels.

3. Impacted Parties - Impacted parties of this rule are motor fuel outlets that must comply with the rule and any individual that purchases motor fuel. IDOH estimates that there are at least 4,000 motor fuel outlets in the state. According to the Indiana Vehicle Fuel Dashboard data on 2024 vehicle registrations and discounting approximately the 2.83% of vehicle registrations where the fuel type is unknown, approximately 0.50% of vehicles registered in Indiana rely on electric batteries. At least 96% of the 6.6 million vehicles registered in Indiana rely partial or totally on some type of motor fuel. Therefore, the owners of at least 6.3 million vehicle vehicles in Indiana would utilize a motor fuel outlet that would be subject to this rule. This estimate cannot account for situations where multiple individuals share a vehicle, situations where a single individual owns multiple vehicles, or situations where vehicles registered outside the state purchase motor fuel in Indiana. For that reason, the number of individuals impacted by this rule is likely different but could be higher or lower than 6.3 million.

4. Changes in Proposed Rule - This is a rule readoption process, and no changes are being proposed.

5. Benefits Analysis

a. Estimate of Primary and Direct Benefits of the Rule - The benefit of this rule is that Hoosiers can expect motor fuel purchased is not contaminated with water or other chemicals and that motor fuel meets standards that the motor vehicles were designed for. The Department cannot estimate the value of damage that might occur to vehicles in the absence of the rule or how consumers inability to rely on the quality of motor fuel might impact their automobile and fuel purchasing behavior and their lives generally.

b. Estimate of Secondary or Indirect Benefits of the Rule - An indirect benefit of this rule to the public is economic productivity because individuals can expect proper miles per gallon on their vehicles and will not have to worry about vehicle damage due to contaminated fuel.

c. Estimate of Any Cost Savings to Regulated Industries - There are minimal cost savings to this rule because it requires compliance with ASTM standards, which are both industry standard and required by IC 16-44-3-5.

6. Cost Analysis

a. Estimate of Compliance Costs for Regulated Entities - The compliance cost with this rule is ensuring that motor fuel complies with the 2013 ASTM and NIST standard when ASTM and NIST adopts yearly standards and is currently on the 2025 standard.

b. Estimate of Administrative Expenses Imposed by the Rule - There are minimal to no administrative expenses imposed by this rule. Sections 2, 2.3 and 2.5 set substantive requirements on regulated entities but these requirements come from the NIST and ASTM handbooks adopted by reference into the rule and Indiana Code already permits the adoption of these handbooks. Section 3 of this rule creates documentation standards for motor fuel that was delivered but these standards are extensions of the registration requirement set by IC 16-44-3-8 and the labeling requirement set by 16 CFR 306.12. Section 4 of this rule sets a registration requirement that mirrors IC 16-44-3-8.

c. The fees, fines, and civil penalties analysis required by IC 4-22-2-19.6 - There are no fees, fines or civil penalties under this rule.

d. If the implementation costs of the proposed rule are expected to exceed the threshold set in IC 4-22-2-22.7(c)(6) – There are no implementation costs associated with this rule because it is a readoption.

7. Sources of Information

a. Independent Verifications or Studies - IDOH did not independently verify the information in this analysis or rely on any studies.

b. Sources Relied Upon in Determining and Calculating Costs and Benefits - IDOH did not use any outside sources to determine the costs and benefits of this rule and did not consult with industry groups.

8. Regulatory Analysis - This rule imposes some costs on regulated entities because it adopts an outdated ASTM standard. Industry representatives have requested IDOH adopt the latest ASTM standard. This rule incorporates the 2013 ASTM D4814-13a, ASTM D2699-13a and ASTM D2700-13a standards. ASTM D4814-2025 incorporates updated schedules for gasoline that improves how fuel performs given seasonal weather changes. This change allows for improved engine performance. The update to ASTM D2699-13a allows the sale of fuels containing up to 25% ethanol, which is an increase from 10% ethanol in the 2013 standard. The ASTM D2700-13a was updated with new methodology for fuels with lower octane ratings, such as alternative fuel blends.

It is impossible for IDOH to estimate the cost of having an outdated ASTM standard but failure to follow the most recent ASTM standards prevents the sale of fuels with up to 25% ethanol and prevents the sale of alternative fuel blends, which has an impact on individuals purchasing motor fuels.

However, despite being unable to quantify the exact costs and benefits of this rule, the benefits of a single fuel standard within the state outweigh any compliance cost until the rule is updated or transferred to the Indiana Code.

V. Alternative Methods of Achieving the Purpose of the Rule

No alternative methods exist. The ASTM and NIST handbooks adopted by this rule are the industry standard for motor fuel. However, relying on businesses to self-regulate would allow for motor fuel to be sold that has been mixed with other substances, potentially unsafe or harmful solutions.

VI. Complaints and Comments

IDOH has not received any complaints but has received requests from industry representatives for IDOH to update this rule to the latest ASTM and NIST handbooks.

VII. Difficulties Encountered

IDOH has not experienced any difficulties enforcing this rule.

VIII. Changes in Technology, Economic Conditions, or Other Factors

This rule was last amended in 2013. Since then, ASTM and NIST have issued new handbooks.

IX. Other State or Federal Requirements

- Federal requirements are set forth in 16 CFR 306.12 and 40 CFR Part 1090.
- Illinois adopts ASTM in 815 ILCS 370/4 without reference to year.
- Idaho requires the latest ASTM in Idaho Code § 37-2506.
- Kentucky adopts the latest year of ASTM handbook in KRS 363.904.
- Michigan adopts various years ASTM handbooks depending on the specific standard in MICH. ADMIN. CODE R 285.564.11.
- Ohio – no ASTM standards found in OAC Ann. 901:6-5-01 or ORC Ann. 1327.70.
- South Dakota adopts ASTM fuel standards that were in existence on January 1, 2020, in S.D. Codified Laws § 37-2-6.

X. Previous Amendments

This rule has not been substantively amended since 2013. However, IDOH is working to update the rule to adopt the 2025 handbooks.

XI. Integration into Indiana Code

This rule could be incorporated into the Indiana Code because IC 16-44-3-5 explicitly requires IDOH to adopt ASTM Handbooks.

XII. Contact Information of Staff to Answer Substantive Questions

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410 IAC 13, SANITARY BEDDING

I. Statement Whether the Subject Matter Covered by the Rule Remains Carried out by the Agency

IDOH continues to regulate the resale of bedding.

II. Rationale for the Continued Need for the Rule

There is a continued need for this rule because this rule creates standards for sale of bedding. Without this rule, customers may have issues with bed bugs, improperly filled, or cleaned mattresses.

III. Analysis of fees, fines, and civil penalties under IC 4-22-2-19.6

There are no fees, fines, or civil penalties under this rule.

IV. Cost-Benefit, Economic Impact, Fiscal Impact, or Regulatory Burden Statements

No previously published cost-benefit, economic impact, fiscal impact, or regulatory burden statements are available from the Indiana Register. A copy of a regulatory burden statement that meets the requirements of IC 4-22-2-22.7 follows:

1. Description of Rule

a. History and Background of the Rule - This rule sets standards for sale of bedding to protect the public from unsafe goods or inaccurate goods. This rule prohibits the manufacture or sale of bedding which is unsanitary or contains filling material that is inaccurate.

b. Scope of the Rule - This rule sets the standards for sale of mattresses and has been unchanged since its promulgation.

c. Statement of Need - Without this rule, consumers would be sold mattresses in unsanitary conditions, which would allow for the spread of pests and disease. This rule also ensures that customers are not misled by misrepresentations regarding filling materials in bedding.

d. Statutory Authority for the Proposed Rule - IC 16-19-3-4; IC 16-41-32-14.

e. Fees, Fines, and Civil Penalties - There are no fees, fines or civil penalties. 16-41-32-30 sets the penalties for violation of this rule.

2. Fiscal Impact Analysis

a. Anticipated Effective Date – January 1, 2026.

b. Estimated Fiscal Impact on State and Local Government - This rule does not have an impact on state or local government because IDOH was already tasked with enforcing this rule and does not utilize local government staff.

c. Sources of Expenditures or Revenues Affected by the Rule - This rule does not impact the revenue of state because IDOH is already obligated to enforce IC 16-41-32.

3. Impacted Parties - Parties impacted by this rule are sellers of mattresses, which include large retailers like Mattress Firm and resellers, who are usually thrift stores, and any purchasers of those mattresses. The parties that impacted this rule are any parties that sell goods and commodities or transport those goods or commodities.

4. Changes in Proposed Rule – There are no changes because this is a readoption.

5. Benefits Analysis

a. Estimate of Primary and Direct Benefits of the Rule - The benefit of this rule is that Hoosiers can expect mattresses purchased are not contaminated with pests and are properly sanitized. The Department is unable to quantify this benefit, however, without knowing the total number of resold mattresses, including those resold by individuals, and whether the purchaser would have purchased the same used mattress without the rule, and if not the price of the mattress the purchaser would have purchased instead.

According to the information that the Department has available, the average cost of a single bed bug remediation starts is $5,000 but the cost of remediation can be substantially higher for hotels and larger buildings. Therefore, the benefit of this rule is avoidance of these remediation costs.

b. Estimate of Secondary or Indirect Benefits of the Rule - An indirect benefit of this rule to the public is economic productivity because individuals who purchase mattresses subject to this rule would not be at risk of disease and would not have to purchase a new mattress.

c. Estimate of Any Cost Savings to Regulated Industries - **–** This rule does not present cost savings to regulated industries because it requires compliance with standards that do not reflect current sanitization practices and regulated industries must undertake additional cost to comply with this rule when those costs would not exist if this rule were up to date.

6. Cost Analysis

a. Estimate of Compliance Costs for Regulated Entities - The compliance cost with this rule is ensuring that secondhand mattresses are cleaned in a manner that complies with this rule when newer sanitization standards exist. The cost of cleaning will vary based on mattress size and the type of disinfectant or sanitization necessary, with the average cost of mattress cleaning being approximately $150.

Businesses that offer cleaning services will need to purchase HEPA-filtration vacuums, equipment like disinfectant sprayers, steam sterilizers or other sanitation systems, and dryers to ensure the mattress is not susceptible to mold growth and labelling equipment. The cost of this equipment can vary from $10,000 at the lower end to over $100,000 for more sophisticated models.

Newer sanitization technologies and standards can ensure a more effective cleaning of the mattress without creating an environmental nuisance that could lead to enforcement actions by the local health department. Newer technologies can also ensure quicker sanitation that lowers costs on regulated entities. These costs could be one half to one fourth lower than the cleaning cost under Indiana’s current standard. However, IDOH is unable to provide definitive cost savings to industry by adopting newer standards because the costs of remediation depend on a variety of factors.

There are limited implementation costs to this rule because this rule substantially matches Indiana Code, and this rule has been unchanged since promulgation. Resellers may have initial difficulties complying with the requirements in section 5 but only because of the reselling community’s apparent unfamiliarity with this rule.

b. Estimate of Administrative Expenses Imposed by the Rule - There are no administrative expenses imposed by this rule.

c. The fees, fines, and civil penalties analysis required by IC 4-22-2-19.6 - There are no fees, fines, or civil penalties under this rule.

d. If the implementation costs of the proposed rule are expected to exceed the threshold set in IC 4-22-2-22.7(c)(6) – There are no implementation costs because this is a readoption.

7. Sources of Information

a. Independent Verifications or Studies - IDOH did not independently verify the information in this analysis or rely on any studies.

b. Sources Relied Upon in Determining and Calculating Costs and Benefits - IDOH did not use any outside sources to determine the costs and benefits of this rule and did not consult with industry groups.

8. Regulatory Analysis - This rule imposes some costs on regulated entities because it does not cover newer sanitation technologies that are not covered by this rule, which means that resellers will need to find older and potentially less effective methods of sanitizing bedding for sale.

The cost to sanitize a mattress under this rule will vary depending on the size of the mattress and the specific cleaning agent used. The average cost of compliance is $150. While 410 IAC 13-1-6(B) sets a permitting fee, IDOH has not attempted to collect this fee since 1995.

The benefit of compliance with this rule is the elimination of pests like bed bugs. The average cost to remediate a bedbug infestation will vary based on the size of the location and the severity of the infestation. However, the average cost of bed bug remediation is approximately $5,000. For that reason, the cost of the rule is outweighed by the benefits of this rule.

V. Alternative Methods of Achieving the Purpose of the Rule

Industry self-regulation is an unsuitable alternative to this rule because customers may be unaware of the risks of unclean mattresses and therefore could be sold contaminated mattresses. This rule also creates an informal standard for the hospitality industry.

VI. Complaints and Comments

The only complaints IDOH has received about this rule are from resellers who are unaware of this rule and their duty to comply with it.

VII. Difficulties Encountered

IDOH previously had inspectors checking thrift stores for resold mattresses but has been required to perform compliance driven inspections.

VIII. Changes in Technology, Economic Conditions, or Other Factors

This rule was first filed in 1950 and has not been amended since. IDOH is unfamiliar with new mattress filling materials and new disinfectants for sanitizing used bedding materials. Changes in filling materials, disinfectants and cleaning standards may justify a rule amendment but no changes are being proposed at this time.

IX. Other State or Federal Requirements

There are no federal requirements. The only states that have requirements comparable to this rule are Illinois and Ohio. Illinois statute 410 ILCS 68/35 is substantially similar to the prohibitions in this rule, but no statute or regulation was found that were comparable to sections four through six.

Ohio Administrative Code OAC Ann. 4101:6-1 is substantially similar to this rule because it contains the licensing and sanitation requirements to Indiana, though Ohio Administrative Code 4101:6-1-17 covers some miscellaneous fillers not

covered by this rule.

Kentucky and Michigan allow the sale of used mattresses but require them to be labeled as such. Idaho and South Dakota require resellers to contact their local health department.

Bed bug infestation of used mattresses (and other used items, such as furniture) is a known problem. Indiana has chosen to try to prevent it, rather than leaving people to choose to risk infestation or with having to go to court for a remedy when labels are not applied. Indiana's status as a crossroads means that more people could be affected by bed bugs and disease due to improperly cleaned mattresses.

While no laws in the OMB identified states were equivalent to requirements in sections 3 through 5 related to filing and labeling requirements, these sections create standards necessary to enforce false advertising laws related to bedding.

X. Previous Amendments

This rule has not been substantively amended since adoption in 1950.

XI. Integration into Indiana Code

This rule has not been amended since its adoption in 1950, and the Department has not been asked to amend this rule. Therefore, this rule can be integrated into the Indiana Code with any needed updates to address new technologies and remove the permit fee that is no longer collected.

XII. Contact Information of Staff to Answer Substantive Questions

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410 IAC 16.2, HEALTH FACILITIES; LICENSING AND OPERATIONAL STANDARDS

I. Statement Whether the Subject Matter Covered by the Rule Remains Carried out by the Agency

The Indiana Department of Health licenses and inspects all nursing homes and residential care facilities in the state and is the designated surveyor for certified facilities for the Centers for Medicare and Medicaid Services.

II. Rationale for the Continued Need for the Rule

As the designated surveyor for certified facilities, IDOH will lose the related CMS funding if it fails to meet the required expectations. In other words, these regulations ensure the cost of IDOH's programs, including the salaries and benefits of those employees involved in regulatory activities, are covered by federal funds.

The rule largely mirrors federal regulations which all skilled nursing facilities and nursing facilities which accept Medicare and/or Medicaid must follow. Nursing facilities certified by the Medicare and/or Medicaid program are subject to federally mandated and state-enforced quality and safety standards. IDOH has entered into an agreement with the Secretary of Health and Human Services under Section 1864 of the Social Security Act whereby IDOH is tasked with surveying facilities and enforcement activities. HHS provides funding for these activities. IDOH's rules are written to give clarity and ease of reference.

The rule largely mirrors federal regulations which all skilled nursing facilities and nursing facilities which accept Medicare and/or Medicaid must follow. Nursing facilities certified by the Medicare and/or Medicaid program are subject to federally mandated and state-enforced quality and safety standards.

Because these rules are based on CMS regulatory requirements, no action on behalf of IDOH can minimize the economic impact.

III. Analysis of fees, fines, and civil penalties under IC 4-22-2-19.6

The rule provides for civil penalties for comprehensive care facilities at 410 IAC 16.2-3.1-2(m)(1) and 410 IAC 16.2-3.1-2(m)(2) and for residential care facilities at 410 IAC 16.2-5-1.1(m)(1) and 410 IAC 16.2-5-1.1(m)(2). The civil penalties are statutory in nature, being set forth at 16-28-5-4. Both the statute and corresponding rule set forth a fine not to exceed 10,000 in addition to other penalties. The rule categorizes breaches of the rules into offenses or deficiencies. An offense presents a substantial probability that death or a life-threatening condition will result and a fine shall be issued not to exceed $10,000. A deficiency presents an immediate or direct, serious adverse effect on the health, safety, security, rights, or welfare of a resident and a fine shall be issued not to exceed $5,000.

The program uses a template (please refer to table below) to determine the amount of a fine to maintain consistency. The issuance of a fine is subject to appeal rights under AOPA. This fine section of the rule is currently being updated to include the factors used to determine the fine.

IV. Cost-Benefit, Economic Impact, Fiscal Impact, or Regulatory Burden Statements

No previously published cost-benefit, economic impact, fiscal impact, or regulatory burden statements are available from the Indiana Register. A copy of a regulatory burden statement that meets the requirements of IC 4-22-2-22.7 follows:

1. Description of Rule

a. History and Background of the Rule - Through a written agreement, the Indiana Department of Health (IDOH) is the agency tasked with regulating health facilities on behalf of the Center for Medicaid Services (CMS). IDOH is also responsible for licensing health facilities pursuant to state law (IC 16-28-1-7) in addition to its work for CMS. The present rules became effective on April 1, 1997, and were readopted in 2001, 2007, 2013, and 2019. The rules were promulgated to match the federal regulations for health facilities that participate in Medicare/Medicaid.

b. Scope of the Rule - The IDOH licenses the following health facilities: comprehensive care facilities (i.e. nursing and skilled nursing homes), residential care facilities, Intermediate Care Facilities for the Mentally Retarded, Health Care Facilities for Children, and Health Facilities for Developmentally Disabled Persons. IDOH has an Agreement with the Secretary of Health and Human Services to provide regulatory enforcement and compliance activities. The licensure requirements are meant to protect the health, safety, security, rights, and welfare of residents. This includes regulation of facilities, ownership groups, and medical staffing and service requirements. The rules are based on federal regulations that we survey on behalf of CMS to simplify state and federal compliance, address licensure as required by CMS, and clarify things where CMS requires compliance but does not elaborate to ensure that facilities understand the minimum required to meet compliance. The rules do apply to facilities that are only licensed by the state and do not participate in Medicare/Medicaid, but those facilities must meet the same standards for licensure as all other facilities even if they are not required to comply with the federal regulations to ensure the same standard of care for residents. A highlighted portion of the rule is attached, showing the differences in our rule from the federal.

c. Statement of Need - This rule is necessary because IDOH is required to license health facilities to protect the health, safety, security, rights, and welfare of the residents in facilities. For Indiana to receive the necessary federal funds to perform our statutory regulatory duties we are required to follow the rules and regulations set by CMS.

d. Statutory Authority for the Proposed Rule - IC 16-28-1-7; IC 16-28-12-1

e. Fees, Fines, and Civil Penalties - The fines in the rule match the statutorily set limits in 16-28-9-6. The rule further clarifies how fines are calculated, in compliance with IC 4-22-2-19.6.

2. Fiscal Impact Analysis

a. Anticipated Effective Date – January 1, 2026.

b. Estimated Fiscal Impact on State and Local Government - This rule is designed to ensure compliance with federally mandated conditions to ensure no impact on expenditures and revenues of State Government. Failure to readopt the rules places the majority of the program's funding at risk. Approximately 2/3 of the funding for Indiana's regulatory activity relating to health facilities comes from the federal government, providing $17,186,484 through various CMS grants (TITLE18, TITLE19, CLIA, and Hospice).

Out of IDOH's consumer health regulatory division total spending of $27,973,632, $26,181,788 was for federally regulated activities and $1,791,844 was for state-only regulated activities. The $1,791,844 is part of the $6,566,443 spent from Medicare State Fund 17610. Of the $26,181,788 spent on federally regulated activities, $17,186,464 was funded by the Federal Government through various CMS grants (TITLE18, TITLE19, CLIA, and Hospice).

c. Sources of Expenditures or Revenues Affected by the Rule - The rule is designed to ensure funding is maintained through the federal government, and appropriations traditionally made to IDOH for its statutory licensing and enforcement duties. Of the $26,181,788 spent on federally regulated activities, $17,186,464 was funded by the Federal Government through various CMS grants. Fines collected go directly to the state's general fund and are not included as revenue.

3. Impacted Parties - Health facilities that are licensed by IDOH are impacted by this rule and members of the public who require health facility services. There are approximately 229 state only licensed facilities and 509 CMS regulated facilities. Of those 509 facilities, approximately 151 have licensed residential care beds.

4. Changes in Proposed Rule – There are no changes because this is a readoption.

5. Benefits Analysis

a. Estimate of Primary and Direct Benefits of the Rule - These rules are necessary to ensure compliance with both federal and state licensure requirements. 42 CFR **§ 483.70(a) requires states to license facilities.** This rule benefits the residents of health facilities to ensure that health facilities meet minimum standards of care to protect the health and safety of patients. It sets standards for different levels of facilities to ensure that residents are at the proper type of facility to meet their needs, for example, nursing versus skilled nursing facilities. It provides the minimum services that are provided, for example, nursing services, physician services, and dietary services, among many others. These standards ensure basic levels of care that are consistent for any licensed facility. The standards vary depending on the facility type so residents can find the level of care to meet their needs.

This rule benefits the residents of health facilities to ensure that health facilities meet minimum standards of care to protect the health and safety of patients. It sets standards for different levels of facilities to ensure that residents are at the proper type of facility to meet their needs, for example, nursing versus skilled nursing facilities. It provides the minimum services that are provided, for example, nursing services, physician services, and dietary services, among many others. These standards ensure basic levels of care that are consistent for any licensed facility. The standards vary depending on the facility type so residents can find the level of care to meet their needs. It ensures that all facilities in the state meet the same standards to protect patients.

The rule also ensures continued funding by the federal government. Of IDOH's consumer health regulatory division's total spending of $27,973,632, $26,181,788 was for federally regulated activities and $1,791,844 was for state-only regulated activities. The $1,791,844 is part of the $6,566,443 spent from Medicare State Fund 17610. Of the $26,181,788 spent on federally regulated activities, $17,186,464 was funded by the Federal Government through various CMS grants (TITLE18, TITLE19, CLIA, and Hospice).

b. Estimate of Secondary or Indirect Benefits of the Rule - A secondary benefit of our rule is that it clarifies expectations that would require guesswork by facilities in creating processes for compliance with federal and state regulations. The rules are designed to clearly set forth the minimum standards for facilities to maintain compliance and retain their provider status.

c. Estimate of Any Cost Savings to Regulated Industries - By clearly setting forth expectations required to comply with federal and state requirements, the rule allows facilities to draft policies and procedures that will enable the facilities to show compliance during regulatory and licensing surveys.

6. Cost Analysis

a. Estimate of Compliance Costs for Regulated Entities - This rule is based on Indiana's requirements to ensure CMS federal regulations are met. Differences in our rule versus the federal requirements is attached, with highlights. The majority of Indiana's rules mirror federal rules, clarify expectations of what would be necessary to meet conditions of participation, and establish licensing processes as 42 CFR §483.70(a) and 16-28-2 require licensure.

Indiana's rules do not impose additional costs for the facilities who accept Medicaid that must comply with the federal regulations upon which Indiana's rules are based. Therefore, the cost of compliance is based on the federal regulations rather than the state regulations. There are approximately 229 state only licensed facilities and 509 CMS regulated facilities. Of those 509 facilities, approximately 151 have licensed residential care beds. The cost of the rule is mainly for the state-only facilities because they do not already have to comply with the federal regulations.

Cost of compliance has never been researched in Indiana, and very little research on direct costs of regulation of nursing homes in general is available. Even the federal regulations do not have fiscal analyses of their rules. However, one study completed in 2013 showed, very generally, that approximately 1% of a nursing home's operating expenses are attributable to regulatory compliance

b. Estimate of Administrative Expenses Imposed by the Rule - Indiana's rules do not impose additional administrative expenses on facilities who accept Medicare/Medicaid as those facilities must comply with the federal regulations upon which Indiana's rules are based. There are approximately 229 state only licensed facilities and 509 CMS regulated facilities. Of those 509 facilities, approximately 151 have licensed residential care beds. Additional administrative costs likely involve having staff spend time on administrative matters and reporting issues that they may not otherwise have to do. However, we cannot quantify how much administrative time is spent on ensuring regulatory compliance versus everyday administrative duties. No research on this particular issue can be found. However, administrative portions of the regulations such as reporting, documentation, and record-keeping are included in the 1% estimate reported in subsection a.

c. The fees, fines, and civil penalties analysis required by IC 4-22-2-19.6 - This analysis is provided in Section III above.

d. If the implementation costs of the proposed rule are expected to exceed the threshold set in IC 4-22-2-22.7(c)(6)

7. Sources of Information

a. Independent Verifications or Studies - Indiana has no independent verifications or studies as these rules are required by federal regulation. However, the lack of such analysis amongst all states was noted in a research article titled "The Effect of State Regulatory Stringency on Nursing Home Quality." Mukamel DB, Weimer DL, Harrington C, Spector WD, Ladd H, Li Y. The effect of state regulatory stringency on nursing home quality. Health Serv Res. 2012 Oct;47(5):1791-813. doi: 10.1111/j.1475-6773.2012.01459.x. Epub 2012 Sep 4. PMID: 22946859; PMCID: PMC3513606.

IDOH used Mukamel DB, Li Y, Harrington C, Spector WD, Weimer DL, Bailey L. Does state regulation of quality impose costs on nursing homes? Med Care. 2011 Jun;49(6):529-34. doi: 10.1097/MLR.0b013e318207ef9e. PMID: 21558967.

b. Sources Relied Upon in Determining and Calculating Costs and Benefits - No other sources were relied upon.

IV. Alternative Methods of Achieving the Purposes of the Rule

Because these rules are based on CMS regulatory requirements, no action on behalf of IDOH can minimize the economic impact.

V. Complaints and Comments

Complaints or comments received from the public regarding this rule, or the subject matter, have been in regard to parts of the rules that need to be updated to conform to federal requirements, new guidance for tuberculosis testing, and parts that can be eliminated for more efficient and quality delivery of care to residents.

VII. Difficulties Encountered

There have been no difficulties encountered in administering the rule or in small businesses complying with it. The majority of facilities are owned by either large corporate entities or hospitals.

VIII. Changes in Technology, Economic Conditions, or Other Factors

Changes in technology include the widespread use of electronic medical records. Economic changes include the national nursing shortage, which can affect a facilities staff to patient ratio. This has been addressed statutorily by expanding the use of qualified medication assistants.

IX. Other State or Federal Requirements

Because all states must follow CMS regulations, none are less restrictive than the federal rules. The only exception is assisted living facilities, which are not required to be licensed in Indiana if they do not provide nursing services. By statute we do have regulations addressing memory care units. Most states license all facilities as residential facilities. The following charts show the areas that Indiana regulates compared to CMS and the identified states:

Long Term Care	INDIANA	KENTUCKY	OHIO	MICHIGAN	ILLINOIS	IDAHO	SOUTH DAKOTA	CMS
	410 IAC16.2-3	902 KAR 20:048	Ohio Admin. Code 3701-17	Mich. Admin. Code r. 325.20101	"Ill. Admin. Code tit. 77 § 300	IDAPA 16.03.02 Iowa	Art 44:73	42 CFR 483
RESIDENT RIGHTS	x	x	x	x	x	X BY INCORPORATION	x	x
THE ADMINISTRATION AND MANAGEMENT OF HEALTH FACILITIES	x	x	x	x	x	X	x	x
SANITATION AND SAFETY STANDARDS	x	x	x	x	x	X	x	x

ASSESSMENT OF RESIDENTS' NEEDS	x	x	x	x	x	X	x	x
MEDICAL AND NURSING SERVICES	x	x	x	x	x	X	x	x
FOOD AND NUTRITION SERVICES	x	x	x	x	x	X	x	x
INFECTION CONTROL	x	x	x	x	x	X	x	x
ACTIVITIES AND SOCIAL SERVICES PROGRAMS	x	x	x	x	x	X	x	x
CLINICAL RECORDS	x	x	x	x	x	X	x	x

Types of facilities	INDIANA	KENTUCKY	OHIO	MICHIGAN	ILLINOIS	IDAHO	SOUTH DAKOTA	CMS
COMPREHENSIVE CARE FACILITIES	X	X	X	x	X	X	X	x
INTERMEDIATE CARE FACILITIES FOR THE MENTALLY RETARDED	X	X	X	x	X	X	X	x
RESIDENTIAL CARE FACILITIES	X	X	x	x	X	X	X	x
HEALTH CARE FACILITIES FOR CHILDREN	X	X	X	x	X	X	X	x
HEALTH CARE FACILITIES FOR DEVELOPMENTALLY DISABLED PERSONS	X	X	x	x	X	X	X (REGULATIONS FOR BOTH MENTALLY AND DEVELOPMENTAL DISABILITIES COMBINED)	x
ASSISTED LIVING	**Dementia Units only**	X	x	N/A	X	X (COMBINED WITH RESIDENTIAL	X (COMBINED WITH RESIDENTIAL CARE FACILITIES)	N/A

						CARE FACILITIES)		

X. Previous Amendments

This rule was filed originally in 2003, and most recently readopted in 2019.

XI. Integration into Indiana Code

This rule is complex and lengthy, but IDOH will explore ways to possibly transfer it to the Indiana Code.

XII. Contact Information of Staff to Answer Substantive Questions

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410 IAC 21-1, STATE CANCER REGISTRY

I. Statement Whether the Subject Matter Covered by the Rule Remains Carried out by the Agency

IDOH is required by Indiana and federal law to maintain a cancer registry. The data required to be input by reporters is specific and detailed. Unless the provisions of the administrative rule are incorporated into statute, the subject matter covered in 410 IAC 21-1 remains carried out by IDOH and the rule should be readopted.

II. Rationale for the Continued Need for the Rule

There is a continued need for 410 IAC 21-1, implementing the State Cancer Registry. The Indiana State Cancer Registry (ISCR) was established in 1985 with the passage of IC 16-38-2 "for the purpose of recording all cases of malignant disease and other tumors and precancerous diseases required to be reported by federal law or federal regulation or the National Program of Cancer Registries that are diagnosed or treated in Indiana."

Readoption of 410 IAC 21-1 will continue to have the same impact on regulated entities, such as hospitals, laboratories, and other facilities that are mandated reporters. Reporting facilities are offered the use of free cancer data abstracting software, and the registry provides IT user support to facilities at no cost to minimize the expenses to regulated entities. Persons who pay taxes or fees for government services are not affected by the rule, nor are consumers of products and services of regulated entities affected by the rule.

410 IAC 21-1 achieves the regulatory goal of administering the ISCR in the least restrictive manner while incorporating best practices as defined by the CDC's National Program of Cancer Registries (NPCR) and the Indiana State Cancer Registrars' Association. The rule is divided into sections that provide definitions; general requirements; reporting requirements specific to hospitals; reporting requirements for physicians, dentists, and medical laboratories; provisions for the security and confidentiality of data; and reporting responsibilities for IDOH.

410 IAC 21-1 incorporates the NPCR's requirements for state cancer registries, including for the collecting and submitting of reportable data, the use of standardized coding and formats, and the maintenance of data security. These requirements need to be reduced to statute or administrative rule by Indiana.

410 IAC 21-1 is written for ease of comprehension in that the two main types of entities regulated, hospitals and individual/smaller providers, are covered in separate sections of the rule. Sections on definitions and general requirements provide basic information, and the section on data security and confidentiality places responsibility on IDOH to safeguard data belonging to individuals with cancer.

410 IAC 21-1 does not contain any fees, fines, or civil penalties for mandatory reporters.

III. Analysis of fees, fines, and civil penalties under IC 4-22-2-19.6

There are no fees, fines, or civil penalties for reports to the ISCR; free software is provided for reporters to use, and technical support is provided without charge to reporters by IDOH.

IV. Cost-Benefit, Economic Impact, Fiscal Impact, or Regulatory Burden Statements

No previously published cost-benefit, economic impact, fiscal impact, or regulatory burden statements are available from the Indiana Register. A regulatory burden statement that meets the requirements of IC 4-22-2-22.7 follows:

1. Description of Rule

a. History and Background of the Rule - Cancer has been a reportable disease since January 1, 1987, when IC 16-38-2 (codified as IC 16-4-9-3 prior to 1993) became effective. All healthcare providers, including hospitals, physicians, dentists, medical laboratories, freestanding radiation or medical oncology clinics, ambulatory outpatient clinics, ambulatory outpatient surgical centers, nursing homes, and other health facilities, must report confirmed cases of cancer and other specified tumors and precancerous diseases. This reporting is essential for conducting epidemiologic surveys and applying appropriate preventive and control measures.

b. Scope of the Rule - The scope of the rule implements the ISCR by including sections on definitions, general guidelines, specific reporting requirements for hospitals and other medical facilities, data security and confidentiality, and IDOH reporting requirements.

c. Statement of Need - The need for the rule is to specify reporting requirements and provide for data security and confidentiality required to participate in the NPCR program.

d. Statutory Authority for the Proposed Rule - The ISCR is established by IC 16-38-2-1 and IC 16-38-2-10 directs the IDOH to adopt rules under IC 4-22-2 "necessary to carry out this chapter."

e. Fees, Fines, and Civil Penalties - 410 IAC 21-1 does not add or increase any fees, fines, or civil penalties.

2. Fiscal Impact Analysis

a. Anticipated Effective Date – January 1, 2026

b. Estimated Fiscal Impact on State and Local Government - The adoption of this rule is not expected to have a fiscal impact on state or local government. The cost of the registry has been partially supported by federal funding since the NPCR was established by legislation in 1992. Over the years, electronic reporting has increased, and administrative expenses incurred by the cost of abstracting paper reports to IDOH should decrease from its current level of based on the mandate from the Indiana Cancer Registrar's Association that members use electronic reporting methods beginning January 1, 2026. Amending the administrative rule or combining the sections of the administrative rule IDOH wishes to retain into statute would allow for a further reduction of administrative expenses.

c. Sources of Expenditures or Revenues Affected by the Rule – There are no expenditure or revenues affected by the rule.

3. Impacted Parties - ISCR receives cancer case reports from about 160 hospitals, 40 pathology laboratories, and 120 non-hospital facilities, including freestanding radiation or medical oncology clinics, ambulatory outpatient surgical centers, nursing homes, and mammography or other radiology facilities.

4. Changes in Proposed Rule – There are no changes because this is a readoption

5. Benefits Analysis

a. Estimate of Primary and Direct Benefits of the Rule - There are two sections that set out information integral to the orderly submission of data to the cancer registry in the administrative rule: 410 IAC 21-1-3, which sets out the data terms required to be submitted to the ISCR by hospitals, and 410 IAC 21-1-4, which does the same for physicians,

dentists, and medical laboratories. These two sections provide specific information necessary to implement the statute and provide a benefit as the registry must comply with federal guidelines to receive funding for the cancer registry.

b. Estimate of Secondary or Indirect Benefits of the Rule – There are no secondary or indirect benefits of this rule.

c. Estimate of Any Cost Savings to Regulated Industries – There are no cost savings to regulated entities as a result of this rule.

6. Cost Analysis

a. Estimate of Compliance Costs for Regulated Entities - Regulated entities, e.g., hospitals, physicians, dentists, and medical laboratories, have had an obligation to comply with the statute mandating reporting to the cancer registry since its passage in 1985. Even before that, private cancer registries were in existence and common use in Indiana. While there are no known studies of the amount of costs of compliance for mandatory reporters, the reporters are a key beneficiary of research and public health policy based on the information contained in the cancer registry. There are no additional costs for Regulated Entities imposed by the administrative rule that do not already exist pursuant to IC 16-38-2. The cost of reporting comes from the requirement to report, not how IDOH has implemented the reporting.

b. Estimate of Administrative Expenses Imposed by the Rule - The statute establishing the cancer registry does not specify how reports are to be made to IDOH. The administrative rule as originally promulgated allows for both paper and electronic reporting at no or limited cost to the reporter. The software for electronic reporting is free to the reporters.

c. The fees, fines, and civil penalties analysis required by IC 4-22-2-19.6 - There are no fees, fines, or civil penalties associated with this rule.

d. If the implementation costs of the proposed rule are expected to exceed the threshold set in IC 4-22-2-22.7(c)(6) – There are no implementation costs associated with this rule because it is a readoption.

7. Sources of Information

a. Independent Verifications or Studies – IDOH did not use any independent verifications or studies for this analysis.

b. Sources Relied Upon in Determining and Calculating Costs and Benefits – IDOH did not rely any sources for this analysis.

8. Regulatory Analysis - The cost of reporting to the cancer registry is minimal to the regulated entities, e.g., the hospitals, physicians, dentists, and medical laboratories and is imposed by the statutory requirement rather than the rule. The cost of the cancer registry to IDOH is decreasing due to increased use of electronic reporting methods and the diminution of paper reporting methods. The people of Indiana are the main beneficiaries of the cancer registry, particularly in terms of the value of the research the registry supports and the public health decisions that are informed by registry data. While there is no quantification available of the contribution made over the years to cancer research and policy, the benefit far outweighs the cost to both IDOH and the mandated reporters.

V. Alternative Methods of Achieving the Purpose of the Rule

ISCR must meet NPCR standards for data quality and reporting standards to obtain federal funding. To this end, hospitals and medical facilities that treat cancer patients must know what and how to report data to the registry. This information must be contained in statute or rule. 410 IAC 21-1 should be readopted unless its provisions are enacted as statute.

VI. Complaints and Comments

IDOH has not received any complaints about the current reporting format from facilities.

VII. Difficulties Encountered

IDOH has been impacted financially and operationally from processing large quantities of paper reports of cancer cases coming from non-hospital facilities and some pathology laboratories as permitted by the current administrative rule. Because the rule allows for facilities to report cases by paper, IDOH spends $101,292 per year ($69.00/hour for 1468 hours) for abstracting costs. Other states have phased out paper reporting, with reporters required to submit data electronically. IDOH has a backlog of over 19,000 cases, which undermines data completeness and caused IDOH to miss CDC standards for years 2022 through 2024 due to incomplete case counts.

IDOH seeks to amend the existing administrative rule or shift the administrative rule to Indiana Code. The Indiana Cancer Registrar's Association, representing stakeholders, has independently moved its members to transition to electronic reporting only as of January 1, 2026. IDOH has been stepping up the encouragement of reporters to shift from paper reporting to electronic reporting

VIII. Changes in Technology, Economic Conditions, or Other Factors

IDOH would like to change the terms of 410 IAC 21-1 so that only electronic reporting is used by reporters. In July 2024 and independent of IDOH, the Indiana State Cancer Registrars' Association voted to mandate e-reporting as the only reporting method for its members beginning in January 2026. Technology has expanded options for both large and small providers, and IDOH provides free abstracting software and tech support to reporters. A savings of $101,292 in agency funds would benefit the taxpayers of Indiana, and shifting to electronic reporting only would promote Indiana's efforts to gain compliance with CDC standards.

IX. Other State or Federal Requirements

Federal Regulations – The Cancer Registries Amendment Act (October 1, 1992) requires all states to enact an authorizing law and regulations in eight categories: 1) require reporting of newly diagnosed cancer cases by hospitals and other health-care facilities; 2) require reporting of cancer cases by physicians and other health-care practitioners; 3) guarantee access by the statewide cancer registry to all records of medical status of persons with cancer; 4) require the use of standardized reporting formats; 5) ensure confidentiality of cancer case data; 6) allow use of confidential case data by certain researchers; 7) authorize the conduct of studies using cancer registry data; and 8) ensure the protection of persons complying with the law from liability. *See* 42 USCS §280e(c)(2).

Illinois – The Illinois Department of Public Health may promulgate rules or regulations directing hospitals, laboratories, etc. to submit information to the cancer registry, including the types of information required to be submitted, methods of submission, and "any other detail … necessary or appropriate for administration" of the statute at 410 ILCS 525. The Illinois administrative code at 77 Ill. Adm. Code 840 divides applicable rules into general registry provisions encompassing six public health-related registries, including the Illinois State Cancer Registry. Included are sections on definitions, incorporated and referenced materials, availability of registry information, administrative hearings, quality control measures, and fees for summaries or analyses of data not already prepared by the department. Illinois' statute is more restrictive than Indiana's in that fines can be assessed against non-compliant reporting facilities.

Kentucky – The Kentucky Cancer Registry (KCR) is established at KRS 214.556 in the statute enacting the Breast Cancer Screening Program. The state cancer patient management system is administered by the Lucille Parker Markey Cancer Center. Information is reported to the KCR through the cancer patient management system. Failure to do so can be punished by fines. Information in the registry is privileged and not subject to public records requests. The registry is tasked with reporting responsibilities to various legislative and executive bodies. There is no administrative rule in Kentucky for the

cancer registry. The statute is more restrictive than Indiana's in that Kentucky statute provides that fines can be assessed against non-complaint reporting facilities.

Michigan – Michigan's cancer registry is found in Part 26 of the Public Health statute on Data, Information, And [sic] Research at §333.2619. The section establishes the registry and provides for its purpose, reports, records, rules, collection of data, and reporting. The statute directs the promulgation of rules on 1. a list of diseases to be reported, 2. how cases and information are to be reported, and 3. the terms and conditions under which individual records are to be released. Administrative rules on Cancer Reporting are found at Mich. Admins. Code R 325.9050 through 325.9056. Sections cover details about the registry, definitions, reportable diagnoses, quality of data, confidentiality of reports, the establishment of a scientific advisory panel to review research requests, release of cancer data for research, and exchange of records to other state or national cancer registries. The main difference between Michigan's administrative rule and Indiana's is that Michigan's rule provides for a scientific advisory panel to review research requests and for the exchange of cancer records with other state or national cancer registries.

Ohio – The statute for the state cancer registry is found at Title 37 §3701.262 of the Ohio Revised Code. It includes definitions and authorizes the director of the health department to adopt rules to establish the registry, specify the types of cancer and related diseases to be reported, establish reporting requirements, and establish standards for research projects seeking individual case information. Health care providers and hospitals are required to provide information. The department is granted access to individual medical records. An Ohio cancer hospital and university research institute are directed to analyze and evaluate the reports made to the registry and publish publicly available reports each year. Reporters are not to be held liable for damages for reporting. Facilities can keep their own registries in addition to reporting to the registry. Ohio's administrative rules for the Ohio Cancer Incidence Surveillance System are found at OAC 3701-4-1. It includes sections on definitions, reporting, and confidentiality of data and availability of data to researchers. Ohio's program is similar to Indiana's, except that Ohio gives a cancer hospital and research institute reporting responsibility.

Idaho – Idaho statute at Idaho Code § 57-1701-1707 establishes funding and general provisions for the Idaho cancer registry, including a grant of immunity for reporters unless unauthorized disclosure is due to gross negligence or willful misconduct. References in Idaho Administrative Code are woven into the chapter on Idaho Reportable Diseases and Control Measures, IDAPA 16.02.10. IDAPA 16.02.10.170 addresses reporting requirements to the Cancer Data Registry of Idaho. Idaho administrative code combines cancer registry-specific information within the broader subject of reportable diseases.

South Dakota – The South Dakota central cancer data collection system is established by South Dakota statute at S.D Codified Laws § 1-43-11 through 13. All details about the program are contained in administrative code at ARSD 44:22:01 through 44:22:05. Sections include definitions, organization and structure, and functions; required reporters, reportable conditions (broken down into specific subchapters); corrections, validation, and editing of data; and confidentiality, publication, research, and reporting of data. The reporting scheme for the South Dakota cancer registry has been unchanged since 2005. Paper reporting is allowed (although electronic reporting is encouraged), and if a facility is unable to comply with reporting procedures, the facility can submit patient records to the SD Department of Health (SDDOH) for completion. The SDDOH is authorized to audit reporting facilities. The registry has incorporated the reporting standards of the North American Association of Central Cancer Registries (NAACCR) into its administrative rules. While South Dakota has a small population compared to Indiana, it has a significant portion of AIAN (American Indian and Alaska Native) residents;

the SDDOH works with Indian Health Service (HIS) and tribal organizations to reduce racial misclassification of AIAN residents. This is an area of increased focus for South Dakota that is not present in Indiana. Overall, South Dakota's regulatory scheme is more restrictive than Indiana's.

X. Previous Amendments

This administrative rule has been readopted several times since it was first adopted in 1986; the substantive content of the rule has not been amended.

XI. Integration into Indiana Code

Since federal law requires that certain elements be incorporated into Indiana's cancer registry program, those elements (at minimum) must be included in either statute or rule. Until such time as registry specifics are added to statute, Indiana needs to maintain the administrative rule. This rule could be shifted to the Indiana Code which could also eliminate the paper submission option.

XII. Contact Information of Staff to Answer Substantive Questions

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410 IAC 25, ARTIFICIAL INSEMINATION

I. Statement Whether the Subject Matter Covered by the Rule Remains Carried out by the Agency

IDOH continues to oversee efforts to reduce HIV and sexually transmitted infection (STI) rates in Indiana.

II. Rationale for the Continued Need for the Rule

There is a continued need for testing during the artificial insemination process to protect the people being inseminated and infants. The program that oversees the artificial insemination rule still exists, and intended benefits are still being obtained. Expenses for regulated entities performing artificial inseminations should be minimal and routine. A study from 1995 concluded that infection with HIV through donor artificial insemination performed before routine HIV screening of semen donors represents a potentially serious threat to individuals who underwent artificial insemination. Requiring testing of donor semen does not restrict donation and artificial insemination, thereby achieving the regulatory goal in the least restrictive manner. 410 IAC 25 does not duplicate standards found in other state or federal laws. The rule is simple and written for ease of comprehension. Enforcement is practicable. IDOH has not identified any alternatives.

III. Analysis of fees, fines, and civil penalties under IC 4-22-2-19.6

The rule does not have any fees, fines, or civil penalties. Criminal penalties are in IC 16-41-14-16 and 20.

IV. Cost-Benefit, Economic Impact, Fiscal Impact, or Regulatory Burden Statements

No previously published cost-benefit, economic impact, fiscal impact, or regulatory burden statements are available from the Indiana Register. A copy of a regulatory burden statement that meets the requirements of IC 4-22-2-22.7 follows:

1. Description of Rule

a. History and Background of the Rule - 410 IAC 25 provides requirements for testing for communicable and sexually transmitted diseases under IC 16-41-14, including the diseases to be tested and the types of tests to use. There are some federal requirements, but this rule tests for more STIs than federal regulations require. This Rule was promulgated in 1992 and has not been amended. IDOH recommends that this Rule goes into Code, but we are readopting it until then.

b. Scope of the Rule - This rule applies to facilities where artificial insemination takes place, for example, fertility clinics. It requires facilities to test semen for HIV/STIs before use in artificial insemination when the donor is not the husband

of the recipient. If the donor and recipient are in a mutually monogamous relationship, the sample must only be tested for HIV. Additional testing for STIs is required when the donor and recipient are not in a mutually monogamous relationship.

c. Statement of Need - The rule protects women undergoing invitro fertilization and any children born from HIV/STI infections. It promotes efforts to reduce HIV and STI rates in Indiana.

d. Statutory Authority for the Proposed Rule - 16-41-14-6

e. Fees, Fines, and Civil Penalties – There are no fees, fines, or penalties for this rule.

2. Fiscal Impact Analysis

a. Anticipated Effective Date – January 1, 2026.

b. Estimated Fiscal Impact on State and Local Government - There is limited cost to IDOH. If it receives a complaint, it will investigate. IDOH has not received any complaints about compliance with this rule in years so there have been no costs. There is no cost to local government.

c. Sources of Expenditures or Revenues Affected by the Rule - The source of the expenditures described above would be IDOH's payroll budget but, as noted, there have not been any costs.

3. Impacted Parties - Parties performing artificial insemination and donors. IDOH does not have specific numbers because artificial insemination providers are not required to report to or register with IDOH

4. Changes in Proposed Rule

5. Benefits Analysis

a. Estimate of Primary and Direct Benefits of the Rule - This rule helps to protect women who are undergoing invitro fertilization and any children born from that process from becoming infected with HIV or another STI from the semen used in the process. Indiana has a higher rate of congenital syphilis among other STIs so additional testing beyond the federal requirements protects Indiana residents from the elevated risk. Because the rate of HIV or STIs among women undergoing artificial insemination in the absence of the rule is unknown, the value of this benefit cannot be quantified, but it is significant, especially to the patients. In the absence of the rule, some women might choose not to risk being artificially inseminated.

b. Estimate of Secondary or Indirect Benefits of the Rule – There are no secondary benefits for this rule.

c. Estimate of Any Cost Savings to Regulated Industries – There are no cost savings as a result of this rule.

6. Cost Analysis

a. Estimate of Compliance Costs for Regulated Entities - Testing is already required at the federal level so the cost of the rule is the cost of additional tests of the same samples already being taken. It does not cost more than $150 per sample to comply with the additional state requirements for non-mutually monogamous relationships.

b. Estimate of Administrative Expenses Imposed by the Rule - The cost from this rule comes from the testing of samples and not from administrative costs.

c. The fees, fines, and civil penalties analysis required by IC 4-22-2-19.6 - There are no fees, fines, or civil penalties for this rule.

d. If the implementation costs of the proposed rule are expected to exceed the threshold set in IC 4-22-2-22.7(c)(6) – There are no implementation costs associated with this rule because it is a readoption.

7. Sources of Information

a. Independent Verifications or Studies – No independent verifications or studies were used in this analysis.

b. Sources Relied Upon in Determining and Calculating Costs and Benefits – IDOH used Indiana STI infection rates as part of its analysis.

8. Regulatory Analysis - There are no new requirements; 410 IAC 25 has been in place since 1992. The additional cost is less than $150 per state required testing for non-monogamous/non-married relationships. The IDOH has determined that the benefits of the rule to prevent transmission of HIV or STIs to women undergoing artificial insemination and to allow women to undergo artificial insemination confident that neither they nor their potential child will contract HIV or STIs outweigh the costs.

V. Alternative Methods of Achieving the Purpose of the Rule

Testing samples in a medical setting is not intrusive or restrictive on the artificial insemination process. IDOH has not identified any other alternative methods to make sure semen samples are safe for insemination.

VI. Complaints and Comments

No comments or complaints have been received regarding this rule.

VII. Difficulties Encountered

This rule has no impact on the HIV/STI/Viral Hepatitis Division and regulated entities have not expressed any difficulty in complying with the rule.

VIII. Changes in Technology, Economic Conditions, or Other Factors

There have not been any such changes.

IX. Other State or Federal Requirements

Illinois regulates through administrative rule requiring donor testing for HIV and any other causative agent for AIDS for sperm and tissue.77 IL Admin Code § 470.40. Indiana requires a broader test panel and quarantine period than Illinois. Illinois has a state registry for sperm/tissue banks, Indiana only focuses on practitioner duties and testing/record rules.

Kentucky regulates through statute, KRS 311.281. Kentucky's statute requires, "[t]esting of organs, skin, or other human tissue for HIV and other communicable diseases, with informed consent," but does not explicitly state "sperm" or "semen" are required to be tested. There is no definition of "other human tissue" but it is read to include donated semen. The statute requires testing for "other communicable diseases specified by the … American Association of Tissue Banks…." The American Association of Tissue Banks includes guidance for sperm and semen (reproductive) tissue on its website. Kentucky requires the federal testing requirements.

Michigan's statute is found at MCL 333.16273. Michigan is less restrictive than Indiana because it only tests for HIV and does not require ongoing testing or recipient testing. Indiana's rule is more comprehensive by addressing a wider range of infectious diseases and more rigorous testing protocols.

Ohio: Ohio's statute does not require testing unless frozen semen is being used and the physician involved in the non-spousal artificial insemination considers the testing appropriate. The laboratory studies may include, but are not limited to, venereal disease, karyotyping, GC culture, cytomegalo, hepatitis, Kem-zyme, Tay-Sacks, sickle cell, Ureaplasma, HLTV-III, and chlamydia. ORC 3111.91. Ohio is less restrictive than Indiana because testing is at the discretion of the physician. It does not specify mandatory testing for infectious diseases or impose a quarantine period for fresh semen specimens regardless of marital status. Indiana rule with quarantine periods maximizes recipient safety because some diseases take time to manifest. The Indiana rule also protects offspring, mitigates legal risks, and provides quality assurance and standardization.

Idaho: Idaho's statute is found at Idaho Code 39-54. Idaho only requires testing for HIV. Idaho does not require a quarantine period or retesting.

South Dakota: South Dakota does not have a rule or a statute.

Federal: Testing is required for HIV, Hepatitis B, C, and Treponema pallidum. 21 CFR Part 1271. There is some overlap between the federal regulation and Indiana's program, but Indiana requires testing for additional STIs. Indiana has a higher rate of congenital syphilis among other STIs so additional testing beyond the federal requirements protects Indiana residents from the elevated risk. This additional testing is only required when the donor and recipient are not in a mutually monogamous relationship and the risk is higher.

X. Previous Amendments

There are no previous amendments.

XI. Integration into Indiana Code

410 IAC 25 has not been changed since its original adoption in 1992. The IDOH recommends it for integration into the Indiana Code.

XII. Contact Information of Staff to Answer Substantive Questions

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410 IAC 29, REPORTING, MONITORING AND PREVENTIVE PROCEDURES FOR AN ELEVATED BLOOD LEAD LEVEL

I. Statement Whether the Subject Matter Covered by the Rule Remains Carried out by the Agency

IDOH still oversees lead exposure to children in Indiana. The program has multiple functions to manage lead exposure in Indiana.

II. Rationale for the Continued Need for the Rule

410 IAC 29 provides a set of rules and guidelines needed to assist children affected by lead exposure. When elevated lead levels are reported to the state, the program established by the rule provides case management. Lead is a neurotoxin and irreparably impacts brain development in young children. Lead exposure can lead to negative health outcomes for any child, and there are no safe levels of lead in a child's body. Children exposed to low levels can suffer a 5-point loss in IQ, brain and nervous system damage, slowed growth, hearing problems, and headaches. This rule allows IDOH to support affected families around the state, provide education on lead sources and impacts, and improve Indiana's ability to manage lead exposure within the residential environment.

There is not a less costly/intrusive way to ensure families receive the necessary support. This rule does not apply to small businesses. Families always can opt out of the services offered, so there is not an obligation to families to accept state resources. Most, if not all, pediatricians test lead levels as a part of well-child visits. The rule is written for ease of comprehension and enforcement is practicable. IDOH is well equipped to administer the rule and work closely with local health departments.

III. Analysis of fees, fines, and civil penalties under IC 4-22-2-19.6

There are no fines, fees, or penalties.

IV. Cost-Benefit, Economic Impact, Fiscal Impact, or Regulatory Burden Statements

A previous Economic Impact Statement was published, and no changes are needed. It can be found at 20220608-IR-410220119EIA.

V. Alternative Methods of Achieving the Purpose of the Rule-

There is not a less costly/intrusive way to ensure families with children are receiving the necessary support to protect against the harm of lead exposure.

VI. Complaints and Comments

We interact with local health departments daily and have not heard any complaints. There are portions of the code that will benefit from clarification at such time as the rule is revised, but there is no concern over scope, implementation, or extent of the rule/need of services.

VII. Difficulties Encountered

IDOH is well equipped to be able to administer this rule. IDOH staff work closely with the local health departments to administer the rule. Staff turnover at the local level can be a challenge but IDOH is able to handle the challenge. Our team is able to support local health departments during times of change and assist with the training of new team members. IDOH checks in with local health departments at specific intervals after training.

VIII. Changes in Technology, Economic Conditions, or Other Factors

Changes in economic conditions have not dictated the need to change the rule. Additionally, with the support of Health First Indiana funds, local health departments have become much better resourced to handle their role in the lead program.
On the technology side and to comply with the rule, IDOH moved everybody in 2020 to an online cloud-based case management system which allows for real time access to updates and case management. This has resulted in greater effectiveness for the program.

IX. Other State or Federal Requirements

IDOH sets intervention levels based on the federal requirements with the local health department intervention being based on the severity of the case. While Indiana has interventions at lower levels, it is minimal to be less costly while still providing the families of children at risk with information to help prevent the levels from worsening.
Illinois: Illinois is the same to slightly stricter by way of an administrative Rule. Illinois Lead Prevention Act 410 ILCS 45 & Illinois Lead Poisoning Prevention Code 77 IL. Admin Code 845. Illinois has stricter timelines for reporting and confidentiality safeguards. Illinois complements testing with licensing for environmental lead professionals.
Kentucky: Kentucky’s program features a statute and administrative rule like Indiana, except Kentucky has a lower statutory reporting trigger than Indiana for case management. Kentucky Revised Statutes 211 & Kentucky Administrative Rules 486.
Michigan: Michigan is the same as Indiana except case management starts at 3.5 micrograms per deciliter versus 5 in Indiana. Testing is required for children older than six if they fall into any of the high-risk categories. Michigan Compile Law 333.5474d & Michigan Administrative Code R 330.301, R 330.302, R 330.303, and R 330.304
Ohio: Ohio Administrative Code, Chapter 3701-30. Ohio is the same as Indiana except case management starts at 3.5 micrograms per deciliter.
Idaho: The Idaho rule that requires reporting, and not much by way of further action is required to be done once the levels are reported. Indiana’s rule is stricter because Indiana has an interest in reducing blood lead levels. Idaho’s rule states that each reported case of lead poisoning or excess lead exposure may be investigated to confirm blood lead levels, determine the source, and whether actions need to be taken to prevent additional cases. The Idaho Health Department may investigate; the rule doesn’t require it. According to the CDC, childhood lead poisoning is still considered to be the most preventable environmental disease of young children. Yet an estimated 450,000 children in the United States have elevated

blood lead levels (EBLL's) >5µg/dL. Lead poisoning, a BLL of >15µg/dL can affect nearly every system in the body. A simple early childhood screening blood test can help to prevent a lifetime of irreversible adverse effects on the body.

South Dakota: South Dakota requires reporting as of January 1, 2025. South Dakota has screening, testing, and follow-up guidelines. https://doh.sd.gov/laboratory/medical-microbiology-testing/blood-lead-testing/. South Dakota does not have specified reporting timelines or enforcement penalties.

Federal: The EPA sets standards and has recommended actions based on lead levels. https://www.epa.gov/lead/lead-regulations#paint & https://www.hudexchange.info/programs/lead-based-paint/

X. Previous Amendments

The Rule was last amended in 2023 to set the elevated blood lead level (EBLL) that requires intervention. Intensive case management is necessary for 3.5 to 4.9 and is recommended for lead levels above 5mg/dL.

XI. Integration into Indiana Code

The Rule has been amended recently. Not recommended to integrate a Rule that changes.

XII. Contact Information of Staff to Answer Substantive Questions

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410 IAC 34, STATE TRAUMA REGISTRY

I. Statement Whether the Subject Matter Covered by the Rule Remains Carried out by the Agency

IDOH continues to administer the State Trauma Registry (STR) pursuant to IC 16-19-3-28: "(a) The state department is the lead agency for the development, implementation, and oversight of a statewide comprehensive trauma care system to prevent injuries, save lives, and improve the care and outcome of individuals injured in Indiana. (b) The state department may adopt rules under IC 4-22-2 concerning the development and implementation of the following: (1) A state trauma registry. (2) Standards and procedures for trauma care level designation of hospitals."

II. Rationale for the Continued Need for the Rule

There is a continued need for 410 IAC 34, implementing the STR. The registry was established in 2006 with the passage of IC 16-19-3-28. The citizens of Indiana rely on IDOH to coordinate and lead the statewide trauma care system, of which the registry is an important part.

Readoption of 410 IAC 34 will continue to have the same impact on regulated entities, e.g., the hospitals, trauma centers, rehabilitation hospitals, and EMS providers, that are mandated reporters. Persons who pay taxes or fees for government services are not affected by the rule, nor are consumers of products and services of regulated entities affected by the rule.

410 IAC 34 achieves the regulatory goal of implementing the STR. The administrative rule supports the collection and analysis of trauma related data to evaluate the delivery of trauma care. The goal of the registry is to improve outcomes for injured patients. It details which facilities are required to report what information into the registry. It also prescribes a reporting schedule and provides how confidential data is protected and shared when appropriate with researchers.

410 IAC 34 is written for ease of comprehension in that it is organized into topics by section. Sections include definitions, the purpose of the registry, management of the registry, required reporting, submission of data, reporting deadlines, failure to report, risk adjustment, and protected information.

Enforcement of the rule at 410 IAC 34-7-1 provides that reporters failing to submit data to the registry will be ineligible for designation by IDOH as a trauma center and the receipt of grants and other IDOH-sponsored sources of funding.

III. Analysis of fees, fines, and civil penalties under IC 4-22-2-19.6

There are no fees, fines, or civil penalties for reports to the STR. However, pursuant to 410 IAC 34-7-1, health care facilities that fail to submit data to the registry as specified will be ineligible for designation by IDOH as a trauma center and the receipt of grants and other IDOH-sponsored sources of funding.

IV. Cost-Benefit, Economic Impact, Fiscal Impact, or Regulatory Burden Statements

The following Economic Impact Statement was published in the Indiana Register on July 3, 2013, to which no revisions are necessary: 20130703-IR-410120617EIA

V. Alternative Methods of Achieving the Purpose of the Rule

To collect high quality data and drive performance improvement, IDOH must maintain a trauma patient registry. The current fiscal impact of maintaining the trauma registry is low – around $62,000 annually to support ongoing data collection and necessary analysis. Other available healthcare data sources, i.e., administrative claims data, do not include sufficient data to accurately monitor trauma system performance and support quality improvement. IDOH continues to discuss adding hospital registrar support (training, education, and possibly contractors) and statewide automation for registry submission as future enhancements to the registry. The information in 410 IAC 34 must be contained in statute or rule. 410 IAC 34 should be readopted until such time as its provisions are enacted as statutes.

VI. Complaints and Comments

IDOH has received expressions of concern from smaller hospitals that they lack personnel to serve as registrars, lack awareness surrounding submission requirements, and have technological issues with system integration. IDOH has discussed providing additional hospital registrar support (training, education, and possibly contractors) and statewide automation for registration submission as enhancements to the registry in response to these concerns.

VII. Difficulties Encountered

There are no difficulties encountered in administering the rule.

VIII. Changes in Technology, Economic Conditions, or Other Factors

Hospitals make upgrades to their systems that can impact their ability to submit data to the registry. However, many of the upgrades and current systems already interface with the state's system (ImageTrend), so impact has been minimal. IDOH continues to maintain the trauma registry and implement fixes with the vendor when identified or scheduled on a quarterly basis. Additional hospital registrar support (training, education, and possible contractors) and statewide automation have been discussed by IDOH as possible enhancements to the registry.

IX. Other State or Federal Requirements

While there are no federal regulations for state trauma registries, the American College of Surgeons (ACS) has established standards and guidelines for trauma centers and registries. Indiana follows the National Trauma Data Standard (NTDS), which are set on an annual basis by the ACS. Indiana is in compliance with NTDS, as are Illinois and Michigan. Kentucky requires participation in its trauma registry from trauma centers only, whereas in Indiana, the following are mandatory reporters: hospitals with emergency rooms, trauma centers, rehabilitation hospitals, and both basic and advanced life support EMS service providers. Ohio's registry also is limited to trauma centers. Idaho repealed its trauma registry statute this year and does not have any hospitals that are designated trauma centers. South Dakota's scheme is similar in scope to Indiana's and is designed to be compliant with the NTDS. The main difference between Indiana and South Dakota's trauma registry scheme is that South Dakota strictly prohibits the sharing of confidential information from its trauma registry for research purposes, whereas Indiana's does allow for such exchange with proper safeguards; otherwise, the two states are similar in terms of mandatory reporters and adherence to NTDS standards.

Illinois – Illinois Administrative Code §515.2050 (found in Title 77 of the code) requires each trauma center to have specific computer equipment and for the Illinois Department of Health to provide software. Reports are to be made quarterly. The code specifies the data fields to be reported, states which types of patients and accidents must be reported and mandates the department to draft a deidentified annual report. Requirements for the release of confidential data for research are listed, along with the type of agreements. Registry data is not subject to public records request. The department may access hospital information for two years. The Illinois administrative code covering the trauma registry is found in the section on trauma centers. It is more prescriptive than Indiana's rule in terms of the equipment that must be used by each trauma center. Additionally, it requires each hospital to provide the Illinois Department of Health with access to all hospital records related to registry information for cases that have been open for less than two years.

Kentucky – Kentucky statute at KRS 211.494 provides for a statewide trauma care system with a trauma care director and registrar. The Kentucky Trauma Registry and Data Bank System (KTDB) is established by 902 KAR 28:040. Each trauma center must keep a trauma registry and upload data quarterly to the KTDB electronically maintained by the Kentucky Department of Public Health. Data in the registry is considered protected health information (PHI). The Kentucky registry requires only trauma centers to submit data to the KTDB.

Michigan – Michigan's statewide trauma registry is found at Mich. Admin. Code R 325.134 Rule 10. The registry is organized under the Michigan Department of Public Health to collect and analyze trauma system data. The department is responsible for incorporating data elements and definitions, methods for submitting data, timetables, formats, and protections for confidentiality of records. Facilities must submit data, and the department and regional advisory councils use the data in reports and analyses. Michigan's rule is like Indiana's, except that Michigan adds regional advisory councils to the program.

Ohio – Ohio's trauma system registry is found at Chapter 4765-4 of the Ohio Administrative Code. The chapter includes sections with definitions, purpose, required reporting, risk adjustment, protected information, submission of data, deadlines for reporting, consequences for failure to report, and provision for regional (as opposed to statewide) reporting. Ohio's rule is like Indiana's, except that Ohio provides for a system of regional reporting.

Idaho – According to legislative information, the Idaho trauma registry (originally enacted in October 2005) was repealed effective July 1, 2025. Note: Idaho's only trauma center lost certification from the American College of Surgeons in December 2023.

South Dakota – S.D. Codified Laws § 34-12-53 directs the South Dakota Department of Health to "develop, implement, and administer a trauma care system including a statewide trauma registry that involves all hospitals, freestanding medical care facilities, rural emergency hospitals, and emergency medical services within the state." Two sections of administrative rules have been passed, ARSA 44:68:04:01 defining reporting duties, timelines, and methods (electronic or paper) and ARSA 44:68:04:02 providing that trauma registry data is "strictly confidential medical Information" which cannot be shared, made public, or made subject to subpoena or made admissible as evidence. Nonidentifiable information can be made public by the department for statistical purposes.

X. Previous Amendments

This administrative rule has been readopted one time, on November 13, 2019, since first adopted in 2013. Then, on July 19, 2021, 410 IAC 34-1-3 only was corrected in response to the statutory name change from ISDH to IDOH. No substantive content of the rule has been amended.

XI. Integration into Indiana Code

Because no substantive changes have been made to this rule, it could likely be put into Indiana Code.

410 IAC 34 should be readopted until such time unless a decision is made to incorporate the rule into statute.

XII. Contact Information of Staff to Answer Substantive Questions

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410 IAC 35, DISPOSITION OF ABORTED REMAINS

I. Statement Whether the Subject Matter Covered by the Rule Remains Carried out by the Agency

IDOH continues to regulate healthcare facilities and enforce the requirements on healthcare facilities set by 410 IAC 35.

II. Rationale for the Continued Need for the Rule

There is a continued need for this rule because this rule creates standards for disposition of fetal remains. Record keeping standards also ensure that patient medical records are properly maintained.

III. Analysis of fees, fines, and civil penalties under IC 4-22-2-19.6

There are no fees, fines, or civil penalties under this rule.

IV. Cost-Benefit, Economic Impact, Fiscal Impact, or Regulatory Burden Statements

20150826-IR-410150152EIA While there have been changes to the number of regulated entities, there haven't been substantive changes to the analysis and the economic impact to entities subject to this rule remains minimal.

V. Alternative Methods of Achieving the Purpose of the Rule

No alternative methods exist because private regulation and medical standards do not create the medical records and death certificates necessary to fulfill other provisions of Indiana law.

VI. Complaints and Comments

IDOH has not received any complaints regarding this rule.

VII. Difficulties Encountered

IDOH has not experienced any difficulties enforcing this rule.

VIII. Changes in Technology, Economic Conditions, or Other Factors

This rule was promulgated in 2015 and amended in 2021. There have not been changes in technological, economic or other conditions warranting a change in this rule.

IX. Other State or Federal Requirements

- No federal requirements were found.
- Illinois and Idaho do not have laws on disposition of aborted remains. Idaho has the Idaho Unborn Infants Dignity Act in Title 39, Chapter 93 but that law prohibits the sale, transfer, distribution, donation, accepting, or use of aborted remains and is substantively different than Indiana's rule.
- Michigan's law, MCLS § 333.2848, only relates to authorization for disposition or burial and is substantively different from Indiana's law.
- Ohio Ann. 3726 states that fetal remains are to be disposed of via cremation or internment as chosen by the mother, who must fulfill the reporting requirement setting forth her wishes. ORC Ann. 3726.10 requires the medical facility to fulfill a reporting requirement that is substantially similar to Indiana's requirement.
- South Dakota Codified Laws § 34-25-32.4 provides that only a medical facility is required to arrange for the disposal of fetuses via cremation, interment by burial, or by incineration in a medical waste incinerator. This law is closer to

Michigan's law than Indiana's because it does not include a reporting requirement beyond the certificate of birth and fetal death report.

X. Previous Amendments

This rule was adopted in 2015 and amended in 2021 to update definitions and to add 410 IAC 35-2-2 because of updated Indiana Code requirements.

XI. Integration into Indiana Code

This law could be incorporated into the Indiana Code because the definitions in rule 1 mirror definitions in IC 16-18-2. The substantive provisions in rule 2 can be incorporated into IC 16-21 because they are healthcare provider obligations.

XII. Contact Information of Staff to Answer Substantive Questions

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410 IAC 38, INSPECTION AND CLEAN UP OF PROPERTY CONTAMINATED WITH CHEMICALS USED IN THE ILLEGAL MANUFACTURE OF A CONTROLLED SUBSTANCE

I. Statement Whether the Subject Matter Covered by the Rule Remains Carried out by the Agency

IDOH still oversees certified inspector qualifications. There is an ongoing need to protect human health by ensuring that properties previously used for illegal controlled substance manufacturing are properly evaluated, decontaminated, tested, and deemed fit for re-occupancy. This rule was transferred to IDOH from the Department of Environmental Management in 2018.

II. Rationale for the Continued Need for the Rule

The need to promote human health by ensuring that properties previously used for illegal controlled substance manufacturing are properly evaluated, decontaminated, tested, and deemed fit for re-occupancy still exists. There are still benefits to the Rule.

Testing and remediation are the only and therefore the most effective methods for achieving the rule's purpose. There are no alternative methods to correct the problem, and the rule does not impose any unnecessary expenses on impacted parties. 410 IAC 38 applies to entities that test and remediate controlled substance contamination, owners of contaminated properties, and counties that take possession of a contaminated property in accordance with Indiana law. The rule does not duplicate Federal requirements; it is written for ease of comprehension, and its enforcement is practicable.

III. Analysis of fees, fines, and civil penalties under IC 4-22-2-19.6

There are no fines, fees, or penalties.

IV. Cost-Benefit, Economic Impact, Fiscal Impact, or Regulatory Burden Statements

No previously published cost-benefit, economic impact, fiscal impact, or regulatory burden statements are available from the Indiana Register. A copy of a regulatory burden statement that meets the requirements of IC 4-22-2-22.7 follows:

1. Description of Rule

a. History and Background of the Rule - 410 IAC 38 establishes remediation standards for sites contaminated by illegal drug manufacturing. It details the qualifications required to become a certified inspector, outlines the procedures for issuing a decontamination certification, and lists the documentation necessary for the remediation process. The Rule was promulgated by the Indiana Department of Environmental Management in 2007 and transferred to IDOH in 2018.

b. Scope of the Rule - This rule addresses certifications for individuals working to decontaminate property that has been contaminated with illegal substances and the standards for inspection and decontamination of property that has been

contaminated with illegal substances.

c. Statement of Need - IDOH is required by statute to regulate these areas. The rule ensures that properties are properly remediated or destroyed so that people are not exposed to illegal substances that are harmful to health.

d. Statutory Authority for the Proposed Rule - IC 16-19-3.1-1.

e. Fees, Fines, and Civil Penalties – None.

2. Fiscal Impact Analysis

a. Anticipated Effective Date – January 1, 2026.

b. Estimated Fiscal Impact on State and Local Government - The costs to state government for certifying qualified inspectors are limited and are tied to the statutory requirement for this program (IC 16-19-3.1-1) rather than how it is implemented in the rule. Local health departments are responsible for some of this work, but any costs attributable to that work are a result of IC 16-19-3.1-2 which references local health department obligations for dwellings unfit for human habitation in IC 16-41-20.

c. Sources of Expenditures or Revenues Affected by the Rule - The IDOH annual budget is impacted to the limited extent described above.

3. Impacted Parties - The impacted parties are the owner of a contaminated property as defined in 410 IAC 38-2-18, a person who applies to be listed or who is listed by the department as qualified as qualified to inspect and clean up contaminated property, a person who cleans up contaminated property under this rule, and counties that take possession of contaminated properties in accordance with IC 6-1.1-25.4.1. The most recent list of inspectors can be found here: https://www.in.gov/health/eph/files/Qualified-Inspectors-List_-Updated-6_30_25.pdf.

IDOH does not maintain a list of contaminated properties, so an estimated number of contaminated properties cannot be provided. IDOH does not keep a record of homes that have been contaminated, so an estimate cannot be provided.

4. Changes in Proposed Rule – There are no changes because this is a readoption.

5. Benefits Analysis

a. Estimate of Primary and Direct Benefits of the Rule - The benefit of the rule is that contaminated properties are properly remediated and do not expose more individuals to illegal substances that are harmful to health. A study published in the National Library of Medicine has identified a range of health effects that occur while residing in contaminated properties, which include behavioral effects or issues, sleep issues, respiratory effects, skin and eye effects, and headaches. In addition, methamphetamine was also detected in the analysis of hair samples collected from a number of individuals, including children, exposed at these properties.

https://pmc.ncbi.nlm.nih.gov/articles/PMC7560285/#abstract1. The Department of Justice lists a variety of health risks from exposure to the chemicals, including intoxication, dizziness, nausea, disorientation, lack of coordination, pulmonary edema, serious respiratory problems, severe chemical burns, and damage to internal organs. This rule ensures that property cleanups are verified to protect current owners and buyers of affected properties. Although IDOH lacks the data on the health effects that would occur in the absence of the rule, it believes these benefits are significant.

b. Estimate of Secondary or Indirect Benefits of the Rule - Future inhabitants are not exposed to the chemicals and as a result, burden the health care system.

c. Estimate of Any Cost Savings to Regulated Industries – There are no cost savings to the industry because of this rule.

6. Cost Analysis

a. Estimate of Compliance Costs for Regulated Entities - The costs associated with this rule for property owners are a result of the statute rather than the rule itself. The statute requires qualified inspectors to do the remediation work and to issue a certification of decontamination for properties that have been properly remediated (IC 16-19-3.1-3). Further, while the rule prevents anyone from occupying property that has been contaminated by illegal substances, it is because the property is unfit for human habitation. IC 16-19-3.1-2 requires IDOH to coordinate with local health departments on contaminated property because they have obligations concerning property that is unfit for human habitation pursuant to IC 16-41-20. The property would be unfit for human habitation pursuant to IC 16-41-20 even if this rule did not exist. The rule provides clear processes for decontaminating the property so it can be lived in again or demolishing/destroying it properly, so it no longer poses a risk.

Costs for being a qualified inspector are training/hours of experience, taking an exam issued by IDOH, and maintaining insurance. IDOH provides the training free of charge as is the required test. Insurance in this type of work is generally standard and is a minimal cost compared to protection for property owners that it provides.

Additional costs of the rule are the costs associated with testing samples required for the clearance testing. IDOH does not prescribe how decontamination is performed, just what tests must be met for a qualified inspector to issue a clearance certificate for the property. Sample testing is approximately $45 per sample with the average home needing 13-18 samples. This sampling is only required for contaminated rooms and is what is necessary to demonstrate that the property has been decontaminated.

b. Estimate of Administrative Expenses Imposed by the Rule - IDOH requires qualified inspectors to maintain certain documents for 5 years after the certificate is issued. The documents are existing documents, so the only cost is the retention, which is minimal.

c. The fees, fines, and civil penalties analysis required by IC 4-22-2-19.6 – There are no fees, fines, or penalties associated with this rule.

d. If the implementation costs of the proposed rule are expected to exceed the threshold set in IC 4-22-2-22.7(c)(6) – There are no implementation costs because this is a readoption.

7. Sources of Information

a. Independent Verifications or Studies – IDOH did not use any independent verifications or studies for this analysis.

b. Sources Relied Upon in Determining and Calculating Costs and Benefits – IDOH did not use any sources to calculate the costs and benefits of this rule.

8. Regulatory Analysis - The majority of the costs of the rule come from the statute requiring the regulation of this work rather than the implementation through the rule. The costs associated with becoming a qualified inspector are minimal, with the state providing training and testing options at no cost. Maintaining insurance is a cost but it is generally done with this sort of work and helps to protect the property owner if there is a problem with the work performed. Finally, the implementation of testing samples is necessary to demonstrate that property is decontaminated and no longer a danger to human health. The IDOH has determined that the benefits of protecting people from all the health hazards posed by living in a contaminated property outweighs the costs.

V. Alternative Methods of Achieving the Purpose of the Rule

No alternatives to testing and remediation.

VI. Complaints and Comments

The agency has not received any significant complaints regarding the rule or its implementation, and the feedback has been positive, highlighting the agency's commitment to protecting human health. The limited complaints received have come from property owners having financial difficulties regarding the cost of remediating their property so it can be habitable.

VII. Difficulties Encountered

This rule is straightforward. The agency has managed it effectively, has not encountered administrative issues, and small businesses have complied with certification requirements without difficulties.

VIII. Changes in Technology, Economic Conditions, or Other Factors

The revision of the EPA Voluntary Guidelines for Methamphetamine Cleanup now includes a chapter on Fentanyl, marking the most significant change in illegal drug lab remediation since the last readoption.

IX. Other State or Federal Requirements

The states that are less restrictive than Indiana are ones that have no rules or statutes. Indiana statute requires IDOH to regulate this area so IDOH could not be at the same level of regulation as those states.

Illinois does not have any rules or statutes.

Kentucky: Kentucky has a statute and a rule. Kentucky's laws are more stringent than Indiana's because the contamination threshold that must be met is lower in Kentucky. Indiana has less formalized disclosure or enforcement mechanisms. Indiana's primary focus is on IDOH oversight through certification, while Kentucky has formal contamination disclosure requirements and penalties (including criminal) for nondisclosure. (https://eec.ky.gov/Environmental-Protection/Waste/superfund/methamphetamine-lab-cleanup/Pages/default.aspx)

Michigan does not have any specific statutes or rules.

Ohio does not have any specific statutes or rules.

Idaho: Idaho has a statue and a rule. IDAPA 16.02.24 - Rules for Clandestine Drug Laboratory Cleanup. Idaho has a stricter contamination threshold than Indiana and encourages voluntary compliance by offering immunity once proper cleanup is confirmed. Idaho places more of an emphasis on disclosure than Indiana. That is probably because the Indiana State Police maintains Indiana's list of contaminated properties. In Idaho there is no state licensing, but the cleanup must be certified by qualified industrial hygienists. Indiana requires a certified cleaner; Idaho allows self-cleanup. It is not safe to be exposed to the chemicals, so Indiana's rule makes sure that the people exposed during the clean-up process are properly trained to reduce health problems that result from being exposed to the chemicals used in illegal drug manufacturing.

South Dakota: South Dakota has guidelines only. It has no statewide law that requires cleanup of meth labs, that stipulates the type of training or equipment required of those who clean them, or that provides oversight.

Federal: In October 2009, the U.S. Environmental Protection Agency (USEPA) released Voluntary Guidelines for Methamphetamine Laboratory Cleanup. These guidelines are based on an extensive review of the best available science and practices for cleanup. The federal guidance does not have a specified residue limit, require certifications for cleanup and testing professionals, or detail sampling methods. The Indiana rule includes more requirements to achieve uniform results which the federal guidelines lacked.

X. Previous Amendments

No previous major substantive amendments. "Concentration" was changed to "Surface Loading" in 2007 and there were at least two agency corrections.

XI. Integration into Indiana Code

This matter could remain as an administrative rule or could be transferred to the Indiana Code.

XII. Contact Information of Staff to Answer Substantive Questions

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410 IAC 39-1, PERINATAL HOSPITAL SERVICES

I. Statement Whether the Subject Matter Covered by the Rule Remains Carried out by the Agency

IDOH continues to certify obstetric and neonatal hospitals and birth centers in Indiana pursuant to 410 IAC 39-1. IC 16-21-13-5 gives IDOH the authority to pass administrative rules to implement the chapter on Perinatal Hospital Servies, which "may include regulation of interfacility patient transfers."

II. Rationale for the Continued Need for the Rule

There is a continued need for 410 IAC 39-1. Along with definitions, the rule covers levels of care certification, birth center requirements, obstetrical and neonatal levels of care requirements, obstetrical and neonatal universal standards, transport requirements, perinatal centers and matters incorporated by reference. There are four levels of licenses for obstetric and neonatal facilities, with Level 1 facilities providing the most basic services and Level IV facilities providing the most complex services and augmented staffing requirements. The requirements for licensing under the rule are detailed and cumulative. The rule runs for twenty pages and would make for a very long statute.

Readoption of 410 IAC 39-1 will continue to have the same impact on regulated entities, which are various birth-related facilities and transport organizations. The rule does not have a direct impact on persons who pay taxes or fees for government services or for the consumers of products and services affected by the rule.

410 IAC 39-1 achieves the regulatory goal of creating clear requirements for the four levels of obstetric and neonatal facilities in the least restrictive manner possible in what is a highly regulated area.

410 IAC 39-1 is written for ease of comprehension to the greatest extent possible given that it regulates highly complex entities. Within the rule, the requirements for levels of facilities are cumulative and consistent.

410 IAC 39-1 does not contain any fees, fines, or civil penalties.

III. Analysis of fees, fines, and civil penalties under IC 4-22-2-19.6

There are no fees, fines, or civil penalties for reports to IDOH pursuant to this rule; fees are referenced in the license application fee but not memorialized in the rule or governing statute.

IV. Cost-Benefit, Economic Impact, Fiscal Impact, or Regulatory Burden Statements

The following revisions are relevant to the previously published economic impact statement: 1. *Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule*: Revision: There are now seven birthing centers and seventy-five delivering hospitals that are subject to 410 IAC 39-1. 2. *Estimate of average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rule*: Revision: Birth centers need to provide proof of re-accreditation within three months after the three-year expiration date; all of the birth centers are compliant with this requirement. Licensing fees for birthing centers are based on the number of births per year for the center, *see* 410 IAC 15-5.

The economic impact statement published in the Indiana Register on January 24, 2019: https://www.in.gov/health/files/Small-Business-Economic-Impact-Statement-IR-18-416-2.pdf.

V. Alternative Methods of Achieving the Purpose of the Rule

IC 16-21-13 directs IDOH to establish a certification program based on American College of Obstetricians and Gynecologists (ACOG) and American Academy of Pediatrics (AAP) standards. IC 16-21-13-1 disconnects the perinatal certification from other licensure actions. To achieve the purpose of the rule by alternative methods, the legislature would need to modify IC 16-21-13.

VI. Complaints and Comments

During the surveying process for Perinatal Levels of Care, the state underwent significant changes that impacted clinical practices, particularly due to the Covid-19 pandemic. Consequently, existing regulations have become misaligned with their original objectives. Initially, these rules allowed limited telehealth services and required emergency department staff to ask patients about their pregnancy status within the past twelve months. This rigidity has highlighted the need to reevaluate guidelines to better meet the evolving needs of patients and healthcare providers. IDOH is in the process of updating 410 IAC 39.

VII. Difficulties Encountered

IDOH has not encountered any difficulties administering the rule and is not aware of any difficulties faced by hospitals and birth centers in complying with the rule.

VIII. Changes in Technology, Economic Conditions, or Other Factors

The increased use of telehealth services since the implementation of these standards represents a technological change in how healthcare services are delivered. These rules provided minimal provisions for telehealth services and instituted a stringent protocol in emergency departments mandating that staff inquire about a patient's pregnancy status within the past twelve months. This lack of flexibility in adapting to new healthcare delivery methods has highlighted the need for a re-evaluation of these guidelines to better meet the evolving needs of patients and healthcare providers; however, such a re-evaluation is beyond the scope of rule readoption.

IX. Other State or Federal Requirements

Comparison between Indiana and other states surveyed: Illinois locates perinatal and neonatal levels of care in separate chapters of administrative code. Its rule is more stringent than Indiana's in terms of its application process and the time limit of 30 minutes for facilities to provide critical services (Indiana focuses on services available at a facility). Michigan and Ohio have comparable programs to Indiana's, with Michigan's program found in statute and Ohio's in administrative code. Kentucky, Idaho, and South Dakota do not have programs that regulate perinatal care in four levels but regulate perinatal services with hospitals. These states regulate alternative birth centers and services provided by certified midwives separately.

Federal Regulations –N/A.

Illinois – 20 ILCS 2310/2310-223 Maternal Care. The statute includes only maternal (and not neonatal) levels of care. The four levels are designated as basic, specialty, subspecialty, and regional perinatal care. Illinois standards are not required to conform with ACOG or AAP, but the statute requests that the state department work with the Illinois chapter of the AAP. The rule was passed in 2019 and updated in 2022 (stylistic change). 77 Ill. Admin. Code 640 et seq. includes neonatal levels. The Illinois code includes specific 30-minute time limits to provide critical services as opposed to the "availability" language in Indiana's code. The code requires facilities to submit an application, plan, letter of agreement, and recommendation of department program staff, whereas Indiana just requires an application showing the facility meets the criteria for the level sought; Illinois' certification process is more intensive. Illinois also does an onsite survey and licenses are reviewed every three years.

Kentucky – A new statute establishing freestanding birthing centers just became effective on March 28, 2025, through Kentucky House Bill 90. The statute was created under KRS 216B. The statute sets out the requirements for low-risk birth centers that must be located within 30 miles of a hospital that provides obstetric services with which it has a transfer agreement. Kentucky previously had established an administrative rule for Alternative Birth Centers to provide perinatal care for low-risk pregnancies at 902 KAR 20:150.

Michigan – MCLS § 333.9129 provides for the registration of perinatal facilities as maternal care facilities, broken down into levels I through IV. The Michigan Department of Health is directed to "establish procedures for a perinatal facility to report a verification described in this subsection" every three years. The program is to follow ACOG guidelines. MCLS § 333.9130 directs the department to establish and maintain regional perinatal quality collaboratives in ten "prosperity regions" throughout the state. Michigan does not have administrative rules regarding perinatal care.

Ohio – Ohio regulates perinatal care at OAC Ann. 3701-7; there are no statutes covering perinatal care. 3701-1 covers definitions, licensing, inspections, facility and equipment requirements, Level I through IV standards, neonatal care standards, administrative requirements, and waivers. Application fees range from $250 - $750, and inspection fees range from $750 to $3,750. Ohio allows for a variance or waiver from any requirements and does an onsite survey with review every three years.

Idaho – Idaho does not provide for perinatal services or levels of care by statute or administrative rule; the only place the term perinatal comes up in Idaho law is regarding licensing of midwifes.

South Dakota – South Dakota does not provide for perinatal services or levels of care by statute or administrative rule; routine perinatal care is provided for in the professional standards for certified professional midwifes at SDAC 20:86:03:10.

X. Previous Amendments

410 IAC 39 was enacted in September 2019 following a detailed analysis of birthing facilities and hospitals in Indiana and has not been amended.

XI. Integration into Indiana Code

Administrative rules implementing hospital and other health care facility licensing schemes are some of the most detailed and lengthy impacting entities regulated by IDOH. Given the length and detail of the rule, and because there are ongoing changes in the methods of delivery of health services (e.g., rise of telehealth) and the standards for licensure as a perinatal facility are based on those set by ACOG and AAP, it would be difficult to convert the rule into statute.

XII. Contact Information of Staff to Answer Substantive Questions

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