1. **Date the Notice of Intended Rulemaking was published in the Oklahoma Register:**
   December 15, 2016 Vol. 34 Ok Reg 7, Docket No. 16-868

2. **Name and address of the Agency:**
   Oklahoma State Department of Health
   1000 N.E. Tenth Street
   Oklahoma City, Oklahoma 73117-1299

3. **Title and Number of the Rule:**
   Title 310. Oklahoma State Department of Health
   CHAPTER 667. HOSPITAL STANDARDS

4. **Citation to the Statutory Authority for the Rule:**
   Oklahoma State Board of Health; Title 63 O.S. § 1-104; 63 O.S. Section 1-106.1; and 63 O.S. Section 1-705; and 63 O.S. Section 1-707.

5. **Brief Summary of the Content of the Adopted Rule:**
   The proposal amends physical plant requirements in Subchapter 41 by updating references to the Facility Guidelines Institute (FGI): Guidelines for Design and Construction of Hospitals and Outpatient Facilities, 2014 Edition, and the Life Safety Code adopted by the Centers for Medicare & Medicaid Services on July 5, 2016. Added are criteria and a process for hospitals to request exceptions and temporary waivers of the requirements of this Chapter for design or construction techniques that represent innovations or improvements. Subchapter 47 is updated by revising the requirements for stage one, stage two, and special construction plan submittals, and by giving hospitals the option to move directly to the stage two plan submittal. The proposal sets fees for related services including review of temporary waivers and applications for self-certification. The proposal establishes a process to ensure timely review of design and construction documents. The proposal establishes requirements and a process for hospitals to self-certify compliance of their plans for certain types of projects.

6. **Statement explaining the Need for the Adopted Rule:**
   These changes address outdated life safety and design and construction requirements and the need for a predictable method for resolving discrepancies in plan review, with provisions for expedited self-certification. The current rule provides for an obsolete review and approval functional programs, which in the past has contributed to project delays and uses the OSDH’s limited clinical staff resources that would otherwise be performing hospital surveys. This change is needed to prepare for anticipated reductions in the required state appropriations subsidy for the hospital licensure program where we may be unable to continue to support the optional services provided by OSDH for construction projects undertaken to improve patient health and safety.
7. Date and Location of the Meeting at which such Rules Were Adopted:
   Adopted February 14, 2017, in the offices of the Oklahoma State Department of Health.

8. Summary of the Comments and Explanation of Changes or Lack of any Change Made in
   the Adopted Rules as a Result of Testimony Received at Public Hearings:
   Written comments were received endorsing the modernization of Chapter 667 by updating to

   At a public meeting convened by the OSDH and attended by representatives of the industry, one
   commenter asked about the documentation and process to demonstrate compliance with the FGI
   Guidelines: what format would be used, what documents would be submitted or maintained at
   the facility, and how would the rule be enforced? Commenters suggested the Department and
   health care providers should continue to work together to develop administrative practices and
   educational materials while the rule moves toward final adoption. The Department agreed and
   will consult with industry representatives to develop administrative practices and templates to
   standardize the plan review process. Additionally, OSDH will collaborate with the industry to
   offer public training events on the updated guidelines and codes.

   Commenters requested the Department publish the decisions on exception and waiver requests.
   Publication of decisions on exception and waiver requests would be of benefit to facilities,
   architects and engineers designing and building facilities, it would serve to make the process
   more transparent, and would serve as the basis for future rule amendments to enable innovation
   and improvement. The Department amended the rule include publication of decisions on
   requests for exceptions and waivers and making them available to facilities and the public.

   Comments were received for clarification on the applicability of Part 2 of the FGI Guidelines,
   which only applies to hospitals, and Part 3 of the FGI Guidelines, which applies to outpatient
   facilities and would be used in the design and construction of ambulatory surgical centers.

   Based on comments, corrections to errors in numbering, references, and clarifications inserted to
   address the scope of applicability.

   A full summary of public comment is attached as Exhibit A.

9. List of Persons or Organizations Who Appeared or Registered For or Against the
   Adopted Rule at Any Public Hearing Held by the Agency or Those Who Have
   Commented in Writing Before or After the Hearing:

   OSDH received written comments from:
   - Ms. Rebecca Anderson of McFarland Architects, P.C.;
   - Ms. Betsy Guthrie-Brunsteter of ADG, PC; and
   - Mr. Curtis Wilson.

10. Rule Impact Statement: Hereto annexed as Exhibit B.

11. Incorporation by Reference Statement:
310:667-41-1. General

(a) The following national standards are incorporated by reference:


12. Members of the Governing Board of the Agency Adopting the Rules and the Recorded Vote of Each Member:

Dr. Jenny Alexopulos – Absent
Mrs. Martha Burger – Absent
Dr. Terry Gerard – Absent
Dr. Charles Grim - Aye
Dr. R. Murali Krishna - Aye
Mr. Timothy Starkey - Aye
Dr. Robert Stewart - Aye
Ms. Cris Hart-Wolfe - Aye
Dr. Ronald Woodson – Aye

13. Additional information: Information regarding this rule may be obtained by contacting Lee Martin, Director, Medical Facilities Service, Oklahoma State Department of Health, 1000 N.E. 10th Street, Oklahoma City, OK 73117-6576, telephone (405) 271 6576, or by e-mail to LeeM@health.ok.gov.
RULE COMMENT SUMMARY AND RESPONSE

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 667. HOSPITAL STANDARDS

The rule report submitted to the Governor, the Speaker of the House of Representatives and the President Pro Tempore of the Senate, pursuant 75:303.1(A) of the Administrative Procedures Act, shall include: (9) A summary of the comments and explanation of changes or lack of any change made in the adopted rules as a result of testimony received at all hearings or meetings held or sponsored by an agency for the purpose of providing the public an opportunity to comment on the rules or of any written comments received prior to the adoption of the rule. The summary shall include all comments received about the cost impact of the proposed rules; (10) A list of persons or organizations who appeared or registered for or against the adopted rule at any public hearing held by the agency or those who have commented in writing before or after the hearing.[75:303.1(E)(9)&(10)]

Rule Section 310:667-41-1. General

Summary of Comment: Ms. Rebecca Anderson of McFarland Architects, P.C., in a January 4, 2017 email to Oklahoma State Department of Health (OSDH) staff, questioned proposed requirements in the Oklahoma Administrative Code (OAC) 310:667-41-1(b). That subsection states the Oklahoma statutes prevail if there is conflict between the Facility Guidelines Institute (FGI) Guidelines and Oklahoma statutes. Ms. Anderson asked if facilities should not use OAC 310:667-49-56 and instead use the FGI Guidelines. Ms. Anderson also asked whether there would always be a conflict between Oklahoma statutes and FGI Guidelines because the Oklahoma statutes are out of date.

OSDH Explanation: An explanation of the difference between statutes and rules should resolve these concerns. The Oklahoma statutes referenced in OAC 310:667-41-1(b) are Oklahoma laws passed by the Legislature and codified in the Oklahoma Statutes (O.S.). The statutes differ from the rules, which are promulgated by the State Board of Health in OAC Chapter 310:667. Ms. Anderson is correct that the FGI Guidelines, 2014 Edition, incorporated by reference in OAC 310:667-41-1(a) will prevail over other conflicting provisions in OAC 310:667. However, if conflicts are identified between Oklahoma statutes and the FGI Guidelines, Oklahoma statutes will prevail. OSDH currently is not aware of conflicts between Oklahoma statutes and the FGI Guidelines.

Change: No change is required.


Change:  No change is required.

________________________________________________________________________

Summary of Comment: At a January 7, 2017 meeting sponsored by the OSDH with the Oklahoma Hospital Association and other interested persons, one commenter asked whether OSDH would publish the decisions on exception and waiver requests.

OSDH Explanation: Publication of decisions on exception and waiver requests could benefit facilities, architects and engineers designing and building facilities, serve to make the process more transparent, and serve as the basis for future rule amendments to foster innovation and improvement.

Change: Subsection 310:667-41-1(e) should be amended with a new paragraph (7) to read as follows:

(7) The Department shall publish decisions on requests for exceptions and waivers and make them available to facilities and the public. The Department shall remove facility identifying information to maintain confidentiality pursuant to 63 O.S. Section 1-709.

________________________________________________________________________

Summary of Comment: At a January 7, 2017 meeting sponsored by the OSDH with the Oklahoma Hospital Association and other interested persons, one commenter asked about the documentation and process to demonstrate compliance with the FGI Guidelines. What format would be used, what documents would be submitted to OSDH or maintained at the facility, and how would the rule be enforced? Several commenters suggested OSDH and the hospital industry should continue to work together to develop administrative practices and educational materials while the rule moves towards final adoption.

OSDH Explanation: OSDH agrees that it will be beneficial to work collaboratively with the hospital industry to transition to the updated guidelines. OSDH will consult with industry representatives to develop administrative practices and templates to standardize the plan review process. Additionally, OSDH will collaborate with the hospital industry to offer public training events on the updated guidelines and codes.

Change: No change is required.

________________________________________________________________________

Rule Section 310:667-47-1. Submission of plans and specifications and related requests for services

Summary of Comment: Ms. Esther Houser, in a January 5, 2017 email to OSDH staff, identified a drafting error in a rule proposal for another chapter, OAC 310:675-5-23(a)(1)(x). That error is repeated in the present Chapter at OAC 310:667-47-1(a)(1)(x).

OSDH Explanation: The proposal included a drafting error and correction of the error results in clarification but no substantive alteration of the rule. Although Ms. Houser was not
commenting specifically on the proposed changes to OAC 310:667, the correction is made here for consistency across the Chapters in OAC Title 310 dealing with health facility plan reviews. In the process of this correction an error in number sequence was identified for this paragraph as well as an error in numbering for the subparagraphs.

**Change:** Subparagraphs (i) through (xii) will be re-sequenced and renumbered to (A) through (K)

Subparagraph (x) was changed to (I) and corrected as follows:

(I) Replacement of fixed medical equipment if the alteration requires any work noted in (A) through (H) of this paragraph;

Summary of Comment: Ms. Rebecca Anderson of McFarland Architects, P.C., in a January 4, 2017 email to OSDH staff, questioned OAC 310:667-47-1(a)(1)(i through xii) which relate to the types of major alterations required to be submitted to OSDH. Ms. Anderson requested identification of the types of alterations that would be appropriate for self-certification, and recommended adding a monetary value to limit the types of projects submitted for self-certification.

**OSDH Explanation:** The types of design and construction plans eligible for self-certification are specified in a proposed new section, OAC 310-667-47-10(c). The proposed rule includes a maximum cost of $15,000,000 for projects affecting areas where patients are intended to be examined or treated.

**Change:** As noted above, subparagraphs (i) through (xii) will be re-sequenced and renumbered to (A) through (K). No other change is required.

Summary of Comment: At a January 9, 2017 meeting sponsored by the OSDH with the Oklahoma Hospital Association and other interested persons, several commenters questioned the fee for self-certification in OAC 310:667-47-10. They asked whether the self-certification fee is in addition to the review fees specified in OAC 310:667-47-1(b).

Mr. Curtis Wilson in a January 17, 2017 email to OSDH staff noted a typographical error in existing rule language in 310:667-47-1 (b)(5). Mr. Wilson recommended adding fees in excess of $2,500.

**OSDH Explanation:** The self-certification fee is not intended to be added to the fee charged for review of design and construction plans. The rule should be amended to clarify that the plan review fees in OAC 310:667-47-1 apply to plans and specifications for stage one, stage two, and fast-track projects submitted pursuant to OAC 310:667-47-2. Additionally, OSDH notes that instead of requiring a check for the fee, the rule should be more flexible to allow for other methods of payment. The typographical error in 310:667-47-1(b)(5) should be corrected. Pursuant to 63 O.S. Section 1-707, fees for submission or resubmission of
architectural and building plans are not to exceed $2,000; increasing fees to $2,500 or higher would require a statutory change.

**Change:** Subsection 310:667-47-1(b) should be amended to read as follows:

(b) Each construction project submission submitted for approval under OAC 310:667-47-2 shall be accompanied by a check for the appropriate review fee based on the cost of design and construction of the project. Review fees are as follows:

1. Project cost less than $10,000.00: $250.00 Fee
2. Project cost $10,000.00 to $50,000.00: $500.00 Fee
3. Project cost $50,000.00 to $250,000.00: $1000.00 Fee
4. Project cost $250,000.00 to $1,000,000.00: $1500.00 Fee
5. Project cost greater than $1,000,000.00: $2000.00 Fee

**Summary of Comment:** Mr. Curtis Wilson in a January 17, 2017 email to OSDH commented that adding fees for additional services and re-inspections are fair because the overall review fees have not increased.

Ms. Betsy Guthrie-Brunsteter of ADG, PC, in a January 17, 2017 email to OSDH supported the proposed changes to the fee structure.

**Change:** No change is required.

**Summary of Comment:** A commenter on OAC 310:675, Nursing and Specialized Facilities, requested a reduction in the time, from 15 days to 10 days, for OSDH to complete the administrative review on resubmitted materials. OAC 310:667-47-1(d)(1)(A) as proposed includes the same 15-day review time frame.

**OSDH Explanation:** For consistency with other health-facility plan review processes, including OAC 310:675, OSDH proposes reducing the 15-day administrative review time for resubmitted materials.

**Change:** Subparagraph OAC 310:667-47-1(d)(1)(A) should be revised to read as follows:

(A) **Not complete.** Upon determining that the application is not administratively complete, the Department shall immediately notify the applicant in writing and shall indicate with reasonable specificity the inadequacies and measures necessary to complete the application. Such notification shall not require nor preclude further review of the application and further requests for specific information. If the Department fails to notify the applicant as specified in this Paragraph, the period for technical review shall begin at the close of the administrative completeness review period. Upon submission of correction of inadequacies, the Department shall have an additional ten (10) calendar days to review the application for completeness.

**Rule Section 310:667-47-2. Preparation of plans and specifications [AMENDED]**
**Summary of Comment:** Mr. Curtis Wilson, in a January 17, 2017 email to OSDH, recommended a $1,000,000 maximum on projects eligible to bypass the stage 1 plan review per 310:667-47-2(a), based on the increased risk to hospitals and complexity of the functional-narrative review.

The Hospital Advisory Council in a public meeting on January 26, 2017, recommended the following changes:

- Clarify that the option to bypass stage one submittal does not apply if the project is being fast-tracked;
- Clarify that fast-track process is a method for phased approval of projects that allows hospitals to start work on packages as they are approved by the Department.

The Hospital Advisory Council recommended adoption of the proposed amendments to OAC 310:667, with the clarifications added to the fast-track project language.

**OSDH Explanation:** The option to bypass stage 1 plan reviews gives hospitals the flexibility to move more expeditiously through the OSDH approval process. The change reflects current practice and puts all hospitals on notice that they have the option if they accept the risk to modify items in the stage 2 review that might have been identified in a stage 1 review. Proposed changes in OAC 310:667-41-1-(e) recognize the authority of the hospital's governing body to approve the functional narrative, which will alleviate use of OSDH resources to review and approve functional narratives.

OSDH agrees with the clarifications recommended by the Hospital Advisory Council.

**Change:** Modify 310:667-47-2(a) and (c) to read as follows:

(a) **Stage one.** Preliminary plans and outline specifications shall be submitted and include sufficient information to establish for approval by the Department of the following: scope of project; project location; required fire-safety and exiting criteria; building-construction type, compartmentation showing fire and smoke barriers, bed count and services; the assignment of all spaces, areas, and rooms for each floor level, including the basement. A hospital has the option, at its own risk, to bypass the stage one submittal and proceed directly to submittal of stage two documents. The option to bypass the stage one submittal does not apply if the project is being submitted for the stage two fast-track project review.

(c) **Special submittals.**

1. **Fast-track Stage two fast-track projects.** The fast track process is a method for phased approval of a project as specified in this paragraph.
   
   (A)(i) Site work, foundation, structural, underslab mechanical, electrical, plumbing work, and related specifications.
   
   (B)(ii) Complete architectural plans and specifications.
(C)(iii) All mechanical, electrical, and plumbing plans and specifications.
(D)(iv) Equipment and furnishings.
(D) The hospital may begin site work on packages after approval by the Department.

Rule Section 310:667-47-10. Self-certification of plans [NEW]

Summary of Comment: Mr. Curtis Wilson in a January 17, 2017 email to OSDH commented that the expedited reviews will "increase the outcome and health, safety and welfare of the patients served by the medical community within Oklahoma." Mr. Wilson recommended amendment of OAC 310:667-47-10 by setting a $1,000,000 maximum on projects eligible for self-certification, and disallowing self-certification for new facilities, new beds, operating rooms and advanced technologies. The purpose is to protect hospitals against losses if a project is later found to be out of compliance.

Ms. Betsy Guthrie-Brunsteter of ADG, PC, in a January 17, 2017 email to OSDH staff, expressed concern regarding the attestation requirement in OAC 310:667-47-10(c)(3). Ms. Guthrie-Brunsteter said that the attestation "may require a contractual assumption of liability by Architect that exceed Architect’s liability under law." Ms. Guthrie-Brunsteter recommended adding this language: “Architect’s attestation is an expression of Architect’s professional opinion having applied the standard of professional due care prevailing in Oklahoma for architectural services of the kind and at the time provided by Architect and shall neither state nor imply a warranty or guarantee in any form. Such extra-legal assumptions of liability may be excluded from available professional liability insurance.”

Additionally, Ms. Guthrie-Brunsteter stated that self-certification benefits the hospital, but the architect’s only benefit is that willingness to apply for self-certification may weigh favorably in the hospital’s selection of the architect.

OSDH Explanation: The option for self-certification was requested by persons with experience in hospital design and construction who have used the self-certification process successfully in other states, including Kansas. OSDH research found that states using self-certification (including Massachusetts, New York, Texas, Virginia, and Arkansas) were able to reduce the workload of their plan review staff and to reduce processing times while maintaining appropriate standards of oversight. The eligibility criteria proposed by OSDH will ensure that higher-risk projects are disqualified from self-certification and that experienced, licensed architects or engineers are used to certify plans for compliance with OAC 310:657. The self-certification review is optional and would only be used by hospitals, architects and engineers willing to assume the risk associated with constructing a facility not in compliance with the OAC 310:657, including the FGI Guidelines and the Life Safety Code incorporated by reference.

OSDH was unable to find in Oklahoma law or rules governing architects a liability limitation that would conflict with the proposed attestation requirement in OAC 310:667-47-10. OSDH believes liability could be addressed in the contract between the architect and the hospital.
Given that the provision is an option for expedited review, if the architect chooses not to attest to the self-certification process, then the default will be the plan review and approval process in OAC 310:667-47-2.

The requirements for the self-certification request form and eligibility criteria, including the language to be used for the attestation are set out in OAC 310:667-47-10. OSDH will be obligated to use language in the form that closely parallels the rule.

In reviewing these comments on OAC 310:667-47-10, OSDH noted an inconsistency in references to architects and engineers, which should be corrected as noted below.

**Change:** To clarify that the form includes the items in 310:667-47-10(c), OSDH proposes an amendment to subsection (b), as shown below. To make the references to architects and engineers consistent, OSDH proposes to add the phrase term "or engineer" as indicated below. This change also incorporates a renumbering of subparagraphs (c)(4)(i) through (iv) to (c)(4)(A) through (D).

### 310:667-47-10. Self-certification of plans [NEW]

(a) The Department shall make available professional consultation and technical assistance services covering the requirements of this section to a hospital considering self-certification of plans. The consultation and technical assistance is subject to the fee for professional consultation and technical assistance services set in OAC 310:667-47-1. The consultation is optional and not a prerequisite for filing a request through the self-certification review process.

(b) The hospital and the project architect or engineer may elect to request approval of design and construction plans through a self-certification review process. The hospital and the project architect or engineer shall submit a self-certification request on a form provided by the Department, along with a self-certification application fee set in OAC 310:667-47-1. The form shall be signed by the hospital and the project architect or engineer attesting that the plans and specifications are based upon and comply with the requirements of this Chapter. The form shall require information necessary to demonstrate compliance with OAC 310:667-47-10(c).

(c) To be eligible for self-certification, projects must comply with the following requirements:

(1) The project involves any portion of the hospital where patients are intended to be examined or treated and the total cost of design and construction is fifteen million dollars ($15,000,000.00) or less; or

(2) The project involves only portions of the hospital where patients are not intended to be examined or treated; and

(3) The project architect or engineer attesting the application has held a license to practice architecture or engineering for at least five (5) years prior to the submittal of the application, is licensed to practice in Oklahoma; and

(4) The hospital owner/operator acknowledges that the Department retains the authority to:

   (A) Perform audits of the self-certification review program and select projects at random for review;
(B) Review final construction documents;
(C) Conduct on-site inspections of the project;
(D) Withdraw approval based on the failure of the hospital or project architect or
to comply with the requirements of this Chapter; and
(5) The hospital agrees to make changes required by the Department to bring the
construction project into compliance with this Chapter.

(d) Within twenty-one (21) calendar days after receipt of a complete application, the
Department shall approve or deny the application for self-certification and send notification
to the hospital. If the application is denied, the hospital shall have thirty (30) calendar days
to submit additional or supplemental information demonstrating that the application complies
with the requirements for self-certification of plans and specifications. The Department shall
have fourteen (14) calendar days after receipt of supplemental information to reconsider the
initial denial and issue a final approval or denial of the self-certification request.
(e) After denial of the application for self-certification and prior to the start of construction,
the hospital shall pay the applicable fee for plan review specified in OAC 310:667-47-1(b)(1)
through (5). Upon receipt of the plan review fee, the Department shall review the hospital's
plans in accordance with the process in OAC 310:667-47-1(d).

Persons or organizations who appeared or registered for or against the adopted rule at any
public hearing held by the agency or those who have commented in writing before or after
the hearing were:

OSDH received written comments from:
- Ms. Rebecca Anderson of McFarland Architects, P.C.;
- Ms. Betsy Guthrie-Brunsteter of ADG, PC; and
- Mr. Curtis Wilson.

Agency Rule Contact:
Lee Martin, Director, Medical Facilities Service, Oklahoma State Department of Health,
1000 N.E. 10th Street, Oklahoma City, OK 73117-6576, telephone (405) 271 6576, or by e-mail
to LeeM@health.ok.gov.
RULE IMPACT STATEMENT

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 667. HOSPITAL STANDARDS

1. DESCRIPTION:
The proposal amends physical plant requirements in Subchapter 41 by updating references to the Facility Guidelines Institute (FGI): Guidelines for Design and Construction of Hospitals and Outpatient Facilities, 2014 Edition, and the Life Safety Code adopted by the Centers for Medicare & Medicaid Services on July 5, 2016. Added are criteria and a process for hospitals to request exceptions and temporary waivers of the requirements of this Chapter for design or construction techniques that represent innovations or improvements.

Subchapter 47 is updated by revising the requirements for stage one, stage two, and special construction plan submittals, and by giving hospitals the option to move directly to the stage two plan submittal. The proposal sets fees for related services including review of temporary waivers and applications for self-certification. The proposal establishes a process to ensure timely review of design and construction documents. The proposal establishes requirements and a process for hospitals to self-certify compliance of their plans for certain types of projects.

2. DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:
The classes of persons affected are hospitals proposing to construct new buildings or make major alterations to existing buildings. Additionally, affected professionals working with hospitals may include architects, engineers, clinicians, and attorneys. The OSDH requested in the notice of rulemaking intent information from businesses on cost impacts. The OSDH received written comment from three individuals who commented on other aspects of the rule but did not express concern with the cost impact. The Hospital Advisory Board reviewed the proposed rule and voted to approve recommendation of the rule to the Board of Health. The OSDH convened an industry working group examining the plan review process which met over the last 18 months. This work group was the genesis for the proposed rule.

3. DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED HEALTH OUTCOMES:
Persons benefiting will include hospitals, associated professionals, and customers of hospitals. The benefits include updating the rule to incorporate current life-safety codes adopted by the Centers for Medicare & Medicaid Services, and design and construction requirements adopted by the Facility Guidelines Institute. Persons admitted or visiting a hospital also benefit from the changes in health and safety protections due to the adoption of the new codes. The addition of the exception and waiver process affords hospitals a method to resolve differences between national standards and Oklahoma State Department of Health (OSDH) requirements. Hospitals will benefit from access to an optional and expedited self-certification process to reduce the time required for review and approval of design and construction documents. The proposal was developed in cooperation with representatives of health care facilities, architects, attorneys and engineers. The goal of the working group is to reduce the time from concept to market for health services, by ensuring that OSDH reviews are timely completed while reducing the proportion of plans denied or requiring rework. Health facility customers will benefit from more timely access to health services with lower project development and implementation costs.
For the period from July 2015 to August 2016, the average time from submittal of plans to approval by the OSDH was 94 days for design documents, with 27% completed in less than 45 days. For final construction documents, the time from original submittal to OSDH approval averaged 60 days, with 50% completed in less than 45 days. The objective of the proposed changes is to complete all reviews within 45 days after submittal.

The average time from original submittal of plans to completion of construction averaged just over 400 days from July to December 2015. The average improved slightly to about 380 days from July to September 2016. An objective of the project is to achieve 15% annual reductions in total project completion times until the review process demonstrates statistical control.

Note: The data above are for projects submitted by hospitals and ambulatory surgical centers. The OSDH processing times referenced include time taken by facilities to correct or revise plans following comments or rejections by OSDH. Actual OSDH review days are about one-third of total construction completion statistics.

4. ECONOMIC IMPACT, COST OF COMPLIANCE AND FEE CHANGES:

Hospitals may benefit economically from reduced times required to obtain clearance to start construction. The upgraded codes and guidelines are anticipated to include a combination of cost increases and decreases because of new construction technologies and methods. The rule includes fee increases for operational services. The fee increases are as follows:

(A) Request for exception or temporary waiver fee: Five Hundred Dollars ($500.00);
(B) Application for self-certification fee: One Thousand Dollars ($1,000.00);
(C) Courtesy construction inspection fee: Five Hundred Dollars ($500.00);
(D) Professional consultation or technical assistance fee: Five Hundred Dollars ($500.00) for each eight hours or major fraction thereof of staff time. For technical assistance requiring travel, the fee may be increased to include the OSDH's costs for travel.

Based on State Fiscal Year (SFY) 2016 experience, the changes are projected to generate a total of $62,500 for SFY2018, based on the following:

- $2,500 in exception or temporary waiver fees, assuming 5 requests at $500
- $15,000 in self-certification fees, assuming 15 certifications at $1,000 each
- $40,000 in courtesy inspection fees, assuming 80 inspections at $500 each
- $5,000 in professional consultation fees, assuming 10 projects at $500 each
- $62,500 total increased fees.

5. COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY:

The cost to the OSDH to implement the amendments will be approximately $3,252.32 to cover the costs of rule drafting, adoption, publication, distribution, and education. The proposed rules will be implemented and enforced by existing OSDH personnel and will not result in an increase in authorized full-time equivalent personnel. For SFY2017, health facility plan review expenses of $469,349 are projected to exceed fees of $162,958, for a deficit of $330,836. The deficits in SFY2017 and subsequent years must be covered by state appropriations. This proposal has the potential to reduce the required state appropriations subsidy by approximately $60,000 in FY 2018 and subsequent years. No impacts on other agencies are anticipated.

6. IMPACT ON POLITICAL SUBDIVISIONS:
Hospitals operated by political subdivisions may be affected by the upgrade in codes and guidelines, the new review process, and the fees for optional services.

7. **ADVERSE EFFECT ON SMALL BUSINESS:**
   The new fees for optional construction-related services may have an adverse effect on small businesses that engage in construction projects. Additionally, the costs of commissioning required in the updated construction guidelines may have an adverse effect on small businesses. OSDH has requested comments by January 17, 2017 from businesses identifying direct and indirect costs expected to be incurred to comply with this rule. Comments from business entities will be considered by OSDH and the State Board of Health and may result in additional modifications to the rule proposal prior to adoption.

8. **EFFORTS TO MINIMIZE COSTS OF RULE:**
   The proposed changes add flexibility and minimize costs by providing a waiver and exception process, by allowing for self-certification of plans, and by providing fees for optional services.

9. **EFFECT ON PUBLIC HEALTH AND SAFETY:**
   This change will enable health care facilities to use the most current national codes and guidelines, which represent enhancements to patient safety and health care quality. Additionally, the rule makes provisions to ensure OSDH reviews are timely accomplished.

10. **DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:**
    If this change is not made, Oklahoma will continue to have outdated life safety and design and construction requirements. The OSDH review process will not offer a predictable method for resolving discrepancies, and it will not include a provision for expedited self-certification. Without this change, the OSDH will continue to review and approve functional programs, which in the past have contributed to project delays and uses the OSDH’s limited clinical staff resources that would otherwise be performing hospital surveys. If this change is not adopted, OSDH will lose an opportunity to prepare for anticipated reductions in the required state appropriations subsidy for the hospital licensure program and may be unable to continue to support the optional services provided by OSDH for construction projects undertaken to improve patient health and safety.

11. **PREPARATION AND MODIFICATION DATES:**
    This rule impact statement was prepared on December 15, 2016. This rule impact statement was modified on December 21, 2016 to: correct non-substantive spelling and grammatical errors; correct an error in section 5 of this statement regarding revenues, expenses and deficits for health facility plan reviews; clarify the reduction of the required state appropriations subsidy referenced in sections 5 and 10; and clarify the detrimental effects of failure to adopt the fees for optional services referenced in section 10. The statement was modified on January 25, 2017, to incorporate public comment.
FEE JUSTIFICATION

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 667. HOSPITAL STANDARDS

The Oklahoma State Department of Health is proposing fees pertaining to ancillary physical plant plan review requirements. The proposed amendments also incorporate industry requested updates to incorporate references to the Facility Guidelines Institute (FGI): Guidelines for Design and Construction of Hospitals and Outpatient Facilities, 2014 Edition, and the Life Safety Code adopted by the Centers for Medicare & Medicaid Services on July 5, 2016. As a cost offsetting measure we add criteria and a process for hospitals to request exceptions and temporary waivers of the requirements of this Chapter for design or construction techniques that represent innovations or improvements.

The proposal revises the requirements for stage one, stage two, and special construction plan submittals, and gives hospitals the option to move directly to the stage two plan submittal. The proposal sets fees for related services including review of temporary waivers and applications for self-certification. The proposal establishes a process to ensure timely review of design and construction documents. The proposal establishes requirements and a process for hospitals to self-certify compliance of their plans for certain types of projects.

This regulatory activity is labor-intensive and the costs associated with it is not easy to avoid or minimize. Based upon the premise that a regulated industry should bear all or substantially all of the costs routinely or regularly incurred by the State, the absent fee structure for these ancillary but needed services is not adequate to recoup the Department’s expenses. The rule changes will permit the Department to offset the costs that promote services in hospitals that are safe and delivered in settings that conform to industry standards for best practice. The increased revenue will assist the program to meet the budget demands for the operation and maintenance of this program, provide timely plan review to the industry, and reduce the public health risk due to insufficient physical plant plan review.

The proposed fee change will enable the Department to accomplish our responsibilities without creating an undue burden on all of the State’s taxpayers. The changes are necessary to cover increasing costs and workload for plan review and to allow flexibility to the industry in the plan review process.

COST IMPACT RESPONSE: The proposed rules were developed over the course of 18 months in cooperation with representatives of health care facilities, architects, attorneys and engineers. The goal of the working group was to reduce the time from concept to market for health services, by ensuring that OSDH reviews are timely completed while reducing the proportion of plans denied or requiring rework. Those participating sought the changes based on their assertions that health facility customers will benefit from more timely access to health services with lower project development and implementation costs.

BENEFITS: Persons benefiting will include hospitals, associated professionals, and customers of hospitals. The benefits include updating the rule to incorporate current life-safety codes adopted by the Centers for Medicare & Medicaid Services, and design and construction requirements adopted by the Facility Guidelines Institute. Persons visiting hospitals also benefit


from the changes in health and safety protections due to the adoption of the new codes. The addition of the exception and waiver process affords hospitals a method to resolve differences between national standards and Oklahoma State Department of Health (OSDH) requirements.

Hospitals may benefit economically from reduced times required to obtain clearance to start construction. The upgraded codes and guidelines are anticipated to include a combination of cost increases and decreases because of new construction technologies and methods.

Hospitals will benefit from access to an optional and expedited self-certification process to reduce the time required for review and approval of design and construction documents. The proposal was developed in cooperation with representatives of health care facilities, architects, attorneys and engineers. The goal of the working group is to reduce the time from concept to market for health services, by ensuring that OSDH reviews are timely completed while reducing the proportion of plans denied or requiring rework. Health facility customers will benefit from more timely access to health services with lower project development and implementation costs.

For the period from July 2015 to August 2016, the average time from submittal of plans to approval by the OSDH was 94 days for design documents, with 27% completed in less than 45 days. For final construction documents, the time from original submittal to OSDH approval averaged 60 days, with 50% completed in less than 45 days. The objective of the proposed changes is to complete all reviews within 45 days after submittal.

The average time from original submittal of plans to completion of construction averaged just over 400 days from July to December 2015. The average improved slightly to 380 days from July to September 2016. An objective of the project is to achieve 15% annual reductions in total project completion times until the review process demonstrates statistical control.

Note: The data above are for projects submitted by hospitals and ambulatory surgical centers. The OSDH processing times referenced include time taken by facilities to correct or revise plans following comments or rejections by OSDH. Actual OSDH review days are about one-third of total construction completion statistics.

**PROPOSED FEES:** The fees are proposed fees for ancillary services requested by the industry. The base plan review fees are not amended. A discussion of the proposed fees and further justification follows.

The rule includes fees for optional ancillary services. The fees are as follows:

(A) Request for exception or temporary waiver fee: Five Hundred Dollars ($500.00);

(B) Application for self-certification fee: One Thousand Dollars ($1,000.00);

(C) Courtesy construction inspection fee: Five Hundred Dollars ($500.00);

(D) Professional consultation or technical assistance fee: Five Hundred Dollars ($500.00) for each eight hours or major fraction thereof of staff time. For technical assistance requiring travel, the fee may be increased to include the OSDH's costs for travel.
Based on State Fiscal Year (SFY) 2016 experience, the changes are projected to generate a total of $62,500 for SFY2018, based on the following:

- Exception or temporary waiver fees, assuming 5 requests at $500: $2,500
- Self-certification fees, assuming 15 certification at $1,000 each: 15,000
- Courtesy inspection fees, assuming 80 inspections at $500 each: 40,000
- Professional consultation fees, assuming 10 project at $500 each: $5,000

Total additional revenue: $62,500

The proposed rules will be implemented and enforced by existing OSDH personnel and will not result in an increase in authorized full-time equivalent personnel. For SFY2017, health facility plan review expenses of $469,349 are projected to exceed fees of $162,958, for a deficit of $330,836. The deficit in SFY2017 and subsequent years must be covered by state appropriations. This proposal has the potential to reduce the required state appropriations subsidy by approximately $62,500 in FY 2018 and subsequent years.
310:667-41-1. General

(a) These requirements are intended as minimum standards for constructing and equipping hospital and specialized hospital projects. For brevity and convenience, these standards are presented in "code language". Use of words such as "shall" is mandatory. Insofar as practical, these standards relate to desired performance or results or both. Details of construction and engineering are assumed to be part of good design practice and local building regulations. Design and construction shall conform to the requirements of these standards. Requirements set forth in these standards shall be considered as minimum. For aspects of design and construction not included, local governing building codes shall apply. Where there is no local governing building code, the prevailing model code used within the geographic area is hereby specified for all requirements not otherwise specified in these standards. (See OAC 310:667-41-4(b) for wind and seismic local requirements.) Where American Society of Civil Engineers (ASCE 9-72) is referenced, similar provisions in the model building code are considered substantially equivalent.

(b) These standards are not intended to restrict innovations and improvements in design or construction techniques. Accordingly, the Department may approve plans and specifications which contain deviations if it is determined that the respective intent or objective has been met.

(c) Some projects may be subject to the regulations of several different programs, including those of other state agencies, local agencies, and federal authorities. While every effort has been made for coordination, individual project requirements shall be verified, as appropriate.

(d) The Centers for Medicare & Medicaid Services (CMS), which is responsible for Medicare and Medicaid reimbursement, has adopted the National Fire Protection Association 101 Life Safety Code (NFPA 101). To ensure non-conflicting requirements, the 2000 version of this code is hereby adopted by the Department and all new construction shall comply with that code. Existing construction may continue to comply with the version of NFPA 101 for which construction was approved.

(e) The health care provider shall supply for each project a functional program for the facility that describes the purpose of the project, the projected demand or utilization, staffing patterns, departmental relationships, space requirements, and other basic information relating to fulfillment of the institution's objectives. This program shall include a description of each function or service; the operational space required for each function; the quantity of staff or other occupants of the various spaces; the numbers, types, and areas (in net square feet) of all spaces; the special design features; the systems of operation; and the interrelationships of various functions and spaces. The functional program shall include a description of those services necessary for the complete operation of the facility and shall also include the Infection Control Risk Assessment (ICRA). Services available elsewhere in the institution or community need not be duplicated in the facility. The functional program shall also address the potential future expansion of essential services which may be needed to accommodate increased demand. The approved functional program shall be available for use in the development of project design and construction documents.

(f) An ICRA is a determination of the potential risk of transmission of various agents in the facility. This continuous process is an essential component of a facility functional or master
program to provide a safe environment of care. The ICRA shall be conducted by a panel with expertise in infection control, risk management, facility design, construction, ventilation, safety, and epidemiology. The design professional shall incorporate the specific, construction related requirements of the ICRA in the contract documents. The contract documents shall require the contractor to implement these specific requirements during construction. The ICRA is initiated in design and planning and continues through construction and renovation. After considering the facility's patient population and programs, The ICRA shall address but not be limited to the following key elements:

1. The impact of disrupting essential services to patients and employees;
2. Patient placement or relocation;
3. Placement of effective barriers to protect susceptible patients from airborne contaminants such as Aspergillus sp.
4. Air handling and ventilation needs in surgical services, airborne infection isolation and protective environment rooms, laboratories, local exhaust systems for hazardous agents, and other special areas;
5. Determination of additional numbers of airborne infection isolation or protective environment room requirements;
6. Consideration of the domestic water system to limit Legionella sp. and waterborne opportunistic pathogens.

(a) The following national standards are incorporated by reference:

(b) Oklahoma statutes prevail if there is conflict between the FGI Guidelines and Oklahoma statutes. For Medicare-certified hospitals, the Life Safety Code adopted by the Centers for Medicare & Medicaid Services prevails if there is a conflict between the Life Safety Code and this Chapter.

(c) A hospital may submit a request for exception or temporary waiver if the FGI Guidelines create an unreasonable hardship, or if the design and construction for the hospital property offers improved or compensating features with equivalent outcomes to the FGI Guidelines.

(d) The Department may permit exceptions and temporary waivers of the FGI Guidelines if the Department determines that such exceptions or temporary waivers comply with the requirements of 63 O.S. Section 1-701 et seq., this Chapter, and the following:

1. Any hospital requesting an exception or temporary waiver shall apply in writing on a form provided by the Department and pay the exception to, or temporary waiver of, FGI Guidelines fee set in OAC 310:667-47-1. The form shall include:
   (A) The FGI Guidelines section(s) for which the exception or temporary waiver is requested;
   (B) Reason(s) for requesting an exception or temporary waiver;
   (C) The specific relief requested; and
   (D) Any documentation which supports the application for exception.

2. In consideration of a request for exception or temporary waiver, the Department shall consider the following:
   (A) Compliance with 63 O.S. Section 1-701 et seq.;
(B) The level of care provided;
(C) The impact of an exception on care provided;
(D) Alternative policies or procedures proposed; and
(E) Compliance history with provisions of the FGI Guidelines, Life Safety Code and this
Chapter.

(3) The Department shall permit or disallow the exception or waiver in writing within forty-
five (45) calendar days after receipt of the request.

(4) If the Department finds that a request is incomplete, the Department shall advise the
hospital in writing and offer an opportunity to submit additional or clarifying information.
The applicant shall have thirty (30) calendar days after receipt of notification to submit
additional or clarifying information in writing to the Department of Health, or the request
shall be considered withdrawn.

(5) A hospital which disagrees with the Department's decision regarding the exception or
temporary waiver may file a written petition requesting relief through an individual
proceeding pursuant to OAC 310:2 (relating to Procedures of the State Department of
Health).

(6) The Department may revoke an exception or temporary waiver through an administrative
proceeding in accordance with OAC 310:2 and the Oklahoma Administrative Procedures Act
upon finding the hospital is operating in violation of the exception or temporary waiver, or
the exception or temporary waiver jeopardizes patient care and safety or constitutes a distinct
hazard to life.

(7) The Department shall publish decisions on requests for exceptions and waivers, subject to
the confidentiality provisions of 63 O.S. Section 1-709.

(e) Documentation of the hospital governing body's approval of the functional program shall be
sufficient to meet the requirements in this Chapter relating to Department approval of the
functional program.

SUBCHAPTER 47. SUBMITTAL REQUIREMENTS

310:667-47-1. Submission of plans and specifications and related requests for services

(a) Before construction is begun, plans and specifications, covering the construction of new
buildings or major alterations to existing buildings, shall be submitted to the Department for
review and approval as provided in OAC 310:667-47-2 or OAC 310:667-47-10.

(1) Plans and specifications are required for the following alterations:
   (A) Changes that affect path of egress;
   (B) Change of use or occupancy;
   (C) Repurposing of spaces;
   (D) Structural modifications;
   (E) Heating, ventilation and air conditioning (HVAC) modifications;
   (F) Electrical modifications that affect the essential electrical system;
   (G) Changes that require modification or relocation of fire alarm initiation or notification
devices;
   (H) Changes that require modification or relocation of any portion of the automatic fire
sprinkler system;
   (I) Replacement of fixed medical equipment if the alteration requires any work noted in
   (A) through (H) of this paragraph;
(J) Replacement of or modifications to any required magnetic or radiation shielding; 
(K) Changes to or addition of any egress control devices or systems.

(2) Plans and specifications are not required for the following alterations:
   (A) Painting, papering tiling, carpeting, cabinets, counter tops and similar finish work 
       provided that the new finishes shall meet the requirements of this Chapter;
   (B) Ordinary repairs and maintenance;
   (C) Modifications to nurse call or other hospital signaling/communication/information 
       technology systems provided the modifications meet the requirements of this Chapter; or
   (D) Replacement of fixed or moveable medical equipment that does not affect electrical, 
       HVAC, or shielding requirements noted above.

(b) Each construction project submission submitted for approval under OAC 310:667-47-2 shall be 
accompanied by a check for the appropriate review fee based on the cost of design and construction 
of the project. Review fees are as follows:

   (1) Project cost less than $10,000.00: $250.00 Fee
   (2) Project cost $10,000.00 to $50,000.00: $500.00 Fee
   (3) Project cost $50,000.00 to $250,000.00: $1000.00 Fee
   (4) Project cost $250,000.00 to $1,000,000.00: $1500.00 Fee
   (5) Project cost greater than $1,000,000.00: $2000.00 Fee

(c) The review fee shall cover the cost of review for up to two (2) stage one and two (2) stage 
two submittals and one final inspection. If a stage one or stage two submittal is not approved 
after two (2) submissions, another review fee based on the cost of the project shall be required 
with the third submittal. Fast-track projects shall be allowed two reviews for each package 
submitted. If a fast-track stage package is not approved after the second submittal, another 
review fee based on the cost of the project shall be required with the third submittal of the 
package.

(d) Review process. All construction project submittals. Design and construction plans and 
specifications shall be reviewed within 45 calendar days of receipt by the Department in 
accordance with the following process.

   (1) Administrative completeness review. Unless otherwise provided in this Subchapter, the 
       Department shall have ten (10) calendar days in which to determine if the filed application is 
       administratively complete

       (A) Not complete. Upon determining that the application is not administratively complete, the Department shall immediately notify the applicant in writing and shall 
           indicate with reasonable specificity the inadequacies and measures necessary to complete 
           the application. Such notification shall not require nor preclude further review of the 
           application and further requests for specific information. If the Department fails to notify 
           the applicant as specified in this Paragraph, the period for technical review shall begin at 
           the close of the administrative completeness review period. Upon submission of 
           correction of inadequacies, the Department shall have an additional ten (10) calendar 
           days to review the application for completeness.

       (B) Complete. Upon determination that the application is administratively complete, the 
           Department shall immediately notify the applicant in writing. The period for technical 
           review begins.

   (2) Technical review. The Department shall have forty-five (45) calendar days from the date 
a completed application is filed to review each application for technical compliance with the 
relevant regulations and reach a final determination.
(A) **When times are tolled.** The time period for technical review is tolled (the clock stops) when the Department has asked for supplemental information and advised the applicant that the time period is tolled pending receipt.

(B) **Supplements.** To make up for time lost in reviewing inadequate materials, a request for supplemental information may specify that up to 30 additional calendar days may be added to the deadline for technical review, unless the request for supplemental information is a second or later request that identifies new deficiencies not previously identified.

(C) **Delays.** An application shall be deemed withdrawn if the applicant fails to supplement an application within 90 calendar days after the Department's request, unless the time is extended by agreement for good cause.

(D) **Extensions.** Extensions may be made as provided by law.

(e) **Fees for other services.** Fees for other services related to construction projects are as follows:

1. Request for exception to or temporary waiver of FGI Guidelines fee: Five Hundred Dollars ($500.00);
2. Application for self-certification fee: One Thousand Dollars ($1,000.00);
3. Courtesy inspection, prior to final inspection for approval of occupancy, fee: Five Hundred Dollars ($500.00);
4. Professional consultation or technical assistance fee: Five Hundred Dollars ($500.00) for each eight staff hours or major fraction thereof. For technical assistance requiring travel, the fee may be increased to include the Department's costs for travel.

310:667-47-2. **Preparation of plans and specifications**

(a) **Stage one.** Preliminary plans and outline specifications shall be submitted and include sufficient information to establish for approval by the Department of the following: scope of project; project location; required fire-safety and exiting criteria; building-construction type, compartmentation showing fire and smoke barriers, bed count and services; the assignment of all spaces, areas, and rooms for each floor level, including the basement. A hospital has the option, at its own risk, to bypass the stage one submittal and proceed directly to submittal of stage two documents. The option to bypass the stage one submittal does not apply if the project is being submitted for the stage two fast-track project review.

(b) **Stage two.** A proposed construction document shall be submitted that includes final drawings and specifications adequate for proposed contract purposes approval by the Department. All final plans and specifications shall be appropriately sealed and signed by an architect registered by the State of Oklahoma. All construction modifications of approved documents are subject to review and approval, and shall be submitted timely.

(c) **Special submittals.**

1. **Fast-track Stage two fast-track projects.** The fast track process is a method for phased approval of a project as specified in this paragraph.

   (A) Equipment and built-in furnishings are to be identified in the stage one submittal.

   (B) The hospital has the option to submit two packages: civil, landscaping and structural in stage one, and the balance of the components in stage two.

   (C) Fast-track projects shall have prior approval and be submitted in no more than four (4) separate packages.
(A)(i) Site work, foundation, structural, underslab mechanical, electrical, plumbing work, and related specifications.
(B)(ii) Complete architectural plans and specifications.
(C)(iii) All mechanical, electrical, and plumbing plans and specifications.
(D)(iv) Equipment and furnishings.
(D) The hospital may begin site work on packages after approval by the Department.
(2) **Automatic sprinkler systems.** At least two (2) sets of sprinkler system show drawings, specifications, and calculations (if applicable), prepared by the installer, shall be submitted to the Office of the State Fire Marshal for review and approval prior to installation of the proposed system in the project.
(3) **Radiation protection.** Any project that includes radiology or special imaging equipment used in medical diagnosis, treatment, and therapy of patients, shall include plans, specifications, and shielding criteria, prepared by a qualified medical physicist. These plans shall be submitted and approved by the Department prior to installation of the equipment.
(d) **Floor plan scale.** Floor plans are to be submitted at a scale of one-eighth (1/8) inch equals one (1) foot, with additional clarifying documents as required.
(e) **Application form.** The submittal shall be made using a Department application form which requests information required by this Chapter and specifies the number of copies and format for document submittal.

310:667-47-10. Self-certification of plans
(a) The Department shall make available professional consultation and technical assistance services covering the requirements of this section to a hospital considering self-certification of plans. The consultation and technical assistance is subject to the fee for professional consultation and technical assistance services set in OAC 310:667-47-1. The consultation is optional and not a prerequisite for filing a request through the self-certification review process.
(b) The hospital and the project architect or engineer may elect to request approval of design and construction plans through a self-certification review process. The hospital and the project architect or engineer shall submit a self-certification request on a form provided by the Department, along with a self-certification application fee set in OAC 310:667-47-1. The form shall be signed by the hospital and the project architect or engineer attesting the application has held a license to practice architecture or engineering for at least five (5) years prior to the submittal of the application, is licensed to practice in Oklahoma; and the hospital owner/operator acknowledges that the Department retains the authority to:
   (A) Perform audits of the self-certification review program and select projects at random for review;
   (B) Review final construction documents;
(C) Conduct on-site inspections of the project;

(D) Withdraw approval based on the failure of the hospital or project architect or engineer to comply with the requirements of this Chapter; and

(5) The hospital agrees to make changes required by the Department to bring the construction project into compliance with this Chapter.

(d) Within twenty-one (21) calendar days after receipt of a complete application, the Department shall approve or deny the application for self-certification and send notification to the hospital. If the application is denied, the hospital shall have thirty (30) calendar days to submit additional or supplemental information demonstrating that the application complies with the requirements for self-certification of plans and specifications. The Department shall have fourteen (14) calendar days after receipt of supplemental information to reconsider the initial denial and issue a final approval or denial of the self-certification request.

(e) After denial of the application for self-certification and prior to the start of construction, the hospital shall pay the applicable fee for plan review specified in OAC 310:667-47-1(b)(1) through (5). Upon receipt of the plan review fee, the Department shall review the hospital's plans in accordance with the process in OAC 310:667-47-1(d).