

TITLE 410 INDIANA DEPARTMENT OF HEALTH

Final Rule
LSA Document #24-370

DIGEST

RURAL EMERGENCY HOSPITAL LICENSURE

Adds 410 IAC 15.2 to establish the process to obtain a license to operate a rural emergency hospital (REH) in Indiana and for the department to regulate REHs following licensure. Effective 30 days after filing.

HISTORY

Notice of First Public Comment Period published September 25, 2024: 20240925-IR-410240370FNA

Regulatory Analysis submitted with Notice of First Public Comment Period: 20240925-IR-410240370RAA

Date of First Hearing: October 28, 2024

60 Day Requirement (IC 4-22-2-19): 20240925-IR-410240370ARA

SUMMARY/RESPONSE TO COMMENTS

The Indiana Department of Health (IDOH) requested public comment from September 24, 2024, through October 25, 2024, and during the public hearing on October 28, 2024. The IDOH received no comments in response to the Notice of First Public Comment Period.

410 IAC 15.2

SECTION 1. 410 IAC 15.2 IS ADDED TO READ AS FOLLOWS:

ARTICLE 15.2. RURAL EMERGENCY HOSPITALS

Rule 1. Definitions

410 IAC 15.2-1-1 Applicability

Authority: IC 16-19-3-4

Affected: IC 16-21-2-2

Sec. 1. The definitions in this rule apply throughout this article. (*Indiana Department of Health; 410 IAC 15.2-1-1*)

410 IAC 15.2-1-2 "CMS" defined

Authority: IC 16-19-3-4

Affected: IC 16-21-2-2

Sec. 2. "CMS" means the United States Centers for Medicare and Medicaid Services. (*Indiana*

Department of Health; 410 IAC 15.2-1-2)

410 IAC 15.2-1-3 "Commissioner" defined

Authority: IC 16-19-3-4

Affected: IC 16-21-2-2

Sec. 3. "Commissioner" means the state health commissioner or the state health commissioner's designee. (*Indiana Department of Health; 410 IAC 15.2-1-3*)

410 IAC 15.2-1-4 "Department" defined

Authority: IC 16-19-3-4

Affected: IC 16-21-2-2

Sec. 4. "Department" means the Indiana department of health. (*Indiana Department of Health; 410 IAC 15.2-1-4*)

410 IAC 15.2-1-5 "Hospital" defined

Authority: IC 16-19-3-4

Affected: IC 16-18-2-179; IC 16-21-2-2

Sec. 5. "Hospital" has the meaning set forth in IC 16-18-2-179(b). (*Indiana Department of Health; 410 IAC 15.2-1-5*)

410 IAC 15.2-1-6 "Rural emergency hospital" defined

Authority: IC 16-19-3-4

Affected: IC 16-18-2-320.5; IC 16-21-2-2

Sec. 6. "Rural emergency hospital" or "REH" has the meaning set forth in IC 16-18-2-320.5. (*Indiana Department of Health; 410 IAC 15.2-1-6*)

Rule 2. Licensure of Rural Emergency Hospitals

410 IAC 15.2-2-1 License

Authority: IC 16-19-3-4

Affected: IC 4-21.5-3-5; IC 16-21-2-2

Sec. 1. (a) A license shall be obtained from the commissioner under IC 4-21.5-3-5 before:

- (1) establishing;**
- (2) conducting;**
- (3) operating; or**
- (4) maintaining;**

a REH. An REH may not operate without a license issued by the commissioner.

(b) A license to operate an REH:

- (1) expires two (2) years after the date of issuance unless otherwise stated in this article;**
- (2) is not assignable or transferable;**
- (3) is issued only for the premises named in the application; and**

(4) must be posted in a conspicuous place in the facility.

(c) After an REH is closed, the license must be returned to the department. *(Indiana Department of Health; 410 IAC 15.2-2-1)*

410 IAC 15.2-2-2 Compliance with federal and state law

Authority: IC 16-19-3-4

Affected: IC 16-21-2-2

Sec. 2. (a) REHs shall comply with the following:

(1) The terms and participation requirements of REHs as set forth by CMS.

(2) Applicable Indiana statutes and regulations for hospitals relating to outpatient services the REH provides.

(b) An REH shall immediately notify the department if the REH is no longer operating as an REH under CMS. *(Indiana Department of Health; 410 IAC 15.2-2-2)*

410 IAC 15.2-2-3 Application for license

Authority: IC 16-19-3-4

Affected: IC 16-21-2-2

Sec. 3. (a) To obtain a license to operate a REH, an application for a license to operate shall be submitted to the department within thirty (30) days after receiving certification as an REH by CMS.

(b) The license application must include the following:

(1) An application for a license to operate an REH on a form prescribed by the department.

(2) Documents required by the department as prescribed on the application for a license to operate an REH, including a copy of the documentation of REH status certification by CMS.

(3) The appropriate license fee.

(c) An eligible facility shall report on the application all outpatient services the REH will offer or will remain when the facility is licensed as an REH. *(Indiana Department of Health; 410 IAC 15.2-2-3)*

410 IAC 15.2-2-4 Review and approval of license application

Authority: IC 16-19-3-4

Affected: IC 16-21-2-2

Sec. 4. (a) On determination by the commissioner that an applicant has complied with the licensing requirements for a REH under this article, the commissioner shall issue a license to operate an REH.

(b) A hospital license serves as the state license for the REH until the commissioner issues a license to operate as an REH. The effective date of the REH state license is the date CMS certifies the facility to be an REH. If an eligible facility is not licensed as a hospital at the time of applying to be an REH, a hospital license is not first required. A hospital license shall be revoked on the same date the

REH state license becomes effective, if applicable.

(c) On determination by the commissioner that an applicant has failed to comply with this article, the commissioner may:

- (1) request additional information concerning the application;**
 - (2) conduct a further investigation to determine whether a provisional license may be granted;**
- or**
- (3) deny the application.**

(d) On determination by the commissioner that an applicant has complied with the provisional licensing requirements for an REH under this article, the commissioner may:

- (1) provisionally approve the application for an REH; and**
- (2) issue a provisional license to operate an REH. The provisional license expires ninety (90) days after issue.**

(e) After the REH opens and before the provisional license expires, the department shall conduct a licensing survey to ensure the REH is operating in compliance with this article.

(f) If the REH is found on the initial licensing survey to be in compliance with this article, the commissioner shall issue a full license to operate an REH.

(g) If the REH is not found to be in compliance with this article on the initial licensing survey, the commissioner may extend the provisional license for up to ninety (90) days. If the provisional license is extended, a revisit survey will be conducted or additional documentation requested, or both, before the end of the provisional period to ensure compliance with this article. If the REH is then found to be in compliance with this article, the commissioner shall issue a full license to operate an REH. If the REH is found to not be in compliance with this article after the extended provisional period, the commissioner may:

- (1) request additional information concerning the application;**
 - (2) conduct a further investigation to determine whether a provisional license may be granted;**
- or**
- (3) deny the application.**

(Indiana Department of Health; 410 IAC 15.2-2-4)

410 IAC 15.2-2-5 Denial of license

Authority: IC 16-19-3-4

Affected: IC 16-21-2-2; IC 27-13-1

Sec. 5. The commissioner may deny a license to operate a REH for any of the following reasons:

- (1) The licensee or licensees are not of reputable and responsible character.**
- (2) The REH is not in compliance with the minimum standards for an REH adopted under this article.**
- (3) Violating any of the applicable provisions of IC 16-21 or this article.**
- (4) Permitting, aiding, or abetting the commission of an illegal act in the REH.**
- (5) Knowingly collecting or attempting to collect from:**
 - (A) a subscriber, as defined in IC 27-13-1-32; or**
 - (B) an enrollee, as defined in IC 27-13-1-12;**

of a health maintenance organization as defined in IC 27-13-1-19 any amounts owed by the health maintenance organization.

(6) Conduct or practices of the REH are found to be detrimental to the welfare of the patients of the REH.

(7) The application for a license to operate an REH, or supporting documentation, provided inaccurate statements or information.

(Indiana Department of Health; 410 IAC 15.2-2-5)

410 IAC 15.2-2-6 Issuance of license

Authority: IC 16-19-3-4

Affected: IC 16-21-2-2

Sec. 6. (a) A REH shall file an application that meets the requirements of this article for licensure on a biennial basis with the department not less than thirty (30) days before the current license expires. The initial license may be issued for a period of less than two (2) years to ensure the REH is on the same two (2) year cycle as other REHs and hospitals.

(b) The initial REH license period for currently operating hospitals shall be for the remaining period of the hospital license.

(c) Reapplication must be filed when a change of at least fifty percent (50%) ownership occurs.

(d) An application for license from a newly constructed REH may be obtained from the department and submitted after the physical plant plans have been approved under 410 IAC 15-1.5-8. After receiving a design release from the state building commissioner, an application may be submitted to the department on the form provided, along with the documents required by the application form.

(e) REHs shall meet the provisions of 410 IAC 15-1.5-8.

(f) Fully or partially replacing the physical plant of an REH, an addition or a renovation to the physical plant of an REH, or acquiring additional buildings under the current license of an existing REH must meet the provisions of 410 IAC 15-1.5-8. *(Indiana Department of Health; 410 IAC 15.2-2-6)*

410 IAC 15.2-2-7 Rural emergency hospital license fees

Authority: IC 16-19-3-4; IC 16-21-2-12; IC 16-21-2-14

Affected: IC 16-21-2-2

Sec. 7. (a) A REH licensed under IC 16-21-2 and this article shall pay a biennial renewal fee as directed by the department.

(b) An initial application for an REH license currently operating as a hospital does not require an accompanying licensing fee. The biennial renewal of an REH must be accompanied by a licensing fee at the rate set in the fee schedule in this subsection. Biennial renewal fees are due on biennial renewal of an REH's license based on total operating expenses, as reported to the department on the application form. The fee schedule is as follows:

Total Operating Expenses	Fee
0 – \$49,999,999	\$2,000
\$50,000,000 – \$99,999,999	\$4,000
\$100,000,000 – \$199,999,999	\$6,000
\$200,000,000 – \$299,999,999	\$8,000
\$300,000,000 and above	\$10,000

(c) A previously closed facility that applies to reopen as an REH shall pay an initial license fee of two thousand dollars (\$2,000). (*Indiana Department of Health; 410 IAC 15.2-2-7*)

410 IAC 15.2-2-8 Notice

Authority: IC 16-19-3-4

Affected: IC 16-21-2-2

Sec. 8. (a) An eligible facility shall give at least sixty (60) days written notice to the department that it intends to become certified as an REH by CMS, unless waived by the department, and a period less than sixty (60) days is permitted.

(b) The notice shall be written by the highest officer in charge of the eligible facility.

(c) The notice required by this section may be sent through United States mail or electronic means. (*Indiana Department of Health; 410 IAC 15.2-2-8*)

410 IAC 15.2-2-9 Enforcement actions

Authority: IC 16-19-3-4; IC 16-21-3

Affected: IC 6-21-2-2; IC 27-13-1

Sec. 9. (a) The commissioner may take any of the following actions on any of the grounds listed in subsection (b):

- (1) Issue a letter of correction.
- (2) Issue a probationary license.
- (3) Conduct a resurvey.
- (4) Deny the renewal of a license.
- (5) Revoke a license.
- (6) Impose a civil penalty in an amount not to exceed ten thousand dollars (\$10,000) per violation.

(b) The commissioner may take action under subsection (a) on any of the following grounds:

- (1) Violating any provision of this article.
- (2) Permitting, aiding, or abetting the commission of an illegal act in a REH.
- (3) Knowingly collecting or attempting to collect from:
 - (A) a subscriber, as defined in IC 27-13-1-32; or
 - (B) an enrollee, as defined in IC 27-13-1-12;
of a health maintenance organization as defined in IC 27-13-1-19 any amounts owed by the health maintenance organization.
- (4) Conduct or practice found by the department to be detrimental to the welfare of the patients of an REH.

(Indiana Department of Health; 410 IAC 15.2-2-9)

410 IAC 15.2-2-10 Probationary license

Authority: IC 16-19-3-4; IC 16-21-3

Affected: IC 16-21-2-2

Sec. 10. A probationary license may be:

- (1) issued for a period of three (3) months; and**
- (2) reissued;**

but not more than three (3) probationary licenses may be issued during a twelve (12) month period. Issuing a probationary license results in the automatic expiration of any other license held under this article. *(Indiana Department of Health; 410 IAC 15.2-2-10)*

410 IAC 15.2-2-11 Licensing surveys

Authority: IC 16-19-3-4

Affected: IC 16-21-2-2

Sec. 11. (a) The department shall conduct a licensing survey of each REH at least once every two (2) years. The licensing survey is conducted to ensure that an REH is operating in compliance with this article.

(b) The department shall notify the REH of the licensing survey results in writing.

(c) The REH may request the department to accept an accreditation or certification survey instead of a licensing survey. The department may accept an accreditation or certification survey report from a nationally recognized accreditation or certification agency, association, or organization determined by the department to have survey standards consistent with this article. On request by the REH, the department shall review the accreditation or certification survey report for the facility. If the department finds, based on the accreditation report, the REH was found to have substantially complied with the standards referenced in this subsection, the department shall accept the accreditation report as a licensing survey. If, based on the accreditation report, the REH failed to significantly comply with the standards required in this subsection, the department may:

- (1) request a plan of correction; or**
- (2) conduct a licensing survey.**

If the department accepts an accreditation or certification survey as a licensing survey, the department shall conduct at least one (1) licensing survey in a four (4) year period. *(Indiana Department of Health; 410 IAC 15.2-2-11)*

410 IAC 15.2-2-12 Complaint surveys

Authority: IC 16-19-3-4

Affected: IC 16-21-2-2

Sec. 12. (a) The department shall investigate credible complaints received by the department that allege noncompliance with this article.

(b) Complaints will be assigned a priority for investigation under department policy.

(c) A licensing survey may be conducted simultaneously with and in addition to a complaint survey.

(d) The department shall notify the REH of the results of the complaint survey in writing. *(Indiana Department of Health; 410 IAC 15.2-2-12)*

410 IAC 15.2-2-13 Survey procedures

Authority: IC 16-19-3-4

Affected: IC 16-21-2-2

Sec. 13. (a) REHs shall fully cooperate with surveys conducted by representatives of the department.

(b) Documents, registers, reports, records, and minutes of an REH must be made available to the department on request for inspection and copying.

(c) An REH shall file an acceptable plan of correction with the department within ten (10) days after receiving a survey report that documents noncompliance with this article. *(Indiana Department of Health; 410 IAC 15.2-2-13)*