

TITLE 410 INDIANA DEPARTMENT OF HEALTH**Regulatory Analysis****LSA Document #26-356****Reportable Events****I. Description of Rule**

This regulatory analysis supports repealing Indiana rules that require certain medical errors to be reported to the Indiana Department of Health (IDOH) under [410 IAC 15-1.4-2.2](#) (Hospitals), [410 IAC 15-2.4-2.2](#) (Ambulatory Outpatient Surgical Centers), and [410 IAC 27-6-2](#) (Birthing Centers). These reporting rules were originally promulgated to implement the Medical Error Reporting System (MERS) created by Executive Order 0510 (Jan. 11, 2005) and subsequent rulemakings, requiring facilities to report "serious adverse events" to IDOH for public reporting and quality improvement.

a. History and Background of the Rule - IDOH established MERS effective January 1, 2006, and adopted facility-specific reporting rules (hospitals: [410 IAC 15-1.4-2.2](#); ASCs: [410 IAC 15-2.4-2.2](#); birthing centers: [410 IAC 27-6-2](#)) to mandate electronic reporting within defined timelines and to enable statewide public reporting by facility.

In 2023, the General Assembly enacted P.L. 190-2023, codified at [IC 16-21-1-7.1](#), which requires hospital quality programs to determine and report only "serious reportable events" (SREs) as identified by the National Quality Forum (NQF) and expressly prohibits IDOH's executive board from requiring hospitals to report any other event types. Subsection (a) of [410 IAC 15-1.4-2.2](#) was accordingly voided by statute effective July 1, 2023. While subsection (a) was voided, the remaining sections were not updated, and this results in a gap that dictates how information must be reported without requiring any specific information to be reported.

b. Scope of the Rule - This rulemaking repeals medical error reporting provisions in [410 IAC 15-1.4-2.2](#), [410 IAC 15-2.4-2.2](#), and [410 IAC 27-6-2](#) to: (1) align IDOH rules with [IC 16-21-1-7.1](#); (2) eliminate duplicative, prescriptive lists and processes that are now superseded by statute and national alignment efforts (NQF/Joint Commission).

c. Statement of Need - Repeal is necessary to:

- Ensure that hospital reporting is limited to NQF SREs as required by [IC 16-21-1-7.1](#). (Rules that mandate broader or different event lists conflict with statute).
- Modernize IDOH's regulatory framework, reduce duplicative burdens, and support national alignment with NQF/Joint Commission SRE frameworks (with full alignment effective January 1, 2027).

d. Statutory Authority for the Proposed Rule - General and specific authorities include [IC 16-21-1](#) (Hospitals); [IC 16-18-2-14](#) (ASC definition); [IC 16-21-2-2.5](#) (facility licensure); and [IC 4-22-2](#) (rulemaking procedures). Repeal aligns with [IC 16-21-1-7.1](#) and the OMB regulatory analysis standards updated on July 1, 2024.

e. Fees, Fines, and Civil Penalties - This repeal does not add or increase any fees, fines, or civil penalties and therefore does not implicate [IC 4-22-2-19.6](#) budget committee steps.

II. Fiscal Impact Analysis

Repealing the identified reporting rules is expected to reduce state administrative costs associated with maintaining duplicative rule frameworks and legacy reporting processes within MERS[\[in.gov\]](#), without reducing hospital reporting that is required by [IC 16-21-1-7.1](#) (NQF SREs) [\[qualityforum.org\]](#). Removing obsolete or conflicting rule text reduces regulatory maintenance and clarifies the statutory baseline (SRE-only).

a. Anticipated Effective Date of the Rule- January 1, 2027

b. Estimated Fiscal Impact on State and Local Government - The repeal of the rule may impact administrative costs for IDOH, such as, reducing staff time to interpret and enforce superseded rule text; fewer updates to legacy rule-based forms; clearer reliance on statute/NQF guidance. Approximately 25-50 hours are spent each quarter on maintaining the reporting data.

c. Sources of Expenditures or Revenues Affected by the Rule - The rule repeal does not directly impact expenditures and revenues of state agencies or local government.

III. Impacted Parties

For regulated entities (hospitals, ASCs, birthing centers), repeal eliminates potential confusion on where rule lists/processes differ from the statutory SRE requirement, reduces legal review time to reconcile overlapping mandates, and streamlines internal policy alignment with NQF and Joint Commission guidance.

Regulated entities and roles.

- Hospitals licensed under Article 15 (170 total): quality programs must determine/report NQF SREs under [IC 16-21-1-7.1](#). Repeal removes obsolete rule text ([410 IAC 15-1.4-2.2](#)) that was partially voided by statute. [\[law.justia.com\]](#), [\[law.cornell.edu\]](#)
- Ambulatory Outpatient Surgical Centers (ASCs) licensed under Article 15 (161 total): repeal of [410 IAC 15-2.4-2.2](#) (reportable events) aligns ASC policies with NQF SRE frameworks. [\[law.cornell.edu\]](#)
- Birthing Centers licensed under Article 27 (7 total): repeal of [410 IAC 27-6-2](#) removes a legacy list/process so centers can align with the statutory baseline and perinatal program requirements. [\[regulation...justia.com\]](#)

IV. Changes in Proposed Rule

Proposed repeal elements (by citation).

- [410 IAC 15-1.4-2.2](#) (Hospitals-Reportable events): repeal entire section to remove conflict with [IC 16-21-1-7.1](#) and rely on statutory SREs/NQF guidance. (Subsection (a) already voided by P.L. 190-2023.) [\[law.cornell.edu\]](#), [\[law.justia.com\]](#)
- [410 IAC 15-2.4-2.2](#) (ASCs-Reportable events): repeal to eliminate duplicative rule lists/processes in favor of statutory/NQF alignment. [\[law.cornell.edu\]](#)
- [410 IAC 27-6-2](#) (Birthing centers-Reportable events): repeal to modernize and align with statutory baseline and perinatal program oversight; retain Article 27 quality program requirements without legacy event lists. [\[regulation...justia.com\]](#)

Requirements imposed by other law (unchanged).

- Hospitals must determine and report NQF SREs per [IC 16-21-1-1.7](#); repeal does not remove this statutory reporting obligation. [\[law.justia.com\]](#)

V. Benefit Analysis

Repealing the outdated medical-error-reporting provisions provides a set of meaningful benefits for public administration, patient-safety oversight, regulated healthcare entities, and the broader community that relies on accurate and consistent safety information. By removing legacy rule language that no longer aligns with Indiana's statutory requirements or modern national frameworks, the repeal strengthens regulatory clarity, supports alignment with forthcoming national patient-safety reporting updates, and enables the Indiana Department of Health (IDOH) to prioritize statutory and nationally standardized reporting activities. Although the benefits cannot currently be monetized, they represent substantial non-quantifiable improvements in administrative efficiency, reduced compliance burden, and clearer expectations for regulated industries.

a. Estimate of Primary and Direct Benefits of the Rule - The primary and direct benefits of repealing the outdated medical error reporting provisions arise from the immediate improvement in regulatory clarity, operational consistency, and administrative efficiency. By removing legacy rule language that no longer aligns with current statutory requirements or national patient-safety frameworks, the repeal ensures that hospitals, ambulatory surgery centers, and birthing centers operate under one clear, unified reporting standard. This consolidation materially reduces the time and effort facilities must devote to reconciling conflicting event definitions, outdated reporting timelines, and overlapping regulatory expectations. Staff who formerly needed to compare rule-based categories with statutory requirements and national guidance can redirect that time toward core patient-safety activities, improving responsiveness, and reducing internal workflow frustration. Although these direct benefits cannot yet be quantified, they represent significant nonmonetizable improvements in regulatory coherence, reduced administrative duplication, and more transparent and consistent public reporting for individuals and families who rely on accurate safety information.

b. Estimate of Secondary or Indirect Benefits of the Rule - The repeal also produces secondary and indirect benefits that, while not the explicit goal of this regulatory action, form important ancillary advantages for the healthcare system and public administration. By clearing away obsolete reporting mandates, the repeal enables Indiana's regulated entities to more easily prepare for national alignment with the consolidated Serious Reportable Event and Sentinel Event frameworks scheduled for January 1, 2027. This harmonization reduces friction and confusion when facilities interpret and apply national patient-safety guidance, indirectly supporting more coordinated quality-improvement efforts. As administrative burdens decrease, regulated entities may be able to reallocate saved staff time and resources toward technology modernization, enhanced training programs, expanded analytic capacity, or other improvements that strengthen patient-safety initiatives. IDOH may similarly benefit by redirecting staff time previously spent maintaining outdated rule provisions toward more efficient transparency tools, modernized reporting infrastructure, or expanded evaluative capabilities. These indirect benefits, though not quantifiable at present, represent substantial improvements in statewide regulatory efficiency and healthcare system modernization.

c. Estimate of Any Cost Savings to Regulated Industries - Repealing the outdated reporting rules is expected to yield meaningful cost savings for regulated industries, particularly hospitals, ambulatory surgery centers, and birthing centers. These savings result from changes to existing requirements-specifically, the removal of legacy rule-based reporting obligations-rather than from the addition of any new mandates. By eliminating outdated event lists, redundant reporting processes, and conflicting regulatory expectations, facilities can reduce time spent on legal interpretation, policy reconciliation, and staff training tied solely to obsolete provisions. Compliance officers, quality-improvement teams, and legal counsel will no longer need to devote resources to comparing outdated rule language with current statutory and national patient-safety frameworks. While exact financial savings cannot be determined without facility-specific data, the nature of these administrative reductions indicates that the repeal will lower compliance costs, reduce workflow inefficiencies, and improve operational productivity for regulated entities across the state.

VI. Cost Analysis

Repealing the outdated medical-error-reporting provisions does not impose new regulatory obligations, alter existing statutory reporting requirements, or require facilities or agencies to adopt new processes, purchase equipment, or implement new software systems. Instead, the repeal eliminates legacy rule-based expectations that have become redundant due to statutory updates and national alignment efforts. As a result, the changes in the proposed rule do not generate new tangible or intangible costs for the general public, regulated healthcare entities, IDOH, local partners, or other agencies. Because the repeal removes outdated requirements rather than adding new ones, it does not require individuals or businesses to change their behavior, modify procedures, hire additional staff, or invest in any additional training or compliance tools. Although the absence of new costs cannot be monetized, it is nonetheless significant because it ensures that the repeal produces a net reduction-not an expansion-of administrative and regulatory burdens across the healthcare sector.

a. Estimate of Compliance Costs for Regulated Entities - The repeal imposes no compliance costs on hospitals, ambulatory surgery centers, birthing centers, or other regulated entities. It does not require new **documentation**, reporting activities, or internal procedural changes, nor does it mandate the acquisition of technology, supplies, or specialized personnel. Instead, by removing outdated rule-based reporting obligations, the repeal eliminates the need for regulated entities to reconcile obsolete definitions and reporting timelines with their statutory and national patient-safety duties. Because the rule change removes requirements rather than creating them, facilities will not incur direct costs such as fees, training expenditures, or equipment purchases, nor will they face indirect costs such as developing new supervisory structures, internal workflows, or compliance protocols. While compliance costs therefore cannot be quantified, the absence of any new requirements ensures that regulated entities experience no cost increases as a result of this action.

b. Estimate of Administrative Expenses Imposed by the Rules - The repeal imposes no administrative expenses on regulated entities or state agencies. Regulated parties do not need to spend additional time understanding new regulatory mandates, creating new reporting mechanisms, or revising policies to meet new expectations. Instead, administrative burdens decrease because facilities no longer need to devote time to

interpreting outdated rule language or performing redundant policy reconciliation. The Indiana Department of Health likewise incurs no new administrative obligations, as the repeal reduces rather than expands the agency's workflow. IDOH will not need to develop replacement forms, create new guidance documents, or devote additional legal or staff resources to new compliance processes. For these reasons, administrative expenses cannot be monetized or quantified—they are effectively zero, representing a net reduction in burden rather than an incurred cost.

c. The fees, fines, and civil penalties analysis required by [IC 4-22-2-19.6](#) - The repeal does not add or increase any fee, fine, or civil penalty. The proposed rule is purely a removal of outdated reporting requirements and does not include any enforcement mechanisms or monetary assessments. Because no new fee, fine, or civil penalty exists in the proposed rule, the analysis required under [IC 4-22-2-19.6](#) is not triggered. There are no circumstances in which the agency would assess a fee, nor is there any dollar amount or formula associated with a fine or civil penalty. Similarly, considerations related to deterrence, prior violations, or impacts on health and safety are not applicable because the repeal does not create any new punitive or cost-based compliance elements.

d. If the implementation costs of the proposed rule are expected to exceed the threshold set in [IC 4-22-2-22.7\(c\)\(6\)](#) - The repeal does not impose implementation or compliance costs approaching the statutory threshold of five hundred thousand dollars (\$500,000) over any two-year period for businesses, individuals, or governmental units. Because the proposed rule removes requirements instead of imposing new ones, no new implementation costs exist for regulated entities or agencies, and no multi-year cost impacts are anticipated. Accordingly, the proposed rule falls far below the threshold requiring additional analysis under [IC 4-22-2-22.7\(c\)\(6\)](#).

VII. Sources of Information

a. Independent Verifications or Studies - No independent verifications or studies were relied upon in the cost benefit analysis.

b. Sources Relied Upon in Determining and Calculating Costs and Benefits - IDOH did not use any outside sources to calculate costs and benefits.

VIII. Regulatory Analysis

Across all components of the proposed repeal, the agency's analysis shows that the changes impose no new costs—tangible or intangible—on regulated entities, individuals, families, small businesses, local partners, or state agencies. The repeal does not require additional reporting, procedural changes, new equipment, new staff, or new training. It does not increase compliance obligations, administrative expenses, fees, fines, or civil penalties. It also does not trigger implementation or compliance costs anywhere near the statutory threshold set in [IC 4-22-2-22.7\(c\)\(6\)](#). In contrast, the repeal produces clear and meaningful benefits, including improved regulatory clarity, reduced administrative burden, increased alignment with statutory and national patient-safety frameworks, and enhanced operational efficiency for both regulated entities and the Indiana Department of Health. Although the benefits cannot presently be monetized, they are significant, wide-ranging, and directly supportive of a more coherent statewide reporting system. Based on this aggregated tally, the agency determines that the benefits of

the proposed repeal substantially exceed the costs, resulting in a net positive regulatory outcome for all affected stakeholders.

IX. Contact Information of Staff to Answer Substantive Questions

Z. Claire Dyer

Advisory Chief, Indiana Department of Health

ZDyer@health.in.gov

Notice of First Public Comment Period: [20261007-IR-410260356FNA](#)

Notice of Determination Received: September 14, 2026

Posted: 10/07/2026 by Legislative Services Agency