

ADMINISTRATIVE AGENCY RULE REPORT
75 O.S. Supp. 2000, § 303.1
SUBMITTED TO THE GOVERNOR AND TO THE LEGISLATURE

- 1. Date the Notice of Intended Rulemaking was published in the Oklahoma Register:**
December 15, 2016 Vol. 34 Ok Reg 7, Docket No. 16-870

- 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 615. AMBULATORY SURGICAL CENTERS

- 4. Citation to the Statutory Authority for the Rule:**
Oklahoma State Board of Health, Title 63 O.S. § 1-104 and 63 O.S. Section 1-106.1; and 63 O.S. Section 2662.

- 5. Brief Summary of the Content of the Adopted Rule:**
The proposal amends physical plant requirements in Subchapter 1 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 ambulatory surgical centers 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 ambulatory surgical centers 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 ambulatory surgical centers to self-certify compliance of their plans for certain types of projects.

- 6. Statement explaining the Need for the Adopted Rule:**
The Oklahoma State Department of Health is proposing to create fees for ancillary services related to 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 off-setting measure we add criteria and a process for ambulatory surgical centers to request exceptions and temporary waivers of the requirements of this Chapter for design or construction techniques that represent innovations or improvements.

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:

At a public meeting convened by the OSDH and attended by representatives of ambulatory surgical centers, 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 applicable days were applied and clarifications inserted to address the scope of applicability.

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:

Ms. Rebecca Anderson – McFarland Architects, P.C.

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

11. Incorporation by Reference Statement:

310:615-1-3. General considerations

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

(1) Facility Guidelines Institute (FGI): Guidelines for Design and Construction of Hospitals and Outpatient Facilities, 2014 Edition; and

(2) National Fire Protection Association (NFPA) 101: Life Safety Code, 2012 Edition, adopted in 81 Federal Register 26871 by the Centers for Medicare & Medicaid Services on July 5, 2016.

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

Dr. Jenny Alexopoulos – 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, or by e-mail to LeeM@health.ok.gov.

RULE COMMENT SUMMARY AND RESPONSE

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 615. AMBULATORY SURGICAL CENTERS

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 310:615-1-3. General considerations

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) 310:615-1-3(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 OAC 310:615-5 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 310:615-1-3(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 310:615. Ms. Anderson is correct that the FGI Guidelines, 2014 Edition, incorporated by reference in OAC 310:615-1-3(a) will prevail over other conflicting provisions in OAC 310:615. 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.

Summary of Comment: At a January 7, 2017 meeting sponsored by the OSDH staff and attended by representatives of ambulatory surgical centers, one commenter asked whether OSDH would publish the decisions on exception and waiver requests.

OSDH Explanation: 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.

Change: Subsection 310:615-1-3(d) 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.

Summary of Comment: At a January 7, 2017 meeting sponsored by the OSDH staff and attended by representatives of ambulatory surgical centers, 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 health care providers 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 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 industry to offer public training events on the updated guidelines and codes.

Change: No change is required.

Summary of Comment: At a January 7, 2017 meeting sponsored by the OSDH staff and attended by representatives of ambulatory surgical centers, one commenter asked whether Part 2 of the FGI Guidelines would apply to ambulatory surgical centers.

OSDH Explanation: Part 2 of the FGI Guidelines applies to hospitals and would not apply to ambulatory surgical centers licensed under OAC 310:615. Part 3 of the FGI Guidelines, including standards incorporated by reference in Part 3, applies to outpatient facilities and would be used in the design and construction of ambulatory surgical centers if the amendments to OAC 310:615-1-3 are adopted.

Change: No change is required.

Summary of Comment: This issue was identified by OSDH staff during a discussion with representatives of ambulatory surgical centers. The proposed new language in OAC 310:615-1-3(d)(2)(i) referenced the ambulatory surgical center licensing law as 63 O.S. Section 1-2567. The correct reference is 63 O.S. Section 2657.

OSDH Explanation: This error does not change the intent or effect of the rule and should be corrected. In the process of this correction an error in numbering was identified for this paragraph. Subparagraphs (i) through (v) will be re numbered to (A) through (E)

Change: Subparagraph 310:615-1-3(d)(2)(A) should be revised to read as follows:

(A) Compliance with 63 O.S. Section 2657 et seq.;

Rule Section 310:615-1-3.1 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 OAC 310:675-5-23(a)(1)(x), which is repeated in the present Chapter at OAC 310:615-1-3.1(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. 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 (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 310:615-1-3.1(a)(1)(i through xii) which relate to the types of major alterations required to be submitted to OSDH. Ms. Anderson requested asterisks by the types of alterations that would be appropriate for self-certification.

OSDH Explanation: The types of design and construction plans eligible for self-certification are specified in a proposed new section, OAC 310-615-1-5. The proposed rule includes a maximum cost of \$5,000,000 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 (A) through (K). No other change is required.

Summary of Comment: At a January 7, 2017 meeting sponsored by the OSDH staff and attended by representatives of ambulatory surgical centers, several commenters questioned the fee for self-certification in OAC 310:615-1-3.1(e). They asked whether the self-certification fee is in addition to the review fees specified in OAC 310:615-1-3.1(b).

Mr. Curtis Wilson in a January 17, 2017 email to OSDH staff noted a typographical error in existing rule language in OAC 310:615-1-3.1(b)(5).

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 310:615-1-3.1(b) apply to plans and specifications for stage one, stage two, and fast-track projects submitted pursuant to OAC 310:615-1-3.2.

The typographical error in OAC 310:615-1-3.1(b)(5) should be corrected.

Change: Subsection 310:615-1-3.1(b) should be amended to read as follows:

(b) Each construction project ~~submission~~ submitted for approval under OAC 310:615-1-3.2 shall be accompanied by 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~~ \$1,000,000.00: \$2000.00 Fee

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 310:615-1-3.1(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 310:615-1-3.1(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 310:615-1-5. Self-certification of plans

Summary of Comment: Ms. Rebecca Anderson of McFarland Architects, P.C., in a January 4, 2017 email to OSDH staff and recommended adding a monetary value to limit the types of projects submitted for self-certification

OSDH Explanation: The proposed rule includes a maximum cost of \$5,000,000 for projects affecting areas where patients are intended to be examined or treated.

In reviewing these comments on OAC 310:615-1-5, OSDH noted an inconsistency in references to architects and engineers, which should be corrected as noted below. Additionally, a comment on OAC 310:667 identified a need to clarify the items required in the form to request self-certification in that the form includes the items in 310:615-1-5(c). OSDH proposes an amendment to subsection (b), as shown below.

Change: To clarify that the form includes the items in 310:615-1-5(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.

310:615-1-5. Self-certification of plans

(a) The Department shall make available professional consultation and technical assistance services covering the requirements of this section to an ambulatory surgical center 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: 310:615-1-3.1. The consultation is optional and not a prerequisite for filing a request through the self-certification review process.

(b) The ambulatory surgical center and the project architect or engineer may elect to request approval of design and construction plans through a self-certification review process. The ambulatory surgical center 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: 310:615-1-3.1. The form shall be signed by the ambulatory surgical center 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 310:615-1-5(c).

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

(1) The project involves any portion of the ambulatory surgical center where patients are intended to be examined or treated and the total of design and construction cost is five million dollars (\$5,000,000.00) or less; or

(2) The project involves only portions of the ambulatory surgical center 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 ambulatory surgical center 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 ambulatory surgical center or project architect or engineer to comply with the requirements of this Chapter; and

(5) The ambulatory surgical center 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 ambulatory surgical center. If the application is denied, the ambulatory surgical center 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 ambulatory surgical center shall pay the applicable fee for plan review specified in OAC 310: 310:615-1-3.1. Upon receipt of the plan review fee, the Department shall review the ambulatory surgical center's plans in accordance with the process in 310:615-1-3.1.

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.;

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 615. AMBULATORY SURGICAL CENTERS

1. **DESCRIPTION:**

The proposal amends physical plant requirements in Subchapter 1 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 ambulatory surgical centers 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 ambulatory surgical centers 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 ambulatory surgical centers 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 ambulatory surgical centers proposing to construct new buildings or make major alterations to existing buildings. Additionally, affected professionals working with ambulatory surgical centers may include architects, engineers, clinicians, and attorneys. The OSDH requested in the notice of rulemaking intent information from businesses on cost impacts. As noted in the rule comment summary, those commenting sought clarification on the rule but were supportive of the revisions and additional review options and their associated fees.

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.

3. **DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED HEALTH OUTCOMES:**

Persons benefiting will include ambulatory surgical centers, associated professionals, and customers of ambulatory surgical centers. 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 ambulatory surgical centers 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 ambulatory surgical centers a method to resolve differences between national standards and Oklahoma State Department of Health (OSDH) requirements. Ambulatory surgical centers 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.

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

Ambulatory surgical centers 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 fees are proposed fees for ancillary services requested by the industry. The base plan review fees established in 2010 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 \$5,500 for SFY2018, based on the following:

Exception or temporary waiver fees, assuming 2 requests at \$500	\$1,000
Self-certification fees, assuming 1 certification at \$1,000 each	\$1,000
Courtesy inspection fees, assuming 6 inspections at \$500 each	\$3,000
Professional consultation fees, assuming 1 project at \$500 each	\$500
Total additional revenue:	\$5,500

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 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 \$4,500 in FY 2018 and subsequent years. No impacts on other agencies are anticipated.

6. **IMPACT ON POLITICAL SUBDIVISIONS:**

Ambulatory surgical centers 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 that 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 ambulatory surgical center 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 ambulatory surgical center 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. Final formatting and conclusions were completed January 26, 2017.

FEE JUSTIFICATION

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 615. AMBULATORY SURGICAL CENTERS

The Oklahoma State Department of Health is proposing to amend those fees pertaining to 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 off-setting measure we add criteria and a process for ambulatory surgical centers 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 ambulatory surgical centers 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 ambulatory surgical centers to self-certify compliance of their plans for certain types of projects.

Each of these regulatory activities are labor-intensive and the costs associated with them are 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 current fee structure for these entities is not adequate to recoup the Department's expenses. The rule changes will permit the Department to offset the costs that promote services in ambulatory surgical centers 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 these programs, 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 ambulatory surgical centers, associated professionals, and customers of ambulatory surgical centers. 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 ambulatory surgical centers 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 ambulatory surgical centers a method to resolve differences between national standards and Oklahoma State Department of Health (OSDH) requirements.

Ambulatory surgical centers 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.

Ambulatory surgical centers 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 established in 2010 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 \$5,500 for SFY2018, based on the following:

Exception or temporary waiver fees, assuming 2 requests at \$500	\$1,000
Self-certification fees, assuming 1 certification at \$1,000 each	\$1,000
Courtesy inspection fees, assuming 6 inspections at \$500 each	\$3,000
Professional consultation fees, assuming 1 project at \$500 each	<u>\$500</u>
Total additional revenue:	\$5,500

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 \$5,500 in FY 2018 and subsequent years.

**TITLE 310: OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 615. AMBULATORY SURGICAL CENTERS**

SUBCHAPTER 1. GENERAL PROVISIONS

310:615-1-3. General considerations

~~(a) **Narrative program.**—The sponsor for each ambulatory surgical center shall provide a narrative program which describes the functional requirements, staffing patterns, departmental relationships, and other basic information relating to the fulfillment of the institution's objectives.~~

~~(b) **Services.**—Ambulatory surgical centers shall contain but not be limited to all the elements described herein, or the narrative program shall indicate the manner in which the services are to be made available to the ambulatory patient. When services are to be shared or purchased, appropriate modifications or deletions in space and equipment requirements should be made to avoid duplication. Each element provided in the ambulatory surgical center must meet the requirements outlined herein as a minimum, with the understanding that in some instances the elements will need to be expanded to fulfill the program requirements.~~

~~(c) **Location.**—An ambulatory surgical center may be located within a hospital setting, but it may be located apart from a hospital.~~

~~(d) **Size.**—The number and types of clinical facilities to be provided will be determined by the services contemplated and the estimated patient load as described in the narrative program.~~

~~(e) **Applicable requirements.**—If the facility is an integral part of the hospital and is intended to accommodate hospital inpatients as well as outpatients, the applicable requirements relating to general hospital facilities shall apply. If an ambulatory surgical center is not part of a hospital building, the facilities listed herein shall be provided unless they are available for convenient use by the patients in an associated health facility.~~

~~(f) **Privacy for patient.**—The planning of ambulatory surgical centers shall provide for the privacy and dignity of the patient during interview, examination, and treatment. The facilities shall be located so that ambulatory patients do not traverse inpatient areas.~~

~~(g) **Parking.**—In the absence of a formal parking study, off street vehicle parking for ambulatory surgical centers shall be provided at the ratio of two spaces for each recovery bed plus sufficient parking spaces to accommodate the maximum number of staff on duty at one time. Exceptions may be made with approval of the appropriate State agency for facilities located in areas with a high population density if adequate public parking is available or if the facility is accessible to a public transportation system.~~

~~(h) **Environmental pollution control.**—In accordance with the National Environmental Policy Act, the site and project shall be developed to minimize any adverse environmental effects on the neighborhood and community.~~

~~(i) **Equipment.**—All equipment necessary for the operation of the facility as planned shall be shown on the drawings or equipment list.~~

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

~~(1) Facility Guidelines Institute (FGI): Guidelines for Design and Construction of Hospitals and Outpatient Facilities, 2014 Edition; and~~

~~(2) National Fire Protection Association (NFPA) 101: Life Safety Code, 2012 Edition, adopted in 81 Federal Register 26871 by the Centers for Medicare & Medicaid Services on July 5, 2016.~~

~~(b) Oklahoma statutes prevail if there is conflict between the FGI Guidelines and Oklahoma~~

statutes. For Medicare-certified ambulatory surgical centers, 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) An ambulatory surgical center 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 ambulatory surgical center 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 2657 et seq., this Chapter, and the following:

(1) Any ambulatory surgical center 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 310:615-1-3.1. 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 2657 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 ambulatory surgical center 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) An ambulatory surgical center 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 ambulatory surgical center 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 and make them available to facilities and the public.

(e) Documentation of the ambulatory surgical center 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.

310:615-1-3.1. 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 Oklahoma State Department of Health ~~for review and approval~~ as provided in OAC 310:615-1-3.2 or 310:615-1-5.

(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 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 310:615-1-3.2 shall be accompanied by 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~~ \$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.

310:615-1-3.2. 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. An ambulatory surgical center has the option, at its own risk, to bypass the stage one submittal and proceed directly to submittal of stage two documents.

(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 projects.** The fast track process applies only to stage two submittals. A stage one submittal and functional program must be approved before entering the fast track process.

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

(B) The ambulatory surgical center 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.

(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 Oklahoma State Department of Health 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.

310:615-1-5. Self-certification of plans

(a) The Department shall make available professional consultation and technical assistance services covering the requirements of this section to an ambulatory surgical center 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: 310:615-1-3.1. The consultation is optional and not a prerequisite for filing a request through the self-certification review process.

(b) The ambulatory surgical center and the project architect or engineer may elect to request approval of design and construction plans through a self-certification review process. The ambulatory surgical center 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: 310:615-1-3.1. The form shall be signed by the ambulatory surgical center 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 310:615-1-5(c).

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

(1) The project involves any portion of the ambulatory surgical center where patients are intended to be examined or treated and the total of design and construction cost is five million dollars (\$5,000,000.00) or less; or

(2) The project involves only portions of the ambulatory surgical center 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 ambulatory surgical center 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 ambulatory surgical center or project architect or engineer to comply with the requirements of this Chapter; and

(5) The ambulatory surgical center 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 ambulatory surgical center. If the application is denied, the ambulatory surgical center 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 ambulatory surgical center shall pay the applicable fee for plan review specified in OAC 310: 310:615-1-3.1. Upon receipt of the plan review fee, the Department shall review the ambulatory surgical center's plans in accordance with the process in 310:615-1-3.1.