

**Agenda for the 11:00 a.m., Tuesday, December 10, 2013
Regular Meeting of the Oklahoma State Board of Health**

Posted at www.health.ok.gov

Oklahoma State Department of Health
1000 N.E. 10th Street – Room 1102
Oklahoma City, OK 73117-1299

- I. CALL TO ORDER AND OPENING REMARKS
- II. REVIEW OF MINUTES
- a) **Approval of Minutes for October 8, 2013, Special Meeting**
 - b) **Approval of Minutes for October 8, 2013, Tri-Board Meeting**
- III. APPOINTMENTS
- c) **Home Care and Hospice Advisory Council** (Presented by Henry F. Hartsell, Jr.)
Appointments: One Member
Authority: 63 O.S., § 1-103a.1
Members: The Advisory Council shall consist of seven (7) members. Membership is defined in statute. One member, who is a representative of an association which advocates on behalf of home care or hospice issues, shall be appointed by the State Board of Health.
 - d) **Advancement of Wellness Advisory Council** (Presented by Julie Cox-Kain)
Appointments: One Member
Authority: 63 O.S., § 1-103a.1
Members: The Advisory Council shall consist of seven (7) members. Membership is defined in statute. One member, who is the Executive Director of the Tobacco Settlement Endowment, shall be appointed by the State Board of Health.
 - e) **Infant and Children’s Health Advisory Council** (Presented by Edd Rhoades)
Appointments: One Member
Authority: 63 O.S., § 1-103a.1
Members: The Advisory Council shall consist of seven (7) members. Membership is defined in statute. One member, who is a physician licensed by the state of Oklahoma and specializes in the diagnosis and treatment of childhood injuries in a trauma setting, shall be appointed by the State Board of Health.
- IV. PROPOSED RULEMAKING ACTIONS
Discussion and possible action on the following:

PROTECTIVE HEALTH SERVICE

f) **CHAPTER 2. PROCEDURES OF THE STATE DEPARTMENT OF HEALTH**

[PERMANENT] [EMERGENCY] Presented by James Joslin

PROPOSED RULES:

Subchapter 29. Criminal History Background Checks [NEW]

310:2-29-1. Purpose [NEW]

310:2-29-2. [RESERVED]

310:2-29-3. Implementation [NEW]

310:2-29-4. [RESERVED]

310:2-29-5. Appeals [NEW]

AUTHORITY: Oklahoma State Board of Health; Title 63 O.S. § 1-104; Title 63 O.S. § 1-1947(T)(2) and 1-1947(Y).

SUMMARY: This proposal promulgates new rules in the procedures of the Department of Health as required in amendments to the Long Term Care Security Act (Title 63 O.S. § 1-1944 et. seq.), as adopted in 2012, House Bill 2582. This bill authorized fingerprint based criminal history background checks on those applicants who would be employed in a variety of long-term care settings as defined in the law at Title 63 O.S. Section 1-1945(4). The law at Title 63 O.S. § 1-1947(T)(2) requires that

the Department shall specify rules for issuing a waiver of the disqualification or employment denial and further specifies in paragraph (Y) the State Board of Health shall promulgate rules prescribing effective dates and procedures for the implementation of a national criminal history record check for the employers and nurse aide scholarship programs defined in Section 1-1945 of Title 63 of the Oklahoma Statutes.

g) CHAPTER 100. LICENSURE OF CREMATORIES [REVOKED]

[PERMANENT] Presented by James Joslin

PROPOSED RULES: Chapter 100. Licensure of Crematories [REVOKED]

AUTHORITY: Oklahoma State Board of Health; Title 63 O.S. § 1-104; Title 59 O.S. § 396.30.

SUMMARY: This proposal revokes the rules of the Board of Health concerning the licensure of crematories. The duties and functions concerning licensure of crematories were transferred by statutory modification from the Oklahoma State Department of Health to the Oklahoma Funeral Board. The Department's authority for rulemaking was found at Title 63 O.S. 1981, § 1-331 and renumbered as 59 O.S. § 396.30 by Laws 2003, HB 1270, c. 57, § 31, effective April 10, 2003. The Oklahoma Funeral Board has adopted rules for the licensure of crematories [see Title 235 – Oklahoma Funeral Board, Chapter 10 – Funeral Services Licensing, Subchapter 14 – Crematories].

h) CHAPTER 276. HOME INSPECTION INDUSTRY [REVOKED]

[PERMANENT] Presented by James Joslin

PROPOSED RULES: Chapter 276. Home Inspection Industry [REVOKED]

AUTHORITY: Oklahoma State Board of Health, Title 63 O.S. § 1-104; 59 O.S. § 1000.4.

SUMMARY: This proposal revokes the rules of the Board of Health concerning the home inspection industry. Effective November 1, 2008, the authority to "adopt, amend, repeal, and promulgate rules as may be necessary to regulate . . . home inspectors" was transferred from the Oklahoma State Department of Health to the Construction Industries Board [see 59 O.S., § 1000.4]. The Construction Industries Board promulgated emergency rules, effective November 11, 2008, and later superseded those emergency rules with permanent rules, effective July 11, 2009 [see Construction Industries Board rules OAC 158:70 and 158:10-3-5].

i) CHAPTER 658. INDEPENDENT REVIEW ORGANIZATION CERTIFICATION RULES

[PERMANENT] Presented by James Joslin

PROPOSED RULES: Chapter 658. Independent Review Organization Certification Rules [REVOKED]

AUTHORITY: Oklahoma State Board of Health, Title 63 O.S. § 1-104; Title 36 O.S. § 6475.1.

SUMMARY: This proposal revokes the rules of the Board of Health concerning independent review organization certification and external review. Effective August 26, 2011, The Uniform Health Carrier External Review Act, sections 25 through 41 of House Bill 2072 (2011), transferred responsibility for external reviews and approval of independent review organizations to the Oklahoma Insurance Department [see Title 36 O.S. § 6475.1 et. seq.]. The Oklahoma Insurance Department promulgated emergency rules, effective September 12,, 2011, and later superseded those emergency rules with permanent rules, effective July 14, 2012 [see Title 365, Insurance Department, Chapter 10, Subchapter 29 - External Review Regulations.]

j) CHAPTER 675. NURSING AND SPECIALIZED FACILITIES

[PERMANENT] Presented by James Joslin

PROPOSED RULES

Subchapter 9. Resident Care Services

310:675-9-9.1. Medication services [AMENDED]

AUTHORITY: Oklahoma State Board of Health; Title 63 O.S. § 1-104; Title 63 O.S. § 1-1950(C)(1).

SUMMARY: This proposal amends rules promulgated in accordance with 63 O.S. Section 1-1950(C)(1) which authorized the State Board of Health to promulgate rules necessary for proper control and dispensing of nonprescription drugs in nursing facilities. Section 310:675-9-9.1(i) addresses those procedures for maintaining nonprescription drugs for dispensing from a common or bulk supply. This proposed rule amendment deletes the requirement in OAC 310:675-9-9.1(i)(8) which limits the bulk nonprescription drugs that nursing facilities may maintain for residents. The current requirement provides that only oral analgesics, antacids, and laxatives may be dispensed from bulk supplies. This change will allow nursing facilities to maintain bulk supplies of other nonprescription drugs, such as cough medicines.

PREVENTION AND PREPAREDNESS SERVICES

k) CHAPTER 515. COMMUNICABLE DISEASE AND INJURY REPORTING

[PERMANENT] Presented by Toni Frioux

PROPOSED RULES: Subchapter 1. Disease and Injury Reporting Requirements

310:515-1-3 Diseases to be reported immediately [AMENDED]

310:515-1-4 Additional diseases, conditions, and injuries to be reported [AMENDED]

AUTHORITY: Oklahoma State Board of Health, Title 63 O.S. § 1-104; and Title 63 O.S., §§ 1-502 and 1-503.

SUMMARY: The proposal updates the existing rules in accordance with recommendations from the Council of State and Territorial Epidemiologists (CSTE), the Centers for Disease Control and Prevention, and local health care partners pertaining to reportable diseases. The proposal amends the lists of reportable diseases, regarding diseases or conditions that are required to be reported to the Department. These changes minimally increase the reporting burden placed upon clinicians, have no impact on the reporting burden placed upon laboratories, and do not adversely affect the public health disease control and prevention activities.

l) CHAPTER 550. NEWBORN SCREENING PROGRAM

[PERMANENT] Presented by Toni Frioux

PROPOSED RULES:

Subchapter 1. General Provisions

310:550-1-1 [AMENDED]

310:550-1-2 [AMENDED]

Subchapter 3. Testing Of Newborns

310:550-3-1 [AMENDED]

Subchapter 5. Specimen Collection

310:550-5-1 [AMENDED]

310:550-5-2 [AMENDED]

Subchapter 7. Hospital Recording

310:550-7-1 [AMENDED]

Subchapter 13. Parent And Health Care Provider Education

310:550-13-1 [AMENDED] Subchapter

17. Follow-Up For Physicians

310:550-17-1 [AMENDED]

Subchapter 19. Reporting

310:550-19-1 [AMENDED]

Subchapter 21. Information

310:550-21-1 [AMENDED]

Appendix A Instructions For Filter Paper Sample Collection [REVOKED]

Appendix A Instructions For Filter Paper Sample Collection [NEW] Appendix B

Report Form [REVOKED]

Appendix B Report Form [NEW] Appendix C

Refusal Form [REVOKED] Appendix C

Refusal Form [NEW]

Appendix D Recommended Pulse Oximetry Screening Protocol [NEW]

Appendix E Pulse Oximetry Result Form [NEW]

AUTHORITY: Oklahoma State Board of Health, Title 63 O.S. Section 1-104; and Title 63 O.S. Sections 1-534, 1-550.5, and 1-705.

SUMMARY: This proposal requests amendatory language to the existing rule to include Severe Combined Immunodeficiency Syndrome (SCID) as a new test in the core panel of 29 genetic disorders for newborn screening (NBS) in Oklahoma, as recommended by the Advisory Committee on Heritable Disorders in Newborns and Children – Recommended Uniform Screening Panel (January 21, 2010). This proposal also adds Pulse Oximetry screening for the detection of Critical Congenital Heart Disease to existing newborn screening rules as legislated by HB 1347 (2013) [63 O.S. § 1-550.5]. The new law requires inpatient or ambulatory health care facilities licensed by the State Department of Health that provide birthing and newborn care services to perform a pulse oximetry screening on every newborn in its care prior to discharge from the birthing facility. In addition, minor changes to the newborn screening report form that is submitted by the infant's specialist or primary care provider to include additional information based on new clinical practice and the requisition/collection form to bring the rules up to date with practice. Additional

documents include a recommended pulse oximetry screening protocol and a pulse oximetry screening result form.

m) CHAPTER 667. HOSPITAL STANDARDS

[PERMANENT] Presented by Toni Frioux

PROPOSED RULES: Subchapter 19. Medical Records Department

310:667-19-2 [AMENDED]

AUTHORITY: Oklahoma State Board of Health, Title 63 O.S. Section 1-104; and Title 63 O.S. Sections 1- 534, 1-550.5, and 1-705.

SUMMARY: This proposal requests amendatory language to the existing rule to include Severe Combined Immunodeficiency Syndrome (SCID) as a new test in the core panel of 29 genetic disorders for newborn screening (NBS) in Oklahoma, as recommended by the Advisory Committee on Heritable Disorders in Newborns and Children – Recommended Uniform Screening Panel (January 21, 2010). This proposal also adds Pulse Oximetry screening for the detection of Critical Congenital Heart Disease to existing newborn screening rules as legislated by HB 1347 (2013) [63 O.S. § 1-550.5]. The new law requires inpatient or ambulatory health care facilities licensed by the State Department of Health that provide birthing and newborn care services to perform a pulse oximetry screening on every newborn in its care prior to discharge from the birthing facility. In addition, minor changes to the newborn screening report form that is submitted by the infant’s specialist or primary care provider to include additional information based on new clinical practice and the requisition /collection form to bring the rules up to date with practice. Additional documents include a recommended pulse oximetry screening protocol and a pulse oximetry screening result form.

COMMUNITY AND FAMILY HEALTH SERVICES

n) CHAPTER 526. DENTAL SERVICES

[PERMANENT] Presented by Jana Winfree

PROPOSED RULES: Subchapter 3. Oklahoma Dental Loan Repayment Program

310:526-3-2 [AMENDED]

310:526-3-3 [AMENDED]

AUTHORITY: Oklahoma State Board of Health; Title 63 O.S. Sections 1-103a.1 and 1-104; and Title 70 O.S. Section 1210.284.

SUMMARY:

310:526-3-2(b) The current Rule sets forth the description and operation of the Oklahoma Dental Loan Repayment Program (Program). The proposed action allows flexibility in selecting the number and types of participants and in the time period for participation in the Program. The circumstance for the Rule change is compelled by legislation, HB 2587, effective November 1, 2012. The intended effect is to allow the Advisory Committee and Department to select the appropriate number of participants based on funding and the appropriate type of participant (Oklahoma University College of Dentistry faculty or non-faculty), and allow the service obligation period to be adjusted.

310:526-3-2(d) The current Rule states that each award shall be distributed by a two-party draft made payable to the dentist and the loan agency. The proposed action states that each award shall be distributed in accordance with state law. The circumstance for the Rule change is because state preference is to distribute awards by direct deposit and the intended effect is to streamline administration of the Program. 310:526-3-3(b)(3) and (e)(5) The current Rule sets forth eligibility requirements for participants. The non-faculty participant agrees that Medicaid patients will represent 30% of all patient visits at a minimum. The proposal clarifies the count will be by number of patient visits. The rule change takes into consideration that dental software used by participants favors this type of reporting and the Department’s intent to facilitate this reporting requirement.

o) CHAPTER 531. VISION SCREENING

[PERMANENT] Presented by Ann Benson

PROPOSED RULES:

Subchapter 1. General provisions

310:531-1-2. Authority [AMENDED]

310:531-1-3. Definitions [AMENDED]

Subchapter 3. Advisory Committee

310:531-3-1. Purpose [REVOKED]

310:531-3-2. Advisory Committee [REVOKED]

310:531-3-3. Rules of Order [REVOKED]

Subchapter 5. Vision Screening Standards for Children
 310:531-5-2. Oklahoma Vision Screening Standards [AMENDED]
 310:531-5-3. Approval of ~~Vision Screening Providers~~ vision screening providers [AMENDED]
 310:531-5-5. Re-approval of vision screening providers [AMENDED]
 310:531-5-6. Approval of ~~trainers of vision screening providers~~ vision screening trainers [AMENDED]
 310:531-5-7. Re-approval of ~~trainers of vision screening providers~~ vision screening trainers [AMENDED]
 310:531-5-8. Approval of ~~trainers of vision screening trainers~~ vision screening trainers of trainers [AMENDED]
 310:531-5-9. Re-approval of ~~trainers of vision screening trainers~~ vision screening trainers of trainers [AMENDED]
 Subchapter 7. Registry Enforcement for Vision Screening
 310:531-7-2. Grounds for discipline [AMENDED]
 310:531-7-3. Complaint investigation [AMENDED]
 310:531-7-4. Summary removal [AMENDED]
 310:531-7-5. Appearance before the Advisory Committee [REVOKED]
 310:531-7-6. Right to a hearing [AMENDED]
 Subchapter 9. Sports Eye Safety Resource
 310:531-9-1. Purpose [REVOKED]
 310:531-9-2. Eye safety resource [REVOKED]
AUTHORITY: Oklahoma State Board of Health; Title 63 O.S. Sections 1-103a.1 and 1-104; and Title 70 O.S. Section 1210.284.
SUMMARY: The proposed rule changes implement provisions of Section 44, House Bill 1467, which creates the Infant and Children’s Health Advisory Council, and Section 79, which replaces the Vision Screening Advisory Committee established in 70 O.S. 2011, Section 1210.284, with the Infant and Children’s Health Advisory Council and eliminates the role of the Advisory Committee in carrying out programmatic activities. The proposed rule changes delineate the responsibilities of the Department in carrying out statewide vision screening for children.

V. 2014 LEGISLATION

Mark Newman, Ph.D., Director, Office of State and Federal Policy

VI. CONSIDERATION OF STANDING COMMITTEES’ REPORTS AND ACTION

Executive Committee – Dr. Krishna, Chair

Discussion and possible action on the following:

p) Update

Finance Committee – Dr. Woodson, Chair

Discussion and possible action on the following:

q) Update

Accountability, Ethics, & Audit Committee – Ms. Wolfe, Chair

Discussion and possible action on the following:

r) 2014 Audit Plan

s) Update

Public Health Policy Committee – Dr. Gerard, Chair

Discussion and possible action on the following:

t) Update

VII. PRESIDENT’S REPORT

Related discussion and possible action on the following:

u) Update

VIII. COMMISSIONER'S REPORT

Discussion and possible action

IX. NEW BUSINESS

Not reasonably anticipated 24 hours in advance of meeting.

X. PROPOSED EXECUTIVE SESSION

Proposed Executive Session pursuant to 25 O.S. Section 307(B)(4) for confidential communications to discuss pending department litigation, investigation, claim, or action; pursuant to 25 O.S. Section 307(B)(1) to discuss the employment, hiring, appointment, promotion, demotion, disciplining or resignation of any individual salaried public officer or employee and pursuant to 25 O.S. Section 307 (B)(7) for discussing any matter where disclosure of information would violate confidentiality requirements of state or federal law.

- Annual performance evaluation for the Office of Accountability Systems Director & Internal Audit Unit Director, and Board of Health Secretary
- Discussion of potential or anticipated investigation or litigation concerning long term care issues.

Possible action taken as a result of Executive Session.

XI. ADJOURNMENT

STATE BOARD OF HEALTH
Northeast Regional Health and Wellness Campus
2600 NE 63rd Street, Board Room 108
Oklahoma City, OK 73111

Tuesday, October 8, 2013 11:30 a.m.

R. Murali Krishna, President of the Oklahoma State Board of Health, called the 383rd special meeting of the Oklahoma State Board of Health to order on Tuesday, October 8, 2013 at 11:36 a.m. The final agenda was posted at 10:19 a.m. on the OSDH website on October 7, 2013, and at 10:01 .m. at the building entrance on October 7, 2013.

ROLL CALL

Members in Attendance: R. Murali Krishna, M.D., President; Ronald Woodson, M.D., Vice-President; Martha Burger, M.B.A., Secretary-Treasurer; Terry Gerard, D.O.; Charles W. Grim, D.D.S.; Timothy E. Starkey, M.B.A.; Robert S. Stewart, M.D.; Cris Hart-Wolfe.

Absent: Jenny Alexopulos, D.O.

Central Staff Present: Terry Cline, Commissioner; Julie Cox-Kain, Chief Operating Officer; Henry F. Hartsell, Deputy Commissioner, Protective Health Services; Steve Ronck, Deputy Commissioner, Community and Family Health Services; Toni Frioux, Deputy Commissioner, Prevention and Preparedness Services; Mark Newman, Director of Office of State and Federal Policy; Don Maisch, Office of General Counsel; Lloyd Smith, Director of Internal Audit and Office of Accountability Systems; Pamela Williams, Office of Communications; VaLauna Grissom, Secretary to the State Board of Health; Commissioner’s Office; Felesha Scanlan.

Visitors in attendance: (see sign in sheet)

Call to Order and Opening Remarks

Dr. Krishna called the meeting to order. He welcomed special guests in attendance.

PROPOSED EXECUTIVE SESSION

Ms. Burger moved Board approval to go in to Executive Session at 11:37 AM pursuant to 25 O.S. Section 307(B)(4) for confidential communications to discuss pending department litigation, investigation, claim, or action; pursuant to 25 O.S. Section 307(B)(1) to discuss the employment, hiring, appointment, promotion, demotion, disciplining or resignation of any individual salaried public officer or employee and pursuant to 25 O.S. Section 307 (B)(7) for discussing any matter where disclosure of information would violate confidentiality requirements of state or federal law.

● Complaints and Grievances concerning OSDH Reclassification Program

● Review of proposed forms for physicians as required by state statute

Second Ms. Wolfe. Motion carried.

AYE: Burger, Gerard, Grim, Krishna, Starkey, Stewart, Woodson, Wolfe

ABSENT: Alexopulos

Ms. Wolfe moved Board approval to move out of Executive Session. Second Mr. Starkey. Motion carried.

AYE: Burger, Gerard, Grim, Krishna, Starkey, Stewart, Woodson, Wolfe

ABSENT: Alexopulos

Dr. Stewart moved Board approval to adopt proposed forms for physicians as required by state statute with below modifications:

1 **No change to the Parental Consent Form; Physician Medical Emergency Affidavit Form should replace**
2 **the word reviewed for the word examined and should add the word attending on the physician signature**
3 **line. (see attachments A-B)**
4

5 **AYE: Burger, Grim, Krishna, Starkey, Stewart, Woodson, Wolfe**

6 **ABSENT: Alexopulos**

7 **ABSTAIN: Gerard**
8

9 **ADJOURNMENT**

10 **Mr. Grim moved Board approval to Adjourn. Second Dr. Stewart. Motion carried.**
11

12 **AYE: Burger, Gerard, Grim, Krishna, Starkey, Stewart, Woodson, Wolfe**

13 **ABSENT: Alexopulos**
14

15 The meeting adjourned at 12:53 p.m.
16

17 Approved
18

19 _____
20 R. Murali Krishna, M.D.

21 President, Oklahoma State Board of Health

22 December 10, 2013

1 **Oklahoma State Board of Health (OSBH)**
 2 **Oklahoma City-County Board of Health (OCCBH)**
 3 **Tulsa City-County Board of Health (TCCBH)**
 4 **Tuesday, October 8, 2013, 1:00 p.m.**

5
 6 **Northeast Regional Health and Wellness Campus**
 7 **2600 NE 63rd Street, Board Room 100**
 8 **Oklahoma City, OK 73111**

9
 10 **Tuesday, October 8, 2013 1:00 p.m.**

11
 12 R. Murali Krishna, President of the Oklahoma State Board of Health, called the 384th regular meeting of the
 13 Oklahoma State Board of Health to order on Tuesday, October 8, 2013 at 1:00 p.m. The final agenda was
 14 posted at 10:19 a.m. on the OSDH website on October 7, 2013, and at 10:01 .m. at the building entrance on
 15 October 7, 2013.

16
 17 **ROLL CALL**

18 Members in Attendance: R. Murali Krishna, M.D., President; Ronald Woodson, M.D., Vice-President; Martha
 19 Burger, M.B.A., Secretary-Treasurer; Terry Gerard, D.O.; Charles W. Grim, D.D.S.; Timothy E. Starkey,
 20 M.B.A.; Robert S. Stewart, M.D.; Cris Hart-Wolfe.

21 Absent: Jenny Alexopoulos, D.O.

22
 23 Central Staff Present: Terry Cline, Commissioner; Julie Cox-Kain, Chief Operating Officer; Henry F. Hartsell,
 24 Deputy Commissioner, Protective Health Services; Steve Ronck, Deputy Commissioner, Community and
 25 Family Health Services; Toni Frioux, Deputy Commissioner, Prevention and Preparedness Services; Mark
 26 Newman, Director of Office of State and Federal Policy; Don Maisch, Office of General Counsel; Lloyd Smith,
 27 Director of Internal Audit and Office of Accountability Systems; Pamela Williams, Office of Communications;
 28 VaLauna Grissom, Secretary to the State Board of Health; Commissioner’s Office; Felesha Scanlan.

29
 30 OCCBH Members in Attendance: Dr. Cagle, Dr. Gray, Dr. Hill, Dr. Mills, Dr. Raskob, Dr. Salmeron

31
 32 TCCBH Members in Attendance: Dr. Patrick Grogan, Dr. Geraldine Ellison, Ms. Nancy Keithline

33
 34 Visitors in attendance: (see sign in sheet)

35
 36 **Call to Order and Opening Remarks**

37 Dr. Cagle welcomed the visitors to the OCCHD Northeast Regional Health and Wellness Campus.
 38 Dr. Krishna thanked Gary Cox and the OCCHD Board of Health for hosting the 2013 Tri-Board of Health
 39 meeting.

40
 41 **REVIEW OF MINUTES – OCCBH**

42 Dr. Cagle called for approval of minutes of the OCCBH September Board meeting as presented.

43
 44 Dr. Salmeron moved Board approval of the minutes of the September Board meeting. Second Dr. Gray

45 **AYE:** Dr. Cagle, Dr. Gray, Dr. Hill, Dr. Mills, Dr. Raskob, Dr. Salmeron

Minutes of the September meeting were approved.

REVIEW OF MINUTES – OSBH

Dr. Krishna directed attention to the minutes of the July 9, 2013 regular meeting and the August 16-18, 2013 Annual Board of Health Retreat for review and approval.

Dr. Gerard moved Board approval of the July 9, 2013 meeting minutes as presented. Second Ms. Wolfe. Motion carried.

AYE: Burger, Gerard, Grim, Krishna, Starkey, Stewart, Woodson, Wolfe

ABSENT: Alexopoulos

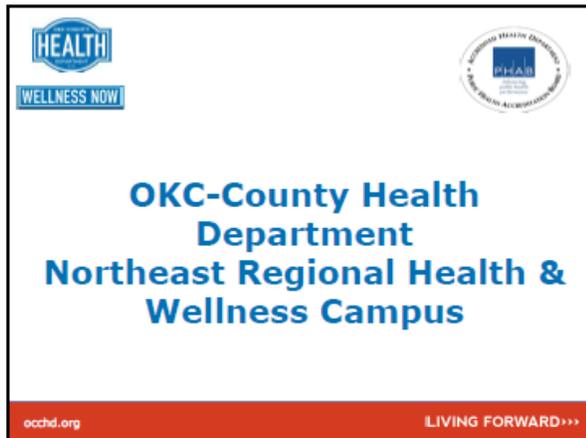
Dr. Gerard moved Board approval of the August 16-18, 2013 meeting minutes as presented. Second Dr. Grim. Motion carried.

AYE: Burger, Gerard, Grim, Krishna, Starkey, Stewart, Woodson, Wolfe

ABSENT: Alexopoulos

OKLAHOMA HEALTH IMPROVEMENT PLAN (OHIP)

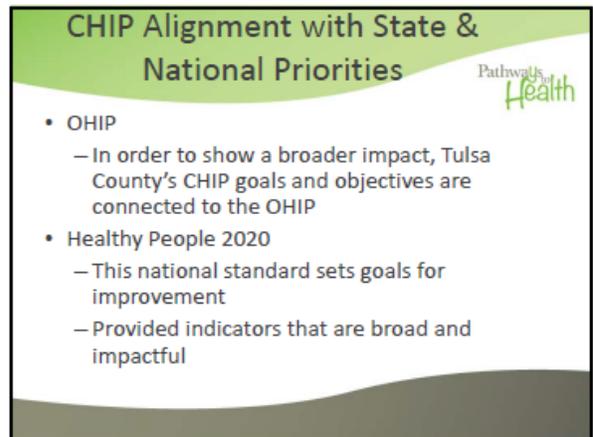
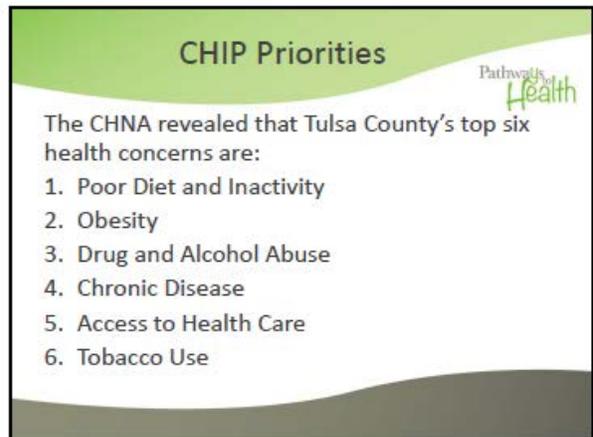
Gary Cox, Ph.D., Oklahoma City-County Health Department local perspectives.



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Local Perspectives; Bruce Dart, Ph.D., Tulsa Health Department local perspectives



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Solution Focused

Pathways to Health

- Each priority section begins with CHNA data that demonstrates why these issues are concerning
- Potential challenges to making improvement in these areas are addressed
- Opportunities to make the greatest impact are highlighted

THD's Role

Pathways to Health

- Our role now becomes promoting the messages within the CHIP
- Starting conversations about community health improvement
- This is our CHIP
 - THD is a partner in health improvement, as employees we are part of the collaboration
 - This plan is also for the residents of Tulsa County- we are those residents

CHIP Goals and Objectives

Pathways to Health

The new CHIP will be released in 2013. This is a short term goal.

Goal	Objective	Indicator	Target	2013	2015
Improve health outcomes	Reduce the prevalence of chronic diseases	Prevalence of chronic diseases	10% decrease	10%	10%
Improve health outcomes	Reduce the prevalence of tobacco use	Prevalence of tobacco use	10% decrease	10%	10%

Adapted from Healthy People 2020 national goals
Adapted from Healthy People 2020 national objectives
Performance indicators used to evaluate the effectiveness of strategies and tactics to reach priority goals
Data obtained through studies such as the Community Health Needs Assessment in a health fair comparison
The Healthy People 2020 strategy advocates for 10% improvement by 2020

Evaluation & Next Steps

Pathways to Health

- Alliance Groups
 - Healthy Kids
 - Healthy Aging
 - Healthy Worksites
 - Healthy Choices
 - Healthy Places
 - Access to Health Care
- Starting conversations about community health improvement with community partners and in Tulsa County neighborhoods
- Mayoral Health Forum October 28th

Community Engagement

Pathways to Health

Showing community residents what community partners are doing to address their concerns.



Follow P2H

Pathways to Health

- Keep the conversation going: www.pathwaystohealthtulsa.org

Like us on Facebook: Pathways to Health
Follow us on Twitter: @TulsaP2H



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P2H Block Parties



- One Block Party in each of the 6 Regions.
- Hicks Park – September 19th
- Cooper Elementary – October 3rd
- Next – Marshall Elementary on November 7th

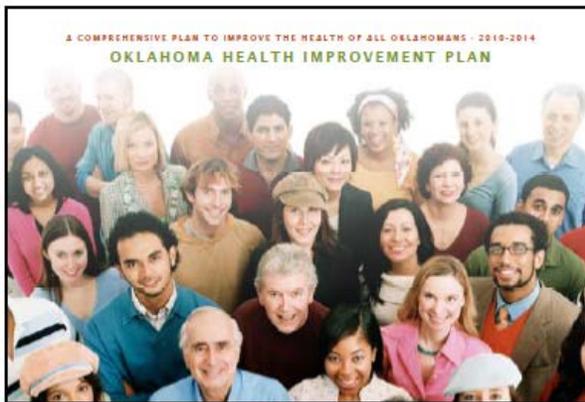



Team Leadership

OHIP Team (Dr. Terry Cline)
FLAGSHIP (Dr. Gary Raskob)
Tobacco Use Prevention (Tracey Strader & Jennifer Lepard)
Obesity Reduction (Dr. Bruce Dart)
Children's Health (Drs. Mary Anne McCaffree, Marry Dunlap, & Edd Rhoades)
INFRASTRUCTURE (Gary Cox)
Workforce Development (Monty Evans & Judy Grant)
Access to Care (Julie Cox-Kain)
Health Systems Effectiveness (P/P Partnerships) (Dr. Terry Cline & Ted Haynes)



OKLAHOMA HEALTH IMPROVEMENT PLAN



Team Leadership

OHIP Team (Dr. Terry Cline)
FLAGSHIP (Dr. Gary Raskob)
Tobacco Use Prevention (Tracey Strader & Jennifer Lepard)
Obesity Reduction (Dr. Bruce Dart)
Children's Health (Drs. Mary Anne McCaffree, Marry Dunlap, & Edd Rhoades)
INFRASTRUCTURE (Gary Cox)
Workforce Development (Monty Evans & Judy Grant)
Access to Care (Julie Cox-Kain)
Health Systems Effectiveness (P/P Partnerships) (Dr. Terry Cline & Ted Haynes)



OKLAHOMA HEALTH IMPROVEMENT PLAN

OHIP TEAM



Oklahoma Health Improvement Plan Team Members include:

- health leaders
- business
- tribes
- non-profits
- private citizens
- non-traditional groups
- labor
- academia
- state & local governments
- professional organizations

OHIP Mission: Working together to lead a process to improve and sustain the physical, social, and mental well being of all people in Oklahoma.



OKLAHOMA HEALTH IMPROVEMENT PLAN



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FLAGSHIP GOALS
Tobacco Use Prevention
Obesity Reduction
Children's Health

INFRASTRUCTURE GOALS
Workforce Development
Access to Care
Health Systems Effectiveness/Partnerships

SOCIETAL & POLICY INTEGRATION
Policies and Legislation
Social Determinants of Health & Health Equity

OKLAHOMA HEALTH IMPROVEMENT PLAN

Tobacco Outcomes



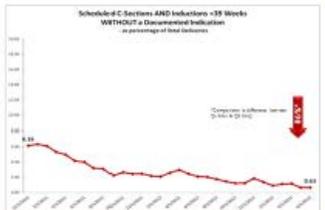
- Adults who smoke in OK has **decreased by 10.7%** in the last year from 26.1 to 23.3%
- The number of schools with tobacco-free policies since 2012 has increased by **23%**!
- The Governor's Executive Order for tobacco-free properties impacted approximately **37,000** state employees and **countless** visitors to state properties.

OKLAHOMA HEALTH IMPROVEMENT PLAN

Every Week Counts



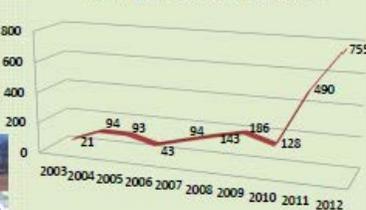
Scheduled C-sections AND inductions - 19 Weeks WITHOUT a Documented Indication (as percentage of total births)



OKLAHOMA HEALTH IMPROVEMENT PLAN

Certified Healthy Oklahoma

Growth in Number of Healthy Certifications

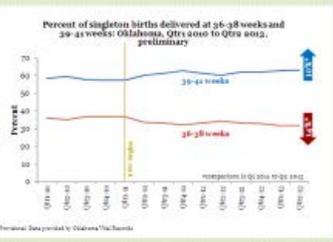


OKLAHOMA HEALTH IMPROVEMENT PLAN

Every Week Counts



Percent of singleton births delivered at 36-38 weeks and 39-45 weeks: Oklahoma, Q1: 2004 to Q4: 2012, preliminary



OKLAHOMA HEALTH IMPROVEMENT PLAN

Obesity, Nutrition, and Physical Activity
2012 Certified Healthy Applications and Beyond



- 418** schools, **135** businesses, and **61** communities (**614** total organizations) implemented one or more policies related to physical activity or nutrition!
- In addition, **405** schools participated in non-policy related programs including breakfast nutrition program, backpack program, or summer food service.
- Online Toolkit** being developed for communities, schools, and organizations in selection and implementation of nutrition and physical fitness activities and policies to assist in health improvement endeavors.

OKLAHOMA HEALTH IMPROVEMENT PLAN

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Infant Mortality Rate



- The Oklahoma Infant Mortality Rate has decreased by **10.5%** in the last five years from 8.6 per 1000 in 2007 to 7.7 in 2012.

OKLAHOMA HEALTH IMPROVEMENT PLAN

Certified Healthy Physical Fitness & Nutrition Incentive Grant Activities & Enhancements



- Sidewalks
- Skate Park
- Community Garden
- Exercise Equipment
- Walking Trail Lights & Renovation
- Bike Racks on Buses
- Walking Trails
- Basketball Courts
- Benches & Soccer Field Equipment
- Playground Equipment
- Pedestrian Crosswalks
- 9 Station Disc Golf Course
- Nutrition & Fitness Campaigns

OKLAHOMA HEALTH IMPROVEMENT PLAN

Public Health Accreditation



- Oklahoma is the **only** state in the nation with the **state** and **three** local public health departments accredited! Our state also has the distinction of having the **most** accredited departments in the US!

OKLAHOMA HEALTH IMPROVEMENT PLAN

OHIP PARTNERS



Oklahoma State Board of Health	The State Chamber of Oklahoma
Tulsa City-County Board of Health	Cherokee Nation Health Services
Oklahoma City-County Board of Health	Oklahoma Turning Point Council
Oklahoma State Department of Health	Oklahoma Institute for Child Advocacy
Tulsa Health Department	Oklahoma Tobacco Research Center
Oklahoma City-County Health Department	American Lung Association
Oklahoma Health Care Authority	American Heart Association
Oklahoma Department of Mental Health & Substance Abuse Services	American Cancer Society
Oklahoma Tobacco Settlement Endowment Trust	OKC Area Inter-Tribal Health Board
Oklahoma Legislature	Cheyenne-Arapaho Tribe
Oklahoma State Department of Education	Muskogee Creek Nation
Oklahoma Hospital Association	Indian Health Service
Oklahoma Catastrophic Association	Blue Cross Blue Shield
Oklahoma State Medical Association	Indian Health Care Resource Center of Tulsa
	Oklahoma University Health Science Center

OKLAHOMA HEALTH IMPROVEMENT PLAN

Continued Successes!




- Twenty-four (24)** Oklahoma birthing hospitals stopped providing formula gift discharge bags due to breastfeeding policies put into place.
- 28.4% increase** from 64% to 82.2% in proper child restraint use among infants less than one year of age.
- SB 501** was passed and permits local counties and municipalities to pass ordinances to ban smoking on county or municipal properties, as well as codifying the portion of the Governor's Executive Order that makes all state properties smoke-free!

OKLAHOMA HEALTH IMPROVEMENT PLAN

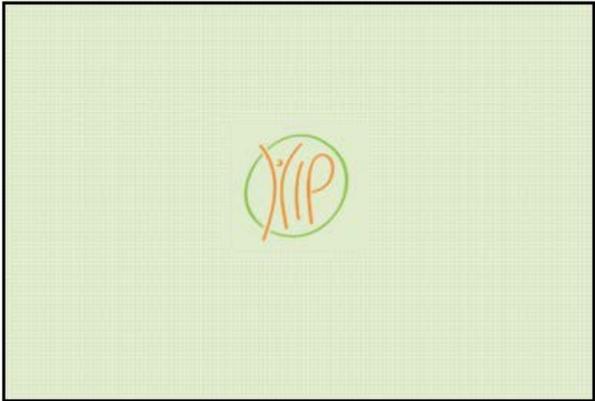
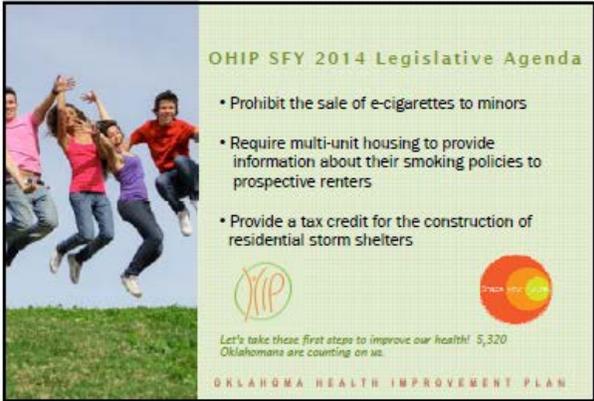
OHIP PARTNERS



Oklahoma Association of Health, Physical Education, Recreation and Dance	Oklahoma Employment Security Commission
YMCA of Tulsa	Oklahoma Primary Care Association
Cimarron Alliance	Oklahoma State University Center for Health Sciences
Leadership Oklahoma	AARP Oklahoma
Schools for Healthy Lifestyles	Community Service Council of Greater Tulsa
Regional Food Bank of Oklahoma	Oklahoma Nurses Association
Intaglia Health	Children's Hospital of Oklahoma/ American Academy of Pediatrics
George Kaiser Family Foundation	Citizens at Large
Oklahoma Management Enterprise Services	
Oklahoma Policy Institute	
Chickasaw Nation	
Physician's Manpower Training Center	
Oklahoma Healthcare Workforce Center	

OKLAHOMA HEALTH IMPROVEMENT PLAN

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The presentation concluded.

LEGISLATIVE REPORT

Mark Newman (OSDH), Tammie Kilpatrick (OCCHD), Scott Adkins (THD) Tammie Kilpatrick indicated the 2014 agenda will focus on prohibiting the sale of e-cigarettes to minors, requiring multi-unit housing smoking disclosure for prospective renters, and providing a tax credit for the construction of residential storm shelters or safe-rooms.

Dr. Cagle requested a motion from the OCCHD Board to support the OHIP Legislative Agenda. Motion made by Dr. Hill for the OCCHD to support the OHIP Legislative Agenda for FY '14 as stated in the legislative report. Motion seconded by Dr. Gray. Vote taken: Dr. Cagle, Dr. Gray, Dr. Hill, Dr. Mills, Dr. Raskob and Dr. Salmeron, Aye. Motion carried.

Dr. Gerard moved Board approval in support of the 2014 OHIP Legislative Agenda as presented. Second Dr. Grim. Motion carried.

AYE: Burger, Gerard, Grim, Krishna, Starkey, Stewart, Woodson, Wolfe
ABSENT: Alexopulos

BUDGET PRIORITIES

Julie Cox-Kain (OSDH), Bob Jamison (OCCHD), Reggie Ivey (THD) presented successes and updates regarding the previous year's joint budget request. The three health departments updated the Boards on their efforts around Children's Health including budgetary updates, evidence-based strategies, and community-based projects.

THD will continue to expand the REACH (Raising Educational Awareness for Community Health) Program and the Maternal and Child Health Case Management services in Tulsa County. The program will identify high risk clients, both during pregnancy and after.

OCCHD will continue to work on the Maternal and Child Health Outreach Program which will conduct outreach and educational activities to facilitate the reduction of infant mortality in the Oklahoma City metropolitan area.

THD
TULSA HEALTH
DEPARTMENT

“Expansion of REACH and MCH Programs”
*Tri-Board Meeting
October 8, 2013*

THD
TULSA HEALTH
DEPARTMENT

Program Rationale
Preparing for a Lifetime Recommendations

Identify High Risk Clients; both during pregnancy
and after (community and clinic)



THD

THD
TULSA HEALTH
DEPARTMENT

The Plan:

In accordance with the Oklahoma Health Improvement Plan, Tulsa City-County Health Department (TCCHD) proposes to expand the REACH (Raising Educational Awareness for Community Health) Program as well as expand Maternal and Child Health (MCH) Case management services in Tulsa County to improve perinatal outcomes and reduce infant mortality. Staff will work through the TCCHD sites to assure services and linkage to resources to prevent adverse maternal and infant outcomes.

THD

THD
TULSA HEALTH
DEPARTMENT

Program Rationale (con't)

Provide intensive education; focused on the following:

- Early Entry into Prenatal Care
- Importance of Folic Acid
- Smoking Cessation
- Provide Linkage to Early Prenatal Care
- Safe Sleep for Infants
- Offer education about reproductive life planning

THD

THD
TULSA HEALTH
DEPARTMENT

TCCHD hired two Clinical Social Workers (one bilingual) and two Community Outreach Workers (one bilingual)

A Clinical Social Worker and an Outreach Worker were hired in the first quarter of 2013. The second Outreach Worker was hired in July (2013) and the second Clinical Social Worker was hired in September (2013)

THD

THD
TULSA HEALTH
DEPARTMENT

Program Rationale (con't)

Education shared individually as well as in group settings (community and clinic)

Key feature of the Clinical Social Workers' role includes identifying and addressing domestic violence issues and depression screening specifically for clients who are pregnant or have children under the age of one.

THD

Progress
Outreach Services:

- Provided 22 presentations to Childcare providers and parent groups; topic specific (Impact: 855)
- Spent 585 hours canvassing neighborhoods, distributing information and connecting patients to providers or other services. (Impact: 25 patients)
- Spent 203 hours following up with clients that miss appointments. (Impact: 77 patients)





Progress (con't)

Case Management Services (one case manager):

- Offer depression and tobacco screening assessments
- Spent 800 hours providing resources, information and education to high risk clients (Impact: 126 patients)




Progress (con't)

Maximized Funding:

Community Connector

Maternal and Child Health Initiative

- Safe Sleep Demonstrations (Hospitals, Baby Stores, Emergency Infant Services, etc.)
- In the process of planning a Safety Fair for Child Care Providers and Parents (10.12.13)

Internal Referrals

Impact: less than 0.50% of patients case managed have experienced a poor infant outcome




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Maternal and Child Health Outreach
*Tri-Board Meeting
 October 8, 2013*

5

 **Maternal and Child Health Outreach (MCHO)**

The MCH Outreach Project will conduct outreach and educational activities to facilitate the reduction of infant mortality in the Oklahoma City metropolitan statistical area. Activities include:

- Provide leadership in initiating selected interventions recommended by the Community Action Team (CAT) of the Central Oklahoma Fetal and Infant Mortality Review (FIMR) Project while identifying and building relationships to transition interventions to appropriate community partners
- Provide consultation to health care professionals, community organizations, faith-based organizations, etc. on interventions/recommendations identified to reduce infant mortality
- Raise public awareness of positive health practices and lifestyle choices to improve overall health of mothers and infants and decrease infant mortality
- Promote interconception care for families experiencing a fetal/infant death targeted to high risk health or lifestyle behaviors affecting previous pregnancy loss
- Promote family planning for appropriate spacing of pregnancies to promote positive outcomes in future pregnancies as well as improve maternal and infant health



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HEALTH Strategies

Hospital Advocate Initiative was developed after educating over 1029 nurses in all 14 delivery hospitals in the metropolitan area. This initiative was developed to transition the education and awareness activities back to staff.

Faith-based Outreach has had multiple approaches. First, working with the Oklahoma Conference of Churches to reach faith-based groups with educational materials and resources on infant safe sleep. A second strategy has been developed to work within the African American Churches to address disparity issues within their community. Quarterly round table discussions are scheduled to identify specific strategies within the community to help reduce infant mortality.

Working with law enforcement agencies to assist in the data collection by standardizing the information documented during death scene investigations.

Staff positions funded include MCHO Epidemiologist and FIMR Specialist. EPI was hired to help identify and prioritize specific strategies identified through the Central Oklahoma Fetal and Infant Mortality Review process. Specialist was hired to conduct home interviews and outreach activities.

Two new social worker positions are in development and will be hired. These positions will work on outreach and case management of individuals/families who have experienced fetal/infant loss or other poor pregnancy outcomes.

WELLNESS NOW
F.I.M.R.

HEALTH Progress

Hospital Advocate Initiative. A hospital advocate has been named in all but one area delivery hospital plus St. Anthony's Shawnee Hospital. Monthly information and resources are sent to the 'Advocate' to be distributed to hospital staff. This effort continues to reach nurses in nearly every hospital while leveraging staff time and effort.

Faith-based Outreach. Working with the Oklahoma Conference of Churches we reach over 2000 faith-based groups with educational materials and resources on infant safe sleep. Second, quarterly round table discussions are scheduled to identify specific strategies within the community to help reduce infant mortality. To date we have approached over 34 African American Churches with information, presentations and resources on reducing infant mortality within their community. Information can now be downloaded from OCHO website.

Twenty-three law enforcement agencies have pledged to utilize the CDC developed Sudden Unexpected Infant Death Investigation (SUIDI) form. An additional six more are pending.

MCHO Epidemiologist. The MCHO EPI has been instrumental in identifying new zip code data allowing for targeted outreach activities that include addressing disparity issues. **FIMR Specialist has seen an increase in the number of home interviews conducted.** Of the families contacted only 15% conducted the interview in 2010 with expansion in 2011 and 2012 those numbers increased to 39% and 32% respectively.

Two new social worker positions are in development and positions are posted. These positions will work on outreach and case management of individuals/families who have experienced fetal/infant loss or other poor pregnancy outcomes. These social workers will be instrumental in the promotion of interconception care and family planning for appropriate spacing of pregnancies along with other lifestyle behaviors that affect birth outcomes.

WELLNESS NOW
F.I.M.R.

Budget Presentation

TRI-BOARD MEETING · OCTOBER 2013

JULIE COX-KAIN, MPA REGGIE IVEY, MHR BOB JAMISON, MBA

Presentation Overview

- ❑ SFY '15 Capital Improvement Budget – Public Health Laboratory
- ❑ SFY '13 & SFY '14 – Children's Health Budget Update
 - Oklahoma State Department of Health
 - Tulsa Health Department
 - Oklahoma City-County Health Department

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5

State Fiscal Year 2015 Public Health Laboratory

- ❑ Increase space
- ❑ Increase testing capacity
- ❑ Safety
- ❑ Improve Public Health Emergency Response Capabilities
- ❑ Improve efficiencies
- ❑ Accreditation

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Public Health Laboratory

- ❑ Capital Improvement Budget for \$ 41.2 million
 - Site work and Parking Lot
 - Construction Costs
 - Professional Fees and Project Management
- ❑ Functional facility separated physically and mechanically from current structure
 - Increased security
 - Stronger controlled access
 - Specifically designed and engineered for lab services

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Budget Update

State Fiscal Year 2013 & 2014
Children's Health Funding

\$1.7 Million



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Evidence-Based Strategies



- **Every Week Counts Collaborative**
 - March of Dimes Elimination of Non-medically Indicated Deliveries Before 39 Weeks Gestational Age Toolkit
 - Contract: OUHSC Office of Perinatal Quality Improvement to work with birthing hospitals
 - Achieved 86% reduction in early elective deliveries since January 2011
 - Reduce the rate of premature births by 8% by 2014 (ASTHO Presidential and March of Dimes Challenge)

Preparing for a Lifetime
OKLAHOMA STATE DEPARTMENT OF HEALTH - CREATING A STATE OF HEALTH - WWW.HEALTH.OK.GOV

Evidence-Based Strategies



- **Becoming Baby-Friendly In Oklahoma Project (Inclusive of Breastfeeding Education Project)**
 - A global program sponsored by the World Health Organization & United Nations Children's Fund
 - Women who breastfeed have shown decreased health risks
 - Contract: OUHSC Dept of OB-GYN to assist facilities to train/adopt policies that promote breastfeeding
 - 24 hospitals no longer providing formula gift discharge bags
 - Goal of engaging 10 new hospitals each year
 - Claremore Indian Hospital is Oklahoma's first Baby-Friendly Hospital

Preparing for a Lifetime
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Strategies Continued



- **Infant safe Sleep**
 - American Academy of Pediatrics (AAP) recommendations
 - Promoting environment which reduces risk of injury and death to infants when sleeping
 - Targeting 10 hospitals that deliver the largest numbers of minority populations
 - Assisting hospitals in developing and implementing infant safe sleep policy
 - Providing safe sleep education to staff and families
 - Providing infant sleep sacks to families
 - 5 hospitals with agreements in place

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Strategies Continued



- **Abusive Head Trauma**
 - Period of PURPLE Crying - 34 hospitals participating
 - Assisting hospitals in developing and implementing policy
 - Assisting parents with understanding normal part of infant development
 - Providing parents with education and Period of Purple Crying DVDs to use in educating other family members and caretakers
 - Click for Babies - collected/distributed nearly 3,000 purple baby caps

Preparing for a Lifetime
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Community-Based Projects

OSDH County Health Departments (48 counties)

Focusing on:

- Preconception/Interconception health, including tobacco
- Infant safe sleep
 - Pre-term birth
 - Activities:
 - Community health events
 - Community outreach
 - Public & provider education
 - Local media campaigns
 - Placement of 6 Social Workers based on risk criteria such as infant mortality, poverty, education



Preparing for a Lifetime
OKLAHOMA STATE DEPARTMENT OF HEALTH - CREATING A STATE OF HEALTH - WWW.HEALTH.OK.GOV

1 The presentation concluded.
2

3 **CHAIRMAN'S REPORT – OCCBH**

4 Dr. Cagle highlighted a recent visit from Taiwan health delegates regarding the Public Health
5 Accreditation process and their interest in the health improvement planning efforts. Dr. Cagle thanked
6 Blue Cross Blue Shield, the Oklahoma Department of Tourism, and Integris for their recent donations to
7 further the trails and sports fields at the Northeast Regional Health and Wellness campus.
8

9 **CHAIRMAN'S REPORT – TCCBH**

10 Dr. Grogan thanked OCCHD for their hospitality. Dr. Grogan thanked the THD staff for the engagement
11 of the Tulsa community. He briefly addressed successful and productive meetings with community
12 leaders regarding such issues as water safety. It is important to engage and educate both community
13 leaders and members of the public around these issues as well as strategic planning. He mentioned that
14 THD staff have become certified education counselors for the ACA.
15

16 **PRESIDENT'S REPORT – OSBH**

17 Discussion and possible action

18 Proposed 2014 Board of Health Meeting Dates (second Tuesday of each month at 11:00 a.m.):

19 January 14, 2014

20 February 11, 2014

21 March 11, 2014

22 April 8, 2014

23 May 13, 2014

24 June 10, 2014

25 July 8, 2014

26 August 15-17, 2014 (Location TBD)

27 October 14, 2014 - Tri-Board (Tulsa Health Department North Regional Health and Wellness Center 1:00
28 p.m.)

29 December 9, 2014
30

31 **Dr. Grim moved Board approval of the 2014 Board of Health meeting dates as presented. Second Mr.
32 Starkey. Motion carried.**
33

34 **AYE: Burger, Gerard, Grim, Krishna, Starkey, Stewart, Woodson**

35 **ABSENT: Alexopoulos, Wolfe**
36

37 Dr. Krishna briefly discussed the state of the state's health and the successes accomplished throughout the
38 state. However; obesity, tobacco and mental health need to be addressed at the national level in order to
39 see continued improvement. He thanked the staff and personnel working in public for their contributions.
40

41 **NEW BUSINESS**

42 No new business.
43

44 **ADJOURNMENT**

45 **Mr. Gerard moved State Board of Health approval to Adjourn. Second Dr. Woodson. Motion carried.**

1 **AYE: Burger, Gerard, Grim, Krishna, Starkey, Stewart, Woodson**
2 **ABSENT: Alexopulos, Wolfe**

3
4 The OSDH adjourned at 12:53 p.m.

5
6 Tulsa City-County Board of Health adjourned at 12:53 p.m.

7
8 Approved

9
10 _____
11 R. Murali Krishna, M.D.
12 President, Oklahoma State Board of Health
13 December 10, 2013

**STATE OF OKLAHOMA
OKLAHOMA STATE DEPARTMENT OF HEALTH**

November 13, 2013

TO: State Board of Health Members

FROM: Terry Cline, Ph.D. T. C.
Commissioner
Secretary of Health and Human Services

SUBJECT: Home Care and Hospice Advisory Council

This requests appointment by the Oklahoma State Board of Health of one member of the Home Care and Hospice Advisory Council. The State Board of Health appoints one member representing an association which advocates on behalf of home care or hospice issues. The candidates for appointment are the following:

Home Care or Hospice Association Representative

- Lavane Y. Vowell, Executive Director, Oklahoma Hospice and Palliative Care Association
- Karen Vahlberg, RN, BSN, Board Member, Oklahoma Association for Home Care and Hospice

The State Health Department's staff conducted a check of the histories of these proposed appointees using public information, including the Oklahoma Department of Corrections Offender Lookup, the Oklahoma State Court Networks Court Dockets, and Oklahoma State Department of Health licensure records. The staff identified no offenses or adverse actions that would impair the ability of these two individuals to perform the responsibilities of the advisory council.

Each nominee meets the qualifications of the positions for which they are nominated. Dr. Henry Hartsell contacted each of the nominees and confirmed their willingness to serve and attend public meetings of the Advisory Council.

Additional information for the Advisory Council is as follows.

Statutory Citation

The Home Care and Hospice Advisory Council is authorized in Title 63 O.S. Section 1-103a.1.

Appointing Authorities and Advisory Council Membership

The Advisory Council has seven members. The appointing authorities and membership categories are:

Governor Appointments

- Owner or administrator of entity licensed under Hospice Licensing Act

- Owner or administrator of entity licensed under Home Care Act

President Pro Tempore of the Senate Appointments

- Owner or administrator of entity licensed under Hospice Licensing Act
- Owner or administrator of entity licensed under Home Care Act

Speaker of the House of Representatives Appointments

- Public member who is/was legal guardian of hospice recipient
- Public member who is/was a home health services recipient or legal guardian of home health services recipient

State Board of Health Appointment

- Representative of association which advocates on behalf of home care or hospice issues.

Advisory Council Duties/Responsibilities

The Advisory Council is appointed to:

- Make recommendations to the State Board of Health on rules;
- Conduct public rulemaking hearings;
- Make nonbinding written recommendations to the State Board of Health and the State Department of Health;
- Provide a public forum for the discussion of issues, pass nonbinding resolutions, and make recommendations concerning the need for meetings, workshops and seminars; and
- Cooperate with other Advisory Councils, the public, the State Board of Health, and the State Department of Health to coordinate rules.

The jurisdiction of the Advisory Council includes “all issues that arise in the areas of home care or hospice services, and such other areas as designated by the State Board of Health.” [63:1-103a.1(G)]

Advisory Council Meeting Frequency

The Advisory Council must meet at least twice a year, but not more than four times a year.

Appointment Process

The steps in the appointment process are as follows:

- Representatives of the Oklahoma Hospice and Palliative Care Association, and the Oklahoma Association for Home Care and Hospice, submitted recommended appointments to the State Department of Health;
- State Department of Health staff members reviewed the qualifications of the candidates and contact nominees to confirm qualifications and willingness to serve;
- The Commissioner of Health submits the proposed appointment to the State Board of Health; and
- The State Board of Health appoints one member.

Attachments

- Resume and biography for Lavane Y. Vowell
- Letter of Interest for Karen Vahlberg

**STATE OF OKLAHOMA
OKLAHOMA STATE DEPARTMENT OF HEALTH**

DATE: November 26, 2013

TO: State Board of Health Members

FROM: Terry Cline, Ph.D.
Commissioner
Secretary of Health and Human Services

SUBJECT: Advancement of Wellness Advisory Council

Appointing Authority

The State Board of Health shall appoint one member, *who is the Executive Director of the Tobacco Settlement Endowment Trust*, to the Advancement of Wellness Advisory Council as directed in **Title 63, Section 1-103a.1**. The appointee is:

Executive Director of the Oklahoma Tobacco Settlement Endowment Trust

- Tracey Strader, Oklahoma City

Additional information for the advisory board is as follows.

Statutory Citation

The Advancement of Wellness Advisory Council is authorized in Title 63 O.S. Section 1-103a.1.

Membership

The Advisory Council has seven members. The membership includes:

1. One member for breast and cervical cancer
2. One member for organ donation
3. One mayor of certified healthy community in urban setting
4. One president/COO of certified healthy business (unspecified, assume in rural setting, see below)
5. One mayor of a certified healthy community in rural setting
6. One president/COO of certified healthy business (specified in urban setting)
7. The Executive Director of TSET

Advisory Council Duties/Responsibilities

The Advisory Board is appointed to:

Assist and advise the State Board of Health and the State Department of Health in rule development, review and recommendation; and adoption of nonbinding resolutions to the State Department of Health or the State Board of Health concerning matters brought before the Advisory Council; provide a public forum for the discussion of issues it considers relevant to its area of jurisdiction; make recommendations to the State Board of Health or the State Department of Health concerning the need and the desirability of conducting meetings, workshops and seminars; and to cooperate with each other Advisory Council, the public, the State Board of Health and the Commissioner of Health in order to coordinate the rules within their respective jurisdictional areas and to achieve maximum efficiency and effectiveness in furthering the objectives of the State Department of Health.

The jurisdictional areas of the Advancement of Wellness Advisory Council shall include all issues that arise in the areas of tobacco usage and cessation, organ and tissue donation, the requirements for a city or town in the state to be designated as a certified healthy community, the requirements for a business to be designated as a certified healthy business and such other areas as designated by the State Board of Health.

Advisory Board Meeting Frequency

Each Advisory Council shall meet at least twice a year, but no more than four times a year.

Appointment Process

The steps in the appointment process are as follows:

- Oklahoma State Department of Health contacts the Executive Director for the Tobacco Settlement Endowment Trust (TSET) and informs the Director of the Statutory Appointment to this council;
- Member's appointment will coincide with member's employment as the Executive Director of TSET;
- The State Board of Health appoints member.

Attachments

- Resume for Tracey Strader

**STATE OF OKLAHOMA
OKLAHOMA STATE DEPARTMENT OF HEALTH**

November 18, 2013

TO: State Board of Health Members

FROM: Terry Cline, Ph.D. *T. Cline 11-21-2013*
Commissioner
Secretary of Health and Human Services

SUBJECT: Infant and Children's Health Advisory Council

This requests appointment by the Oklahoma State Board of Health of one member of the Infant and Children's Health Advisory Council. The State Board of Health appoints one member who is a physician licensed by the state who specializes in the diagnosis and treatment of childhood injuries in a trauma setting. The candidates for appointment are the following:

Physician Specialized in the Diagnosis and Treatment of Childhood Injuries in a Trauma Setting

- Amanda L. Bogie, M.D., Associate Professor, Pediatric Emergency Medicine, Department of Pediatrics, University of Oklahoma College of Medicine, Children's Hospital of Oklahoma, University of Oklahoma Health Sciences Center
- Robert W. Letton, Jr. M.D., Professor of Surgery, Section of Pediatric Surgery, Department of Surgery, University of Oklahoma College of Medicine, Children's Hospital of Oklahoma, University of Oklahoma Health Sciences Center

The State Health Department's staff conducted a check of the histories of these proposed appointees using public information, including the Oklahoma Board of Medical Licensure and Supervision licensure records. The staff identified no offenses or adverse actions that would impair the ability of these two individuals to perform the responsibilities of the Advisory Council.

Each candidate meets the qualifications of the position for which they are nominated. State Department of Health staff contacted each of the candidates and confirmed their willingness to serve and attend public meetings of the Advisory Council.

Additional information for the Advisory Council is as follows.

Statutory Citation

The Infant and Children's Health Advisory Council is authorized in Title 63 O.S. Section 1-103a.1.

Appointing Authorities and Advisory Council Membership

The Advisory Council has seven members. The appointing authorities and membership categories are:

Governor Appointments

- Member who works for the state or a political subdivision on child abuse issues
- Member who is knowledgeable about childhood immunizations

President Pro Tempore of the Senate Appointments

- Member who is knowledgeable about newborn screening issues
- Optometrist licensed by the state who has knowledge of vision screening for children

Speaker of the House of Representatives Appointments

- Physician licensed by the state who works as a pediatrician
- Genetics counselor licensed by the state

State Board of Health Appointment

- Physician licensed by the state who specializes in the diagnosis and treatment of childhood injuries in a trauma setting.

Advisory Council Duties/Responsibilities

The Advisory Council is appointed to:

- Make recommendations to the State Board of Health on rules;
- Conduct public rulemaking hearings;
- Make nonbinding written recommendations to the State Board of Health and the State Department of Health;
- Provide a public forum for the discussion of issues, pass nonbinding resolutions, and make recommendations to the State Board of Health or the State Department of Health concerning the need and the desirability of conducting meetings, workshops and seminars; and
- Cooperate with other Advisory Councils, the public, the State Board of Health, and the State Department of Health to coordinate rules.

The jurisdiction of the Advisory Council includes “all issues that arise in the areas of health care for infants and children and such other areas as designated by the State Board of Health.” [63:1-103a.1(E)]

Advisory Council Meeting Frequency

The Advisory Council must meet at least twice a year, but not more than four times a year.

Appointment Process

The steps in the appointment process are as follows:

- State Department of Health staff identified physicians specialized in the diagnosis and treatment of childhood injuries in a trauma setting recommended as candidates to serve as

a member; reviewed the qualifications of the candidates; and contacted candidates to confirm willingness to serve;

- The Commissioner of Health submits the proposed appointment to the State Board of Health; and
- The State Board of Health appoints one member.

Attachments

- Curriculum vitae for Amanda L. Bogie, M.D.
- Curriculum vitae for Robert W. Letton, Jr., M.D.



2014 LEGISLATIVE PRIORITIES

Mark Newman, Ph.D., Director, Office of State and Federal Policy

1. Prohibit the sale of e-cigarettes to minors

- Oklahoma state law is currently silent on the sale of e-cigarettes to minors
- Research shows that e-cigarette use more than doubled in U.S middle and high school students from 2011 to 2012
- In 2012, more than 1.78 million middle and high school students nationwide experimented with e-cigarettes
- Three-quarters of those who tried e-cigarettes also tried combustible tobacco products
- E-cigarette/vapor products contain carcinogens and nicotine, which is toxic and highly addictive
- Youth should not have access to e-cigarette or vapor products because nicotine can negatively affect the developing brain
- Among e-cigarette/vapor products the concentration of chemical contaminants and nicotine has been shown to vary greatly. This means these unregulated products may provide uncontrolled doses of harmful contaminants
- Some studies suggest that as many as a quarter of smokers surveyed began using e- cigarettes or vapor products prior to switching to tobacco products. The variety of flavors, misleading claims, and marketing that encourages use indoors increases concerns that these products may be used as a gateway to cigarettes or other lit tobacco products for some people, and may keep smoking rates unacceptably high

Policy Proposal

- State law already prohibits the sale of tobacco products to minors
- Legislation is needed to amend the definition of “tobacco product” to clarify that it includes any product that is made or derived from tobacco. This would include e- cigarettes
- This definition is consistent with current court rulings and FDA intent to regulate e-cigarettes as “other tobacco products”

2. Require multi-unit housing smoking disclosure for prospective renters

- Many children with asthma and other chronic conditions affected by secondhand smoke exposure are unwillingly exposed when living in multi-unit housing
- When smoking is allowed in one area of a building, smoke can and will spread to other areas within the building
- There is no safe level of exposure to secondhand smoke

- There are more than 7,000 chemicals that have been identified in secondhand smoke, at least 250 of those are known to be harmful such as hydrogen cyanide, carbon monoxide and ammonia
- Approximately 212,782 Oklahoma households live in multi-unit housing (2 or more)
- Approximately 15% of Oklahoma housing units are multi-unit structures (2 or more)
- Among Oklahoma children ages birth to 14, there were 3,258 in-patient hospital days for asthma in 2010 with total charges of approximately \$13,219,494
- A 30% reduction in hospitalizations for asthma among young adults would save approximately \$611,800 per year

Policy Proposal

- State law already requires disclosure for potential toxins that can result when methamphetamine has been found to be manufactured in one unit of a multi-unit housing complex
- Legislation is needed to amend the disclosure statute to also include whether smoking is permitted on the property and locations in which it is permitted

3. Provide a tax credit for the construction of residential storm shelters or safe-rooms

- The events of this past spring (2013) have reminded us that even with the advanced warning and storm prediction systems in our state, tornadoes can strike suddenly and unpredictably
- In extremely violent EF4 and EF5 storms, the only protection from a direct hit is in a basement or tornado shelter. Few homes in Oklahoma have been built with basements, but, there are many options for the installing a storm shelter in a home
- There is a safe room rebate program through the Oklahoma Department of Emergency Management (SoonerSafe) and it is estimated that more than 11,000 shelters have been built through this program following the May 1999 tornadoes
- Applicants are selected randomly and can receive up to \$2,000 rebate *after* installing a safe room. The rebate is not taxable. However, individuals are not eligible to receive a rebate through this program if they have already built a safe room and must wait until they see if they qualify for the rebate before they can build
- The Oklahoma Constitution provides for up to one hundred square feet of a Safe room installed after January 1, 2002 shall be exempt from taxation
- There are currently no tax credits in place to further incentivize building a tornado shelter

Policy Proposal

- This bill would create a one-time tax credit to individuals and families for the construction of a residential above or below ground storm shelter
- Recommend that this tax credit only apply to families using an Oklahoma company to construct or install their storm shelter or safe-room and Oklahoma manufactured safe rooms and storm shelters
- Recommend that the tax credit be in existence for a defined time period of two or three years and not be indefinite



Oklahoma State Department of Health
Creating a State of Health

RECEIVED
NOV 14 2013
LEGAL DIVISION

To: Board of Health Secretary

Through: Terry Cline, Ph.D.
Commissioner *T.C. 11-20-2013*

Through: James Joslin, Chief *JJ. 11/15/13*
Health Resources Development Service
Agency Rule Liaison

Through: Don Maisch *DM 11-15-2013*
General Counsel

Through: Hank Hartsell, Ph.D. *HH 11/14/13*
Deputy Commissioner

REVISED

From: James Joslin, Chief *JJ 11/14/13*
Health Resources Development Service

Date: November 14, 2013

Subject: Rule Packet Submission for Distribution to Board of Health
CHAPTER 2. PROCEDURES OF THE STATE DEPARTMENT OF HEALTH

The attached documents are submitted for **EMERGENCY and PERMANENT ADOPTION** by the State Board of Health at their December 10, 2013, meeting.

As anticipated, based on comment from advocates and industry and in discussion with our grant partners we revised the schedule of effective dates allowing providers to begin submission as of February 1, 2014, but no later than the effective date proposed, which differs for the various provider and industry segments. The total period of implementation is seven months, with the last effective date being August 1, 2014.

A late revision, as addressed in the comment summary, was made based on comments from the Oklahoma Health Care Authority.

Attachments:

- **RIS (Rule Impact Statement)**
- **Rule Text**
- **Rule Comment Summary**

(Please contact James Joslin at x57209 for corrections, pick-up and delivery.)

RULE IMPACT STATEMENT

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 2. PROCEDURES OF THE STATE DEPARTMENT OF HEALTH

Before the Oklahoma State Board of Health December 10, 2013

1. DESCRIPTION:

This proposal promulgates new rules in the procedures of the Department of Health as required in amendments to the Long Term Care Security Act (Title 63 O.S. § 1-1944 et. seq.), as adopted in 2012, House Bill 2582. This bill authorized fingerprint based criminal history background checks on those applicants who would be employed in a variety of long-term care settings as defined in the law at Title 63 O.S. Section 1-1945(4). The law at Title 63 O.S. § 1-1947(T)(2) requires that the Department shall specify rules for issuing a waiver of the disqualification or employment denial. The law further specifies in subsection Y that the State Board of Health shall promulgate rules prescribing effective dates and procedures for the implementation of a national criminal history record check for the employers and nurse aide scholarship programs defined in Section 1-1945 of Title 63 of the Oklahoma Statutes.

The following outlines the grounds for which, pursuant to Title 75 O.S. Section 253, the Department seeks Emergency adoption of the proposed rules. The requirements in Title 63 O.S. § 1-1947(Y), state, *the State Board of Health shall promulgate rules prescribing effective dates and procedures for the implementation of a national criminal history record check for the employers and nurse aide scholarship programs defined in Section 1-1945 of [Title 63 of the Oklahoma Statutes]. Said dates may be staggered to facilitate implementation of the requirements of this section.* This Emergency rulemaking action is necessary to provide for the staggered effective dates authorized in law; to protect the safety of vulnerable populations by implementing without further delay a more rigorous national background check for those caring for vulnerable adults in our state; and, to implement the program while grant dollars are available, thereby reducing the cost to the State and providers for background checks. An extension to the current grant, awarded for the exploration and development of a fingerprint based national background check, has been offered to April of 2015. Upon an effective date for fingerprinting, grant funds will be utilized for seventy-five percent (75%) of fingerprinting costs for the duration of the grant. For each months delay in an effective date approximately eighty thousand dollars (\$80,000) of grant funds will not be captured to assist in program costs. The implementation dates for this program were dependent on software development and contracting with a vendor for a statewide network to provide live scan collection and digital submission of fingerprints to the State Bureau of Investigation. The software and live scan network are now projected to be complete by December 1, 2013.

310:2-29-1, Purpose. This section specifies the purpose of the rules and authorizing Act.

310:2-29-3, Implementation. This section details procedures for implementing the law and creates staggered effective dates for the fingerprint based background check by various classes of employer. The staggered dates allow for a gradual increase in the volume of requests processed during the initial start-up.

310:2-29-5, Appeals. This section creates the procedures for requesting an appeal of the employment eligibility determination and the criteria to be applied by the hearing officer in making a determination whether the applicant merits a waiver of the applicant's determination of ineligibility. This section also specifies means an applicant may use to demonstrate that the information contained in the criminal history report is inaccurate. The criteria to be applied for the waiver are:

- (1) The time elapsed since the disqualifying criminal conviction, whether the applicant has fulfilled the sentence requirements, and whether there are any subsequent arrests or convictions of any nature;
 - (2) Any extenuating circumstances such as the offender's age at the time of conviction, substance abuse history and treatment, or mental health issues and treatment;
 - (3) Rehabilitation as demonstrated by character references and recommendation letters from past employers, the applicant's record of employment history, education, and training subsequent to conviction; and
 - (4) The relevancy of the particular disqualifying information with respect to the proposed employment of the individual to include the job type and duties, the extent to which the applicant has unsupervised access to service recipients, whether the crime was committed against a vulnerable child or adult, and whether the conviction was related to an employer subject to the requirements of the Long Term Care Security Act.
2. **DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:**
Affected persons will be residents and their families as well as owners, operators, and applicants of employers defined within the Long Term care Security Act. This rule implements statute and creates no additional reporting or processing requirements beyond that required in the enabling legislation. When a disqualified applicant appeals the determination and requests a hearing they will incur costs in time and postage.
3. **DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED HEALTH OUTCOMES:**
Those benefiting from the rule's implementation of fingerprint based criminal history background checks will be residents and their families as well as owners and operators. These groups benefit from enhanced employment screening tools creating a safer environment for vulnerable populations. The applicants found ineligible benefit by having an appeals procedure that allows for the consideration of extenuating or mitigating factors that might merit waiving the ineligible determination.
4. **ECONOMIC IMPACT, COST OF COMPLIANCE AND FEE CHANGES:**
There will be an economic impact to the applicants subject to a background check and to the employers seeking to employ an applicant. The costs for both the applicant and the employer are established in state statute. The monies derived from the costs to the applicant and the employer will cover the costs to obtain the background check and the long-term costs of implementation of the program.
5. **COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY:**
The cost to the Department to implement the amendments will be approximately \$4,000 to cover the costs of rule drafting, adoption, publication, distribution, and education. The proposed rules will be implemented by Department personnel. The initial startup of the program is supported by a grant with long-term funding supported by the applicant's administrative fingerprinting fee and the employer's fee for obtaining the criminal history record results. These fees are as authorized in the enabling legislation, House Bill 2582 (2012).

Benefits to the Department of Health and the Department of Human Services will be more rigorous background checks for those Department staff whose responsibilities include visits to long-term care settings. These staff will be subject to the same fingerprint based national background check as staff working in long-term care settings. These Departments are also projected to benefit by reduced incidents of abuse, neglect and misappropriation in long term care settings.

6. IMPACT ON POLITICAL SUBDIVISIONS:

There are no anticipated impacts on political subdivisions, nor will it require their cooperation in implementing or enforcing the proposed amendment.

7. ADVERSE EFFECT ON SMALL BUSINESS:

No comments were submitted identifying adverse economic effects on small businesses as provided by the Oklahoma Small Business Regulatory Flexibility Act.

8. EFFORTS TO MINIMIZE COSTS OF RULE:

No less costly or non-regulatory methods have been identified.

9. EFFECT ON PUBLIC HEALTH AND SAFETY:

Implementation of fingerprint based criminal history background checks will yield a more credible work force caring for vulnerable residents in the long term care settings and is anticipated to reduce incidents of abuse, neglect and misappropriation in such settings.

10. DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:

Lack of implementation of fingerprint based criminal history background checks will result in continued use of local name based background checks that do not account applicants who cross state lines to avoid their criminal history or who conceal their identity. These applicants are then eligible to work with vulnerable adults after having demonstrated behaviors that in some case are shown to be predictors of abuse, neglect and misappropriation.

11. This rule impact statement was prepared on August 16, 2013 and revised September 27, 2013, and November 8, 2013.

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 2. PROCEDURES OF THE STATE DEPARTMENT OF HEALTH**

SUBCHAPTER 29. Criminal History Background Checks

310:2-29-1. Purpose

These rules implement the Long Term Care Security Act as established at Title 63 O.S. Section 1-1944 et seq., as amended.

310:2-29-2. [RESERVED]

310:2-29-3. Implementation

(a) Authority. Title 63 O.S. Section 1-1947(Y) authorized the Department to establish through rulemaking the effective dates of subsections D through V of Section 1-1945 of Long Term Care Security Act, by category of employer.

(b) Effective dates. The effective dates for subsections D through V of Section 1-1947 (relating to screening and fingerprint based background checks) are defined below.

(1) For the following, compliance may begin February 1, 2014, but shall be required no later than March 1, 2014:

(A) Adult Day Care Centers as defined by Section 1-872 of Title 63 of the Oklahoma Statutes; and

(B) Residential care homes as defined by Section 1-820 Title 63 of the Oklahoma Statutes.

(2) For Specialized Nursing Facilities licensed pursuant to Title 63 O.S. Section 1-1901 et seq., compliance may begin February 1, 2014, but shall be required no later than April 1, 2014:

(3) For the following employers, compliance may begin February 1, 2014, but shall be required no later than May 1, 2014:

(A) Applicants for employment with the State Department of Health and Department of Human Services whose responsibilities include working inside long term care facilities, pursuant to Title 63 O.S. Section 1-1947(A)(1); and

(B) Nursing Facilities licensed pursuant to Title 63 O.S. Section 1-1901 et seq.,

(4) For the following employers compliance may begin February 1, 2014, but shall be required no later than June 1, 2014:

(A) Continuum of Care or Assisted Living facilities licensed pursuant to Title 63 O.S. Section 1-890.1 et seq; and

(B) Hospice programs licensed pursuant to Title 63 O.S. Section 1-860.1 et seq.

(5) For Medicare Certified Home Care Agencies licensed pursuant to Title 63 O.S. Section 1-1960 et seq., compliance may begin February 1, 2014, but shall be required no later than July 1, 2014.

(6) For all other employers defined in Title 63 O.S. Section 1-1945(4), compliance may begin February 1, 2014, but shall be required no later than August 1, 2014.

(7) For Nurse Aide Scholarship Programs operated under contract with the Oklahoma Health Care Authority compliance may begin July 1, 2014, but shall be required no later than August 1, 2014.

(8) For staffing agencies or independent contractors as defined in Title 63 O.S. Section 1-1945(4), compliance shall match the contracted employer.

(9) Pursuant to Title 63 O.S. Section 1-1947(I)(5), Medicaid home and community-based services waived providers as defined in Section 1915 (c) or 1915 (i) of the federal Social Security Act may voluntarily participate in the submission of fingerprints for applicants. In lieu of fingerprinting, said providers shall obtain a name-based state criminal history record check from the [Oklahoma State Bureau of Investigation] at the fee established in Section 150.9 of Title 74 of the Oklahoma Statutes. No other fees shall apply to said providers relying on a name-based state criminal history record check. The determination of employment eligibility shall be made by said providers based on the criteria established in subsection D of [Title 63 O.S. Section 1-1947].

(c) **Nurse Aide Scholarship Programs.** For the purposes of complying with Title 63 O.S. Section 1-1947(G) (related to conducting a registry screening and criminal history record check), the Nurse Aide Scholarship Program may refer the applicant's application and release to the Department for registry screening and authorization to collect fingerprints.

(d) **Alternate Name Based Background Check.** Where the Department is unable to authorize the collection and submission of fingerprints through an authorized collection site pursuant to Title 63 O.S. Section 1-1947(I), the Department shall conduct a name based search of the applicant in the criminal history database maintained by the Oklahoma State Bureau of Investigation.

310:2-29-4. [RESERVED]

310:2-29-5. Appeals

(a) **Notice.** A determination by the Department that finds an applicant not eligible for employment will result in a notice to the applicant to *include the reasons why the applicant is not eligible for employment and a statement that the applicant has a right to appeal the decision made by the Department regarding the employment eligibility. The notice shall also include information regarding where to file and describe the appellate procedures* [63 O.S. § 1-1947(K)(2)].

(b) **Days to initiate an appeal.** Pursuant to Title 63 O.S. 1-1947(T)1), any individual who has been disqualified from or denied employment by an employer pursuant to Title 63 O.S. Section 1-1947 may file an appeal with the Department within thirty (30) days of the receipt of the notice of disqualification.

(c) **Types of appeals.** An applicant may appeal the determination by:

- (1) Challenging the finding that the applicant is the true subject of the results from a name-based registry background check;
- (2) Challenging the criminal history record as inaccurate; or
- (3) Requesting a waiver which gives the applicant the opportunity to demonstrate that the applicant should be allowed to work because he or she does not pose a risk to patients, facilities or their property.

(d) **Inaccuracy of criminal history record.** To demonstrate that the criminal history record is inaccurate, the applicant shall submit to the Department written documents, issued and certified by a governmental entity that demonstrate that the information contained in the criminal history report is inaccurate.

(e) **Criteria for consideration in a waiver review.** Pursuant to Title 63 O.S. Section 1-1947(T)(2), the Department shall consider the following criteria in considering whether the applicant merits a waiver of the applicant's determination of ineligibility:

- (1) The time elapsed since the disqualifying criminal conviction, whether the applicant has fulfilled the sentence requirements, and whether there are any subsequent arrests or convictions

of any nature;

(2) Any extenuating circumstances such as the offender's age at the time of conviction, substance abuse history and treatment, or mental health issues and treatment;

(3) Rehabilitation as demonstrated by character references and recommendation letters from past employers, the applicant's record of employment history, education, and training subsequent to conviction; and

(4) The relevancy of the particular disqualifying information with respect to the proposed employment of the individual to include the job type and duties, the extent to which the applicant has unsupervised access to service recipients, whether the crime was committed against a vulnerable child or adult, and whether the conviction was related to an employer subject to the requirements of the Long Term Care Security Act.

(e) **Where to file.** The applicant's appeal shall be submitted in writing to the Administrative Hearings Clerk for the Oklahoma State Department of Health, 1000 Northeast 10th Street, Oklahoma City, OK 73117, and shall address the criteria specified in (d) of this Section and how the applicant merits a waiver of the disqualification from employment.

(f) **Conduct of hearing.** The appeal shall be conducted as an individual proceeding pursuant to this Chapter and the Administrative Procedures Act.

RULE COMMENT SUMMARY AND RESPONSE

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 2. PROCEDURES OF THE STATE DEPARTMENT OF HEALTH

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)]

Name & Organization: Esther Houser, State Long Term Care Ombudsman, Department of Human Services. Letter dated October 31, 2013

Rule Subchapter and Section: 310:2-29-3. Implementation

Comment: Ms. Houser wrote,

We support the Department of Health in using “staggered” effective dates for the various provider types which will be permitted to participate in the Fingerprint Background Check program. However, as discussed in your 10/29/13 meeting with a variety of interested parties, we believe that the implementation schedule provided in the Draft Rule may be too ambitious. The LTC Ombudsman Program supports extending the implementation period over a longer period of (perhaps) 6 months, to allow for a more gradual inclusion of the various types of providers. This will be especially important when the larger employer groups are allowed to begin to participate in the program.

Response: The Department concurs in this recommendation and has proposed a revised schedule of effective dates allowing providers to begin submission as of February 1, 2014, but no later than the effective date proposed, which differs for the various provider and industry segments. The latest effective date will be August 1, 2014.

Rule Subchapter and Section: 310:2-29-5. Appeals, (a) Notice.

Comment: Ms. Houser wrote, "for clarity, it may be helpful to insert the phrase “to the applicant” after the word “notice” and before the words “to include the reasons...” in line 2 of the first paragraph of this section."

Response: The Department concurs in this recommendation and proposes the revision as shown below.

310:2-29-5. Appeals

(a) Notice. A determination by the Department that finds an applicant not eligible for employment will result in a notice to the applicant to include the reasons why the applicant is not eligible for employment and a statement that the applicant has a right to appeal the decision made by the Department regarding the employment eligibility. The notice shall also include information regarding where to file and describe the appellate procedures [63 O.S. § 1-1947(K)(2)].

Name & Organization: Regular Meeting of the Long-Term Care Facility Advisory Board; October 9, 2013.

LTCFAB members present: Kay Parsons, Chair; Dewey Sherbon, Vice Chair; Theo Crawley; Luke Tallant; Alan Mason; Wendell Short; Dustin Cox; Ivoria Holt; Linda Brannon; Donna Bowers; Diana Sturdevant; and Willie Burkhart.

Guests present: Mary Brinkley, Leading Age OK; Marilyn Kipps, guest; Jim Kipps; Gina Stafford, OK Board of Nursing; Oralene Sherbon, general public; Joyce Clark, Achievis; Marietta Lynch, Oklahoma Association of Health Care Providers; Wes Bledsoe, A Perfect Cause; Bill Whited, State Long Term Care Ombudsman's Office; Greg Frogge, McAfee Taft; Trish Ewing, State Council on Aging; Mark Stratton, University of Oklahoma Department of Pharmacy; Keith Swanson, guest; Gara Wilsie, Sequoia Health Services.

Rule Subchapter and Section: All

Comment: The Advisory Board was provided the Notice of Rulemaking Intent, Draft Rule Impact Statement and Proposed Rule. The members were advised the Department was collecting comment on the proposed schedule for implementation and that the Department anticipated revisions to the schedule to push back the initial effective date and extend the implementation period. A quorum of the Board was not present to allow a formal vote in support of the proposed rule. The members present expressed a consensus opinion in support of the rule and proposed no changes to the rule. Members were advised of the Public Comment Hearing to be held November 1, 2013, at which time they could provide individual written or oral comments.

Response: The Department appreciates the favorable review of the proposed rules. As discussed previously, the Department is proposing a revised schedule of effective dates allowing providers to begin submission as of February 1, 2014, but no later than the effective date proposed, which differs for the various provider and industry segments. The latest effective date will be August 1, 2014.

Name & Organization: Ad Hoc meeting of industry, state government and advocacy group representatives held at the Department October 30, 2013.

Rule Subchapter and Section: All

Present: Gayla Freeman, DHS Aging Services Division; Eleanor Kurtz, DHS Aging Services Division; Jonathan Vanbeber, DHS Aging Services Division; Melissa Holland and Patrick Gaines, Oklahoma Assisted Living Association; Lori Baer, Leading Age; Esther Houser, State Long Term Care Ombudsman, Department of Human Services; Joe Wolfe and Jennifer Buckles, First Call Home Care Agency; Avis Hill, Oklahoma Health Care Authority; Donna Bowers, Daily Living Center.

Comment: The Department provided the group the Notice of Rulemaking Intent, Draft Rule Impact Statement and Proposed Rule. Those present reviewed a proposed schedule of effective dates beginning February 1, 2014, and extending out over nine months. The benefits of deploying over the extended period of time, allowing gradual enrollment and time for training, were discussed as was concern about the availability of name based checks as a fallback if for some reason fingerprint collections could not be authorized. Also discussed was the concern of limiting the time grant dollars would be available to subsidize fingerprinting by delaying effective dates. The members present expressed support of the rule and implementing a fingerprint based national background check.

Response: The Department reviewed the proposed schedule and as discussed previously resolved to revise the schedule of effective dates allowing providers to begin submission as of February 1, 2014, but no later than the effective date proposed, which differs for the various provider and industry segments.

The program implementation budget includes funding for provider training to be held across the state. The total period of implementation is seven months, with the last effective date being August 1, 2014.

The Department concurs with the recommendation concerning an alternative use of a name based background check and proposes the language as shown below for section 310:2-29-3.

(d) Alternate Name Based Background Check. Where the Department is unable to authorize the collection and submission of fingerprints through an authorized collection site pursuant to Title 63 O.S. Section 1-1947(I), the Department shall conduct a name based search of the applicant in the criminal history database maintained by the Oklahoma State Bureau of Investigation.

Name & Organization: Micqueal Ware, Melinda Jones Thomason, Beverly Blake; Oklahoma Health Care Authority (OHCA); telephone calls, November 12 and 14th, 2013.

Comment: A discussion was held with these representatives of the OHCA regarding implementation of the program as it relates to the SoonerCare Nurse Aide Scholarship Program. Concern was expressed regarding the Nurse Aide Training Programs operating under the existing SoonerCare Nurse Aide Scholarship Program contracts. The concern related to the ability of the training programs to process applicants within the current contract and budget. Alternatives were discussed and it was proposed that the rule be modified to authorize a referral to the Department for registry screening and authorization to collect fingerprints where necessary and delaying the effective date for the SoonerCare Nurse Aide Scholarship Program requirements to coincide with contracts issued in the Fiscal Year beginning July 1, 2014.

Response: The Department concurs with the recommendation concerning the Nurse Aide Scholarship Program and proposes the language as shown below for section 310:2-29-3.

(b) Effective dates. The effective dates for subsections D through V of Section 1-1947 (relating to screening and fingerprint based background checks) are defined below.

.....
(7) For Nurse Aide Scholarship Programs operated under contract with the Oklahoma Health Care Authority, compliance may begin July 1, 2014, but shall be required no later than August 1, 2014.

.....
(c) Nurse Aide Scholarship Programs. For the purposes of complying with Title 63 O.S. Section 1-1947(G) (related to conducting a registry screening and criminal history record check), the Nurse Aide Scholarship Program may refer the applicant's application and release to the Department for registry screening and authorization to collect fingerprints.

Agency Rule Contact:

James Joslin, Chief, Health Resources Development Service, Oklahoma State Department of Health, 1000 N.E. 10th Street, Oklahoma City, OK 73117-1207, phone 405-271-6868, or by e-mail to james@health.ok.gov.



Oklahoma State Department of Health
Creating a State of Health

To: Board of Health Secretary

Through: Terry Cline, Ph.D. *F.C. 11-20-2013*
Commissioner

Through: James Joslin *JJ*
Agency Rule Liaison

Through: Hank Hartsell, Ph.D. *HHH*
Deputy Commissioner

From: James Joslin *JJ*
Agency Rule Liaison

Date: November 8, 2013

Subject: Rule Packet Submission for Distribution to Board of Health
CHAPTER 100. LICENSURE OF CREMATORIES

The attached documents are submitted for PERMANENT REVOCATION by the State Board of Health at their December 10, 2013, meeting.

No comments were received and there are no changes to the previously reviewed rule.

Attachments:

- **RIS (Rule Impact Statement)**
- **Rule Text**
- **Rule Comment Summary**

(Please contact James Joslin at x57209 for corrections, pick-up and delivery.)

RULE IMPACT STATEMENT

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 100. LICENSURE OF CREMATORIES

Before the Oklahoma State Board of Health December 10, 2013

1. DESCRIPTION:

This proposal revokes the rules of the Board of Health concerning the licensure of crematories. The duties and functions concerning licensure of crematories were transferred by statutory modification from the Oklahoma State Department of Health to the Oklahoma Funeral Board. The Oklahoma Funeral Board has adopted rules for the licensure of crematories.

2. DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:

Affected persons will be applicants for a license to operate a crematorium and current license holders who operate crematoriums.

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

Those benefiting from the rule's implementation are applicants for a license to operate a crematorium and current license holders who operate crematoriums. The value of the benefit is that the applicants and licensees will have one location, the Oklahoma Funeral Board to obtain services.

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

There will be no economic impact to the applicants and to licensees. There is the revocation of a \$25.00 annual fee for licensees.

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

There will be no cost to the Department of Health to implement and enforce these rule changes. There will be a benefit to the Department of Health due to no longer needed to expend resources for the licensing of crematoriums as that duty is now with the Oklahoma Funeral Board.

6. IMPACT ON POLITICAL SUBDIVISIONS:

The Oklahoma Funeral Board has assumed the duties of the licensure of crematoriums in Oklahoma. The impact on the Oklahoma Funeral Board has already occurred.

7. ADVERSE EFFECT ON SMALL BUSINESS:

There will be no adverse impact or effect on small business with the passage of these rule modifications.

8. EFFORTS TO MINIMIZE COSTS OF RULE:

No less costly or nonregulatory methods have been identified.

9. EFFECT ON PUBLIC HEALTH AND SAFETY:

Implementation of these rule modifications will allow the regulated community the opportunity to have all licensure and enforcement issues handled in one location, as opposed to having these issues split between different agencies.

10. DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:

If these rules are not revoked could have a detrimental effect on the regulated community by causing potential confusion with the program now under the authority of the Oklahoma Funeral Board.

11. This rule impact statement was prepared on August 27, 2013.

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH

CHAPTER 100. LICENSURE OF CREMATORIES [REVOKED]

310:100-1-1. Purpose [REVOKED]

~~The rules in this Chapter implement the crematory licensure law, at 63 O.S. 1981, § 1-331.~~

310:100-1-2. Fee [REVOKED]

~~Licensure requirements for all crematories shall be subject to a licensure fee of \$25.00 each calendar year and each crematory shall be in compliance with the requirements set forth in 63 O.S. 1981, Sections 1-331 through 1-333, with the exception that the State commissioner of Health may exempt from the licensure fee nonprofit crematories that are state owned and/or state operated.~~

RULE COMMENT SUMMARY AND RESPONSE

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 100. LICENSURE OF CREMATORIES**

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)]

No comments were received during the comment period or during the public hearing.

Agency Rule Contact:

James Joslin, Chief, Health Resources Development Service, Oklahoma State Department of Health, 1000 N.E. 10th Street, Oklahoma City, OK 73117-1207, phone 405-271-6868, or by e-mail to james@health.ok.gov.



Oklahoma State Department of Health
Creating a State of Health

To: Board of Health Secretary

Through: Terry Cline, Ph.D. *T.C. 11-20-2013*
Commissioner

Through: James Joslin, Chief *JJ*
Agency Rule Liaison

Through: Hank Hartsell, Ph.D. *HH*
Deputy Commissioner

From: James Joslin *JJ*
Agency Rule Liaison

Date: November 8, 2013

Subject: Rule Packet Submission for Distribution to Board of Health
CHAPTER 276. HOME INSPECTION INDUSTRY

The attached documents are submitted for **PERMANENT REVOCATION** by the State Board of Health at their December 10, 2013, meeting.

No comments were received and there are no changes to the previously reviewed rule.

Attachments:

- **RIS (Rule Impact Statement)**
- **Rule Text**
- **Rule Comment Summary**

(Please contact James Joslin at x57209 for corrections, pick-up and delivery.)

RULE IMPACT STATEMENT

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 276. HOME INSPECTION INDUSTRY

Before the Oklahoma State Board of Health December 10, 2013

1. DESCRIPTION:

This proposal revokes the rules of the Board of Health concerning the home inspection industry. Effective November 1, 2008, the authority to "adopt, amend, repeal, and promulgate rules as may be necessary to regulate . . . home inspectors" was transferred from the Oklahoma State Department of Health to the Construction Industries Board [see 59 O.S., § 1000.4]. The Construction Industries Board promulgated emergency rules, effective November 11, 2008, and later superseded those emergency rules with permanent rules, effective July 11, 2009 [see Construction Industries Board rules OAC 158:70 and 158:10-3-5].

2. DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:

No persons are affected by this revocation. The authority to "adopt, amend, repeal, and promulgate rules as may be necessary to regulate . . . home inspectors" was transferred from the Oklahoma State Department of Health to the Construction Industries Board in 2008. All licensure and oversight of Home Inspectors continues without change under the oversight of the Construction Industries Board.

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

This revocation eliminates confusion to the industry and public in determining the correct regulatory authority applicable to the industry.

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

There will be no economic impact to Home Inspectors or the industry as a whole.

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

There will be no cost to the Department of Health to implement and these rule changes other than the cost of promulgating this rule revocation.

6. IMPACT ON POLITICAL SUBDIVISIONS:

There will be no impact on Political subdivisions.

7. ADVERSE EFFECT ON SMALL BUSINESS:

There will be no adverse impact or effect on small business with the revocation of this Chapter.

8. EFFORTS TO MINIMIZE COSTS OF RULE:

No less costly or nonregulatory methods have been identified.

9. EFFECT ON PUBLIC HEALTH AND SAFETY:

Implementation of the revocation of this Chapter eliminates potential confusion regarding the applicable requirements for licensure of Home Inspectors.

10. DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:

If these rules are not revoked, there could be a detrimental effect on the regulated community by causing potential confusion regarding the agency with authority for licensure, which is now the Construction Industries Board.

11. This rule impact statement was prepared on September 24, 2013.

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 276. HOME INSPECTION INDUSTRY [REVOKED]

SUBCHAPTER 1. GENERAL PROVISIONS [REVOKED]

310:276-1-1. Purpose [REVOKED]

~~The rules in this Chapter implement the Home Inspection Licensing Act, Title 59 O.S. 2001, § 858-621 et seq.~~

310:276-1-2. Definitions [REVOKED]

~~The following words or terms, when used in this Chapter, shall have the following meaning, unless the context clearly indicates otherwise:~~

~~"Act" means the Home Inspection Licensing Act, found at 59 O.S.~~

~~§ 858-621 et seq.~~

~~"Alarm systems" means warning devices, installed or free-standing, including but not limited to: carbon monoxide detectors, flue gas and other spillage detectors, security equipment, ejector pumps and smoke alarms.~~

~~"Applicant" means any person applying for an examination for a license or registration under the Act.~~

~~"Architectural service" means any practice involving the art and science of building design for construction of any structure or grouping of structures and the use of space within and surrounding the structures or the design for construction, including but not specifically limited to, schematic design, design development, preparation of construction contract documents, and administration of the construction contract.~~

~~"Board" means the State Board of Health.~~

~~"Certificates of course completion" means a document acceptable to the Committee which signifies satisfactory completion of course work and reflects the hours of credit earned.~~

~~"Cheating" means any unapproved deviation from any official instruction given before, during or after a home inspector license examination for the purpose of affecting or influencing the examination results or otherwise providing an undue advantage to any examinee.~~

~~"Classroom hour" is equal to fifty (50) minutes out of each sixty (60) minute segment.~~

~~"Client" means a person with a direct material interest in the outcome of a home inspection who hires and compensates a home inspector for the performance of a home inspection.~~

~~"Commissioner" means the State Commissioner of Health.~~

~~"Committee" means the Committee of Home Inspector Examiners~~

established by the Home Inspector Licensing Act, 59 O.S. 858-624.

— "**Component**" means a part of a system.

— "**Continuing education**" means education that is approved by the Committee to satisfy education requirements in order to renew licensure as a home inspector.

— "**Continuing education verification form**" means a form acceptable to the Committee and completed by the course provider, that documents compliance with the continuing education requirements.

— "**Decorative**" means ornamental; not required for the operation of the essential systems and components of a home.

— "**Defect**" means a condition, malfunction or problem, which is not decorative, that would have a materially adverse effect on the value of a system or component, or would impair the health or safety of the occupants or client.

— "**Department**" means the Oklahoma State Department of Health.

— "**Describe**" means to report a system or component by its type or other observed, significant characteristics to distinguish it from other systems or components.

— "**Dismantle**" means to take apart or remove any component, device or piece of equipment that would not be taken apart or removed by a homeowner in the course of normal and routine homeowner maintenance.

— "**Engineering service**" means any professional service or creative work requiring engineering education, training, and experience and the application of special knowledge of the mathematical, physical and engineering sciences to such professional service or creative work as consultation, investigation, evaluation, planning, design and supervision of construction for the purpose of assuring compliance with the specifications and design, in conjunction with structures, buildings, machines, equipment, works or processes.

— "**Further evaluation**" means examination and analysis by a qualified professional, tradesman or service technician beyond that provided by the home inspection.

— "**Home**" or "**residence**" means any dwelling, from one to four (1-4) units in design, intended principally for residential purposes by one (1) or more individuals.

— "**Home inspection**" or "**inspection**" means a visual examination of any or all of the readily accessible physical real property and improvements to real property consisting of four or fewer dwelling units, including structural, lot drainage, roof, electrical, plumbing, heating and air conditioning and such other areas of concern as are specified in writing to determine if performance is as intended. [59:858-622(5)]

— "**Home inspection license unit**" means the staff and administrative support unit to the Committee of Home Inspector

Examiners.

— "**Home inspection report**" means a written opinion of the functional and physical condition of property written by the licensed home inspector pursuant to home inspection.

— "**Home inspector**" means an individual licensed pursuant to the Home Inspection Licensing Act who, for compensation, conducts home inspections.

— "**Inspect**" means to examine readily accessible systems and components of a building in accordance with these Standards of Practice, using normal operating controls and opening readily openable access panels.

"**Installed**" means attached such that removal requires tools.

— "**Instructor**" means a person who presents course materials approved for qualifying education and continuing education credit hours that has the experience, training, and/or education in the course subject matter and has been approved by the Committee.

— "**Normal working order**" means the system or component functions without defect for the primary purpose and manner for which it was installed.

— "**Normal operating controls**" means devices such as thermostats, switches or valves intended to be operated by the homeowner.

— "**Professional craftsman**" means a person who can demonstrate by certification, education or experience, specialized skill in the construction or repair of homes, duplexes, apartment buildings or similar structures. Persons demonstrating specialized skill by experience alone must be able to show that they have been actively engaged in their profession, trade or craft for at least one (1) year prior to the performance of a single item inspection.

— "**Provider**" means a person, corporation, professional association or its local affiliates, or any other entity, which is approved by the Committee and provides approved qualifying and continuing education to home inspectors.

— "**Readily accessible**" means available for visual inspection without requiring moving of personal property, dismantling, destructive measures, or any action which will likely involve risk to persons or property.

— "**Readily openable access panel**" means a panel provided for homeowner inspection and maintenance that is within normal reach, can be removed by one person, and is not sealed in place.

— "**Reciprocity agreement**" means an agreement whereby a home inspector who is licensed in other states with substantially similar or greater licensure requirements may be licensed in this State after payment of a fee for licensing by reciprocity.

— "**Recreational facilities**" means spas, saunas, steam baths, swimming pools, exercise, entertainment, athletic, playground or other similar equipment and associated accessories.

— "**Report**" means to communicate in writing.

~~"Representative number" means one component per room for multiple similar interior components such as windows and electric outlets; one component on each side of the building for multiple similar exterior components.~~

~~"Roof drainage systems" means components used to carry water off a roof and away from a building.~~

~~"Shut down" means a state in which a system or component cannot be operated by normal operating controls.~~

~~"Solid fuel burning appliances" means a hearth and fire chamber or similar prepared place in which a fire may be built and which is built in conjunction with a chimney; or a listed assembly of a fire chamber, its chimney and related factory-made parts designed for unit assembly without requiring field construction.~~

~~"Structural component" means a component that supports non-variable forces or weights (dead loads) and variable forces or weights (live loads).~~

~~"System" means a combination of interacting or interdependent components, assembled to carry out one or more functions.~~

~~"Technically exhaustive" means an investigation that involves dismantling, the extensive use of advanced techniques, measurements, instruments, testing, calculations, or other means.~~

~~"Under-floor crawl space" means the area within the confines of the foundation and between the ground and the underside of the floor.~~

~~"Unsafe" means a condition in a readily accessible, installed system or component which is judged to be a significant risk of personal injury during normal operation. The risk may be due to damage, deterioration, improper installation or a change in accepted residential construction standards.~~

~~"Wiring methods" means identification of electrical conductors or wires by their general type, such as "non-metallic sheathed cable" ("Romex"), "armored cable" ("bx") or "knob and tube", etc.~~

310:276-1-3. Standards of workmanship and practice [REVOKED]

~~(a) General requirements and limitations.~~

~~(1) The inspector shall be governed by the following general requirements:~~

~~(A) Only readily accessible systems and components of homes listed in these Standards shall be required to be inspected.~~

~~(B) Only installed systems and components of homes listed in these Standards shall be required to be inspected.~~

~~(C) The inspector shall report on those systems and components inspected which, in the professional opinion of the inspector, are not in normal working order.~~

~~(D) The inspector shall report a reason why, if not self-evident, the system or component is not in normal working order.~~

~~(E) The inspector shall report the inspector's recommendations to correct or monitor the reported deficiency.~~

~~(F) The inspector shall report on any systems and components designated for inspection in these Standards which were present at the time of the Home Inspection but were not inspected and a reason they were not inspected.~~

~~(G) These Standards are not intended to limit inspectors from including other inspection services, systems or components in addition to those required by these Standards.~~

~~(H) These Standards are not intended to limit inspectors from specifying repairs and providing an opinion of the costs to cure, provided the inspector is appropriately qualified and willing to do so.~~

~~(I) These Standards are not intended to limit inspectors from excluding systems and components from the inspection if requested by the client.~~

~~(J) Beginning July 1, 2006, all home inspectors shall maintain a log or record of all home inspections performed for a minimum period of five years from the date of inspection. The log shall include the name of the client, the address of the property, and the date of the inspection. The home inspector shall maintain a copy of all home inspections completed within the past 36 months. The log may be a hard file or an electronic file and shall be maintained at the home inspector's principal business address. The files shall be available for review upon the request of an authorized representative of the Oklahoma State Department of Health.~~

~~(2) Inspections performed in accordance with these Standards are not technically exhaustive, will not identify concealed conditions or latent defects, and are applicable to buildings with four or fewer dwelling units and their garages or carports.~~

~~(3) The inspector is not required to perform any action or make any determination unless specifically stated in these Standards, except as may be required by lawful authority.~~

~~(4) Inspectors are not required to determine the condition of systems or components which are not readily accessible, the remaining life of any system or component, the strength, adequacy, effectiveness, or efficiency of any system or component, the causes of any condition or deficiency, the methods, materials, or costs of~~

~~corrections, future conditions including, but not limited to, failure of systems and components, the suitability of the property for any specialized use, compliance with any regulatory requirements other than this Chapter (codes, regulations, laws, ordinances, etc.), the market value of the property or its marketability, the advisability of the purchase of the property, the presence of potentially hazardous plants or animals including, but not limited to wood destroying organisms or diseases harmful to humans, the presence of any environmental hazards including, but not limited to toxins, carcinogens, noise, and contaminants in soil, water, and air, the effectiveness of any system installed or methods utilized to control or remove suspected hazardous substances, the operating costs of systems or components, or the acoustical properties of any system or component.~~

~~(5) Inspectors are not required to offer or perform any act or service contrary to law, perform engineering services, perform work in any trade or any professional service other than home inspection, or warranties or guarantees of any kind.~~

~~(6) Inspectors are not required to operate any system or component which is shut down or otherwise inoperable, any system or component which does not respond to normal operating controls, or shut-off valves.~~

~~(7) Inspectors are not required to enter any area which will, in the opinion of the inspector, likely be dangerous to the inspector or other persons or damage the property or its systems or components, or the under-floor crawl spaces or attics which are not readily accessible.~~

~~(8) Inspectors are not required to inspect underground items including, but not limited to underground storage tanks or other underground indications of their presence, whether abandoned or active, systems or components which are not installed, decorative items, systems or components located in areas that are not entered in accordance with these Standards, detached structures other than garages and carports, or common elements or common areas in multi-unit housing, such as condominium properties or cooperative housing.~~

~~(9) Inspectors are not required to perform any procedure or operation which will, in the opinion of the inspector, likely be dangerous to the inspector or other persons or damage the property or its systems or components, move suspended ceiling tiles, personal property, furniture, equipment, plants, soil, snow, ice, or debris, or dismantle any system or component, except as explicitly required by~~

~~these Standards.~~

~~(b) **Structural system inspection requirements.**~~

~~(1) The inspector shall inspect the structural components including foundation and framing, by probing a representative number of structural components where deterioration is suspected or where clear indications of possible deterioration exist. Probing is not required when probing would damage any finished surface or where no deterioration is visible.~~

~~(2) The inspector shall describe the foundation and report the methods used to inspect the under-floor crawl space, the floor structure, the wall structure, the ceiling structure, and the roof structure and report the methods used to inspect the attic.~~

~~(3) The inspector is not required to provide any engineering service or architectural service, or offer an opinion as to the adequacy of any structural system or component.~~

~~(c) **Exterior inspection requirements.**~~

~~(1) The inspector shall inspect the exterior wall covering, flashing and trim, all exterior doors, attached decks, balconies, stoops, steps, porches, and their associated railings, the eaves, soffits, and fascias where readily accessible from the ground level, the vegetation, grading, surface drainage, and retaining walls on the property when any of these are likely to adversely affect the building, and the walkways, patios, and driveways leading to dwelling entrances.~~

~~(2) The inspector shall describe the exterior wall covering.~~

~~(3) The inspector is not required to inspect screening, shutters, awnings, and similar seasonal accessories, fences, geological, geotechnical or hydrological conditions, recreational facilities, outbuildings, seawalls, break-walls, and docks, and erosion control and earth stabilization measures.~~

~~(d) **Roof system inspection requirements.**~~

~~(1) The inspector shall inspect the roof covering, the roof drainage systems, the flashings, the skylights, chimneys, and roof penetrations.~~

~~(2) The inspector shall describe the roof covering and report the methods used to inspect the roof.~~

~~(3) The inspector is not required to inspect antennae, interiors of flues or chimneys which are not readily accessible, or other installed accessories.~~

~~(e) **Plumbing system inspection requirements.**~~

~~(1) The inspector shall inspect the interior water supply~~

~~and distribution systems including all fixtures and faucets, the drain, waste and vent systems including all fixtures, the water heating equipment, the vent systems, flues, and chimneys, the fuel storage and fuel distribution systems, and the drainage sumps, sump pumps, and related piping.~~

~~(2) The Inspector shall describe the water supply, drain, waste, and vent piping materials, the water heating equipment including the energy source, and the location of main water and main fuel shut-off valves.~~

~~(3) The inspector is not required to inspect, the clothes washing machine connections, the interiors of flues or chimneys which are not readily accessible, wells, well pumps, or water storage related equipment, water conditioning systems, solar water heating systems, fire and lawn sprinkler systems, or private waste disposal systems.~~

~~(4) The inspector is not required to determine whether water supply and waste disposal systems are public or private, the quantity or quality of the water supply, or operate safety valves or shut-off valves.~~

~~(f) **Electrical system inspection requirements.**~~

~~(1) The Inspector shall inspect the service drop, the service entrance conductors, cables, and raceways, the service equipment and main disconnects, the service grounding, the interior components of service panels and sub panels, the conductors, the overcurrent protection devices, all readily accessible installed lighting fixtures, switches, ceiling fans, and receptacles, the ground fault circuit interrupters, and accessible wiring and splicing including the basement and attic.~~

~~(2) The Inspector shall describe the amperage and voltage rating of the service, the location of main disconnect(s) and sub panels, and the wiring methods.~~

~~(3) The Inspector shall report the presence of solid conductor aluminum branch circuit wiring, and the absence of smoke detectors.~~

~~(4) The inspector is not required to inspect the remote control devices unless the device is the only control device, the alarm systems and components, the low voltage wiring, systems and components, the ancillary wiring, systems and components not a part of the primary electrical power distribution system, or measure amperage, voltage, or impedance.~~

~~(g) **Heating system inspection requirements.**~~

~~(1) The inspector shall inspect the installed heating equipment, the vent systems, flues, and chimneys.~~

~~(2) The inspector shall describe the energy source, and the~~

heating method by its distinguishing characteristics.

- ~~(3) The inspector is not required to inspect the interiors of flues or chimneys, which are not readily accessible, the humidifier or dehumidifier, the electronic air filter, the solar space heating system, or determine heat supply adequacy or distribution balance.~~

~~(h) **Air conditioning systems inspection requirements.**~~

- ~~(1) The inspector shall inspect the installed central and through-wall cooling equipment.~~
- ~~(2) The inspector shall describe the energy source, and the cooling method by its distinguishing characteristics.~~
- ~~(3) The inspector is not required to inspect electronic air filters, or determine cooling supply adequacy or distribution balance.~~

~~(i) **Interior inspection requirements.**~~

- ~~(1) The inspector shall inspect the readily accessible walls, ceilings, and floors, the steps, stairways, and railings, the countertops and a representative number of installed cabinets, and the readily accessible doors and windows, garage doors and garage door openers, and the following installed household appliances: garbage disposal, stove, cook top, dishwasher, vent hood, and free-standing stove.~~
- ~~(2) The inspector is not required to inspect the paint, wallpaper, and other finish treatments, the carpeting, the window treatments, the central vacuum systems, the household appliances not listed in OAC 310:276-1-3(i)(1), or recreational facilities.~~

~~(j) **Insulation and ventilation inspection requirements.**~~

- ~~(1) The inspector shall inspect the insulation and vapor retarders in unfinished spaces, the ventilation of attics and foundation areas, and the mechanical ventilation systems.~~
- ~~(2) The inspector shall describe the insulation and vapor retarders in unfinished spaces, and the absence of insulation in unfinished spaces at conditioned surfaces.~~
- ~~(3) The inspector is not required to disturb insulation or vapor retarders, or determine indoor air quality.~~

~~(k) **Fireplaces and solid fuel burning appliances inspection requirements.**~~

- ~~(1) The inspector shall inspect the vent systems, flues, and chimneys and the readily accessible portion of the firebox.~~
- ~~(2) The inspector shall describe the fireplaces and solid fuel burning appliances, and the chimneys.~~
- ~~(3) The inspector is not required to inspect the interiors of flues or chimneys, the firescreens and doors, the seals~~

~~and gaskets, the automatic fuel feed devices, the mantels and fireplace surrounds, the combustion make-up air devices, or the heat distribution assists whether gravity controlled or fan assisted.~~

~~(4) The inspector is not required to ignite or extinguish fires, determine draft characteristics, or move fireplace inserts or stoves or firebox contents.~~

SUBCHAPTER 3. PROCEDURES OF THE COMMITTEE [REVOKED]

310:276-3-1. Procedures of the Committee [REVOKED]

~~(a) Committee meetings are generally, and unless otherwise stated by the Committee, held in the State Department of Health Building at 1000 N.E. 10th Street, Oklahoma City, Oklahoma 73117-1299. The committee shall meet as often as is necessary, but at least once each quarter. Meetings of the committee will comply with the Oklahoma Open Meetings Act.~~

~~(b) The Committee shall provide oversight to the overall licensure examination process; shall set minimum standards for certifying qualified applicants; may write examinations; may recommend regulations to the Commissioner and to the Board of Health; and, shall act as advisor to the Commissioner on home inspection matters.~~

~~(c) The only formal procedure available to the public is to apply for a home inspection license. Application for a home inspection license shall be accomplished by filling out an application for examination on a form provided by the Committee.~~

~~(d) The public may communicate with the Committee in person or by mail through the Department. The Department will make available all forms and instructions used by the Committee, rules, and all other written statements of policy or interpretations, all final orders, decisions and opinions. Copies of same may be provided in accordance with OAC 310:2-3-5.~~

SUBCHAPTER 5. LICENSE REQUIREMENTS, LICENSE FEES, LICENSE PERIOD, RE-EXAMINATION, DISPLAY AND INSURANCE [REVOKED]

310:276-5-1. Home inspection license requirements [REVOKED]

~~No person, on behalf of himself or a firm or company engaged in home inspection work shall engage or offer to engage in, by advertisement or otherwise, any home inspection work who does not possess a valid and appropriate license from the Department, unless otherwise exempt by law.~~

310:276-5-2. License fees, license period, re-examination, display, and insurance requirements [REVOKED]

~~(a) **Initial license fees.** The following fees apply to home inspection industry licensure:~~

- ~~(1) Approval fees for schools, instructors and home inspection organizations — \$100.00~~
- ~~(2) Approval fees for educational course content — \$50.00~~
- ~~(3) Application for license — \$30.00~~
- ~~(4) Licensure for reciprocity — \$50.00~~
- ~~(5) Examination fee — \$200.00~~
- ~~(6) License fee — \$250.00~~
- ~~(7) License Renewal — \$150.00~~
- ~~(8) License reactivation — \$50.00~~

~~(b) **License period.**~~

- ~~(1) A license shall expire twelve months after issuance, and may be renewed without penalty during the month following expiration.~~
- ~~(2) A license which has been expired for more than one (1) year shall not be renewed. An individual may obtain a valid license by successful completion of the appropriate examination and other licensure requirements.~~

~~(c) **Re-examination.** Any applicant who fails an examination must wait thirty (30) days before retaking the home inspection examination.~~

~~(d) **License display.** The state issued license number shall be placed on all letterhead stationery, business cards, bids, estimates and printed advertisements, and shall be included in electronic media advertisements. Decals and yard signs shall display the state issued license number.~~

~~(e) **Personal license display.** All persons subject to these rules shall possess the state issued card any time the person is working. The card shall be shown when requested.~~

~~(f) **Insurance requirements.** Each licensee must maintain insurance coverage and furnish and maintain in effect a certificate of insurance therefor which indicates that the licensee has a comprehensive general liability policy. Limits of liability are to be no less than \$50,000.00 combined single limit for bodily injury and property damage. The certificate of insurance shall provide for thirty (30) days notice to the Home Inspection License Unit, prior to cancellation or material alteration of the required insurance.~~

SUBCHAPTER 7. [RESERVED] [REVOKED]

**SUBCHAPTER 9. EXAMINATION APPLICATIONS, EXAMINATIONS, COURSE
APPROVAL REQUIREMENTS, INSTRUCTOR REQUIREMENTS, CONTINUING
EDUCATION, DENIED APPLICATION APPEAL, SUBMISSION OF RECORDS,
AND SUBSTANTIAL COMPLIANCE AND RECIPROCITY [REVOKED]**

**310:276-9-1. Qualifications and examination applications
[REVOKED]**

~~Applicants for home inspection license examinations must be eighteen (18) years of age or older and be of good moral character, and every application must be accompanied by evidence of successful completion of fifty (50) clock hours of home inspection training that is approved pursuant to 310:276-9-3, or its equivalent.~~

310:276-9-2. Examinations [REVOKED]

~~(a) Home inspection license examinations may include, without limitation, written questions, consisting of open book, closed book and problems, based on current national standards, and other related questions.~~

~~(b) The maximum grade value of each part of the examination shall be 100 points. A passing score is 70% or more on each part.~~

~~(c) Each applicant shall pay the examination fee before undertaking any examination. Reexamination fees shall be the same as the initial examination fees.~~

~~(d) Unless authorized by the Committee, only examinees shall be permitted in the examination area.~~

~~(e) Applicants shall present positive identification before undertaking an examination.~~

~~(f) Any applicant who fails an examination must wait thirty (30) days before retaking the home inspection examination.~~

~~(g) An examinee cheating or fraudulently representing an applicant shall immediately be expelled from the examination. A written record of the proceedings shall be made and become a part of the applicant's file. The Committee shall determine when the applicant may retake the exam, which time shall be no fewer than three hundred sixty-five (365) days.~~

310:276-9-3. Course approval requirements [REVOKED]

~~(a) Any person or entity seeking to conduct an approved course for qualifying or continuing education credits shall make application and submit documents, statements and forms as may reasonably be required by the Committee in accordance with~~

~~Section 310:276-5-2.~~

~~(b) Applications shall include the following information:~~

- ~~(1) Name and address of the provider;~~
- ~~(2) Contact person and his or her address, telephone number and fax number;~~
- ~~(3) The location of the courses or programs;~~
- ~~(4) The number and type of education credit hours requested for each course;~~
- ~~(5) Topic outlines, which list the summarized topics, covered in each course and upon request a copy of any course materials;~~
- ~~(6) If a prior approved course has substantially changed, a summarization of these records;~~
- ~~(7) The names and qualifications of each instructor who is qualified in accordance with Section 310:276-9-4 and;~~
- ~~(8) Information as to how the proposed course meets the standard provided in Section 310:276-9-5(b).~~

~~(c) The Department may automatically accept without further review, courses pre-approved by the Committee.~~

~~(d) The Committee may withhold or withdraw approval of any provider for violation of or non-compliance with any provision of this section.~~

~~(e) No person or entity sponsoring or conducting a course shall advertise that it is endorsed, recommended, or accredited by the Committee. Such person or entity may indicate that the Committee has approved a course of study if that course of study has been pre-approved by the committee before it is advertised or held.~~

~~(f) The Committee may decline to renew, or revoke the approval of any qualifying course or any instructor or entity previously approved to conduct a pre-licensing course upon a showing or demonstration that the course, instructor or entity has substantially failed to adequately prepare its attendees or participants to pass the national Home Inspection Examination or similar qualifying examination.~~

310:276-9-4. Instructor requirements [REVOKED]

~~(a) **Instructor Qualifications.** An instructor should have one of the following qualifications:~~

- ~~(1) Three (3) years of recent experience in the subject matter being taught; or~~
- ~~(2) A degree related to the subject area being taught; or~~
- ~~(3) Two (2) years of recent experience in the subject area being taught and twelve (12) hours of college credit and/or vocational technical school technical credit hours in the subject being taught.~~
- ~~(4) Other educational, teaching, or professional~~

~~qualifications determined by the Committee which constitute an equivalent to one or more of the qualifications in the previously stated sub-paragraphs (1), (2), and (3) of this paragraph.~~

~~(b) **Instructor Renewal.**— In order to maintain approved status, an instructor must furnish evidence that the instructor has taught a Committee approved course, or any other CEU course the Committee determines to be equivalent, within a required thirty-six (36) month period.~~

~~(c) **Re-application.**— Any instructor not meeting the requirements of this subsection will be required to re-apply as an original instructor applicant.~~

310:276-9-5. Continuing education [REVOKED]

~~(a) **Continuing education hours.**— No home inspection license shall be renewed unless the licensee has completed at least five (5) clock hours of continuing education prior to the date of renewal.~~

~~(b) **Special Approval requirements for continuing education.**— All continuing education providers shall abide by the following requirements:~~

~~— (1) Course content should be designed to update knowledge and improve inspection skills directly related to the components and systems described in Subchapter 1 of this Chapter.~~

~~— (2) All courses shall be at least two (2) hours in length.~~

~~— (3) Unless provided after regular working hours, the training location shall be outside the regular work place.~~

~~— (4) Each attendee shall complete a course evaluation on a form provided by the Department. The CEU provider shall return the completed evaluation forms to the home inspection license unit with the sign-in sheets.~~

310:276-9-6 Denied application appeal [REVOKED]

~~(a) **Denied Instructor/Provider Application.**— If the Committee fails to approve or rejects any proposed instructor or entity seeking to conduct an approved course, the Committee shall give written notice of the rejection and the cause therefore within fifteen (15) days after such decision. The applicant may appeal the decision by filing a written request for a hearing before the Committee within thirty (30) days after notice of denial. The Committee shall set the matter for hearing to be conducted within sixty (60) days thereafter. No part of the application fee is refundable.~~

~~(b) **Denied Course Application.**— If the Committee fails to~~

~~approve or rejects any proposed continuing education offering or fifty (50) hour home inspection training course, the Committee shall give written notice of the rejection and the cause therefore within fifteen (15) days after such decision to the party applying for approval. Upon the written request from such party, filed within thirty (30) days after such notice of denial, the Committee shall set the matter for hearing to be conducted within sixty (60) days thereafter for an appeal of the determination of the cause for rejection. No portion of the fee is refundable.~~

310:276-9-7 Submission of records [REVOKED]

~~(a) An entity conducting an offering shall, within five (5) working days of the completion thereof, submit to the Committee on a form approved by the Committee, a list of the names and license numbers or social security numbers of the licensees who successfully completed the said offering. Each licensee successfully completing an offering shall be furnished a certificate certifying completion.~~

~~(b) Providers shall maintain course records for at least five (5) years. The Committee may order an examination of the records for good cause shown.~~

310:276-9-8 Substantial compliance and reciprocity [REVOKED]

~~(a) In addition to accepting courses approved as described in this Subchapter, qualifying and continuing education credits may be granted to an individual in such case that said individual supplies acceptable documentation showing that the offering meets applicable Committee requirements for the category of credit applied for, including proof that said individual attended and successfully completed the offering.~~

~~(b) If a non-resident licensee satisfies a continuing education requirement in another state for license renewal, the Committee will exempt the non-resident licensee from the continuing education requirement in the state. In order to qualify for the exemption, the non-resident licensee must file with the license renewal of this state a certificate from the state in which the continuing education was satisfied stating that the non-resident licensee had completed the continuing education requirement for license renewal in that state. The certificate from the state verifying the non-resident's compliance with continuing education in the other state must be received by the Committee within sixty (60) days of issuance by the other state and must be received in conjunction with license renewal.~~

SUBCHAPTER 11. LICENSE REVOCATION AND SUSPENSION AND ADDITIONAL PROHIBITED ACTS [REVOKED]

310:276-11-1. License revocation and suspension [REVOKED]

~~(a) The employment or use of unlicensed individuals may be grounds to suspend, revoke, or deny renewal of the license of the person so employing or using unlicensed individuals.~~

~~(b) The repeated violation of any rule or provision of the Act, or the violation of multiple sections of this Chapter or provisions of the Act, may be grounds to suspend or revoke a licensee's license.~~

~~(c) Any person convicted in a court of competent jurisdiction of forgery, fraud, conspiracy to defraud, or any similar offense, or pleading guilty or nolo contendere to any such offense may be subject to license suspension or revocation.~~

~~(d) Any person failing to comply with a fine assessment or other administrative order of the Department within ninety (90) days of issuance of such assessment or order shall be subject to license suspension.~~

~~(e) Any person whose license is suspended pursuant to these Rules may not perform a home inspection and, prior to reinstatement, must make application therefor, which must be accompanied by evidence of successful completion of the continuing education requirements set forth in OAC 310:276-9-3.~~

~~(f) Any person whose license is revoked pursuant to these rules may not perform a home inspection before attaining licensure pursuant to OAC 310:276-9-1.~~

~~(g) Failure to cooperate or provide information regarding an investigation may be grounds to suspend or revoke a licensee's home inspection license.~~

~~(h) Failure to maintain and furnish a certificate of insurance coverage as provided in OAC 310:276-5-2(f) may be grounds to suspend or revoke a licensee's home inspection license.~~

310:276-11-2. Additional prohibited acts [REVOKED]

~~(a) No person, entity, or firm may perform home inspection work without first obtaining a license or registration pursuant to these Rules.~~

~~(b) No person shall offer to engage in work as a home inspector during the period his or her license is suspended or revoked.~~

~~(c) No employing home inspection firm shall employ or use an unlicensed home inspector to perform home inspection work.~~

~~(d) No person, entity, or firm may transfer a license or registration.~~

~~(c) No home inspector, licensed pursuant to this Chapter, shall enter into an agreement for the use of his or her license with any firm or person who is, or has been adjudicated to be, in violation of any provision of the Act, or whose license is currently suspended or has within the last year been revoked, unless or until otherwise approved by the Department.~~

~~(f) No person shall make a materially false or fraudulent statement in an application for license or for approval of continuing education, engage in cheating, or otherwise commit an act in violation of 310:276-9-2(g).~~

~~(g) No person shall falsify or fail to disclose in a home inspection report a material defect.~~

~~(h) No person shall accept inspection assignments when the employment itself is contingent upon reporting a predetermined estimate, analysis or opinion.~~

~~(i) No person shall accept inspection assignments when the fee to be paid is contingent upon the opinion, the conclusion, analysis, or report reached, or upon the consequences resulting from such assignments.~~

~~(j) No person shall perform a home inspection upon a home, or any part thereof, where the home inspector has solicited or performed any work or repair service therein upon a system or component described in Subchapter 1 of this Chapter, within the previous thirty days. If the person performing the home inspection has performed such work within the previous one-hundred eighty days, such prior work must be disclosed to the client.~~

~~(k) No person shall solicit or perform work or repair services upon, home, or any part thereof, that the home inspector has inspected for one (1) year after the date of the inspection.~~

~~(l) No person shall knowingly accept compensation from more than one client for a single home inspection, unless the home inspector has informed all clients who are paying a fee for that home inspection that such compensation is sought or anticipated.~~

~~(m) Unless upon demand in writing by the Department, a law enforcement agency, or by order of a court of competent jurisdiction, no person shall disclose the results of a home inspection to any person other than the client without the written consent of the client.~~

~~(n) No person shall fail to disclose to the client any conflict of interest of which the inspector knows or should have known that may adversely affect the client. Based upon the potentially adverse affect to the home inspector's ability to produce an unbiased report, some circumstances or conditions are presumed to adversely affect the client and must be disclosed to the client in writing prior to the inspection. These include, but are not limited to, the following:~~

~~(1) Situations where the payment of remuneration or other consideration is made by the home inspector to a third party and representing a reward or compensation to the third party for the home inspector receiving inspection employment.~~

~~(2) Situations where the payment of remuneration or other consideration is received by the home inspector from a third party and representing a reward or compensation for the home inspector recommending services or products to the client or other persons having an interest in the inspected real property.~~

~~(3) In those cases where the client is the buyer of real property, situations where the home inspector has had some prior connection, relationship or association with the seller, his or her assigns or family members related to the seller within the second degree.~~

~~(4) Situations where prior reports or inspections have been made or conducted upon any system or component of the real property that the home inspector has agreed to inspect.~~

~~(e) No person shall fail to submit a written home inspection report within a reasonable time as determined by the Board to the client after compensation has been paid to the home inspector.~~

RULE COMMENT SUMMARY AND RESPONSE

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 276. HOME INSPECTION INDUSTRY**

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)]

No comments were received during the comment period or during the public hearing.

Agency Rule Contact:

James Joslin, Chief, Health Resources Development Service, Oklahoma State Department of Health, 1000 N.E. 10th Street, Oklahoma City, OK 73117-1207, phone 405-271-6868, or by e-mail to james@health.ok.gov.



Oklahoma State Department of Health
Creating a State of Health

To: Board of Health Secretary

Through: Terry Cline, Ph.D. *11-20-2013*
Commissioner

Through: James Joslin *JJ*
Agency Rule Liaison

Through: Hank Hartsell, Ph.D. *HH*
Deputy Commissioner

From: James Joslin, Chief *JJ*
Health Resources Development Service

Date: November 8, 2013

Subject: Rule Packet Submission for Distribution to Board of Health
**CHAPTER 658. INDEPENDENT REVIEW ORGANIZATION
CERTIFICATION RULES**

The attached documents are submitted for PERMANENT REVOCATION by the State Board of Health at their December 10, 2013, meeting.

No comments were received and there are no changes to the previously reviewed rule.

Attachments:

- **RIS (Rule Impact Statement)**
- **Rule Text**
- **Rule Comment Summary**

(Please contact James Joslin at x57209 for corrections, pick-up and delivery.)

RULE IMPACT STATEMENT

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 658. INDEPENDENT REVIEW ORGANIZATION CERTIFICATION RULES

Before the Oklahoma State Board of Health December 10, 2013

1. DESCRIPTION:

This proposal revokes the rules of the Board of Health concerning independent review organization certification and external review. Effective August 26, 2011, The Uniform Health Carrier External Review Act, sections 25 through 41 of House Bill 2072 (2011), transferred responsibility for external reviews and approval of independent review organizations to the Oklahoma Insurance Department [see Title 36 O.S. § 6475.1 et. seq.]. The Oklahoma Insurance Department promulgated emergency rules, effective September 12,, 2011, and later superseded those emergency rules with permanent rules, effective July 14, 2012 [see Title 365, Insurance Department, Chapter 10, Subchapter 29 - External Review Regulations.]

2. DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:

No persons are affected by this revocation. Effective August 26, 2011, The Uniform Health Carrier External Review Act, sections 25 through 41 of House Bill 2072 (2011), transferred responsibility for external reviews and approval of independent review organizations to the Oklahoma Insurance Department. All oversight of independent review organizations and external review continues under the authority of the Oklahoma Insurance Department.

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

This revocation eliminates confusion to the industry and public in determining the correct regulatory authority applicable to the industry.

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

There will be no economic impact to the public or industry. All oversight of independent review organizations and external review continues under the authority of the Oklahoma Insurance Department.

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

There will be no cost to the Department of Health to implement and these rule changes other than the cost of promulgating this rule revocation.

6. IMPACT ON POLITICAL SUBDIVISIONS:

There will be no impact on Political subdivisions.

7. ADVERSE EFFECT ON SMALL BUSINESS:

There will be no adverse impact or effect on small business with the revocation of this Chapter.

8. EFFORTS TO MINIMIZE COSTS OF RULE:

No less costly or nonregulatory methods have been identified.

9. EFFECT ON PUBLIC HEALTH AND SAFETY:

Implementation of the revocation of this Chapter eliminates potential confusion regarding the applicable requirements for independent review organizations and external review now under the authority of the Oklahoma Insurance Department.

10. DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:

If these rules are not revoked, there could be a detrimental effect on the regulated community and public by causing potential confusion regarding the agency with authority for oversight of independent review organizations and external review, which is now the Oklahoma Insurance Department.

11. This rule impact statement was prepared on September 24, 2013.

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 658. INDEPENDENT REVIEW ORGANIZATION CERTIFICATION
RULES [REVOKED]

SUBCHAPTER 1. GENERAL PROVISIONS [REVOKED]

310:658-1-1. Purpose [REVOKED]

~~This Chapter provides for certification of independent review organizations under authority of the following laws: 63 O.S. Supp. 1999, Section 2528.1 et seq., (the Oklahoma Managed Care External Review Act); and 75 O.S. Supp. 1998, Section 250.1 through 323, (Administrative Procedures Act).~~

310:658-1-2. Definitions [REVOKED]

~~The following words or terms, when used in this Chapter, shall have the following meaning unless the context clearly indicates otherwise:~~

~~"Act" means the Oklahoma Managed Care External Review Act, Title 63 O.S. Supp. 1999, Section 2528.1 et seq.~~

~~"Department" means the Oklahoma State Department of Health.~~

~~"Designee" means an individual designated through expressed written consent by an insured person to represent the interests of the insured person, including, but not limited to, the insured person's physician or where applicable such person's primary care physician [Title 63 O.S. Supp. 1999, Section 2528.2].~~

~~"Health benefit plan" or "Plan" means individual or group hospital or medical insurance coverage, a not for profit hospital or medical service or indemnity plan, a prepaid health plan, a health maintenance organization, a preferred provider plan, the State and Education Employees Group Insurance Plan, coverage provided by a Multiple Employer Welfare Arrangement (MEWA), or a self insured plan [Title 63 O.S. Supp. 1999, Section 2528.2].~~

~~"Informed consent form" means a document to be signed by the insured person or the designee of the insured person acknowledging receipt of a copy of the terms and conditions of the external review process as provided by Title 63 O.S. Supp. 1999 Section 2528.5 and acknowledging understanding of and consent to such terms and conditions [Title 63 O.S. Supp. 1999, Section 2528.2].~~

~~"Insured person" means an individual who receives medical care and treatment through a health benefit plan. In the case of a minor child, the term includes the parent or legal guardian of the child and, in the case of an incapacitated or partially incapacitated person, the legal guardian of such person [Title 63 O.S. Supp. 1999, Section 2528.2].~~

SUBCHAPTER 3. APPLYING FOR A CERTIFICATE [REVOKED]

310:658-3-1. Application required [REVOKED]

~~(a) Each prospective independent review organization shall apply for a certificate on a form provided by the Department.~~

~~(b) The individual, partnership, association, corporation, or other public or private legal entity responsible for providing or arranging external reviews shall be the applicant for the certificate.~~

310:658-3-2. Description of application form [REVOKED]

~~(a) The application for a certificate requires information to assess the conformity of an independent review organization to the Act and OAC 310:658 as follows:~~

~~(1) A narrative overview of the independent review organization's operations and its experience in conducting external reviews;~~

~~(2) A copy of the independent review organization's basic organizational documents and bylaws, and a organizational chart;~~

~~(3) The chief executive officer's name and biographical information;~~

~~(4) The contact person's name, business address and telephone number;~~

~~(5) A list of names and official capacities of all persons responsible for the activities of the independent review organization, including:~~

~~(A) All members of the governing body, the officers and directors of a corporation, and the partners or associates of a partnership or association; and,~~

~~(B) Disclosure of any contracts or arrangements between them and the independent review organization, including any appearance of a conflict of interest as specified in the Act;~~

~~(6) A description of the procedures for accomplishing informed consent;~~

~~(7) A description of the procedures or methods for ensuring the independence and objectivity of the review organization and review process, to include a description of the method used to establish fees for external reviews, and a description of the method used to ensure timely selection of expert reviewers;~~

~~(8) A description of the procedures or methods for ensuring the independence and objectivity of health care professionals, including procedures for disseminating to the Department information on the current licenses and clinical practice activities of those professionals;~~

- ~~(9) A description of the procedures or methods for ensuring that the identity of a physician cannot be a factor in the decision on an appeal;~~
 - ~~(10) A description of the procedures or methods for ensuring the confidentiality of medical records and other confidential information;~~
 - ~~(11) A description of the procedures or methods for conducting external reviews and expedited reviews within time frames under the Act and OAC 310:658, to include procedures or methods for ensuring the availability of expert reviewers on a timely basis;~~
 - ~~(12) Such other information as is essential for the Department to determine the applicant's conformity to the Act and OAC 310:658.~~
- ~~(b) The application to renew a certificate requires any changes in information previously submitted to the Department by the independent review organization.~~

SUBCHAPTER 5. STANDARDS FOR INDEPENDENT REVIEW ORGANIZATIONS [REVOKED]

310:658-5-1. Procedures for informed consent [REVOKED]

- ~~(a) The independent review organization's written notice of decision to accept an appeal for full external review shall advise the insured person or the designee to submit the informed consent form prescribed by the Department to the independent review organization.~~
- ~~(b) The independent review organization shall ensure that an appeal does not proceed to a full external review before the independent review organization receives the informed consent form signed by the insured person or the designee.~~

310:658-5-2. Independence and objectivity of review organization and process [REVOKED]

- ~~(a) In addition to eligibility requirements set forth in Section 2528.9.C of the Act, no person or entity shall be certified as an independent review organization if it owns or controls, is owned or controlled by, or exercises common control with any national, state or local illness, health benefit or public advocacy group.~~
- ~~(b) The independent review organization shall ensure that the identities of the insured person, the designee, the health benefit plan, and any health professionals and health facilities associated with the insured and the plan are not disclosed to any person who will render a decision on an appeal.~~
- ~~(c) The independent review organization shall ensure that the fees charged to health benefit plans reflect the reasonable costs~~

~~of conducting external reviews, and that the fees do not vary based on the identity of the health benefit plan.~~

~~(d) The independent review organization shall ensure the availability of expert reviewers adequate to comply with the time requirements for external reviews provided in the Act and OAC 310:658.~~

310:658-5-3. Independence and objectivity of health care professionals [REVOKED]

~~(a) The independent review organization shall ensure that an expert reviewer does not receive from the organization and does not attempt to obtain information identifying any party associated with an appeal.~~

~~(b) The independent review organization shall ensure that the expert reviewer relies upon the written record as provided in Section 2528.8 of the Act.~~

~~(c) The independent review organization shall ensure that an expert reviewer meets the qualifications and standards of Section 2528.10 of the Act.~~

310:658-5-4. Identity of physician [REVOKED]

~~The health benefit plan shall ensure that information which would identify a physician associated with an insured person or with a health benefit plan is not disclosed to any person who will render a decision on an appeal relating to that physician.~~

310:658-5-5. Confidentiality of records and information [REVOKED]

~~(a) The independent review organization shall protect against unauthorized disclosure of medical records and confidential information submitted by the physician, the insured person or the designee.~~

~~(b) The independent review organization shall obtain written acknowledgements from all expert reviewers and other personnel associated with the organization indicating understanding that any person causing, aiding, or abetting the unauthorized release of confidential information is responsible for failure to comply with a standard of due care.~~

~~(c) The independent review organization shall ensure that information about the diagnosis, treatment or health of any insured person shall be available to expert reviewers and other personnel only to the extent necessary to accomplish the purposes of this Act and OAC 310:658 and only with the written consent of the insured person or the designee.~~

~~(d) The independent review organization shall ensure that confidential information is not used for marketing or solicitation.~~

310:658-5-6. Expedited appeals [REVOKED]

~~The independent review organization shall ensure that, in the case of a physician certification of emergency, the full external review shall be completed as provided in Section 2528.7.F of the Act. The independent review organization shall make provisions for expeditiously obtaining:~~

- ~~(1) Medical records;~~
- ~~(2) Other information submitted by the insured or the insured's physician; and~~
- ~~(3) Contracts from the health benefits plan.~~

310:658-5-7. Fair business practices [REVOKED]

~~An independent review organization and anyone associated with the independent review organization shall not:~~

- ~~(1) Enter into any formal or informal relationship or agreement with a health benefit plan to encourage selection of the independent review organization for review of appeals or to influence the outcomes of reviews;~~
- ~~(2) Advertise or market its services, solicit insured persons or designees, or otherwise entice or encourage any insured person or designee to file an appeal of a health benefit plan decision; or~~
- ~~(3) Assert or imply directly or indirectly that certification qualifies the independent review organization to provide external reviews except as authorized under the Act and OAC 310:658.~~

310:658-5-8. Other duties of independent review organizations [REVOKED]

~~Each plan shall provide toll-free incoming telephone service that is capable of receiving, accepting or recording information at all times and that is capable of providing appropriate instructions to incoming telephone callers during other than normal business hours.~~

SUBCHAPTER 7. ISSUANCE OR DENIAL OF CERTIFICATE [REVOKED]

310:658-7-1. Conditions for issuance or renewal [REVOKED]

~~The Department shall issue or renew a certificate when the Department finds that the independent review organization meets the requirements of the Act and OAC 310:658.~~

310:658-7-2. Duration of certificate [REVOKED]

~~— Each certificate issued or renewed by the Department to an independent review organization shall be effective for a period of two (2) years from the date of issue or renewal, unless earlier revoked or suspended by the Department based on violations of the Act or OAC 310:658.~~

310:658-7-3. Denial or nonrenewal of application [REVOKED]

~~(a) An application for a certificate may be denied or not renewed based on the applicant's failure to demonstrate compliance with the Act and OAC 310:658.~~

~~(b) After denial or nonrenewal, a person or entity may submit a new application for certification.~~

310:658-7-4. Certificate transfer [REVOKED]

~~— No certificate shall be issued to any person or entity other than the person or entity making application. A certificate shall not be transferred in whole or part to another person or entity.~~

SUBCHAPTER 9. DUTIES OF HEALTH BENEFIT PLANS [REVOKED]

310:658-9-1. Information provided to the Department [REVOKED]

~~— Immediately upon notifying an independent review organization of its selection under Section 2528.6.B.1 of the Act, the Plan shall provide the following to the Department:~~

- ~~(1) The name of the independent review organization selected by the Plan;~~
- ~~(2) The name, mailing address, and telephone number of the insured person or the designee; and,~~
- ~~(3) A copy of the Plan's final decision to deny coverage or reimbursement.~~

310:658-9-2. Information provided to independent review organization [REVOKED]

~~— Immediately upon notification from the independent review organization that the insured person has filed the documents required in Section 2528.6.C of the Act, the health benefit plan shall provide the independent review organization with information needed by that organization to determine the insured's conformity to Section 2528.6.D of the Act.~~

SUBCHAPTER 11. FORMS FOR USE BY INSURED PERSONS [REVOKED]

310:658-11-1. Request for external review form [REVOKED]

~~— The request for external review form requires the following:~~

- ~~(1) Identifying information for the insured person and the health benefit plan;~~
- ~~(2) A statement of the reasons for the request; and~~
- ~~(3) A blank for the signature of the insured person or the designee.~~

310:658-11-2. Medical records release form [REVOKED]

~~The medical records release form requires the following:~~

- ~~(1) Identifying information for the insured person;~~
- ~~(2) A statement authorizing the independent review organization to obtain necessary medical records; and~~
- ~~(3) A blank for the signature of the insured person or the designee.~~

310:658-11-3. Informed consent form [REVOKED]

~~The informed consent form includes the following:~~

- ~~(1) A copy of the terms and conditions of the external review process as provided in Section 2528.5 of the Act;~~
- ~~(2) An acknowledgement of receipt of the terms and conditions;~~
- ~~(3) An acknowledgement of understanding of and consent to the terms and conditions;~~
- ~~(4) A blank for identifying information for the insured person and the designee; and~~
- ~~(5) A blank for the signature of the insured person or the designee.~~

SUBCHAPTER 13. DEPARTMENT PROCEDURES [REVOKED]

310:658-13-1. Request for external review form [REVOKED]

~~Immediately upon receipt of the notice of selection required in OAC 310:658-9-1, the Department shall provide the insured person with the following:~~

- ~~(1) Notice of the opportunity to object to the selected independent review organization;~~
- ~~(2) Notice of the forms and information to be provided by the insured person to the independent review organization, to include:
 - ~~(A) The request for external review form;~~
 - ~~(B) A copy of the Plan's final decision to deny coverage or reimbursement;~~
 - ~~(C) A medical records release; and~~
 - ~~(D) An informed consent form.~~~~

310:658-13-2. List of certified independent review organizations [REVOKED]

~~The Department shall make available to all health benefit plans, and update at least annually, a list of certified independent review organizations.~~

SUBCHAPTER 15. REPORTING REQUIREMENTS [REVOKED]

310:658-15-1. Records [REVOKED]

~~Independent review organizations shall maintain written records on all requests for external reviews. Said records shall be available for inspection upon request by the Department.~~

310:658-15-2. Annual reports [REVOKED]

~~An independent review organization shall file with the Department not later than March 1 of each year for the preceding calendar year:~~

~~(1) The year's experience in conducting external reviews, on a form provided by the Department, that includes the following:~~

~~(A) Information on appeals received, accepted, pending and completed;~~

~~(B) Information on expedited reviews; and~~

~~(C) Information on reviews terminated due to plan reconsideration; and~~

~~(2) Such other information as is essential for the Department to determine an independent review organization's compliance with the Act and OAC 310:658.~~

310:658-15-3. Decision filings [REVOKED]

~~An independent review organization shall, within thirty (30) days after reaching a final decision on an external review, submit to the Department the written notification of the decision.~~

SUBCHAPTER 17. PROHIBITED ACTS [REVOKED]

310:658-17-1. Prohibited acts [REVOKED]

~~No person or entity shall assert or imply directly or indirectly that it has been certified by the Department as an independent review organization unless that person or entity first obtains a certificate from the Department.~~

RULE COMMENT SUMMARY AND RESPONSE

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 658. INDEPENDENT REVIEW ORGANIZATION CERTIFICATION RULES

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)]

No comments were received during the comment period or during the public hearing.

Agency Rule Contact:

James Joslin, Chief, Health Resources Development Service, Oklahoma State Department of Health, 1000 N.E. 10th Street, Oklahoma City, OK 73117-1207, phone 405-271-6868, or by e-mail to james@health.ok.gov.



Oklahoma State Department of Health
Creating a State of Health

RECEIVED
NOV 14 2013
LEGAL DIVISION

To: Board of Health Secretary

Through: Terry Cline, Ph.D.
Commissioner *TC-20-2013*

Through: James Joslin, Chief *J.J. 11/15/13*
Health Resources Development Service
Agency Rule Liaison

Through: Don Maisch *DM 11-15-2013*
General Counsel

Through: Hank Hartsell, Ph.D. *HH 11/14/13*
Deputy Commissioner

From: Dorya Huser, Chief *DH*
Long Term Care Service

Date: November 8, 2013

Subject: Rule Packet Submission for Distribution to Board of Health
CHAPTER 675. NURSING AND SPECIALIZED FACILITIES

The attached documents are submitted for PERMANENT ADOPTION by the State Board of Health at their December 10, 2013, meeting.

As described in the public comment summary, this rule was revised from the original submission based on public comment.

Attachments:

- **RIS (Rule Impact Statement)**
- **Rule Text**
- **Rule Comment Summary**

(Please contact James Joslin at x57209 for corrections, pick-up and delivery.)

RULE IMPACT STATEMENT

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH Chapter 675. NURSING AND SPECIALIZED FACILITIES

Before the Oklahoma State Board of Health December 10, 2013

1. DESCRIPTION:

This proposal amends rules promulgated in accordance with 63 O.S. Section 1-1950(C)(1) which authorized the State Board of Health shall to promulgate rules necessary for proper control and dispensing of nonprescription drugs in nursing facilities.

Section 310:675-9-9.1(i) addresses those procedures for maintaining nonprescription drugs for dispensing from a common or bulk supply. This proposed rule amendment deletes the requirement in OAC 310:675-9-9.1(i)(8) which limits the bulk nonprescription drugs that nursing facilities may maintain for residents. The current requirement provides that only oral analgesics, antacids, and laxatives may be dispensed from bulk supplies. This change will allow nursing facilities to maintain bulk supplies of other nonprescription drugs, such as cough medicines.

2. DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:

Affected persons will be residents and their families as well as owners, operators, and staff of Nursing and Specialized Facilities. These parties will benefit from greater access to bulk nonprescription drugs that nursing facilities may maintain for residents and the attendant reduction in expenses availability through bulk purchasing.

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

Affected persons will be residents and their families as well as owners, operators, and staff of Nursing and Specialized Facilities. These parties will benefit from greater access to bulk nonprescription drugs that nursing facilities may maintain for residents and the attendant reduction in expenses availability through bulk purchasing. The Department sought comment the public and providers on the value of the benefit and expected health outcomes during the comment period. Comments received were expressing concern that the proposed language was not broad enough as far as medications that would be eligible for bulk purchase and would not serve both residents and facilities as hoped. Participants and experts present provided important information about maintaining the safety to residents and the complex process and medication protocols involved in ordering and administering the medications to reassure those with safety and quality control concerns. . The feedback indicated that the original limitations addressing oral analgesics, antacids, and laxatives for bulk dispensing be retained while adding permissions for drugs listed in a facility formulary developed or approved by the consultant pharmacist, medical director and director of nurses. The number of residents that might benefit is estimated at approximately nineteen thousand (19,000), the approximate statewide nursing facility census at the time of this report.

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

These Rules involve no additional fees. Elimination of the restrictions on bulk medications has the potential to reduce medication costs for residents and facilities.

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

The cost to the Department to implement the amendments will be approximately \$4,000 to cover the costs of rule drafting, adoption, publication, distribution, and education. The proposed rules will be implemented and enforced by existing Department personnel and will have no anticipated effect on state revenues.

6. IMPACT ON POLITICAL SUBDIVISIONS:

There will be no impact on political subdivisions and it will not require their cooperation in implementing or enforcing the proposed amendment.

7. ADVERSE EFFECT ON SMALL BUSINESS:

There is no known adverse economic effect on small business as provided by the Oklahoma Small Business Regulatory Flexibility Act.

8. EFFORTS TO MINIMIZE COSTS OF RULE:

No less costly or nonregulatory methods have been identified.

9. EFFECT ON PUBLIC HEALTH AND SAFETY:

Public comment will be sought on the effects on public health and safety.

10. DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:

Public comment will be sought on any detrimental effects on public health and safety.

11. This rule impact statement was prepared on August 16, 2013 and revised November 14, 2013.

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 675. NURSING AND SPECIALIZED FACILITIES**

SUBCHAPTER 9. RESIDENT CARE SERVICES

310:675-9-9.1. Medication services

(a) **Storage.**

(1) Medications shall be stored in a medication room, a locked cabinet, or a locked medication cart, used exclusively for medication storage.

(2) The medication storage area temperature shall be maintained between 60° F. (15.5° C.) to 80° F. (26.6° C.)

(3) The medication room, the medication storage cabinet, and medication cart shall be locked when not in use.

(4) The key to the medication storage areas shall be in the possession of the person responsible for administering medications.

(5) Scheduled medications shall be in a locked box within the locked medication area or cart.

(6) Medications for external use shall be stored separately from medications for internal use.

(7) Medications requiring refrigeration shall be kept within a temperature range of 36° F. (2.2° C.) to 48° F. (8.8° C.) and separated from food and other items. There shall be a method for locking these medications.

(8) The medication areas shall be well lighted, clean and organized.

(9) Running water shall be in close proximity to the medication area.

(10) Powdered over-the-counter medication for topical use may be kept in the resident's room for administration by a nurse aide if:

(A) The facility develops and implements policies and procedures for safe storage and application of the powder; and

(B) Each aide who applies the over-the-counter topical medication is trained in accordance with the established policies and procedures of the facility.

(b) **Emergency medications.** Emergency medication, policies and equipment shall include but not be limited to:

(1) An electric suction machine with necessary aseptic aspirator tips.

(2) An emergency tray or cart with the following items labeled and accessible to licensed personnel only: resuscitation bag; tongue depressors; and assorted airways; sterile hypodermic syringes in 2 cc, 5 cc, and 20 cc or larger sizes and

appropriate needles. The content shall be limited to emergency medications and contain no scheduled medications. Only two single dose vials of the following medications may be on the tray or cart: 50% Dextrose, respiratory stimulant, a cardiac stimulant, injectable lasix, injectable dilantin and injectable benadryl.

(3) A certified medication aide shall not administer injectable medications from any emergency tray or cart, but shall have access to resuscitation bags, tongue depressors, and assorted sizes of airways.

(c) **Medication accountability.**

(1) Medications shall be administered only on a physician's order.

(2) The person responsible for administering medications shall personally prepare the dose, observe the swallowing of oral medication, and record the medication. Medications shall be prepared within one hour of administration.

(3) An accurate written record of medications administered shall be maintained. The medication record shall include:

(A) The identity and signature of the person administering the medication.

(B) The medication administered within one hour of the scheduled time.

(C) Medications administered as the resident's condition may require (p.r.n.) are recorded immediately, including the date, time, dose, medication, and administration method.

(D) Adverse reactions or results.

(E) Injection sites.

(F) An individual inventory record shall be maintained for each Schedule II medication prescribed for a resident.

(G) Medication error incident reports.

(4) A resident's adverse reactions shall be reported at once to the attending physician.

(d) **Medication labels and handling.**

(1) All prescribed medications shall be clearly labeled indicating the resident's full name, physician's name, prescription number, name and strength of medication, dosage, directions for use, date of issue and expiration, and name, address and telephone number of pharmacy or physician issuing the medication, and the quantity. If a unit dose system is used, medications shall indicate, at least, the resident's full name, physician's name and strength of medication, and directions for use.

(2) When over-the-counter medications are prescribed and obtained in the original manufacturers container, the package directions shall be considered part of the label. The resident's name shall be on the package.

(3) Each resident's medications shall be kept or stored in the originally received containers. Paper envelopes shall not be considered containers.

(4) Medication containers having soiled, damaged, illegible or makeshift labels shall be relabeled by the issuing pharmacy or physician. Labels on containers shall be clearly legible and firmly affixed. No label shall be superimposed on another label on a medication container except for over-the-counter medication containers.

(5) No person shall change labels on medication containers. If the attending physician orders a change of directions, there shall be a procedure to mark the container indicating a label change is needed at the next prescription refill.

(6) A pharmacist shall dilute, reconstitute and label medications, whenever possible. If not possible, a registered nurse may reconstitute, dilute and label medications. A distinctive, indelible, supplementary label shall be affixed to the medication container when diluted or reconstituted for other than immediate use. A licensed practical nurse may reconstitute oral medications only. The label shall include the following: resident's name, dosage and strength per unit/volume, nurse's initials, expiration date, and date and time of dilution or reconstitution.

(7) When a resident is discharged, or is on therapeutic leave, the unused medication shall be sent with the resident, or with the resident's representative, unless there is a written physician's order to the contrary, or the medication has been discontinued, or unless the resident or the resident's representative donates unused prescription medications for dispensation to medically indigent persons in accordance with the Utilization of Unused Prescription Medications Act. The clinical record shall document the quantity of medication sent, and returned or donated, and the signature of the person receiving or transferring the medications.

(8) All medication orders shall be automatically stopped after a given time period, unless the order indicates the number of doses to be administered, or the length of time the medication is to be administered. The automatic stop order may vary for different types of medications. The facility shall develop policies and procedures, in consultation with the medical director and pharmacist, to review automatic stop orders on medications. The policy shall be available to personnel administering medications.

(9) No resident shall be allowed to keep any medications unless the attending physician or interdisciplinary team has indicated on the resident's clinical record that the resident is mentally and physically capable of self-administering

medications.

(10) A resident who has been determined by the physician or interdisciplinary team as capable of self-administering medication may retain the medications in a safe location in the resident's room. The facility shall develop policies for accountability. Scheduled medications shall not be authorized for self-administration, except when delivered by a patient controlled analgesia pump.

(11) A physician's telephone orders shall be conveyed to, recorded in the clinical record, and initialed by the licensed nurse receiving the orders.

(12) Medications shall be administered only by a physician, registered nurse, a licensed practical nurse, or a certified medication aide. The only injectables which a certified medication aide may administer are insulin and vitamin B-12 and then only when specifically trained to do so.

(13) A pharmacy, operating in connection with a facility, shall comply with the State pharmacy law and the rules of the Oklahoma State Board of Pharmacy.

(14) Powdered over-the-counter medication for topical use may be administered by a trained nurse aide when designated in writing by the attending physician and delegated by a licensed nurse. The licensed nurse shall ensure that the aide demonstrates competency in reporting skin changes, storage, application and documentation policies and procedures. The licensed nurse or the attending physician shall document in the resident's record a skin assessment at least twice each week and more often if required by the facility's approved policy.

(e) **Medication destruction.**

(1) Non-controlled medications prescribed for residents who have died and non-controlled medications which have been discontinued shall be destroyed by both the director of nursing and a licensed pharmacist or another licensed nurse. Controlled medication shall be destroyed by a licensed pharmacist and the Director of Nursing. The facility may transfer unused prescription drugs to city-county health department pharmacies or county pharmacies in compliance with the Utilization of Unused Prescription Medications Act and all rules promulgated thereunder. Prescription only medications including controlled medications shall not be returned to the family or resident representatives. The destruction and the method used shall be noted on the clinical record.

(2) Medications prescribed for one resident may not be administered to, or allowed in the possession of, another resident.

(3) There shall be policies and procedures for the destruction of discontinued or other unused medications within a reasonable

time. The policy shall provide that medications pending destruction shall not be retained with the resident's current medications. The destruction of medication shall be carried out in the facility and a signed record of destruction shall be retained in the facility.

(f) **Medication regimen review.** The facility shall ensure that each resident's medications are reviewed monthly, by a registered nurse or a licensed pharmacist. The reviewer shall notify the physician and director of nursing, in writing, when irregularities are evident.

(g) **Consultant pharmacist.** The facility shall have a consultant licensed pharmacist to assist with the medication regimen review and medication destruction. The consultant pharmacist shall discuss policies and procedures for the administration, storage, and destruction of medications with the administrator, director of nursing and other appropriate staff.

(h) **Emergency pharmacy.** The facility shall have a contract, or letter of agreement, with a licensed pharmacy that agrees to serve as the emergency pharmacy. The emergency pharmacy shall be available twenty-four hours a day.

(i) **Bulk nonprescription drugs.** A facility may maintain nonprescription drugs for dispensing from a common or bulk supply if all of the following are accomplished.

(1) **Policy of facility.** The facility must have and follow a written policy and procedure to assure safety in dispensing and documentation of medications given to each resident.

(2) **Acquisition.** The facility shall maintain records which document the name of the medication acquired, the acquisition date, the amount and the strength received for all medications maintained in bulk.

(3) **Dispensing.** Only licensed nurses, physicians, pharmacists or certified medication aides (CMA) may dispense for administration these medications and only upon the written order for as needed (p.r.n.) or nonscheduled dosage regimens dosing from a physician as documented in the clinical record of the resident.

(4) **Storage.** Bulk medications shall be stored in the medication area and not in resident rooms.

(5) **Records.** The facility shall maintain records of all bulk medications which are dispensed on an individual signed medication administration record (MAR).

(6) **Labeling.** The original labels shall be maintained on the container as it comes from the manufacturer or on the unit-of-use (blister packs) package.

(7) **Package size.** The maximum size of packaging shall be established by the facility in its policy and procedures and shall insure that each resident receives the correct dosage;

provided however, that no liquid medications shall be acquired nor maintained in a package size which exceeds 16 fluid ounces.

(8) **Allowed nonprescription drugs.** Facilities may have only oral analgesics, antacids, and laxatives for bulk dispensing and/or drugs listed in a facility formulary developed or approved by the consultant pharmacist, medical director and director of nurses. Non formulary over the counter medications may be prescribed if the resident has therapeutic failure, drug allergy, drug interaction or contraindications to the formulary over the counter medication. ~~No other categories of medication may be maintained as bulk medications.~~

RULE COMMENT SUMMARY AND RESPONSE

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 675. NURSING AND SPECIALIZED FACILITIES

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 Subchapter and Section: Subchapter 9. Resident Care Services; Section 310:675-9-9.1, Medication services

The comments below were received concern the sole section for amendment described above.

Name & Organization: Rebecca Moore, Executive Director; Oklahoma Assoc. of Health Care Providers.

Comment: Ms. Moore appeared at the Public Comment Hearing held November 1, 2013, and voiced support for the rule amendment and the Department's inclusive rulemaking process.

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Regular Meeting of the Long-Term Care Facility Advisory Board; October 9, 2013.

LTCFAB members present: Kay Parsons, Chair; Dewey Sherbon, Vice Chair; Theo Crawley; Luke Tallant; Alan Mason; Wendell Short; Dustin Cox; Ivoria Holt; Linda Brannon; Donna Bowers; Diana Sturdevant; and Willie Burkhart.

Guests present: Mary Brinkley, Leading Age OK; Marilyn Kipps, guest; Jim Kipps; Gina Stafford, OK Board of Nursing; Oralene Sherbon, general public; Joyce Clark, Achievis; Marietta Lynch, Oklahoma Association of Health Care Providers; Wes Bledsoe, A Perfect Cause; Bill Whited, State Long Term Care Ombudsman's Office; Greg Frogge, McAfee Taft; Trish Ewing, State Council on Aging; Mark Stratton, University of Oklahoma Department of Pharmacy; Keith Swanson, OU School of Pharmacy; Gara Wilsie, Sequoia Health Services.

Comment: The Department provided the Advisory Board the Notice of Rulemaking Intent, Draft Rule Impact Statement and Proposed Rule. At this meeting, the attendees named above provided additional input to the proposed rule language. Comments received were expressing concern that the proposed language was not broad enough as far as medications that would be eligible for bulk purchase and would not serve both residents and facilities as hoped. Participants and experts present provided important information about maintaining the safety to residents and the complex process and medication protocols involved in ordering and administering the medications to reassure those with safety and quality control concerns. New language proposed at this meeting was crafted as a result of this feedback. A quorum of the Board was not present to allow a formal vote in support of the proposed rule changes. The members present expressed a consensus opinion in support of changes to the rule language.

Members were advised of the Public Comment Hearing to be held November 1, 2013 at which time they could provide individual written or oral comments.

Response: The Department appreciates the constructive feedback of the proposed rule language. See the proposed response below to address these and other comments.

Name & Organization: Marietta Lynch, provider, Gara Wilsie, Sequoia Health Services, Rebecca Moore, Oklahoma Association of Health Care Providers, email, October 30, 2013

Comments: The Department distributed revised language and received feedback from the persons listed above. Concern was expressed that the draft needed some tweaking. The draft language distributed was a little different from what was proposed at the LTCFAB meeting. The feedback indicated that the original limitations addressing oral analgesics, antacids, and laxatives for bulk dispensing be retained while adding permissions for drugs listed in a facility formulary developed or approved by the consultant pharmacist, medical director and director of nurses.

Response: The Department appreciates the constructive feedback of the proposed rule language. After review, the Department concurs with the proposed recommendations. Long Term Care is moving forward with the agreed proposed changes to the language for the rule. The Department proposes the revision as shown below.

310:675-9-9.1. Medication services

(8) **Allowed nonprescription drugs.** Facilities may have only oral analgesics, antacids, and laxatives for bulk dispensing and/or drugs listed in a facility formulary developed or approved by the consultant pharmacist, medical director and director of nurses. Non formulary over the counter medications may be prescribed if the resident has therapeutic failure, drug allergy, drug interaction or contraindications to the formulary over the counter medication. ~~No other categories of medication may be maintained as bulk medications.~~

Agency Rule Contact:

Mike Cook, Assistant Chief, Long Term Care Service, Oklahoma State Department of Health, 1000 N.E. 10th Street, Oklahoma City, OK 73117-1207, phone 405-271-6868, or by e-mail to mikec@health.ok.gov



Oklahoma State Department of Health
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NOV 12 2013
LEGAL DIVISION

To: Board of Health Secretary

Through: Terry Cline, Ph.D. *TC 11-20-2013*
Commissioner

Through: James Joslin, Chief *JJ 11/13/13*
Health Resources Development Service
Agency Rule Liaison

Through: Don Maisch *DM 11-13-2013*
General Counsel

Through: Toni Frioux, MS, APRN, CNP *TF 11/12/13*
Deputy Commissioner
Prevention and Preparedness Services

From: Lauri Smithee, PhD *LS*
Director, Acute Disease Service

Jan Fox, MPH, RN *JF for Jan Fox 11/12/13*
Director, HIV-STD Service

Date: November 8, 2013

Subject: Rule Packet Submission for Distribution to Board of Health
Chapter 310:515, Communicable Disease and Injury Reporting

The attached documents are submitted for PERMANENT ADOPTION by the State Board of Health at their December 10, 2013, meeting.

There have been no changes to any of the documents since the prior review and there have been no public comment received.

Attachments:

- **RIS (Rule Impact Statement)**
- **Rule Text**
- **Rule Comment Summary**

RULE IMPACT STATEMENT

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 515. COMMUNICABLE DISEASE AND INJURY REPORTING

1. **DESCRIPTION:** The proposal updates the existing rules in accordance with recommendations from the Council of State and Territorial Epidemiologists (CSTE), the Centers for Disease Control and Prevention, and local health care partners pertaining to reportable diseases. The proposal amends the lists of reportable diseases, in order to clarify those conditions and diseases that are required to be reported to the Department. These changes minimally increase the reporting burden placed upon clinicians, have no impact on the reporting burden placed upon laboratories, and do not adversely affect the public health disease control and prevention activities.

The proposal adds novel coronavirus and novel influenza A to the list of infectious diseases, reportable to the Department. The proposal expands reporting of influenza associated hospitalizations and deaths. The proposal is needed prepared for the reporting of suspected cases (especially those due to international travel to endemic areas and areas that such viruses are more likely to be initially spread) and the possibility of pandemic influenza or coronavirus, which have significant public health concern and risk. The proposal also refines requirements for CD4 cell count reporting. With these changes, the Department will receive information that is more rapid and precise, and the Department thereby will be better equipped to respond quickly and effectively to disease outbreaks or unusual or uncommon adverse health conditions.

2. **DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:** Affected persons will be health care providers that report diagnoses of listed diseases and laboratories that perform specific testing that identifies listed diseases.
3. **DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED HEALTH OUTCOMES:** The citizens of Oklahoma will benefit due to the increased ability of the Oklahoma State Department of Health to identify disease and epidemics and prevent additional cases.
4. **ECONOMIC IMPACT, COST OF COMPLIANCE AND FEE CHANGES:** There will be no significant economic impact to Oklahoma health care providers and laboratories. The Department will use the following Performance and Outcome measures.

Change in novel coronavirus reporting:

Performance measure: Number of novel coronavirus reports.

Outcome measure: Change in number of novel coronavirus reports.

Change in novel Influenza A reporting:

Performance measure: Number of novel Influenza A reports.

Outcome measure: Change in number of novel Influenza A reports.

Change in Influenza associated hospitalization or death reporting:

Performance measure: Number of Influenza associated hospitalization or death reports.

Outcome measure: Change in number of Influenza associated hospitalization or death reports.

Change in CD4 cell count reporting:

Performance measure: Number of CD4 cell count reports.

Outcome measure: Change in number of CD4 cell count reports.

5. **COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY:** The cost to the Department to implement the amendments will be approximately \$3,500.00 to publish, distribute, and educate health care provider and laboratory personnel on the amended lists of reportable diseases/organisms and the time frames for reporting. This cost will be borne by federal grants. There will be no increased personnel costs.
6. **IMPACT ON POLITICAL SUBDIVISIONS:** There will be no impact on any political subdivision as a result of implementing or enforcing this rule except for OU Medical Center which would be required to adhere to the reporting of suspected novel cases of coronavirus or influenza A. With regard to the changes in reporting novel cases of coronavirus or influenza A, Influenza associated hospitalization or death, CD4 cell count, the reporting burden will not significantly impact laboratories or clinicians.
7. **ADVERSE EFFECT ON SMALL BUSINESS:** Implementation of the proposed rule should have no adverse effect on small businesses as provided by the Oklahoma Small Business Regulatory Flexibility Act. With regard to the changes, the reporting burden will not significantly impact laboratories or clinicians.
8. **EFFORTS TO MINIMIZE COSTS OF RULE:** No less costly methods were identified.
9. **EFFECT ON PUBLIC HEALTH AND SAFETY:** The proposed rule is designed to reduce the risk to the public health of communicable diseases through requiring rapid disease reporting, especially of suspected cases of novel coronavirus and novel influenza A. The proposed rule will enable the responsible Services of the OSDH to rapidly investigate and intervene in transmission. The proposed rule will have minimal impact on the disease reporting and investigation workload for OSDH program staff and healthcare reporting partners. Although the cost savings is unknown, this person time can be redirected to other critical public health and healthcare activities. The proposal requires the reporting of suspected cases of novel coronavirus and novel influenza A, and expands the requirement of reporting cases of pediatric influenza death to reporting influenza associated hospitalization and death. The proposed rule will allow the ADS of the OSDH to monitor the epidemiology of the severe end of the clinical spectrum for influenza and thus forecast the possible impact on the health services and the State of Oklahoma during influenza season and during an influenza pandemic. These changes increase the alignment of the Department with national health partners in efforts to conduct surveillance for novel coronaviruses and influenza A viruses with pandemic potential. It reflects diseases of concern in Oklahoma as listed CSTE List of Nationally Notifiable Conditions: at <http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/PDFs/CSTENotifiableConditionListA.pdf>.

The proposal refines requirements for reporting CD4 cell count and percentage results based on the federal requirement that states receiving Ryan White Part B funding must calculate the Unmet Need for Health Services, defined as the need for HIV-related health services by individuals with HIV who are aware of their HIV status, but are not receiving regular primary health care. Health Resources and Services Administration (HRSA) provides an Unmet Need Framework for this calculation and determines that an individual with HIV or AIDS is considered to have an unmet need for care (or to be out of care) when there is no evidence that s/he received any of the following three components of HIV primary medical care during a defined 12-month time frame: (1) viral load (VL) testing, (2) CD4 count, or (3) provision of anti-retroviral therapy (ART). Therefore, in order to accurately calculate unmet need in Oklahoma, all CD4 cell count and percentage test results must be reported. See <http://hab.hrsa.gov/tools2/title2/t2SecVIIIChap1.htm#SecVIIIChap1d>. and http://www.qualityforum.org/News_And_Resources/Press_Releases/2013/NOF_Endorses_Infectious_Disease_Measures.aspx.

10. **DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:**

If the proposed rule is not implemented, specific diseases of public health importance as well as clusters of disease which may occur, may not be reported and thus investigation and intervention may not begin in a timely manner. Prompt investigation of such cases and clusters can prevent additional cases of disease.

11. This rule impact statement was prepared on 29 July 2013.

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 515. COMMUNICABLE DISEASE AND INJURY REPORTING**

SUBCHAPTER 1. DISEASE AND INJURY REPORTING

310:515-1-3. Diseases to be reported immediately

The following diseases must be reported by any health practitioner or laboratory personnel to the OSDH electronically via the secure web-based Public Health Investigation and Disease Detection of Oklahoma system or by telephone (405-271-4060 or 800-234-5963) immediately upon suspicion, diagnosis, or testing as specified in the "Oklahoma Disease Reporting Manual".

- (1) Anthrax (*Bacillus anthracis*).
- (2) Bioterrorism - suspected disease.
- (3) Botulism (*Clostridium botulinum*).
- (4) Diphtheria (*Corynebacterium diphtheriae*).
- (5) *Haemophilus influenzae* invasive disease.
- (6) Hepatitis A (Anti-HAV-IgM+).
- (7) Hepatitis B during pregnancy (HBsAg+).
- (8) Measles (Rubeola).
- (9) Meningococcal invasive disease (*Neisseria meningitidis*).
- (10) Novel coronavirus.
- (11) Novel influenza A.
- (12) Outbreaks of apparent infectious disease.
- ~~(11)~~ (13) Plague (*Yersinia pestis*).
- ~~(12)~~ (14) Poliomyelitis.
- ~~(13)~~ (15) Rabies.
- ~~(14)~~ (16) Smallpox.
- ~~(15)~~ (17) Tularemia (*Francisella tularensis*).
- ~~(16)~~ (18) Typhoid fever (*Salmonella Typhi*).
- ~~(17)~~ (19) Viral hemorrhagic fever.

310:515-1-4. Additional diseases, conditions, and injuries to be reported

The following diseases, conditions and injuries must be reported by physicians, laboratories, and hospitals (by infection control practitioners, medical records personnel, and other designees) to the OSDH as dictated in the following subsections:

- (1) **Infectious diseases.** Reports of infectious diseases and conditions listed in this subsection must be submitted electronically via the PHIDDO system, telephoned, or submitted via secure electronic data transmission to the OSDH within one (1) working day (Monday through Friday, state holidays excepted) of diagnosis or positive test as specified in the "Oklahoma Disease Reporting Manual".

(A) Acid Fast Bacillus (AFB) positive smear. Report only if no additional testing is performed or subsequent testing is indicative of *Mycobacterium tuberculosis* Complex.

- (B) AIDS (Acquired Immunodeficiency Syndrome).
- (C) Arboviral infections (West Nile virus, St. Louis encephalitis virus, Eastern equine encephalitis virus, Western equine encephalitis virus, Powassan virus, California serogroup virus).
- (D) Brucellosis (*Brucella* spp.).
- (E) Campylobacteriosis (*Campylobacter* spp.).
- (F) Congenital rubella syndrome.
- (G) Cryptosporidiosis (*Cryptosporidium* spp.).
- (H) Dengue Fever.
- (I) *E. coli* O157, O157:H7, or a Shiga toxin producing *E. coli*.
- (J) Ehrlichiosis (*Ehrlichia* or *Anaplasma* spp.).
- (K) Hantavirus pulmonary syndrome.
- (L) Hemolytic uremic syndrome, postdiarrheal.
- (M) Hepatitis B. If HBsAg+, anti-HBc-IgM+, HBeAg+, or HBV DNA+ then report results of the entire hepatitis panel.
- (N) Hepatitis C in persons < or = 40 years or in persons having jaundice or ALT > or = 400 regardless of age with laboratory confirmation. If hepatitis C EIA is confirmed by ~~RIBA or~~ NAT for HCV RNA, or signal-to-cut-off (s/co) ratio or index is predictive of a true positive then report results of the entire hepatitis panel.
- (O) Human Immunodeficiency Virus (HIV) infection.
- (P) Influenza associated ~~pediatric mortality~~ hospitalization or death.
- (Q) Legionellosis (*Legionella* spp.).
- (R) Leptospirosis (*Leptospira interrogans*).
- (S) Listeriosis (*Listeria monocytogenes*).
- (T) Lyme disease (*Borrelia burgdorferi*).
- (U) Malaria (*Plasmodium* spp.).
- (V) Mumps.
- (W) Pertussis (*Bordetella pertussis*).
- (X) Psittacosis (*Chlamydomphila psittaci*).
- (Y) Q Fever (*Coxiella burnetii*).
- (Z) Rocky Mountain Spotted Fever (*Rickettsia rickettsii*).
- (AA) Rubella.
- (BB) Salmonellosis (*Salmonella* spp.).
- (CC) Shigellosis (*Shigella* spp.).
- (DD) *Staphylococcus aureus* with reduced susceptibility to vancomycin (VISA or VRSA).
- (EE) *Streptococcus pneumoniae* invasive disease, in persons less than 5 years of age.
- (FF) Syphilis (*Treponema pallidum*).
- (GG) Tetanus (*Clostridium tetani*).
- (HH) Trichinellosis (*Trichinella spiralis*).
- (II) Tuberculosis (*Mycobacterium tuberculosis*).
- (JJ) Unusual disease or syndrome.
- (KK) Vibriosis (*Vibrionaceae* family: *Vibrio* spp. (including

cholera), *Grimontia* spp., *Photobacterium* spp., and other genera in the family).

(LL) Yellow Fever.

(2) **Infectious diseases.** Reports of infectious diseases and conditions listed in this subsection must be reported to the OSDH within one (1) month of diagnosis or test result as specified in the OSDH Disease Reporting Manual.

(A) CD4 cell count ~~←500~~ with corresponding CD4 cell count percentage of total (by laboratories only).

(B) Chlamydia infections (*Chlamydia trachomatis*).

(C) Creutzfeldt-Jakob disease.

(D) Gonorrhoea (*Neisseria gonorrhoeae*).

(E) HIV viral load (by laboratories only).

(3) **Occupational or Environmental diseases.** Laboratories must report blood lead level results greater than 10 ug/dL within one (1) week and results less than 10 ug/dL within one (1) month. Health care providers must report blood lead level results 20 ug/dL or greater within twenty-four (24) hours and results 10-19 ug/dL within one (1) week.

(4) **Injuries (hospitalized and fatal cases only).**

(A) Burns.

(B) Drownings and Near Drownings.

(C) Traumatic Brain Injuries.

(D) Traumatic Spinal Cord Injuries.

310:515-1-8. Organisms/specimens to be sent to the Public Health Laboratory

(a) Isolates or appropriate specimens of the following organisms shall be sent to the OSDH Public Health Laboratory for typing.

(1) *Bacillus anthracis*.

(2) *Brucella* spp.

(3) *E. coli* O157, O157:H7, or a Shiga toxin producing *E. coli*.

(4) *Francisella tularensis*.

(5) *Haemophilus influenzae* (sterile site).

(6) *Listeria monocytogenes* (sterile site).

(7) *Mycobacterium tuberculosis*.

(8) *Neisseria meningitidis* (sterile site).

(9) *Plasmodium* spp.

(10) *Salmonella* spp.

(11) *Staphylococcus aureus* that are VISA or VRSA.

(12) *Vibrionaceae* family (*Vibrio* spp., *Grimontia* spp., *Photobacterium* spp. and other genera in the family).

(13) *Yersinia* spp.

(b) Following consultation with an OSDH epidemiologist, clinical specimens from suspected cases of Botulism must be sent to the OSDH Public Health Laboratory for testing.

RULE COMMENT SUMMARY AND RESPONSE

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 515. Communicable Disease and Injury Reporting

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)]

No comments were received during the comment period or during the public hearing.

Agency Rule Contact:

Lauri Smithee, Director, Acute Disease Division, phone (405) 271-4060, e-mail lauris@health.ok.gov or Jan Fox, Director, HIV/STD Service Division, phone (405) 271-4636, email janf@health.ok.gov.



Oklahoma State Department of Health
Creating a State of Health

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NOV 08 2013
LEGAL DIVISION

To: Board of Health Secretary

Through: Terry Cline, Ph.D. Commissioner *11-20-2013*

Through: James Joslin, Chief Health Resources Development Service Agency Rule Liaison *JJ.*

Through: Don Maisch General Counsel *Don 11-8-2013*

Through: Toni D. Frioux, MS, APRN-CNP, Deputy Commissioner Prevention and Preparedness Services *DF 11/7/2013*

From: Sharon Vaz, MSGC, RN, Director Screening & Special Services *SV 11/6/2013*

Date: November 6, 2013

Subject: Rule Packet Submission for Distribution to Board of Health Chapter 550, NEWBORN SCREENING PROGRAM

The attached documents are submitted for **PERMANENT ADOPTION** by the State Board of Health at their December 10, 2013, meeting.

No changes to Rule Impact Statement or Rule Text based on the public comment submitted

Attachments:

- **RIS (Rule Impact Statement)**
- **Rule Text**
- **Rule Comment Summary**

(Please contact Ragina Munguia at x 56749 for corrections, pick-up and delivery.)

RULE IMPACT STATEMENT

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 550. NEWBORN SCREENING PROGRAM

- 1. DESCRIPTION:** The proposed rule changes add amendatory language to the existing rule to include Severe Combined Immunodeficiency Syndrome (SCID) as a new test in the core panel of 29 genetic disorders for newborn screening (NBS) in Oklahoma, as recommended by the Advisory Committee on Heritable Disorders in Newborns and Children – Recommended Uniform Screening Panel (January 21, 2010) - and after consultation with the Newborn Screening Subcommittee of the Oklahoma Genetics Advisory Committee. This proposal also adds pulse oximetry screening for the detection of Critical Congenital Heart Disease (CCHD) to existing newborn screening rules as legislated by House Bill 1347 (2013) [63 O.S. Section 1-550.5].

In addition, in Appendix A the newborn screening report form submitted by the infant's specialist or primary care provider is updated to include additional information based on new clinical practice; as is the requisition/collection form (Appendix B) and refusal form (Appendix C) in order to bring the rules up to date with practice. A new Appendix D and E are provided to include a recommended pulse oximetry screening protocol and a pulse oximetry screening result form.

- 2. DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:**

- All newborns are screened for silent disorders that can be treated if identified before symptoms occur. Adding new screening disorders to the testing panel has immediate positive health benefits for affected infants and families and long-term financial benefits for the Oklahoman health care system.
- Several states (Wisconsin, Texas, Massachusetts, California, Louisiana, and New York) currently doing pilot studies for SCID testing have found that the incidence of the disease is as high as 1/40,000. This is much higher than our previously stated incidence (1/100,000) for this disease.
- The classes of persons affected are newborn babies and their parents who have babies in a birthing facility in Oklahoma.
- Additionally those affected are "birthing facilities" in Oklahoma as defined in House Bill 1347 (2013).
- There were over 52,000 births recorded by the Division of Vital Records for the Oklahoma State Department of Health in 2012.

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

- Estimate that 1-2 infants with SCID will be identified annually, based on the Oklahoma birth rate of approximately 55,000 – 60,000/annum and incidence of disease (~1/40,000).
- Early identification improves health outcomes. Generally, this disease results in life-threatening infections within the first few months of life. Early detection provides a positive contribution to Child Health and improves rates of infant survival, which will reduce Oklahoma's rates of infant mortality and morbidity.
- The Oklahoma State Department of Health will evaluate overall benefits of SCID testing through follow-up of positively-screened infants.

- Cost of treatment (bone marrow transplant) for infants identified at birth is approximately \$250,000 to \$300,000 (for the procedure).
- Cost of treatment of a child not identified at birth is estimated at \$2 million.
- In Oklahoma as many as 105 babies are born annually with a Critical Congenital Heart Defect. This is a rate of approximately 20 babies/10,000.
- All infants born in a birthing facility in Oklahoma will benefit from early detection and treatment for a Critical Congenital Heart Defect.

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

- Cost for treatment, a bone marrow transplant, of infants identified at birth with SCID is approximately \$250,000 to \$300,000 for the procedure.
- Cost for treatment of a child not identified at birth = \$2 million
- Initial cost to NBS for Short Term Follow-up =- \$149,220
 - Cost of public education materials, one time publication of revised rules and regulations, travel and training for in house staff and for hospital staff, MD/PhD consultant and 0.5 FTE for a registered nurse to do Short Term Follow up.
- Annual cost to NBS for Short Term Follow-up - \$141,220
 - Ongoing annual hospital training, in-house staff and MD/PhD consultant.
- Initial cost to the Public Health Laboratory (PHL) NBS program = \$370,914
 - Capital outlay in purchase of new laboratory instrumentation (real-time PCR thermocyclers, centrifuges, paper punching system, plate shakers, freezer, refrigerator, pipettors), warranties, laboratory furniture, computer, personnel, personnel training, consumables and reagents for test development and validation prior to offering test as part of NBS panel
- Annual cost to PHL NBS = \$159,235
 - FY2014 = \$71,846 (estimating 6 months of testing)
 - FY2015 = \$159,235 (includes additional maintenance contract costs that are not incurred in 2013 budget since new instrumentation is under warranty)
- Laboratory, Short Term Follow-up and administrative costs associated with the current NBS panel is \$152.62 per infant. Once SCID testing is developed and added to the NBS panel, it is estimated that the total laboratory/administrative costs of the new NBS panel would be \$158.62 per infant.

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

Cost of implementation SCID:

Total Cost of Rule Development and Dissemination -	\$3,104
Cost of implementation for NBS Short Term Follow-up -	\$149,220
Cost of implementation for PHL	<u>\$370,914</u>
Total Cost	\$523,238

Cost of implementation CCHD rules

Total cost of CCHD implementation (Includes 1.5 FTE, education and travel)	\$124,492
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Avoidable Medical Costs

Approximate treatment costs avoided per discovered cases:	\$ 1,700,000
Lifetime cost of treatment for a child not identified at birth is \$2 million less the \$300,000 cost of a bone marrow transplant for an infant identified at birth with SCID	
Number of new cases detected per year	1
Avoided Medical Expenses from twenty years of testing = Not adjusted for inflation	\$ 34,000,000

6. **IMPACT ON POLITICAL SUBDIVISIONS:** There will be no impact on political subdivisions.
7. **ADVERSE EFFECT ON SMALL BUSINESS:** There will be an impact on those birthing facilities that meet the definition of a small business. The impact will be to perform the newborn screening test that is currently being performed with the addition of the pulse oximetry screen and to recoup that cost from insurance or the consumer.

8. **EFFORTS TO MINIMIZE COSTS OF RULE:**

Proposed SCID testing to be performed in-house in the Public Health Laboratory (PHL) (versus send-out) using a CDC-developed protocol that obviates the need for extensive test development and validation. Training for SCID testing has been provided free by the CDC. This protocol does not require nucleic acid isolation, whereas alternate protocols have the added cost of this step. The PHL has chosen a qPCR system that is at the lower price end of available commercial systems.

The proposed CCHD screening rules implement statutory requirements for screening. The methodology devised is of the lowest cost identified to date.

9. **EFFECT ON PUBLIC HEALTH AND SAFETY:**

- Changes to the Newborn Screening rule will improve the core public health services of Children's Health in Oklahoma. Early identification of at-risk infants can lead to reduction in infant mortality and morbidity.
- <http://statepublichealth.org/Internal.aspx?id=4822> - ASTHO Applauds HHS Adoption of New National Standard for Newborn Screening
- <http://www.astho.org/Internal.aspx?id=3634&terms=newborn+screening> *Newborn Screening* Is a Core Public Health Service and Should Be Mandatory and Consistent, Says Association of State and Territorial Health Officials.

The CDC reports that pulse oximetry screenings can identify infants with Critical Congenital Heart Defects (CCHD). Infants with CCHDs are at significant risk for morbidity or mortality. The CDC reports that pulse oximetry screenings can detect seven to twelve different CCHDs that represent 17-31% of all congenital heart disease in newborns. The detection of the CCHD will allow the newborn to receive a surgical procedure, shortly after birth to correct the CCHD and reduce the morbidity and mortality rate.

10. **DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:** Oklahoma currently ranks 44th in the country for infant mortality. Cases of

SCID are undiagnosed because infants die due to overwhelming infections in the first few months of life. Addition of this screening test to the Newborn Screening Panel will ensure that Oklahoma is following the national Recommended Uniform Screening Panel as recommended by the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children and is aligned with newborn screening algorithms in bordering states.

Undetected CCHDs will lead to a higher morbidity and mortality rate among newborns. The newborns will be discharged from the birthing facility without any evidence of a problem.

11. This rule impact statement was prepared on August 5, 2013, and revised September 24, 2013.

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 550. NEWBORN SCREENING PROGRAM

SUBCHAPTER 1. GENERAL PROVISIONS

310:550-1-1. Purpose

Under 63 O.S., Sections 1-533 and 1-534 the following rules and regulations are established concerning the screening of all infants born in Oklahoma for the disorders of phenylketonuria, congenital hypothyroidism, galactosemia, sickle cell diseases, cystic fibrosis, congenital adrenal hyperplasia, medium-chain acyl coenzyme A dehydrogenase deficiency (MCAD), ~~and after October 1, 2007, upon completion of validation studies and establishment of short term follow up services,~~ biotinidase deficiency, amino acid disorders, fatty acid oxidation disorders, organic acid disorders, and upon completion of laboratory validation studies and establishment of short-term follow-up services, Severe Combined Immunodeficiency (SCID) detectable via the Department's laboratory technology utilized in newborn screening and approved by the Commissioner of Health. This chapter establishes the following rules and regulations concerning screening all infants born at a birthing facility in Oklahoma for critical congenital heart disease (CCDH) via pulse oximetry screening performed by the birthing facility pursuant to 63 O.S. Section 1-550.5.

310:550-1-2. Definitions

The following words or terms, when used in this Chapter, shall have the following meaning, unless the context clearly indicates otherwise:

"Amino Acid Disorders" refers to a group of inherited metabolic conditions in which the body is unable to metabolize or process amino acids properly due to a defective enzyme function. This causes an amino acid or protein build up in the body. If not treated early in life these defects can cause disability, mental retardation or death. Each amino acid disorder is associated with a specific enzyme deficiency. Treatment depends on the specific amino acid disorder.

"Biotinidase Deficiency" means an inherited disease caused by the lack of an enzyme that recycles the B vitamin biotin, which if not treated may cause serious complications, including coma and death.

"Birth Defects Registry" means a registry established by the Commissioner of Health to monitor and track birth defects for all infants born in Oklahoma.

"Birthing Facility" means a facility that provides care during labor and delivery, and their newborn infants. This includes a

unit of a hospital that is licensed and accredited to provide birthing services, or a freestanding birthing center.

"Certified Laboratory" refers to the Oklahoma State Public Health Laboratory and/or a laboratory approved by the Oklahoma State Department of Health to conduct newborn screening.

"CCHD Screening" means the screening test for the detection of critical congenital heart disease that are recommended by the United States Department of Health and Human Services.

"CLIA '88" means the Clinical Laboratory Improvement Amendments of 1988, public law 100-578. This amendment applies to the Federal Law that governs laboratories who examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment, or the assessment of the health of human beings.

"Confirmatory Testing" means definitive laboratory testing needed to confirm a diagnosis.

"Congenital Adrenal Hyperplasia" or "CAH" will refer to the most common form of CAH, 21-hydroxylase deficiency. This genetic disorder is caused by the lack of an enzyme that the adrenal gland uses to process hormones. Serious loss of body salt and water can result in death. In girls the genitalia may appear as a male's, and can result in incorrect sex assignment. Hormone treatment is required for life.

"Congenital Hypothyroidism" means a disease caused by a deficiency of thyroid hormone (thyroxine) production, which if not treated leads to mental and physical retardation.

"Critical Congenital Heart Disease" means a congenital heart defect that places an infant at significant risk for disability or death if not diagnosed soon after birth.

"Cystic Fibrosis" means a multisystem genetic disorder in which defective chloride transport across membranes causes dehydration of secretions. The result is a production of a thick, viscous mucus that clogs the lungs. This leads to chronic lung infections, fatal lung disease, and also interferes with digestion. Early detection and treatment can prevent malnutrition, and enhance surveillance and treatment of lung infections.

"Days of Age" means the age of a newborn in 24-hour periods so that a newborn is one day of age 24 hours following the hour of birth for both blood spot screening and pulse oximetry screening.

"Department" refers to the Oklahoma State Department of Health.

"Discharge" means release of the newborn from care and custody of a perinatal licensed health facility to the parents or into the community.

"Disorder" means any condition detectable by newborn screening that allows opportunities, not available without screening, for early treatment and management to prevent mental retardation and/or reduce infant morbidity and mortality.

"Echocardiogram" means a test that uses ultrasound to provide an image of the heart.

"Fatty Acid Oxidation Disorders" refers to a group of inherited metabolic conditions in which the body is unable to oxidize (breakdown) fatty acids for energy due to a defective enzyme function. If not treated early in life this defect may cause mental retardation or death.

"Form Kit" or "Newborn Screening Form Kit" is a FDA approved (or licensed) filter paper kit bearing a stamped lot number that has been approved by the Commissioner of Health. For an example of a FDA approved kit, see Appendix A, Oklahoma Health Department (OHD) Form Kit #450.

"Galactosemia" means an inherited disease caused by the body's failure to break down galactose due to a defective enzyme function, which if not treated early in life may cause mental retardation or death.

"Hemoglobin" means a protein in the red blood cell that carries oxygen.

"Hemoglobinopathy" means an inherited hemoglobin disorder.

"Infant" means a child 6 months of age and under.

"Infant's Physician" means the licensed medical or osteopathic physician responsible for the care of the newborn.

"Initial Specimen" means the first blood specimen collected subsequent to birth, pursuant to these procedures.

"Long-term Follow-up" means follow-up services that begin with diagnosis and treatment and continues throughout the lifespan, including parent education, networking, referral, and case coordination.

"Medium-chain acyl coenzyme A dehydrogenase deficiency or "MCAD" means a genetic disorder of fatty acid metabolism. This disorder can cause metabolic crisis when an infant/child fasts. This crisis can lead to seizures, failure to breathe, cardiac arrest and death. Treatment is effective by preventing fasting.

"Newborn" means an infant 30 days of age and under.

"Newborn Screening" or "newborn screening tests" means screening infants for the disorders of phenylketonuria, congenital hypothyroidism, galactosemia, sickle cell diseases, cystic fibrosis, congenital adrenal hyperplasia, medium-chain acyl coenzyme A dehydrogenase deficiency (MCAD), and after October 1, 2007, upon completion of validation studies and establishment of short term follow up services, biotinidase deficiency, amino acid disorders, fatty acid oxidation disorders, and organic acid disorders, and upon completion of laboratory validation studies and establishment of short-term follow-up services, Severe Combined Immunodeficiency (SCID) detectable via the Department's laboratory technology utilized in newborn screening and approved by the Commissioner of Health and critical congenital heart

disease (CCHD) via pulse oximetry screening conducted by birthing facilities on all newborns born in the state of Oklahoma.

"Newborn Screening Laboratory" means a laboratory operated by the Department or a laboratory certified by the Department to conduct the tests and carry out the follow-up required by these procedures.

"Newborn Screening Program" refers to the Public Health Laboratory and ~~Family Health~~ Prevention and Preparedness Services Short-term Follow-up Program at the Oklahoma State Department of Health.

"Newborn Screening Program Coordinator" refers to the coordinator of the ~~Family Health~~ Prevention and Preparedness Services Short-term Follow-up Program at the Oklahoma State Department of Health.

"Organic Acid Disorders" refers to a group of inherited metabolic conditions in which the body is unable to metabolize or process organic acids properly. Each organic acid disorder is associated with a specific enzyme deficiency that causes the accumulation of organic acids in blood and urine. The accumulated compounds or their metabolites are toxic, resulting in the clinical features of these disorders including mental retardation and death.

"Pediatric Sub-Specialist" means a physician licensed in Oklahoma, board certified in pediatrics and board certified in a pediatric sub-specialty of pediatric endocrinology, pediatric pulmonology, or pediatric hematology; or a physician licensed in Oklahoma, board certified in pediatrics whose primary area of practice is pediatric endocrinology, pediatric hematology, pediatric pulmonology, or metabolic specialist.

"Phenylketonuria" or "PKU" means an inherited disease caused by the body's failure to convert the amino acid phenylalanine to tyrosine due to defective enzyme function, which if not treated early in life, causes mental retardation.

"Planned Health Care Provider" or "Medical Home" means the health care provider who will be providing health care for the infant after discharge from the hospital.

"Premature Infant" means an infant weighing less than 2500 grams or any live birth before the thirty-seventh week of gestation.

"Pulse Oximetry Screening" means a test using a device placed on an extremity to measure the percentage of oxygen in the blood.

"Repeat Specimen" means an additional newborn screening specimen to be collected after the initial specimen.

"Satisfactory Specimen" means a specimen collected using a single form kit which is suitable in both blood quantity and

quality to perform screening for phenylketonuria, congenital hypothyroidism, galactosemia, sickle cell disease, cystic fibrosis, congenital adrenal hyperplasia, medium-chain acyl coenzyme A dehydrogenase deficiency (MCAD), ~~and after October 1, 2007, upon completion of validation studies and establishment of short term follow-up services,~~ biotinidase deficiency, amino acid disorders, fatty acid oxidation disorders, ~~and~~ organic acid disorders, and upon completion of laboratory validation studies and establishment of short-term follow-up services, Severe Combined Immunodeficiency (SCID) detectable via the Department's laboratory technology utilized in newborn screening and approved by the Commissioner of Health. All requested demographic information on the form kit must be completed. Federal CLIA '88 regulations require that the form kit's laboratory requisition contain sufficient patient data that must include patient's name, date of birth, sex, date of collection, test(s) to be performed, and complete name and address of person requesting the test.

"Screened" means a specimen that has been collected and tested on an infant less than 6 months of age.

"Screening" means a test to sort out apparently well persons who probably have a disease or defect from those who probably do not. A screening test is not intended to be diagnostic.

"Severe Combined Immunodeficiency" means a group of potentially fatal inherited disorders related to the immune system, which if not treated can lead to potentially deadly infections.

"Short-term Follow-up" includes services provided by the Department and the health care provider that begins when the laboratory reports an abnormal or unsatisfactory screen result and ends with a diagnosis of normal, lost (repeat testing not achieved), or affected with appropriate treatment and referral has been initiated.

"Sick Infant" means an infant with any condition or episode marked by pronounced deviation from the normal healthy state; illness.

"Sickle Cell Disease" means an inherited disease caused by abnormal hemoglobin(s) which if not treated early in life may result in severe illness, mental retardation or death (one variation is commonly referred to as sickle cell anemia).

"Specimen" means blood collected on the filter paper Newborn Screening Form Kit.

"Submitter" means a hospital, other facility, or physician submitting a Newborn Screening specimen.

"Transfer" means release of the newborn from care and custody from one licensed health facility to another.

"Unsatisfactory Specimen" means a specimen which is not collected on a form kit and/or is not suitable in blood quantity

and quality to perform screening for phenylketonuria, congenital hypothyroidism, galactosemia, sickle cell disease, cystic fibrosis, congenital adrenal hyperplasia, medium-chain acyl coenzyme A dehydrogenase deficiency (MCAD), ~~and after October 1, 2007, upon completion of validation studies and establishment of short term follow up services,~~ biotinidase deficiency, amino acid disorders, fatty acid oxidation disorders, ~~and organic acid disorders,~~ and upon completion of laboratory validation studies and establishment of short-term follow-up services, Severe Combined Immunodeficiency (SCID) detectable via the Department's laboratory technology utilized in newborn screening and approved by the Commissioner of Health and/or Federal CLIA '88 regulations are not followed and the form kit's laboratory requisition does not include patient's name, date of birth, sex, date of collection, test(s) to be performed, and complete name and address of person requesting test.

SUBCHAPTER 3. TESTING OF NEWBORNS

310:550-3-1. Testing of newborns

(a) All newborns in Oklahoma shall be tested by a Certified Newborn Screening Laboratory for phenylketonuria, congenital hypothyroidism, galactosemia, sickle cell diseases, cystic fibrosis, congenital adrenal hyperplasia, medium-chain acyl coenzyme A dehydrogenase deficiency (MCAD) ~~and after October 1, 2007, upon completion of validation studies and establishment of short term follow up services,~~ infants shall be screened for, biotinidase deficiency, amino acid disorders, fatty acid oxidation disorders, ~~and organic acid disorders,~~ and upon completion of laboratory validation studies and establishment of short-term follow-up services, Severe Combined Immunodeficiency (SCID) detectable via the Department's laboratory technology utilized in newborn screening and approved by the Commissioner of Health; a parent or guardian may refuse screening of their newborn on the grounds that such examination conflicts with their religious tenets and practices.

(b) All newborns in Oklahoma shall be tested for CCHD by a pulse oximetry screening after twenty-four (24) hours of age or prior to discharge from the birthing facility.

(c) A parent or guardian who refuses the newborn screening blood test or pulse oximetry screening of their newborn on the grounds that such examination conflicts with their religious tenets and practices shall also indicate in writing this refusal utilizing the Newborn Screening Program Parent Refusal Form as illustrated in Appendix C of this Chapter. This signed refusal form shall be placed in the newborn's medical record with a copy sent to the

SUBCHAPTER 5. SPECIMEN COLLECTION

310:550-5-1. Specimen collection

(a) **Specimen collection for hospital births.** For all live hospital births, the physician, licensed or certified birth attendant shall order the collection of a newborn screening specimen on all newborns prior to transfusion, as early as possible after 24 hours of age or immediately prior to discharge, whichever comes first. Due to the need to identify infants at risk for the disorders quickly, the specimen should be collected as early as possible after 24 hours of age. Specimens shall be collected on a single Newborn Screening Form Kit using capillary or venous blood. Cord blood is unacceptable. The hospital is responsible for collecting specimens on all infants.

(1) If the initial specimen for any infant is collected prior to 24 hours of age, the hospital and the physician are responsible for notifying the infant's parents verbally and in writing, utilizing the parent educational form on the Newborn Screening Form Kit, that a repeat specimen is necessary at three to five days of age. The infant's physician is responsible for insuring that the repeat specimen is collected.

(2) The hospital is responsible for submitting a Satisfactory Specimen and for documenting all requested information on the form kit including the parent/guardian's name, address, phone or contact phone number and the planned health care provider who will be providing well care for the infant after discharge or if the infant is to be hospitalized for an extended period of time the name of the infant's physician.

(3) The hospital is responsible for documenting specimen collection and results in the infant's hospital record.

(4) Infants who are transferred from one hospital to another during the newborn period shall have specimen collection documented in the infant's hospital record. It is the responsibility of the physician and the receiving hospital to ensure the specimen is collected.

(5) It is the responsibility of the hospital and physician to ensure that all infants are screened prior to discharge. If an infant is discharged prior to specimen collection, the Newborn Screening Program Coordinator shall be notified. The physician is responsible for ensuring the specimen is collected as required.

(b) **Screening for premature/sick infants.** For all premature/sick infants, the physician shall order the collection of a newborn screening specimen prior to red blood cell transfusion, at three

to seven days of age or immediately prior to discharge, whichever comes first. Due to the need to identify infants at risk for the disorders quickly, the specimen should be collected as early as possible after 24 hours of age. It is recommended that a repeat newborn screening specimen be collected at 14 days of age. Specimens shall be collected on the Newborn Screening Form Kit using capillary or venous blood. The hospital and the physician are responsible for ensuring that specimens are collected on all premature/sick infants.

(1) Premature/sick infants screened prior to 24 hours of age must be re-screened between 7-14 days of age.

(2) Premature/sick infants who could not be screened prior to a red blood cell transfusion should be screened by the 7th day of life, with a repeat specimen collected when plasma and/or red cells will again reflect the infant's own metabolic processes and hemoglobin type (the accepted time period to determine hemoglobin type is 90 to 120 days after transfusion).

(3) The recommended follow-up study for an abnormal thyroid screen in a premature infant is a serum free T4 (measured by direct dialysis or an equivalent method) and TSH at 7-14 days of age.

(c) **Specimen collection for out-of-hospital births.**

(1) All infants who are not born in a hospital shall be tested ~~at~~ as early as possible after 24 hours of age. The infant's physician, licensed or certified birth attendant is responsible for submitting a Satisfactory Newborn Screening Specimen. If there is not a physician, licensed or certified birth attendant involved in a non-hospital birth, the person attending the birth and the parents of the infant are responsible for submitting a Satisfactory Newborn Screening Specimen.

310:550-5-2. Technique for filter paper sample collection and pulse oximetry screening

(a) **Filter paper sample collection.**

(1) Specimens obtained with a Newborn Screening Form Kit should be collected in accordance with Appendix A of this Chapter. Failure to follow these methods of blood collection may cause inaccurate results and require repeat specimens.

~~(b)~~ (2) Submitters are responsible for submitting a Satisfactory Newborn Screening Specimen.

(b) **Pulse oximetry screening.**

(1) **Pulse oximetry screening.** Pulse oximetry screening will be performed utilizing hospital protocol. See Appendix E for recommended protocol.

(2) **Authorized provider.** An authorized health care provider shall perform the pulse oximetry screening.

(3) **Newborn Infants Receiving Routine Care.**

- (A) The birthing facility or nurse shall:
- (i) Perform pulse oximetry screening on the newborn infant between twenty-four (24) hours and forty-eight (48) hours of life; or
 - (ii) If unable to perform the pulse oximetry screening, schedule the infant to be screened at the facility between twenty-four (24) hours and forty-eight (48) hours of life; or
 - (iii) Notify the infant's physician if screening was not performed.
- (B) If the newborn infant is discharged from a facility after 12 hours of life but before twenty-four (24) hours of life, the birthing facility shall perform pulse oximetry screening as late as is practical before the newborn infant is discharged from the birthing facility and shall notify the infant's physician of the early screening.
- (C) If the infant is discharged before 12 hours of life, the birthing facility shall perform the pulse oximetry screening between twenty-four (24) hours and forty-eight (48) hours of life.

(4) **Newborn infants in Special Care or Intensive Care.** Birthing facilities shall perform pulse oximetry screening on infants prior to discharge utilizing protocol recommended in appendix E, unless the infant has an identified congenital heart defect or has an echocardiogram done. Continuous pulse oximetry monitoring may not be substituted for CCHD screening.

(5) **Circumstances Where Pulse Oximetry Screening is not Indicated.** There may be instances where screening for CCHD is not indicated, including but not limited to instances where:

- (A) The newborn infant's clinical evaluation to date has included an echocardiogram which ruled out CCHD; or
- (B) The newborn infant has confirmed CCHD based on prenatal or postnatal testing.
- (C) Indicate on NBS filter paper the pulse oximetry screening was not performed.

SUBCHAPTER 7. HOSPITAL RECORDING

310:550-7-1. Hospital recording

(a) Newborn Screening Results.

- (1) The hospital shall implement a procedure to ensure that a newborn screening specimen has been collected on every newborn and transported to the Newborn Screening Laboratory within 24—48 twenty-four (24) to forty-eight (48) hours of collection.
- ~~(b)~~ (2) The hospital shall immediately notify the infant's

physician, parents or guardians, and Newborn Screening Program Coordinator if an infant is discharged without a sample having been collected. This notification shall be documented in the infant's hospital record.

~~(e)~~(3) If no test results are received within fifteen (15) days after the date of collection, the hospital shall contact the Newborn Screening Laboratory to verify that a specimen had been received. If no specimen has been received, the hospital shall notify the physician.

~~(d)~~(4) Any hospital or any other laboratory which collects, handles or forwards newborn screening samples shall keep a log containing name and date of birth of the infant, name of the attending physician, name of the planned health care provider who will be providing well care for the infant after discharge, medical record number, serial number of the Newborn Screening Form Kit used, date the specimen was drawn, date the specimen was forwarded, date the test results were received and the test results.

~~(e)~~(5) Specimens should be transported in the manner designated by the Department.

(b) Pulse Oximetry Screening Results.

(1) Recordation of Results.

(A) All pulse oximetry screening results shall be recorded in the newborn infant's medical record and the results reported to a parent or guardian prior to discharge from the hospital.

(B) All pulse oximetry screening results shall be recorded on the Newborn Screening Collection Kit (ODH #450), found in Appendix A, along with the following information:

(i) Newborn infant's:

(I) Name;

(II) Date of birth;

(III) Place of birth; and

(IV) Primary care physician after discharge; and

(ii) Mother's Name.

(C) If the infant is not screened for CCHD prior to the Newborn Screening Collection Kit being forwarded to the Public Health Laboratory for testing, fax documentation of CCHD screen results to the Oklahoma State Department of Health (OSDH) Newborn Screening (NBS) Program utilizing Appendix E. Include information listed above along with screen results.

(2) Abnormal Pulse Oximetry Screen Results.

(A) Abnormal pulse oximetry screening results shall be reported by the authorized health care provider who conducted the screening to the attending physician or attending clinician immediately.

(B) A newborn infant shall be evaluated immediately by an attending physician in order to complete the recommended protocol.

(C) A newborn infant may not be discharged from care until:

(i) A cause for the abnormal pulse oximetry screen has been determined;

(ii) An echocardiogram has been performed, read, and determined not to indicate CCHD; and/or

(iii) A plan of care and follow-up has been established with the infant's parent or guardian.

(D) The birthing facility shall report pulse oximetry screening results to the OSDH as specified in this regulation.

(E) The birthing facility shall provide notification of abnormal pulse oximetry results to the newborn infant's:

(i) Parent or guardian;

(ii) Physician or clinician following the inpatient infant; and

(iii) Primary care provider.

(3) Newborn Infants Not Screened for CCHD.

(A) If a newborn infant is not screened for CCHD secondary to discharge before 12 hours of life, the birthing facility shall:

(i) Follow-up with the family to screen the infant at their facility between twenty-four (24) and forty-eight (48) hours of life; or

(ii) Follow-up with the family to refer to an authorized facility for screening between twenty-four (24) and forty-eight (48) hours of life after discharge from the facility; and

(iii) Report screening results to the Department utilizing the form in Appendix E and indicating the reason for not screening which shall be "early discharge".

(B) If the newborn infant is not screened for CCHD secondary to screening not being indicated, the birthing facility shall report results to the Department utilizing the form in Appendix E and indicate the reason for not screening, which shall be "screening not indicated," with a notation for the reason pulse oximetry screening was not performed

(C) If the newborn infant is not screened secondary to parent or guardian refusal, the birthing facility shall fax a refusal form to the Department utilizing the form in Appendix C and indicate the reason for not screening, which shall be "parent refusal".

SUBCHAPTER 13. PARENT AND HEALTH CARE PROVIDER EDUCATION

310:550-13-1. Parent and Health Care Provider education

(a) The infant's physician or designee shall have the responsibility to ensure that at least one of each newborn's parent or legal guardian is notified about newborn screening and is provided information about the disorders and instructed to obtain screen results from the planned health care provider or Newborn Screening Program.

(b) The infant's physician or designee shall have the responsibility to ensure that at least one of each of the newborn's parent or legal guardian is notified about the pulse oximetry screening and is provided information about the pulse oximetry screening and instructed to obtain screen results from the birthing facility or the planned health care provider.

(c) The hospital will be responsible or designate a responsible party to distribute the Newborn Screening Program's written educational materials on newborn screening and pulse oximetry screening provided by the Department to at least one of each newborn's parent or legal guardian.

~~(e)~~(d) Hospitals shall provide ongoing training programs for their employees involved with newborn screening and pulse oximetry screening procedures. These training programs shall include methods of collecting a Satisfactory Newborn Screening Specimen satisfactory newborn screening specimen and proper pulse oximetry screening method.

~~(d)~~(e) The hospital is responsible for ensuring that employees who collect, handle or perform newborn screening tests or perform pulse oximetry screening are informed of their responsibilities with respect to screening procedures.

SUBCHAPTER 17. FOLLOW-UP FOR PHYSICIANS

310:550-17-1. Follow-up for physicians

(a) If a physician examines a child in the first three months of life, the physician will verify that the child has been screened, and document results in the infant's medical record. If the child has not been screened or if results of screening are not available, the physician should submit a Satisfactory Newborn Screening Specimen within 48 hours or as soon as possible.

(b) On written notification by the Newborn Screening Program of follow-up requirements for a newborn screen result of abnormal, unsatisfactory and less than 24 hours of age at time of

collection; the infant's physician or designee will obtain required repeat screening, confirmatory testing, or diagnostic studies, in the timeframe specified so that therapy, when indicated, can be initiated expeditiously.

(c) The infant's physician may selectively rescreen infants as clinically indicated.

(d) Because patients may relocate without a forwarding address or contact information, where these rules place responsibility upon physicians and hospitals to follow-up or notify parents, then that shall be deemed to require only that a reasonable search be made and that if the parents are not contacted that the Newborn Screening Program Coordinator be notified of the non-follow-up or non-notification after efforts to contact the parents have been exhausted.

(e) For appropriate comprehensive medical care, all confirmed cases of congenital hypothyroidism, galactosemia, phenylketonuria, sickle cell disease, cystic fibrosis, congenital adrenal hyperplasia, medium-chain acyl coenzyme A dehydrogenase deficiency (MCAD), ~~and after October 1, 2007, upon completion of validation studies and establishment of short term follow up services,~~ biotinidase deficiency, amino acid disorders, fatty acid oxidation disorders, ~~and organic acid disorders,~~ and upon completion of laboratory validation studies and establishment of short-term follow-up services, Severe Combined Immunodeficiency (SCID) detectable via the Department's laboratory technology utilized in newborn screening and approved by the Commissioner of Health, should have a referral to a pediatric sub-specialist, and the parent should be referred for enrollment in newborn screening long-term follow-up services as designated by the Newborn Screening Program. For referral information, please contact the Newborn Screening Short-term Follow-up Program at (405) 271-6617 or 1-800-766-2223, ext. 6617.

SUBCHAPTER 19. REPORTING

310:550-19-1. Physician Reporting and Medical Records

(a) If confirmatory or follow-up testing is not performed by the Newborn Screening Laboratory or through a contract laboratory designated by the Newborn Screening Program, the infant's physician must report to the Newborn Screening Program Coordinator the results within 7 days after the completion of the medical evaluation, using the Department's Newborn Screening Report Form as illustrated in Appendix B of this Chapter. A copy of the confirmatory test results must accompany the report form.

(b) For all diagnosed cases of phenylketonuria, congenital hypothyroidism, galactosemia, sickle cell diseases, cystic

fibrosis, congenital adrenal hyperplasia, medium-chain acyl coenzyme A dehydrogenase deficiency (MCAD), and after October 1, 2007, upon completion of validation studies and establishment of short term follow up services, biotinidase deficiency, amino acid disorders, fatty acid oxidation disorders, and organic acid disorders, and upon completion of laboratory validation studies and establishment of short-term follow-up services, Severe Combined Immunodeficiency (SCID) detectable via the Department's laboratory technology utilized in newborn screening and approved by the Commissioner of Health, the infant's physician shall report treatment date if applicable, and referral information to the Newborn Screening Program Coordinator by completing the Department's Newborn Screening Report Form as illustrated in Appendix B of this Chapter.

(c) These reports shall be confidential and may be utilized only for the purpose of ensuring service delivery, program administration, data analysis, and evaluation.

(d) On request, a birthing facility or health care provider shall make available to the OSDH NBS Program or Oklahoma Birth Defects Registry:

- (1) Medical records;
- (2) Records of laboratory test; and
- (3) Any other medical information considered necessary to:
 - (A) Determine final outcomes of abnormal CCHD screening results; and
 - (B) Evaluate CCHD screening activities in the State; including:
 - (i) Performance of follow-up evaluations and diagnostic tests;
 - (ii) Initiation of treatment when necessary; and
 - (iii) Surveillance of the accuracy and efficacy of the screening.

(e) Information that the Department receives under this chapter is confidential and may only be used or disclosed:

- (1) To provide services to the newborn infant and the infant's family;
- (2) To study the relationships of the various factors determining the frequency and distribution of CCHD;
- (3) For State or federally mandated statistical reports; and
- (4) To ensure that the information received by the Department is accurate and reliable.

SUBCHAPTER 21. INFORMATION

310:550-21-1. Information

(a) For information regarding laboratory procedures, or results of laboratory tests or to order form kits, contact Public Health Laboratory Service, Oklahoma State Department of Health, P.O. Box 24106, Oklahoma City, Oklahoma 73124-0106, (405) 271-5070, FAX (405) 271-4850.

(b) For general information or information regarding follow-up for newborn screening or pulse oximetry screening, contact Newborn Screening Short-term Follow-up Program, Family Health Prevention and Preparedness Services, Oklahoma State Department of Health, 1000 NE Tenth Street, Oklahoma City, Oklahoma 73117-1299, (405) 271-6617, FAX (405) 271-4892, 1-800-766-2223, ext. 6617. General information about the Newborn Screening Program is available on the OSDH Web site at www.health.ok.gov.

**APPENDIX A. INSTRUCTIONS FOR FILTER PAPER SAMPLE COLLECTION
[REVOKED]**

APPENDIX A. INSTRUCTIONS FOR FILTER PAPER SAMPLE COLLECTION [NEW]

Adapted from CLSI *Blood Collection on Filter Paper for Newborn Screening Programs*; Approved Standard-Fifth Edition, LA4-A5, Vol.27 No.20, 2007.

Preliminary Steps

Ensure that the expiration date of the filter paper form kit has not passed. Complete the required information on the filter paper form kit. A ballpoint pen should be used; soft-tip pins will not copy through to the other sheets of paper. Address imprint devices (or adhesive labels) should never be used unless the handling process ensures that the patient information is not obscured and the blood collection area is not compromised. Do not use typewriters or printers that might compress the paper. Avoid touching the area within the circles on the filter paper section before, during and after collection (blood spots) of the specimen. Do not allow water, feeding formulas, antiseptic solutions, glove powder, hand lotion, or other materials to come into contact with the specimen card before or after use.

Precautions

Confirm the identity of the infant and ensure accuracy of the demographic data on the card. Wash hands vigorously before proceeding. All appropriate precautions, including wearing powder-free gloves (changing gloves between infants), should be taken for handling blood and disposing of used lancets in a biohazard container for sharp objects.

Site Preparation

Warm the newborn's heel, since warming the skin-puncture site can help increase blood flow. A warm, moist towel or diaper at a temperature no higher than 42° C may be used to cover the site for 3 minutes. This technique increases the blood flow sufficiently and will not burn the skin. In addition, positioning the infant's leg lower than the heart will increase venous pressure.

Cleaning the Site

The skin should be wiped with alcohol (isopropanol/water: 70/30 by volume, "70%"). Allow the skin to air dry.

Puncture

To obtain sufficient blood flow, puncture the infant's heel on the plantar surface of the heel with a sterile lancet or with a heel incision device. The incision device provides excellent blood flow by making a standardized incision 1.0 mm deep by 2.5 mm long. Any puncture device used should be selected so that the puncture does not exceed 2.0 mm in depth. For infant safety, scalpel blades or needles must not be used to puncture the skin for blood collection. Disposable skin puncture lancets of different designs are commercially available for performing the heel stick on infants. For worker safety, disposable skin puncture

devices that protect the user from unintentional self-inflicted skin punctures should be used.

In small, premature infants, the heel bone (calcaneus) might be no more than 2.0 mm beneath the plantar heel skin surface and half this depth at the posterior curvature of the heel. Studies indicate that for some infants (including full-term infants) a puncturing depth of 2.0 mm might be excessive and might cause bone damage. In this situation other collection methods should be considered.

Direct Application

After the heel has been punctured, wipe away the first drop of blood with a sterile gauze pad or cotton ball and allow a larger drop of blood to form. (Intermittently apply gentle pressure to the heel with the thumb, and ease this pressure as drops of blood form). Touch the filter paper gently against the large blood drop and, in one step, allow a sufficient quantity of blood to soak through and completely fill a preprinted circle on the filter paper. Do not press the filter paper against the puncture site on the heel. Blood should be applied only to one side of the filter paper. Both sides of the filter paper should be examined to assure that the blood uniformly penetrated and saturated the paper. During collection avoid milking or layering:

Milking: Excessive milking or squeezing the puncture might cause hemolysis of the specimen or result in an admixture of tissue fluids with the specimen and might adversely affect the test result.

Layering: Do not apply layers of successive blood drops to the same printed circle. Applying successive drops of blood to already partially dried spots causes nonuniform analyte concentrations and invalidates the specimens.

After blood has been collected from the heel of the newborn, the foot should be elevated above the body, and a sterile gauze pad or cotton swab pressed against the puncture site until the bleeding stops. It is not advisable to apply adhesive bandages over skin puncture site on newborns.

Collection

The required blood spots should be collected so that there is one in each pre-printed circle of the filter paper. Failure to collect and fill each pre-printed circle might result in the specimen being rejected (unsatisfactory) for testing. If blood flow diminishes so that a circle is not completely filled, repeat the sampling technique using a new circle or, if necessary, a new blood collection card.

For alternative methods to specimen collection (e.g., capillary tube, dorsal hand vein, umbilical venous catheter or umbilical arterial catheter) refer to the CLSI *Blood Collection on Filter Paper for Newborn Screening Programs*; Approved Standard-Fifth Edition (LA4-A5, Vol. 27 No. 20) or contact the Newborn Screening Program Coordinator.

Drying

Avoid touching or smearing the blood spots. Allow the blood specimen to air dry on a horizontally level, nonabsorbent, open surface for at least 3 hours at an ambient temperature of 15° C to 22° C. Keep the specimen away from direct sunlight (indirect room light is not usually detrimental unless accompanied by heat). Blood spots on the filter paper should not be heated, stacked, or allowed to touch other surfaces during the drying process.

The Filter Paper has a new fold-over protective cover. This protective cover is used to protect the blood spots from contamination and can be used in the drying process. To use the protective cover in the drying process simply elevate the blood spots to gently rest on the edge of the protective cover. After drying, the protective cover should be placed over the spots to prevent contamination.

Stacking

Since leaching (cross-contamination) between specimens might occur, specimen-to-specimen contact is not appropriate. Before placing the specimens in a paper envelope for mailing, use the fold-over protective cover to cover each individual blood spot. When stacking of exposed blood spots cannot be avoided, the following procedure should be done:

Before placing the specimens in a paper envelope for mailing, the dried blood spots on the collection card should be rotated 180° from the blood spots on the cards in the stack immediately above and below.

If the physical barrier is used (fold-over protective cover), specimen rotation is not necessary.

Mailing

Specimens should be transported in the manner designated by the Department. The collection card should be transported or mailed to the Newborn Screening Program laboratory within twenty-four (24) hours after collection. Mailing delays at collection sites should be avoided, and the postal or transport environment relative to possible delays should be considered. Never place the filter paper specimen in plastic bags. Use the form kit's protective overlay to cover the filter paper spots when mailing or transporting. If mailing the specimens use a U.S. Postal Service approved envelope.

Information

For information regarding specimen collection, Postal regulations, envelope and form kit purchasing, please contact the Newborn Screening Program Laboratory at (405) 271-5070.

1391373

Newborn Screening Form
Oklahoma State Department of Health-P.O. Box 24106,
Oklahoma City, OK 73124-0106 (405) 271-5070

ODH #450 REV/02-2007

DO NOT WRITE IN THIS BOX

INFANT'S INFORMATION

1. Infant's Last Name: _____ Infant's First Name: _____
 2. Sex: M F
 3. Date of Birth: MM DD YY _____ Birth Time: _____ 24 Hour Clock
 5. Birthweight in Grams: _____ 6. If Multiple Birth Indicate Birth Order: A-H 7. _____
 8. Provider ID: _____ 9. Infant's Medical Record or I.D. #: _____
 10. Mom's Medicaid Number: _____ 11. Infant's Provider or Physician's Name: _____
 12. Provider's Phone Number: _____

MOM'S INFORMATION

1. Mom's Last Name, First Name: _____ Mom's Age: _____
 3. Mom's Address: _____ 4. Apt. #: _____
 5. Mom's City: _____ 6. State: _____ 7. Zip: _____
 8. Mom's Telephone or Contact: _____ 9. Mom's Social Security #: _____
 10. Mom's Race/Ethnicity: 1. White 2. Black 3. Hispanic 4. Asian 5. Indian 6. Other

SPECIMEN INFORMATION

1. Collection Date: MM DD YY _____ Collection Time: _____ 24 Hour Clock
 2. Transfusion Date: MM DD YY _____ Time: _____ 24 Hour Clock
 Do not write in this box

3. Has a previous metabolic blood test been done anywhere? Yes No
 Previous OSDH Lab Number: _____
 4. Check all that apply at time of screening:
 ___ TPN ___ Antibiotics ___ Lactose-Free Formula (Soy)
 ___ Meconium ileus ___ Family History of CF
 5. Test Requested:
 All Tests HGB Only GALT CFTR Phe Monitor
 Adoption (check if baby is being adopted)
 (See back of form for instructions)

Pulse Oximetry (CCHD) Screen
 Not Performed Pass Fail

SUBMITTING HEALTH PROVIDER ID # _____
 Return to Submitter at this address:

Hearing Screening Results:

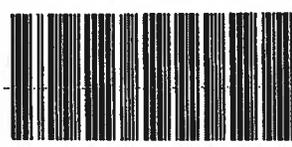
Right Ear: Pass Refer
 Left Ear: Pass Refer

If not screened, reason:
 Technical problem
 Caregiver refused

Hearing risk status—Check all that apply:
 Blood relatives of the infant have a permanent hearing loss that began at birth or in early childhood.
 Infant is suspected of having a congenital infection (neonatal herpes, cmv, rubella, syphilis, toxoplasmosis).
 Infant has craniofacial anomalies (pinna/ear canal abnormality, cleft lip/palate, hydrocephalus).
 Infant had exchange transfusion.
 Infant has serum bilirubin level \geq 15 mg/dL.
 Infant was placed in a Level II or III nursery for more than 24 hours.

IVD

1391373



LOT W112 6930612

2015-08



Oklahoma State Department of Health
Newborn Screening Program

Baby's Last Name

Baby's First Name

NEWBORN SCREENING PROGRAM

ATTENTION PROVIDER
DETACH AND GIVE TO PARENT OR GUARDIAN

THE NEWBORN SCREENING BLOOD TEST

A special blood test has been done to protect your baby from hidden disease. The test screens for the disorders listed on the back of this form. These disorders are harmful if treatment is not started within the first month of life (each disorder is explained on the back of this sheet).

WILL FURTHER TESTING BE REQUIRED?

If your baby is tested before 24 hours of age, the test must be repeated at 3 to 5 days of age. If the blood test is abnormal or inadequate to test, a repeat test will be needed. Please contact your baby's physician to determine if your baby needs a repeat test.

ASK YOUR BABY'S DOCTOR FOR THE TEST RESULTS

Please take this form with you to your baby's first doctor visit and ask for test results. If your baby's doctor does not have the test results and you have not been notified by mail, please call the Oklahoma State Department of Health when your baby is three weeks of age at **(405) 271-6617 or 1-800-766-2223.**

SN 1395395

Early Detection and Treatment Provide Oklahoma Infants a Healthy Start

Congenital Hypothyroidism – Congenital hypothyroidism is usually caused by abnormal development or absence of the thyroid gland. Treatment includes daily thyroid medication to prevent mental retardation and poor growth.

Classic Galactosemia – Galactosemia occurs when the baby cannot break down a special sugar in milk called galactose. Treatment includes a galactose free diet.

Congenital Adrenal Hyperplasia 21-hydroxylase Deficiency (CAH) – CAH is caused by the lack of an enzyme that the adrenal gland uses to process hormones. In girls the genitalia may appear like that of a male, and can result in incorrect sex assignment. Treatment includes medication (hormones) to prevent serious illness and death.

Cystic Fibrosis – Cystic Fibrosis is a disorder that causes thick mucus to collect in the lungs and other body organs, which can result in breathing problems, lung infections, and poor digestion of food. Treatment includes medication and close monitoring by the Cystic Fibrosis Center.

Sickle Cell Disease & other hemoglobin disease – Sickle cell disease occurs when the hemoglobin in the red blood cells does not develop normally. Red blood cells have the important job of delivering oxygen to different parts of the body. Treatment includes medication and close monitoring by a Hematologist.

Medium-chain acyl coenzyme A dehydrogenase deficiency (MCAD) & Other Fatty Acid Oxidation Disorders – These conditions prevent the body from using certain fats for energy, particularly during periods without food (fasting). Treatment includes frequent feedings, dietary management, and medication.

Phenylketonuria (PKU) & Other Amino Acid Disorders – Amino Acid Disorders, including PKU, are caused by the body's inability to break down certain proteins in food, or by the body's inability to handle the extra nitrogen produced by the breakdown of protein. Treatment includes strict dietary management and may include medication.

Organic Acid Disorders – These conditions are caused by the body's inability to process certain proteins and/or fats properly. Treatment includes strict dietary management and may include medication.

Biotinidase Deficiency – The vitamin biotin is found in many foods, and is important for proper growth and development. Biotinidase Deficiency prevents babies from using biotin in a normal manner. Treatment includes biotin (vitamin) supplements and regular monitoring.

For all of these disorders, early treatment is needed to prevent severe illness or death.

Special Note: for sickle cell disease and cystic fibrosis screening, the blood test might find that your baby is a "carrier" of a disorder. Genetic Counseling is recommended.

Questions about the newborn screening blood test?

Call: 405-271-6617 or 800-766-2223

E-mail: newbornscreen@health.ok.gov

Web site: <http://nsp.health.ok.gov>

Instruction on Specimen Collection and Mailing (Complies with CLSI Standard LA 4 - A5)

COMPLETION OF FORM

1. Legibly print and complete all information requested.
2. List submitter's return address and submitter ID number. Submitter means the facility or provider who has collected the specimen.
3. List the provider or physician who will be following the baby for well care or the attending physician if the infant is hospitalized for an extended period of time.
4. List the parent's correct address and phone number for notification of abnormal results.
5. Document results of the infant's pulse oximetry (CCHD) screen.

Note: All results are sent to the submitter and the provider listed on the form.

COLLECTION OF BLOOD SPECIMEN

1. To prevent specimen contamination do not touch any of the filter paper circles before or after collection.
2. Select puncture site and cleanse with 70% isopropanol and allow heel to air dry. Usual puncture site is illustrated below.



3. Use a sterile, disposable lancet or heel incision device to perform a swift clean puncture.
4. Wipe away first drop of blood with a sterile gauze or cotton ball.
5. Gently touch the filter paper against a large drop of blood and allow a sufficient quantity of blood to soak through to completely fill the preprinted circle on the filter paper. Blood must be applied to only one side of the filter paper and circle area should be fully saturated.
6. Fill each circle with ONE large drop of blood.
7. Protect freshly collected specimens from contamination.
8. Allow blood specimen to air dry at room temperature for at least 3 hours in a horizontal position. **Do not stack wet specimens. Insufficient drying will adversely affect the test results. DO NOT PLACE FILTER PAPER SPECIMENS IN A PLASTIC BAG.**

Specimen may be "Unsatisfactory for Testing" for the following reasons:

- a. Circles not completely filled in or not thoroughly saturated.
- b. Uneven saturation of circles or multiple sample application.
- c. Specimen appears contaminated.
- d. Clotted or caked blood on filter paper, or damaged filter paper.
- e. Assay inhibition due to antibiotic or other substance.
- f. Incomplete elution of blood from filter paper.
- g. Laboratory requisition incomplete or improperly completed.
- h. Results inconsistent - possibly due to improper sample collection.
- i. Specimen submitted on incorrect form or expired form.
- j. No specimen received with form.
- k. Specimen placed in plastic bag while wet.
- l. Receipt of specimen was more than 14 days from date of collection.

To Order Newborn
Screening Collection
Kits (ODH #450):
Call (405) 271-5070



Specimens should be transported in the manner designated by the OSDH Public Health Laboratory Service. Send specimens within 24 hours of collection.

Courier Service address:
NEWBORN SCREENING SECTION
Public Health Laboratory Service
1000 NE 10th Street
Oklahoma City, OK 73117-1299

Mailing address: (using United States Postal Service)
NEWBORN SCREENING SECTION
Public Health Laboratory Service
P.O. Box 24106
Oklahoma City, OK 73124-0106

Adoption

If infant is being adopted, check the Adoption box on the front of the form. List the agency or lawyer that is handling the adoption in the "Mom's Information" section. Please note: for proper identification, the "Infant's Information" section must be completed accurately. Questions? Please call (405) 271-6617 or (800) 766-2223.

SUBMITTER RESPONSIBILITY

1. Completion of form.
2. Collection of an adequate specimen for testing.
3. Send specimens within 24 hours of collection.
4. The quality of the specimen received by the Public Health Laboratory Service.
5. Listing the planned health care provider who will be providing well care for the infant after discharge or infant's physician if the infant is to be hospitalized for extended period of time.

SCREENING REQUIREMENTS FOR ALL NEWBORNS

1. Prior to blood transfusion, as early as possible after 24 hours of age or immediately prior to discharge, whichever comes first.
2. If infant is screened at less than 24 hours of age, repeat screen at 3-5 days of age (if premature or a sick infant, repeat screen at 7-14 days of age).
3. All premature and sick infants should have a repeat screen at 14 days of age.

APPENDIX B. REPORT FORM [REVOKED]

APPENDIX B. REPORT FORM [NEW]

Newborn Screening Program Report Form

Infant's Name: _____ Infant's Birth Date __ __ / __ __ / __ __

Newborn Screening Program Lab #: _____ Mother's Name: _____

[] Diagnosis pending, Follow-up Plan:

Final Diagnosis (please attach confirmation lab results)

- [] Normal
- [] Trait Condition (specify carrier status) _____
- [] Classic Galactosemia (GG phenotype/genotype)
- [] Duarte/Galactosemia Compound Heterozygote (DG phenotype/genotype)
- [] Congenital Adrenal Hyperplasia due to 21-Hydroxylase Deficiency
- [] Cystic Fibrosis
- [] Classic Phenylketonuria (PKU)
- [] Hyperphenylalaninemia (not clinically significant)
- [] Hyperphenylalaninemia (clinically significant treatment required)
- [] Congenital Hypothyroidism
- [] Medium-chain Acyl Coenzyme A Dehydrogenase Deficiency (MCAD)
- [] Sickle Cell Disease (specify type) _____
- [] Hemoglobin disease (specify type) _____
- [] Biotinidase deficiency
- [] Fatty Acid Oxidation Disorder (specify) _____
- [] Organic Acid Disorder (specify) _____
- [] Amino Acid Disorder (specify) _____
- [] Severe Combined Immunodeficiency (specify type) _____
- [] Other(specify) _____

Treatment Indicated? [] yes [] no

Date treatment started __ __ / __ __ / __ __

Referred to pediatric sub-specialist:

- [] Endocrinologist (specify name): _____
- [] Hematologist (specify name): _____
- [] Metabolic Specialist (specify name): _____
- [] Pulmonologist (specify name): _____
- [] Immunologist (specify name): _____

Family referred for (check all that apply):

- [] Genetic counseling (check provider):
 __ Sickle Cell Association __ Geneticist __ Other
- [] Enrollment in Newborn Screening Long-term Follow-up Program
- [] Early Intervention Services

Print Physician's Name _____ Telephone _____

Physician Signature _____ Date __ __ / __ __ / __ __

Mail or Fax this follow-up form with complete diagnostic information and confirmation lab results to: Prevention and Preparedness Services; ATTN: Newborn Screening Program Coordinator; 1000 NE Tenth Street, Oklahoma City, OK 73117-1299; Fax: (405) 271-4892; For questions or referral information, please call the Newborn Screening Program Coordinator at (405) 271-6617 or 1-800-766-2223.

APPENDIX C. REFUSAL FORM [REVOKED]
APPENDIX C. REFUSAL FORM [NEW]

Oklahoma State Department of Health
Refusal of the Newborn Screening Blood Test
Religious Tenets and Practices Refusal

Infant's Name: _____ Medical Record Number: _____

Date of Birth: ___ / ___ / ___

Attending Physician or Provider, print name: _____

Place of Birth:

___ Hospital, print name _____

___ Birthing Facility, print name _____

___ Home Birth

Type of Screen Refused: ___ Newborn Blood Test ___ Pulse Oximetry Screen

I have received and read the parent educational brochure printed by the Oklahoma Department of Health on the Newborn Screening blood test and pulse oximetry screening. I understand that these disorders are easily detected by testing a small blood sample from my baby's heel or by measuring the amount of oxygen in my baby's blood.

I have been informed that all newborns are required by law (under 63 O.S. 2002, Sections 1-533 and 1-534) to have a newborn screening test collected and pulse oximetry screening performed.

I have been informed and I understand that this screening is done to detect these disorders because symptoms sometimes do not appear for several weeks or months, and irreversible damage can occur before symptoms become apparent to a family or a physician.

I have been informed and I understand that, if untreated, these conditions may cause permanent damage to my child, including mental retardation, growth failure, and even death. This permanent health damage can be prevented through early detection and treatment.

I have discussed the newborn screening test and pulse oximetry screening with my physician or health care provider and I understand the risks to my child if the screening test is not completed.

I understand that the law allows a parent or guardian to refuse newborn screening and pulse oximetry screening based on the grounds that such examination conflicts with a person's religious tenets and practices. I elect to refuse newborn screening on that such testing of my infant conflicts with my religious tenets and practices. My decision was made freely and I accept the legal responsibility for the consequences of this decision.

Printed Parent/ Guardian's Name

Parent/Guardian Signature

____ / ____ / ____
Date

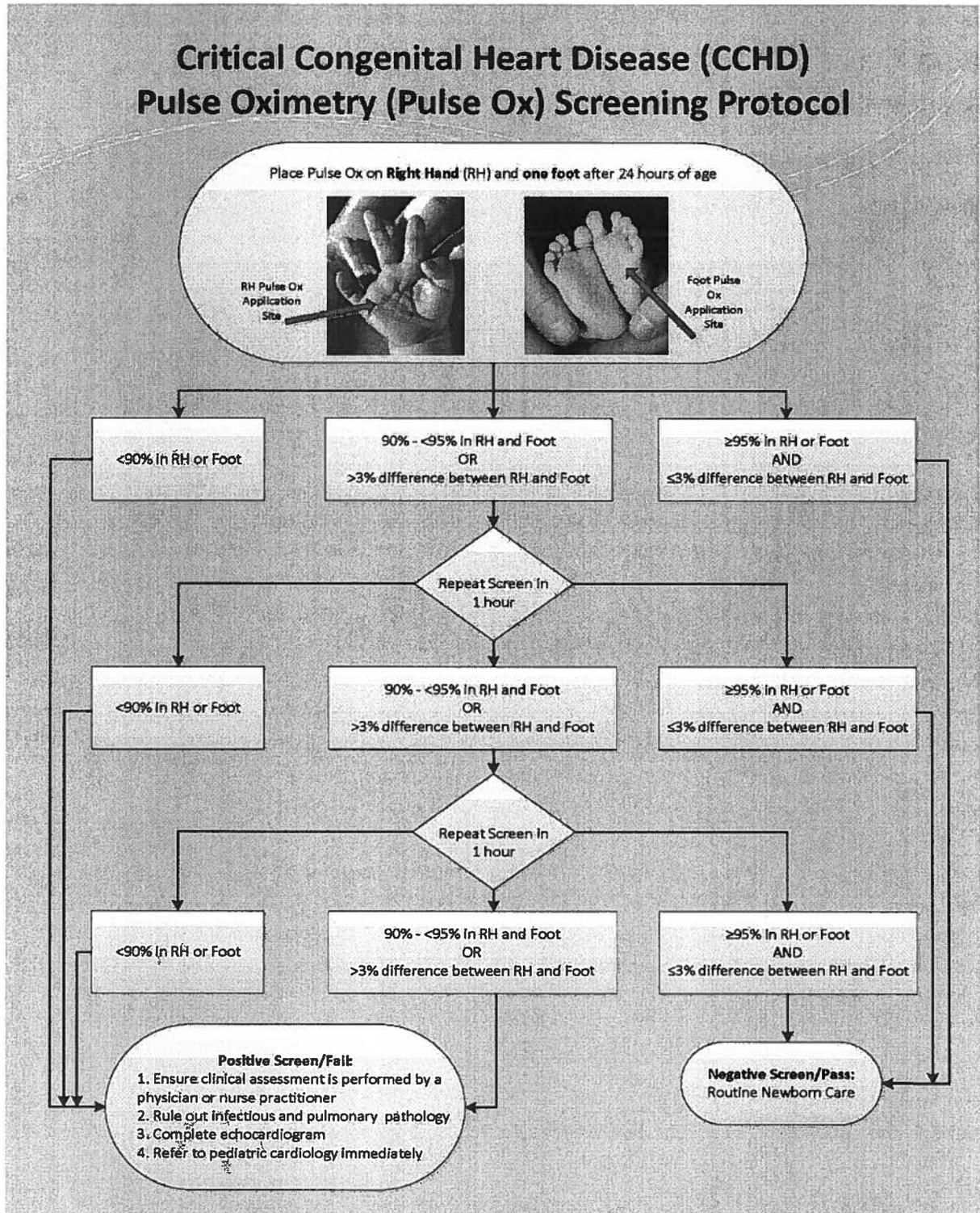
Print Witness Name

Signature of Witness

____ / ____ / ____
Date

Original to infant's record, provide a copy to parent, and forward copy by fax or mail to: Oklahoma State Department of Health, Newborn Screening Program Coordinator, 1000 NE Tenth Street, Oklahoma City, OK 73117-1299, (405) 271-6617 or 1-800-766-2223; Fax (405) 271-4892.

APPENDIX D. Recommended Pulse Oximetry Screening Protocol [NEW]



APPENDIX E. Pulse Oximetry Screening Result Form [NEW]

Oklahoma State Department of Health
Pulse Oximetry Screening Result Form

Infant Information:

Infant's Last Name: _____ Infant's First Name: _____

Medical Record Number: _____ Primary Physician: _____

Date of Birth: ___/___/___ Birth Hospital: _____

Mother's Last Name: _____ Mother's First Name: _____

Pulse Oximetry Screening:

Date of Screening: ___/___/___

Age at Time of Screening: _____ Days or _____ Hours

Result: ___ Pass/Negative ___ Fail/Positive ___ Not Performed

Complete this section only if pulse oximetry screen was not performed:

Reason pulse oximetry screening not perform:

___ Early Discharge

___ Screening Not Indicated due to _____

___ Parent Refusal

Screener's Name: _____

Screener's Signature: _____ Date: ___/___/___

Mail or Fax this follow-up form to: Oklahoma State Department of Health
Prevention and Preparedness Services
ATT: Newborn Screening Program Coordinator
1000 NE Tenth Street
Oklahoma City, OK 73117-1299
Fax: (405) 271-4892

For questions or referral information, please call the Newborn Screening Program Coordinator at (405) 271-6617 or 1-800-766-2223.

RULE COMMENT SUMMARY AND RESPONSE

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 550. NEWBORN SCREENING PROGRAM

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 Subchapter and Section: 310:550-1-1

Rule Subchapter and Section: 310:550-1-2

Rule Subchapter and Section: 310:550-3-1

Rule Subchapter and Section: 310:550-5-1

Rule Subchapter and Section: 310:550-5-2

Rule Subchapter and Section: 310:550-7-1

Rule Subchapter and Section: 310:550-13-1

Rule Subchapter and Section: 310:550-17-1

Rule Subchapter and Section: 310:550-19-1

Rule Subchapter and Section: 310:550-21-1

Name & Organization: Joni Bruce, parent of an infant who died from a genetic disease and Executive Director of the Oklahoma Family Network.

Comment: Ms. Bruce encouraged the addition of Severe Combined Immune Deficiency and Pulse Oximetry Screening to the Newborn Screening rules and the Hospital Standard rules as lifesaving and beneficial to the citizens of the State.

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Gina Antipov, mother of Sam age 12, who was diagnosed with SCID at six months of age and as a public citizen.

Comment: Ms. Antipov presented oral comments on behalf of Jeremy and Sara Penn whose daughter Samantha died at 20 months from SCID. They documented Samantha's illness and diagnostic odyssey, with the ultimate diagnosis of SCID. They strongly advocate for the addition of SCID to the Newborn Screening panel because they feel that if there had been early identification through newborn screening that their daughter would have survived. They stated that medical care for Samantha cost over \$1.1 million and if her disease had been identified earlier the cost of a bone marrow transplant would have been \$350,000 saving \$750,000 (which could be used to cover the cost of SCID screening for over 150,000 births).

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Vlad Antipov, father of Sam age 12, who was diagnosed with SCID at six months of age and a public citizen.

Comment: Mr. Antipov presented oral comments in favor of adding SCID to the Newborn Screening panel. He outlined the diagnostic odyssey that he and his wife underwent when his son got sick and was diagnosed at 6 months of age. He reiterated the financial burden placed on his family when they hit their \$1 million dollar insurance cap and had to change to the state's high risk pool. In addition, he stated that he had to leave a job that he liked to take another one for the health insurance.

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Dr. Tim Trojan, M.D., Oklahoma Institute of Allergy and Asthma.

Comment: Dr. Trojan, M.D. is Board Certified in Immunology. He presented oral comments in favor of adding SCID to the Newborn Screening panel. He provided information regarding sensitivity and specificity of testing; stating that sensitivity was demonstrated to be 100% for detecting SCID patients and the specificity is at 99.98%. He reviewed the Infant Mortality statistics for Oklahoma and offered that SCID screening would be financially cost effective at \$5.44/ child. In addition, he stated that "given the 9% Native American population in Oklahoma and SCID incidence up to 4 times higher in Native American populations" he believes that the SCID incidence in Oklahoma will be much higher than the anticipated 1-2 infants per year.

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Naomi Amaha, Oklahoma Government Relations Director, American Heart Association.

Comment: Ms. Amaha provided oral and written testimony urging the Board of Health to approve proposed rules regarding the Newborn Screening Program, as legislated by HB 1347.

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Erin Taylor, mother of Henry who was born with a congenital heart defect.

Comment: Ms. Taylor provided testimony stating that "Congenital Heart Defects are the most common birth defects in the State of Oklahoma and that there is a large financial impact to the state. Henry has had dozens of heart surgeries and over 35 heart catheterizations and a heart transplant. His medical care is over \$2 million and she has had to get health care for her child in four different states. The tests will track how common these complex congenital heart defects are so that maybe we can increase our capacity and infrastructure in the State of Oklahoma. For the past several years most of the children with complex congenital heart conditions have had to obtain their care out of state. Since 2002, 1200 children in the state have been born with the same condition as Henry costing the state millions of dollars".

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: James Love, MD., Allergy Clinic of Tulsa.

Comment: Received written comment "As a practicing immunologist in the state of Oklahoma for the past 17 years, I can speak to the necessity of newborn screening for immune deficiency. As you are

aware, data has shown that early bone marrow transplantation can prevent death and severe illness in this vulnerable group of children. And it has been shown to be cost-efficient in other states that have implemented the process. Without newborn screening, by the time these children present with overwhelming illness, it is often too late for them. Please consider adding this important test to our current panel of newborn screens."

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Mary Ann Bauman, MD, Medical Director, Women's Health and Community Relations INTEGRIS Health, Volunteer, American Heart Association.

Comment: Received written comment "During the 2013 legislative session, the Oklahoma Legislature and Governor Fallin approved House Bill 1347, a bill that ensured all newborns are screened for a critical congenital heart defect (CCHD) using a simple and non-invasive "pulse-ox" test. A pulse-ox test is a highly effective method to catch a congenital heart defect before a baby is sent home. Every minute is critical when the heart is not functioning properly, and early detection of a heart defect will allow for immediate treatment. I urge the Board of Health to approve the proposed rule 63 O.S. § 1-550.5 and support this solution to ensure detection of critical congenital heart defects in newborns. Thank you for your consideration".

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Pat Penn, Grandmother of Samantha Penn, died at age 18 months from SCID.

Comment: Received written comment "My grand-daughter, who was born in Stillwater, died from this disease because no-one gave her the simple blood test. After she died, her doctor in Stillwater identified another child with this disease, but, was able to send her to Cincinnati for treatment. How many other babies are there in Oklahoma who have SCID? Please, our family would like to help save other babies, perhaps even someone you know and love. Thanks for listening, Grandma Penn, 1220 S. Holly Dr., Sioux Falls SD 57105".

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Marcia Boyle, President and Founder, Immune Deficiency Foundation.

Comment: Received written comment stating that the "IDF supports the amendment to Title 310. Oklahoma State Department of Health Chapter 550. Newborn Screening Program to add SCID to the Newborn Screening panel in Oklahoma. Statement reiterates that infants affected by SCID lack T lymphocytes, the white blood cells that help resist infections due to a wide array of viruses, bacteria and fungi. The diagnosis of SCID very early in life is a true pediatric emergency, and the decision to screen for SCID will literally save the lives of infants in Oklahoma".

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

List of person who attended on behalf of Chapter 550

Name	Representing
Joni Bruce	Parent and Executive Director of the Oklahoma Family Network
Lauren Labeth	Oklahoma Family Network
Gina Antipov	Parent
Vlad Antipov	Parent
Tim Trojan	Physician, Oklahoma Institute of Allergies and Asthma
Naomi Amaha	Government Relations, American Heart Association
Erin Taylor	Parent, Malley and Henry Fund
Shannon Miller	Parent, Pulse Ox Oklahoma
Melissa Moore	Parent, Grayson's Advocates

Agency Rule Contact:

Sharon Vaz, Director, Screening and Special Services, phone (405) 271-6617, e-mail Sharonav@health.ok.gov.



Oklahoma State Department of Health
Creating a State of Health

To: Board of Health Secretary

Through: Terry Cline, Ph.D. 11-20-2013
Commissioner

Through: James Joslin, Chief JA
Health Resources Development Service
Agency Rule Liaison

Through: Don Maisch DM 11-8-2013
General Counsel

Through: Toni D. Frioux, MS, APRN-CNP, Deputy Commissioner
Prevention and Preparedness Services 08/11/7/2013

From: Sharon Vaz, MSGC, RN, Director
Screening & Special Services 2002 11/6/2013

Date: November 6, 2013

Subject: Rule Packet Submission for Distribution to Board of Health
Chapter 667, HOSPITAL STANDARDS

RECEIVED
NOV 08 2013
LEGAL DIVISION

The attached documents are submitted for **PERMANENT ADOPTION** by the State Board of Health at their December 10, 2013, meeting.

No changes to Rule Impact Statement or Rule Text based on the public comment submitted

Attachments:

- **RIS (Rule Impact Statement)**
- **Rule Text**
- **Rule Comment Summary**

(Please contact Ragina Munguia at x 56749 for corrections, pick-up and delivery.)

RULE IMPACT STATEMENT

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

1. **DESCRIPTION:**

The Section proposed for amendment is 310:677-19-2 which describes, for Hospitals, reporting requirements for certain events. The proposed rule changes update the list of diseases and conditions previously updated in the Newborn Screening Program rules, Chapter 550, of Title 310, relating to Newborn Screening Program. The updated list includes cystic fibrosis, congenital adrenal hyperplasia, medium-chain acyl coenzyme A dehydrogenase deficiency (MCAD), biotinidase deficiency, amino acid disorders, fatty acid oxidation disorders, organic acid disorders. In addition this proposal adds amendatory language to the existing rule to include Severe Combined Immunodeficiency Syndrome (SCID) as a new test in the core panel of 29 genetic disorders for newborn screening (NBS) in Oklahoma, as recommended by the Advisory Committee on Heritable Disorders in Newborns and Children – Recommended Uniform Screening Panel (January 21, 2010) - and after consultation with the Newborn Screening Subcommittee of the Oklahoma Genetics Advisory Committee. The updated list of conditions and diseases to this proposal include, cystic fibrosis, congenital adrenal hyperplasia, medium-chain acyl coenzyme A dehydrogenase deficiency (MCAD), This proposal also adds Pulse Oximetry screening for the detection of Critical Congenital Heart Disease (CCHD) to existing newborn screening rules as legislated by HB House Bill 1347 (2013) [63 O.S. Section 1-550.5].

2. **DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:**

- Updated list of disease and conditions is to maintain consistency between Chapter 550 and Chapter 667.
- There is no additional cost to Hospitals and birthing facilities for these named tests. The updated list are already required to conduct newborn screening as listed in Chapter 550.
- Severe Combined Immunodeficiency Syndrome (SCID) is proposed as a new test to the newborn screening panel.
- All newborns are screened for silent disorders that can be treated if identified before symptoms occur. Adding new screening disorders to the testing panel has immediate positive health benefits for affected infants and families and long-term financial benefits for the Oklahoman health care system.
- Several states (Wisconsin, Texas, Massachusetts, California, Louisiana, and New York) currently doing pilot studies for SCID testing have found that the incidence of the disease is as high as 1/40,000. This is much higher than our previously stated incidence (1/100,000) for this disease.
- The second proposed addition to Chapter 667 is Pulse Oximetry screening for the detection of Critical Congenital Heart Disease (CCHD) as legislated by HB 1347 (2013).
- The classes of persons affected are newborn babies and their parents who have babies in a birthing facility in Oklahoma.

- Additionally those affected are “birthing facilities” in Oklahoma as defined in House Bill 1347 (2013).
- There were over 52,000 births recorded by the Division of Vital Records for the Oklahoma State Department of Health in 2012.

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

- Estimate that 1-2 infants with SCID will be identified annually, based on the Oklahoma birth rate of approximately 55,000 – 60,000/annum and incidence of disease (~1/40,000).
- Early identification improves health outcomes. Generally, this disease results in life-threatening infections within the first few months of life. Early detection provides a positive contribution to Child Health and improves rates of infant survival, which will reduce Oklahoma’s rates of infant mortality and morbidity.
- The Oklahoma State Department of Health will evaluate overall benefits of SCID testing through follow-up of positively-screened infants.
- Cost of treatment (bone marrow transplant) for infants identified at birth is approximately \$250,000 to \$300,000 (for the procedure).
- Cost of treatment of a child not identified at birth is estimated at \$2 million.
- In Oklahoma as many as 105 babies are born annually with a Critical Congenital Heart Defect. This is a rate of approximately 20 babies/10,000.
- All infants born in a birthing facility in Oklahoma will benefit from early detection and treatment for a Critical Congenital Heart Defect.

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

There will be no cost to the department for compliance requirements. Compliance monitoring will be absorbed into the current inspection process. There should be no cost of compliance to the “birthing facilities” as a birthing facility was already required by federal requirement to have obtained the equipment necessary to perform a “pulse oximetry screening.” The CDC reports the cost of the screening itself ranges between \$5.00-\$10.00 per newborn and takes between 1-5 minutes per each screening conducted. This cost will be added to the bundle of costs for newborn screenings and paid by insurance or the consumer. There is a proposed request to increase the newborn screening fee by \$6.00 from \$152.62 to \$158.62 to cover the cost of the Public Health Laboratory and the Newborn Screening follow up department for implementation of SCID testing and monitoring.

For implementation of CCHD screening there will be no cost to the birthing facilities.

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

Additional staff time will be required to inspect for compliance of the birthing facilities for the new screening requirement and there will be a cost to the agency to track compliance and to undertake enforcement if compliance is not met. Compliance tracking will be done in collaboration with Prevention and Preparedness Division – Screening and Special Services.

6. **IMPACT ON POLITICAL SUBDIVISIONS:** There will be no impact on political subdivisions
7. **ADVERSE EFFECT ON SMALL BUSINESS:** There will be an impact on those birthing facilities that meet the definition of a small business. The impact will be to perform the newborn screening test that is currently being performed with the addition of the pulse oximetry screen and to recoup that cost from insurance or the consumer.

8. **EFFORTS TO MINIMIZE COSTS OF RULE:**

Proposed SCID testing to be performed in-house in the Public Health Laboratory (PHL) (versus send-out) using a CDC-developed protocol that obviates the need for extensive test development and validation. Training for SCID testing has been provided free by the CDC. This protocol does not require nucleic acid isolation, whereas alternate protocols have the added cost of this step. The PHL has chosen a qPCR system that is at the lower price end of available commercial systems.

The proposed CCHD screening rules implement statutory requirements for screening. The methodology devised is of the lowest cost identified to date.

9. **EFFECT ON PUBLIC HEALTH AND SAFETY:**

Changes to the Newborn Screening rule will improve the core public health services of Children's Health in Oklahoma. Early identification of at-risk infants can lead to reduction in infant mortality and morbidity. The CDC reports that pulse oximetry screenings can identify infants with critical congenital heart defects (CCHD). Infants with CCHDs are at significant risk for morbidity or mortality. The CDC reports that pulse oximetry screenings can detect seven to twelve different CCHDs that represent 17-31% of all congenital heart disease in newborns. The detection of the CCHD will allow the newborn to receive a surgical procedure, shortly after birth to correct the CCHD and reduce the morbidity and mortality rate.

10. **DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:**

Oklahoma currently ranks 44th in the country for infant mortality. Cases of SCID are undiagnosed because infants die due to overwhelming infections in the first few months of life. Addition of this screening test to the Newborn Screening Panel will ensure that Oklahoma is following the national Recommended Uniform Screening Panel as recommended by the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children and is aligned with newborn screening algorithms in bordering states. Addition of pulse oximetry screening for CCHD will allow for early intervention and treatment. Undetected CCHDs will lead to a higher morbidity and mortality rate among newborns.

11. This rule impact statement was prepared on [8/5/2013].

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

Subchapter 19 - Medical Records Department

310:667-19-2. Reports and records

(a) Reports shall be made by each hospital to the appropriate agency, including but not limited to the following:

- (1) Communicable disease.
- (2) Births and deaths.
- (3) Periodic reports to the Department on forms supplied for this purpose.
- (4) Newborn hearing screening report.

(A) All hospital nurseries shall complete a newborn hearing screening report form on all live newborns discharged from their facility. For facilities with a two-year average annual birth census of 15 or greater, physiologic hearing screening results as well as "at risk" indicators must be recorded on the report form; for facilities with a two-year average annual birth census of fewer than 15, "at risk" indicators must be recorded and if physiologic hearing screening is conducted, those results also must be recorded on the report form. It shall be the responsibility of the hospital administrator to assure that the Newborn Hearing Screening Report Form is correctly completed and subsequently submitted to the Department. The hospital administrator may designate one individual, who shall then be responsible for review of all newborn discharge summaries to insure that a report form has been completed for each infant and that the report form is a permanent part of that infant's record. A copy of the hearing screening report form must be given to the infant's caregiver at discharge.

(B) If an infant is transferred from one hospital to another, the second hospital shall be responsible for providing physiologic hearing screening, "risk indicator" screening, and for completion of the report form.

(C) It shall be the responsibility of the hospital administrator to insure that all completed report forms are mailed to the Department within seven (7) days of an infant's birth.

(D) It shall be the responsibility of the attending physician or licensed independent practitioner to inform parents if their infant passed or was referred on the physiologic hearing screening and/or if the infant is to be considered "at risk" for hearing impairment. Prior to discharge, the attending physician or licensed independent practitioner shall review the completed report form and shall inform the parents of their infant's status. Infants who do not pass the physiologic screening shall be referred for a diagnostic audiological evaluation as soon as possible.

(E) It shall be the responsibility of the coordinator of the Newborn Hearing Screening Program at the Department to arrange for hospital in-service training for all hospital personnel involved

in the process of completion of report forms. A manual of procedures shall be available in regard to processing of screening forms. The literature for distribution to parents shall be available from the Department.

(5) Newborn metabolic disorder screening.

(A) **Testing of newborns.** All newborns in Oklahoma shall be tested for phenylketonuria, hypothyroidism, galactosemia and sickle cell diseases ~~by a Certified Newborn Metabolic Disorder Screening Laboratory as defined in Chapter 550 of this Title,~~ cystic fibrosis, congenital adrenal hyperplasia, medium-chain acyl coenzyme A dehydrogenase deficiency (MCAD), biotinidase deficiency, amino acid disorders, fatty acid oxidation disorders, organic acid disorders, and upon completion of laboratory validation studies and establishment of short-term follow-up services, Severe Combined Immunodeficiency (SCID) detectable via the Department's laboratory technology utilized in newborn screening and approved by the Commissioner of Health as defined in Chapter 550 of this Title. All infants born at a birthing facility in Oklahoma shall be screened for Critical Congenital Heart Disease (CCHD) utilizing pulse oximetry. ~~a~~A parent or guardian may refuse ~~metabolic disorder newborn screening and/or pulse oximetry screening~~ of their newborn on the grounds that such examination conflicts with their religious tenets and practices. A parent or guardian who refuses ~~metabolic disorder newborn screening or pulse oximetry screening~~ of their newborn on the grounds that such examination conflicts with their religious tenets and practices shall also indicate in writing this refusal in the newborn's medical record with a copy sent to the Newborn ~~Metabolic Disorder Screening Program, Maternal and Child Health Prevention and Preparedness Service~~Services, Oklahoma State Department of Health, 1000 NE Tenth Street, Oklahoma City, Oklahoma 73117-1299.

(B) **Specimen collection for hospital births.** For all live hospital births, the physician or licensed independent practitioner shall order the collection of a newborn ~~metabolic disorder screening specimen~~ on all newborns prior to transfusion, ~~at three to five days of age as early as possible after 24 hours of age or immediately prior to discharge, whichever comes first.~~ Specimens shall be collected on the Newborn ~~Metabolic Disorder Screening Form Kit~~ as described in Appendix A of Chapter 550 of this Title using capillary or venous blood. Cord blood is unacceptable. The hospital is responsible for collecting specimens on all infants.

(i) If the initial specimen for any infant is collected prior to 24 hours of age, the hospital and the physician or licensed independent practitioner are responsible for notifying the infant's parents that a repeat specimen is necessary at three to five days of age. The infant's physician or licensed independent practitioner is responsible for insuring that the repeat specimen is collected.

(ii) The hospital is responsible for submitting a satisfactory

specimen and for documenting all requested information on the form kit including the parent/guardian's name, address, phone or contact phone number and the planned health care provider who will be providing well care for the infant after discharge, or if the infant is to be hospitalized for an extended period of time, the name of the infant's physician or licensed independent practitioner.

(iii) The hospital is responsible for documenting specimen collection and results in the infant's hospital record.

(iv) Infants transferred from one hospital to another during the newborn period shall have specimen collection documented in the infant's hospital record. It is the responsibility of the physician or licensed independent practitioner and the receiving hospital to insure a specimen is collected.

(v) It is the responsibility of the hospital and physician or licensed independent practitioner to insure that all infants are screened prior to discharge. If an infant is discharged prior to specimen collection, the ~~Newborn Metabolic Disorder~~ Screening Program Coordinator shall be notified by contacting ~~Maternal and Child Health Newborn Screening Program, Prevention and Preparedness Service Services~~, Oklahoma State Department of Health, 1000 NE Tenth Street, Oklahoma City, Oklahoma 73117-1299, (405) 271-6617, FAX (405) 271-4892, 1-800-766-2223, ext. 6617. The physician or licensed independent practitioner is responsible for insuring the specimen is collected ~~at three to five days of age~~ as early as possible after 24 hours of age.

(C) Pulse oximetry screening for birthing hospitals. For all live hospital births, the physician or licensed independent practitioner shall order the pulse oximetry screening for newborns to be performed after 24 hours of age or prior to discharge from a facility.

(i) If unable to perform the screening after 24 hours of age or prior to discharge, schedule the infant to be screened at the hospital between 24 hours and 48 hours of life; or notify the infant's physician if screening was not performed.

(ii) If the newborn infant is discharged from a facility after 12 hours of life but before 24 hours of life, the birthing facility shall perform screening as late as is practical before the newborn infant is discharged from the birthing facility.

(iii) If the infant is discharged before 12 hours of life, the birthing facility shall perform the screening between 24 hours and 48 hours of life.

(iv) For newborn infants in special care or intensive care, birthing facilities shall perform pulse oximetry screen on infants prior to discharge utilizing recommended protocol, unless the infant has an identified congenital heart defect or has an echocardiogram performed. Continuous pulse oximetry monitoring may not be substituted for CCHD screening.

(v) There may be instances where screening for CCHD is not indicated, including but not limited to instances where:

(I) The newborn infant's clinical evaluation to date has included an echocardiogram which ruled out CCHD; or

(II) The newborn infant has confirmed CCHD based on prenatal or postnatal testing.

(III) Indicate on NBS filter paper that screening was not performed.

(D) Screening for premature/sick infants. For all premature/sick infants, the physician or licensed independent practitioner shall order the collection of a newborn ~~metabolic disorder~~ screening specimen prior to red blood cell transfusion, ~~at three to seven days of age~~ as early as possible after 24 hours of age, or immediately prior to discharge, whichever comes first. It is recommended that a repeat newborn ~~metabolic disorder~~ screening specimen be collected at 14 days of age. Specimens shall be collected on the Newborn ~~Metabolic Disorder~~ Screening Form Kit using capillary or venous blood. The hospital is responsible for collecting specimens on all premature/sick infants.

(i) Premature/sick infants screened prior to 24 hours of age must be re-screened between 7-14 days of age.

(ii) Premature/sick infants who could not be screened prior to a red blood cell transfusion should be re-screened by the 7th day of life and a repeat specimen collected when plasma and/or red cells will again reflect the infant's own metabolic processes or phenotype. The accepted time period to determine hemoglobin type is 90 to 120 days after transfusion.

(iii) The recommended follow-up study for an abnormal thyroid screen in a premature infant is a serum free T4 (measured by direct dialysis or an equivalent method) and TSH at 7-14 days of age.

~~(D)~~ (E) Newborn Screening Hospital recording. The hospital shall implement a procedure to assure that a newborn screening specimen has been collected on every newborn and mailed to the Newborn ~~Metabolic Disorder~~ Screening Laboratory within 24 - 48 hours of collection.

(i) The hospital shall immediately notify the infant's physician or licensed independent practitioner, and parents or guardians if an infant is discharged without a sample having been collected. This notification shall be documented in the infant's hospital record.

(ii) If no test results are received within fifteen (15) days after the date of collection, the hospital shall contact the Newborn Metabolic Disorder Screening Laboratory to verify that a specimen had been received. If no specimen has been received, the hospital shall notify the physician or licensed independent practitioner.

(iii) Any hospital or any other laboratory which collects, handles or forwards newborn ~~metabolic disorder~~ screening samples shall keep a log containing name and date of birth of the infant, name of the attending physician or licensed independent practitioner, name of the health care provider who will be

providing well care for the infant after discharge, medical record number, serial number of the form kit used, date the specimen was drawn, date the specimen was forwarded, date the test results were received and the test results, and pulse oximetry screening results.

~~(iv) The hospital is responsible for assuring that employees who collect, handle or perform newborn metabolic screening tests are informed of their responsibilities with respect to screening procedures.~~

(F) Pulse oximetry screening hospital recording. The hospital shall implement a procedure to assure that pulse oximetry screening has been performed on every newborn prior to discharge.

(i) All pulse oximetry screening results shall be recorded in the newborn infant's medical record and results reported to a parent or guardian prior to discharge from the hospital.

(ii) All pulse oximetry screening results shall be recorded on the Newborn Screening Collection Kit (ODH #450), as described in Appendix A of Chapter 550 of this Title, or faxed to the Oklahoma State Department of Health Newborn Screening Program.

~~(E)~~ (G) Parent and health care provider education. The hospital will be responsible or designate a responsible party to distribute the Newborn ~~Metabolic Disorder~~ Screening Program's written educational materials on newborn ~~metabolic disorder~~ screening and pulse oximetry screening provided by the Department to at least one of each newborn's parent or legal guardian.

~~(F)~~ (H) Training. Hospitals shall provide ongoing training programs for their employees involved with newborn screening procedures. These training programs shall include methods of collecting a ~~Ssatisfactory Nnewborn Metabolic Disorder Sscreening Sspecimen-~~ and proper pulse oximetry screening methods. The hospital is responsible for ensuring that employees who collect, handle or perform newborn screening tests; or perform pulse oximetry screening are informed of their responsibilities with respect to screening procedures.

(6) Birth defects. Each hospital shall maintain a list of patients up to six (6) years of age who have been diagnosed with birth defects, and all women discharged with a diagnosis of stillbirth or miscarriage. On request, each hospital shall make the medical records of these individuals available to the State Department of Health.

(7) Abortions. Attending physicians shall complete and submit to the Department a report form for each abortion performed or induced as required by 63 O.S. 1999, Section 1-738.

(b) **Record of patient admission.**

(1) All persons admitted to any institution covered by these standards shall be under the care of a doctor of medicine (M.D.) or osteopathy (D.O.) duly licensed to practice medicine and surgery in the State of Oklahoma or a licensed independent practitioner, whose name shall be shown on the admitting record.

(2) The hospital admitting record also shall show the following for each patient.

- (A) Full name of patient with age, sex, address, marital status, birth date, home phone number, date of admission, and admitting diagnosis.
 - (B) Next of kin, with address, phone number, and relationship.
 - (C) Date and time of admission, the admission and final diagnoses, and the name of physician or licensed independent practitioner.
 - (D) Any advanced directive for health care as defined in the Oklahoma Rights of the Terminally Ill or Persistently Unconscious Act.
- (3) Special clinical reports shall be kept, including the following:
- (A) Obstetrical patients throughout labor, delivery, and post-partum.
 - (B) Newborn, giving the infant's weight, length, and other notes relative to physical examination.
 - (C) Surgical and operative procedures, including pathological reports.
 - (D) Record of anesthesia administration.
- (c) **Orders for medications, treatments, and tests.**
- (1) All medication orders shall be written in ink and signed by the ordering physician or practitioner authorized by law to order the medication, with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment for contraindications. The order shall be preserved on the patient's chart.
 - (2) All orders shall be written in ink and signed by the ordering physician or practitioner. Orders received by resident physicians shall be co-signed if required by medical staff bylaws. The order shall be preserved on the patient's chart.
 - (3) All orders taken from the physician or practitioner, for entry by persons other than the physician or practitioner, shall be countersigned.
 - (4) Telephone or verbal orders may be authenticated by an authorized physician or practitioner other than the ordering physician or practitioner when this practice is defined and approved in the medical staff bylaws. If allowed, medical staff bylaws must identify the physicians or practitioners who may authenticate another physician's or practitioner's telephone or verbal order, e.g. physician partners or attending physicians or practitioners, and define the circumstances under which this practice is allowed. The bylaws must also specify that when a covering or attending physician or practitioner authenticates the ordering physician's or practitioner's telephone or verbal order, such an authentication indicates that the covering or attending physician or practitioner assumes responsibility for his or her colleague's order and verifies the order is complete, accurate, appropriate, and final. The person taking the telephone or verbal order shall read the order back to the physician or practitioner to ensure it was correctly understood and verify on the order the fact that the order was read back. Each facility, within its own procedures and protocols, shall establish a verification process to be placed on orders to demonstrate that the order was read back to the physician.

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 Subchapter and Section: 310:667-19-2

Name & Organization: Joni Bruce, parent of an infant who died from a genetic disease and Executive Director of the Oklahoma Family Network.

Comment: Ms. Bruce encouraged the addition of Severe Combined Immune Deficiency and Pulse Oximetry Screening to the Newborn Screening rules and the Hospital Standard rules as lifesaving and beneficial to the citizens of the State.

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Gina Antipov, mother of Sam age 12, who was diagnosed with SCID at six months of age and as a public citizen.

Comment: Ms. Antipov presented oral comments on behalf of Jeremy and Sara Penn whose daughter Samantha died at 20 months from SCID. They documented Samantha's illness and diagnostic odyssey, with the ultimate diagnosis of SCID. They strongly advocate for the addition of SCID to the Newborn Screening panel because they feel that if there had been early identification through newborn screening that their daughter would have survived. They stated that medical care for Samantha cost over \$1.1 million and if her disease had been identified earlier the cost of a bone marrow transplant would have been \$350,000 saving \$750,000 (which could be used to cover the cost of SCID screening for over 150,000 births).

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Vlad Antipov, father of Sam age 12, who was diagnosed with SCID at six months of age and a public citizen.

Comment: Mr. Antipov presented oral comments in favor of adding SCID to the Newborn Screening panel. He outlined the diagnostic odyssey that he and his wife underwent when his son got sick and was diagnosed at 6 months of age. He reiterated the financial burden placed on his family when they hit their \$1 million dollar insurance cap and had to change to the state's high risk pool. In addition, he stated that he had to leave a job that he liked to take another one for the health insurance.

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Dr. Tim Trojan, M.D., Oklahoma Institute of Allergy and Asthma.

Comment: Dr. Trojan, M.D. is Board Certified in Immunology. He presented oral comments in favor of adding SCID to the Newborn Screening panel. He provided information regarding sensitivity and specificity of testing; stating that sensitivity was demonstrated to be 100% for detecting SCID patients and the specificity is at 99.98%. He reviewed the Infant Mortality statistics for Oklahoma and offered that SCID screening would be financially cost effective at \$5.44/ child. In addition, he stated that "given the 9% Native American population in Oklahoma and SCID incidence up to 4 times higher in Native American populations" he believes that the SCID incidence in Oklahoma will be much higher than the anticipated 1-2 infants per year.

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Naomi Amaha, Oklahoma Government Relations Director, American Heart Association.

Comment: Ms. Amaha provided oral and written testimony urging the Board of Health to approve proposed rules regarding the Newborn Screening Program, as legislated by HB 1347.

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Erin Taylor, mother of Henry who was born with a congenital heart defect.

Comment: Ms. Taylor provided testimony stating that "Congenital Heart Defects are the most common birth defects in the State of Oklahoma and that there is a large financial impact to the state. Henry has had dozens of heart surgeries and over 35 heart catheterizations and a heart transplant. His medical care is over \$2 million and she has had to get health care for her child in four different states. The tests will track how common these complex congenital heart defects are so that maybe we can increase our capacity and infrastructure in the State of Oklahoma. For the past several years most of the children with complex congenital heart conditions have had to obtain their care out of state. Since 2002, 1200 children in the state have been born with the same condition as Henry costing the state millions of dollars".

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: James Love, MD., Allergy Clinic of Tulsa.

Comment: Received written comment "As a practicing immunologist in the state of Oklahoma for the past 17 years, I can speak to the necessity of newborn screening for immune deficiency. As you are aware, data has shown that early bone marrow transplantation can prevent death and severe illness in this vulnerable group of children. And it has been shown to be cost-efficient in other states that have implemented the process. Without newborn screening, by the time these children present with overwhelming illness, it is often too late for them. Please consider adding this important test to our current panel of newborn screens."

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Mary Ann Bauman, MD, Medical Director, Women's Health and Community Relations INTEGRIS Health, Volunteer, American Heart Association.

Comment: Received written comment "During the 2013 legislative session, the Oklahoma Legislature and Governor Fallin approved House Bill 1347, a bill that ensured all newborns are screened for a critical congenital heart defect (CCHD) using a simple and non-invasive "pulse-ox" test. A pulse-ox test is a highly effective method to catch a congenital heart defect before a baby is sent home. Every minute is critical when the heart is not functioning properly, and early detection of a heart defect will allow for immediate treatment. I urge the Board of Health to approve the proposed rule 63 O.S. § 1-550.5 and support this solution to ensure detection of critical congenital heart defects in newborns. Thank you for your consideration".

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Pat Penn, Grandmother of Samantha Penn, died at age 18 months from SCID.

Comment: Received written comment "My grand-daughter, who was born in Stillwater, died from this disease because no-one gave her the simple blood test. After she died, her doctor in Stillwater identified another child with this disease, but, was able to send her to Cincinnati for treatment. How many other babies are there in Oklahoma who have SCID? Please, our family would like to help save other babies, perhaps even someone you know and love. Thanks for listening, Grandma Penn, 1220 S. Holly Dr., Sioux Falls SD 57105".

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Marcia Boyle, President and Founder, Immune Deficiency Foundation.

Comment: Received written comment stating that the "IDF supports the amendment to Title 310. Oklahoma State Department of Health Chapter 550. Newborn Screening Program to add SCID to the Newborn Screening panel in Oklahoma. Statement reiterates that infants affected by SCID lack T lymphocytes, the white blood cells that help resist infections due to a wide array of viruses, bacteria and fungi. The diagnosis of SCID very early in life is a true pediatric emergency, and the decision to screen for SCID will literally save the lives of infants in Oklahoma".

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

List of person who attended on behalf of Chapter 667

Name	Representing
Joni Bruce	Parent and Executive Director of the Oklahoma Family Network
Lauren Labeth	Oklahoma Family Network
Gina Antipov	Parent
Vlad Antipov	Parent
Tim Trojan	Physician, Oklahoma Institute of Allergies and Asthma
Naomi Amaha	Government Relations, American Heart Association
Erin Taylor	Parent, Malley and Henry Fund
Shannon Miller	Parent, Pulse Ox Oklahoma
Melissa Moore	Parent, Grayson's Advocates

Agency Rule Contact:

Sharon Vaz, Director, Screening and Special Services, phone (405) 271-6617, e-mail Sharonav@health.ok.gov.



Oklahoma State Department of Health
Creating a State of Health

To: Board of Health Secretary

Through: Terry Cline, Ph.D.
Commissioner *11-20-2013*

Through: James Joslin, Chief *JJ*
Health Resources Development Service
Agency Rule Liaison

Through: *for Steve W. Ronck*
Steve W. Ronck, MPH *11/4/13*
Deputy Commissioner, Community & Family Health Services Division

From: Jana S. Winfree, DDS
Director, Dental Health Service *JAW 11-4-13*

Date: November 4, 2013

Subject: Rule Packet Submission for Distribution to Board of Health
Chapter 526, Dental Services

The attached documents are submitted for **PERMANENT ADOPTION** by the State Board of Health at their December 10, 2013, meeting.

No comments were received during the comment period or during the public hearing.

There have been no changes to any of the documents since prior review.

Attachments:

- **RIS (Rule Impact Statement)**
- **Rule Text**
- **Rule Comment Summary**

(Please contact Susan Potter at x56760 for corrections, pick-up and delivery.)

RULE IMPACT STATEMENT

(This document may be revised based on comment received during the public comment period.)

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 526. DENTAL SERVICES

Before the Oklahoma State Board of Health December 10, 2013

1. **DESCRIPTION:**

310:526-3-2(b) The current Rule sets forth the description and operation of the Oklahoma Dental Loan Repayment Program (Program). The proposed action allows flexibility in selecting the number and types of participants and in the time period for participation in the Program. The circumstance for the Rule change is compelled by legislation, HB 2587, effective November 1, 2012. The intended effect is to allow the Advisory Committee and Department to select the appropriate number of participants based on funding and the appropriate type of participant (Oklahoma University College of Dentistry faculty or non-faculty), and allow the service obligation period to be adjusted.

310:526-3-2(d) The current Rule states that each award shall be distributed by a two-party draft made payable to the dentist and the loan agency. The proposed action states that each award shall be distributed in accordance with state law. The circumstance for the Rule change is because state preference is to distribute awards by direct deposit and the intended effect is to streamline administration of the Program.

310:526-3-3(b)(3) and (e)(5) The current Rule sets forth eligibility requirements for participants. The non-faculty participant agrees that Medicaid patients will represent 30% of all treated patients at a minimum. The proposal clarifies the count will be by number of patient visits. The Rule change takes into consideration that dental software used by participants favors this type of reporting and the intent of the Department to facilitate their reporting requirements.

2. **DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:**

The proposal will affect the applicants seeking participation in the Program; the recipients of Medicaid dental benefits; the patients, students, and faculty at the University of Oklahoma College of Dentistry; the Oklahoma Health Care Authority; and the Oklahoma State Department of Health. There is no expected cost impact for the affected parties.

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

The proposal will benefit those affected by streamlining Program operations and amending the Rule as compelled by legislation, HB 2587. An increased number of Medicaid recipients may be served due to the flexibility in selection of faculty and non-faculty participants. This could improve the dental health and overall health of the Medicaid population.

4. **ECONOMIC IMPACT, COST OF COMPLIANCE AND FEE CHANGES:**
Participants may realize reduced cost of compliance by simplifying reporting and accounting processes. An increased number of Medicaid recipients may be served due to the flexibility in selection of faculty and non-faculty participants. This could reduce the need and expense of future dental care for the Medicaid population.
5. **COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY:**
The cost to the Department to implement the amendments will be approximately \$4,000 to cover the costs of rule drafting, adoption, publication, distribution, and education. The proposed rules will be implemented and enforced by existing Department personnel and will have no anticipated effect on state revenues.
6. **IMPACT ON POLITICAL SUBDIVISIONS:**
There will be no impact on political subdivisions and it will not require their cooperation in implementing or enforcing the proposed amendment.
7. **ADVERSE EFFECT ON SMALL BUSINESS:**
There is no known adverse economic effect on small business as provided by the Oklahoma Small Business Regulatory Flexibility Act.
8. **EFFORTS TO MINIMIZE COSTS OF RULE:**
No less costly or nonregulatory methods have been identified.
9. **EFFECT ON PUBLIC HEALTH AND SAFETY:**
There are no significant risks known from promulgation of this proposed amendment. The proposal supports the core public health function of assurance by enhancing a competent workforce and providing care to vulnerable populations. The proposal contributes to improving the health status of Oklahomans by reducing health inequities and increasing access to dental care.
10. **DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:**
If this proposal is not adopted, the Program Rules will not be in compliance with state law.
11. This rule impact statement was prepared on July 25, 2013.

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 526. DENTAL SERVICES**

SUBCHAPTER 3. OKLAHOMA DENTAL LOAN REPAYMENT PROGRAM

310:526-3-2. Description and operation of the Program

- (a) **Department's equal opportunity policies applicable.** The Department's Dental Service will administer the Oklahoma Dental Loan Repayment Program in accordance with the Department's policies governing equal opportunity and access to programs, services and activities.
- (b) **General operation of the Program.** The Program will provide educational loan repayment assistance ~~to as many as five (5) for a number not to exceed twenty-five (25) Oklahoma licensed full time (or full time equivalent, or as designated by Advisory Committee or Department) dentists licensed to practice in Oklahoma per year for a 2 to 5 year period per dentist.~~ The Program will provide prorated educational loan repayment assistance based upon the percentage of time worked, ~~up to four full time equivalent dentists working in a designated dental health professional shortage area and one dentist full time equivalent entering or participating in the Program each year agreeing.~~ Dentists entering the Program agree to teach at the University of Oklahoma College of Dentistry if applicable faculty positions are available, or provide dental care and services to Medicaid recipients in a designated dental health professional shortage area (DHPSA).
- (c) **Determining individual awards.** The amount of award, not to exceed \$25,000 per year for each participating full time equivalent dentist, shall be determined by the Department annually based upon the amount of funds appropriated to the Department. If the participating dentist's eligible loans are less than the cumulative repayment assistance total available over 5 years, that participating dentist shall be in the Program no longer than required to pay off the total eligible loans and shall not receive more funding assistance than the total eligible indebtedness.
- (d) **Distributing the awards.** Each award shall be distributed ~~to the participating dentist by two party drafts made payable to the dentist and the appropriate loan agency in equal monthly disbursements throughout the service obligation~~ in accordance with state law.
- (e) **Default.** If the participating dentist does not fulfill the terms of the service obligation, the Department may collect from the participant the entire amount of loan repayment assistance extended to the participant under the Program, plus interest.
- [Source: Added at 24 Ok Reg 203, eff 11-1-06 (emergency); Added at 24 Ok Reg 1983, eff 6-25-07; Amended at 27 Ok Reg 2524, eff 7-25-10]

310:526-3-3. Eligibility to participate in the Program

- (a) **Eligibility requirements common to both non-faculty and faculty participants.** Eligibility for repayment assistance for non-faculty and faculty participants requires compliance with the following requirements:
- (1) receipt or award of a dental degree from an accredited United States dental school within the previous five (5) years;
 - (2) completion of all requirements to receive or be awarded an active unrestricted license to practice dentistry in the State of Oklahoma at the time the service obligation begins; and,
 - (3) a financial need with outstanding eligible dental school loans.

(b) **Additional eligibility requirements for non-faculty participants.** Eligibility for repayment assistance for non-faculty participants requires compliance with the following additional requirements:

- (1) an established general or pediatric dental practice, or the commitment to establish such a practice, located in an Oklahoma DHPSA;
- (2) fulfillment of all applicable requirements of the Oklahoma Health Care Authority to qualify as a Medicaid Dental Provider at the time the service obligation begins; and,
- (3) agree that during the service obligation/contract period, a minimum 30% of patients ~~treated are Medicaid recipients at the time of treatment, or 30% of patient visits~~ are by Medicaid recipients.

(c) **Additional eligibility requirements for faculty participants.** Eligibility for repayment assistance for faculty participants requires compliance with the additional requirement of abiding by the rules and regulations for a faculty member, and the job duties assigned by the Dean of the University of Oklahoma College of Dentistry.

(d) **Limitations upon eligibility common to both non-faculty and faculty participants.** A non-faculty or faculty participant's eligibility may be rescinded or terminated if any of the following conditions occur:

- (1) a breach of an obligation for service to a federal, state, or local government entity;
- (2) an obligation for service to a federal, state, or local government entity that will interfere with the fulfillment of the requirements of the Program that remains unsatisfied; or,
- (3) default or material breach of an agreement to repay a higher education loan or borrowing agreement.

(e) **Additional considerations.**

- (1) Preference will be given to graduates of the University of Oklahoma College of Dentistry.
- (2) Preference will be given to eligible practice sites that are not Medicaid/SoonerCare specific.
- (3) Geographic diversity of the participants is an objective of the Program.
- (4) An eligible practice site is a solo, group, or incorporated private practice, and any federal, state, local, or private for-profit or nonprofit dental facility.
- (5) To qualify for the 30% minimum Medicaid recipient requirement the participant must use ~~an unduplicated count of the patients treated~~ or a count of patient visits during the service obligation. The 30% requirement will be monitored monthly, but the participant will be deemed to be compliant if the yearly average is 30% or greater.

(f) **Eligible loans.** Loans eligible for repayment assistance are any loans for educational expenses while attending dental school from a college, university, government, commercial source, or an organization, institution, association, society, or corporation that is exempt from taxation under 501(c)(3) or (4) of the Internal Revenue Code of 1986. The ODLRP participant must be able to provide, upon request, documentation that commercial loans were used for payment of educational expenses.

[Source: Added at 24 Ok Reg 203, eff 11-1-06 (emergency); Added at 24 Ok Reg 1983, eff 6-25-07; Amended at 25 Ok Reg 1151, eff 5-25-08; Amended at 27 Ok Reg 2524, eff 7-25-10]

RULE COMMENT SUMMARY AND RESPONSE

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 526. DENTAL SERVICES

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)]

No comments were received during the comment period or during the public hearing.

Rule Subchapter and Section:

310:526-3-2(b), 310:526-3-2(d), 310:526-3-3(b)(3), 310:526-3-3(e)(5)

Agency Rule Contact:

Susan Potter, Program Manager, Oklahoma Dental Loan Repayment Program, phone (405) 271-5502, email susanp@health.ok.gov.



Oklahoma State Department of Health
Creating a State of Health

To: Board of Health Secretary

Through: Terry Cline, Ph.D. *11-20-2013*
Commissioner

Through: James Joslin, Chief *JJ*
Health Resources Development Service
Agency Rule Liaison

Through: Stephen W. Ronck, Deputy Commissioner *SWR*
Community and Family Health Services

Through: Suzanna Dooley, Director *SD*
Maternal Child Health Service

From: Ann Benson, Administrative Program Manager *AB*
Child and Adolescent Health
Maternal Child Health Service

Date: November 5, 2013

Subject: Rule Packet Submission for Distribution to Board of Health
Chapter 310, Vision Screening *531*

The attached documents are submitted for PERMANENT ADOPTION by the State Board of Health at their December 10, 2013, meeting.

No changes have been made since the prior review. No comments were received during the comment period or during the public hearing.

Attachments:

- **RIS (Rule Impact Statement)**
- **Rule Text**
- **Rule Comment Summary**

(Please contact Paula Wood at x 58636 for corrections, pick-up and delivery.)

RULE IMPACT STATEMENT

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 531. VISION SCREENING

1. **DESCRIPTION:**
The proposed rule changes implement provisions of Section 44, House Bill 1467, which creates the Infant and Children's Health Advisory Council, and Section 79, which replaces the Vision Screening Advisory Committee in 70 O.S. 2011, Section 1210.284, with the Infant and Children's Health Advisory Council and eliminates the role of the advisory committee in carrying out programmatic activities. The proposed rule changes delineate the responsibilities of the Department in carrying out statewide vision screening for children.
2. **DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:**
No class of persons should be affected by this change. This change should be budget neutral to the agency.
3. **DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED HEALTH OUTCOMES:**
Rule change has no affect on people benefitting from vision screening or expected health outcomes.
4. **ECONOMIC IMPACT, COST OF COMPLIANCE AND FEE CHANGES:**
There are no fees, or cost implementation, associated with this change.
5. **COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY:**
The cost to the Department to implement the amendments will be approximately \$1,800.00 to cover the costs of rule drafting, adoption, publication, distribution, and education. The proposed rules will be implemented and enforced by existing Department personnel and will have no anticipated effect on state revenues. The agency will no longer have to reimburse mileage to members of the Oklahoma Vision Screening Advisory Committee Children that attend quarterly meetings.
6. **IMPACT ON POLITICAL SUBDIVISIONS:**
There is no impact on political subdivisions.
7. **ADVERSE EFFECT ON SMALL BUSINESS:** There will be no adverse effect on small business as provided by the Oklahoma Small Business Regulatory Flexibility Act.
8. **EFFORTS TO MINIMIZE COSTS OF RULE:**
There is minimal effect to the state revenues as projected in implementation and enforcement of the program. No less costly methods have been identified.
9. **EFFECT ON PUBLIC HEALTH AND SAFETY:**
There is no effect on public health and safety with this change. Sports Eye Safety information will remain on the Oklahoma State Department of Health website.
10. **DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:**
There is no detrimental effect of public health and safety if this change is not adopted.
11. This rule impact statement was prepared on July 19, 2013.

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 531. VISION SCREENING**

SUBCHAPTER 1. GENERAL PROVISIONS

310:531-1-2. Authority

Oklahoma State Board of Health; 70 O.S. § 1210.284; 63 O.S. §§ 1-103a.1, 1-105 and 1-106 et seq.

310:531-1-3. Definitions

When used in this Chapter, the following words or terms shall have the following meaning unless the context of the sentence requires another meaning:

~~"Advisory Committee" means the Oklahoma Vision Screening Advisory Committee for Children.~~

"Board" means the State Board of Health.

"Commissioner" means the Commissioner of Health of the Oklahoma State Department of Health.

"Comprehensive Eye Exam" means a clinical assessment and tests administered by a licensed optometrist or ophthalmologist to assess a person's level of vision as well as detect any abnormality or diseases.

"Department" means the Oklahoma State Department of Health.

"HOTV Chart" means a vision screening test that determines relative visual acuity for distance vision using a chart with the four (4) letters: H, O, T and V.

"Infant and Children's Health Advisory Council" means the advisory council to the Board and Department in the area of infant and child health including vision screening.

"Lea Symbol Chart" means a vision screening test that determines relative visual acuity for distance vision using a chart with the four (4) symbols: circle, square, house, and apple.

"Ophthalmologist" means a person licensed by the state of Oklahoma to practice medicine who has a specialty in ophthalmology.

"Optometrist" means a person licensed by the state of Oklahoma to practice optometry.

"Random Dot E Stereo Test" means a vision screening test that determines relative stereo acuity or depth perception.

~~"Professional Examination" means a diagnostic evaluation performed by an appropriately licensed professional whose expertise addresses the diagnostic needs of the individual.~~

"Referral" means parent/guardian notification that the student's screening results indicate a need for a professional examination comprehensive eye exam by an ophthalmologist or optometrist.

"Snellen Letter Chart" means a vision screening test that determines relative visual acuity for distance vision using a chart consisting of eight (8) or more rows of progressively smaller block type letters.

~~"Vision Screening Provider screening provider(s)" means a person(s) who has successfully completed vision screening training using curricula approved by the Advisory CommitteeDepartment, submitted an application to the Advisory CommitteeDepartment, and has been approved by the Advisory CommitteeDepartment as being a vision screening provider.~~

"Vision Screening screening" means the process or system used to identify children in grades K, 1 and 3 who may be at risk of having or developing visual problems that may adversely affect their ability to acquire knowledge, skill or learning, for the purpose of recommending further evaluation by an optometrist or ophthalmologist.

~~"Vision Screening Trainer screening trainer(s) " is a person(s) who has been approved as a vision screening provider and completed additional training approved by the Advisory CommitteeDepartment to provide training to potential vision screening providers.~~

~~"Vision Screening Trainer of Trainers screening trainer(s) of trainers" is a person(s) who has been approved as a vision screening provider and vision screening trainer and completed additional education and practicum approved by the Advisory CommitteeDepartment to become a vision screening trainer of trainers.~~

"Vision Screening Registry" is a system for collecting and maintaining in a structured manner the names of individuals that have been approved by the ~~Advisory Committee~~Department as vision screening providers.

~~"Background Check" is the process of looking up and compiling criminal records of an individual.~~

SUBCHAPTER 3. ADVISORY COMMITTEE

310:531-3-1. Purpose

~~This subchapter creates the Oklahoma Vision Screening Advisory Committee for Children.~~

310:531-3-2. Advisory Committee

~~(a) The Advisory Committee shall consist of five (5) members who shall be appointed by the Commissioner.~~

~~(b) The Advisory Committee is comprised of one licensed optometrist, one licensed ophthalmologist, one representative of the State Department of Education, one representative of the Oklahoma State Department of Health, and one representative of a statewide organization for the prevention of blindness.~~

~~(c) The first Advisory Committee shall serve the following terms: one member for one (1) year, two members for two (2) years, and two members for three (3) years. Thereafter, at the expiration of the term of each member, the Commissioner shall appoint a successor for a four (4) year term.~~

~~(d) Vacancies occurring in the Advisory Committee shall be filled for the remainder of the term by appointment by the Commissioner.~~

~~(e) Any Advisory Committee member may be removed by the Commissioner for incapacity, incompetence, neglect of duty, or misfeasance or malfeasance in office.~~

~~(f) Advisory Committee members may be reappointed at the completion of their term.~~

~~(g) The Advisory Committee will hold a minimum of one regular meeting annually, and special meetings as needed. Meetings shall be held at such time and place as the Advisory Committee may provide. The Advisory Committee shall elect annually the following officers: A chair, a vice chair, and a secretary. Three members of the Advisory Committee shall constitute a quorum.~~

310:531-3-3. Rules of Order

~~Roberts Rules of Order Revised shall be the basis of parliamentary decisions except as otherwise provided by the Advisory Committee.~~

SUBCHAPTER 5. VISION SCREENING STANDARDS FOR CHILDREN

310:531-5-2. Oklahoma Vision Screening Standards

(a) Parents or guardians of any child subject to the Oklahoma School Code shall provide certification of vision screening for any child who is:

(1) in ~~Kindergarten~~ kindergarten, and the vision screening shall be completed within the previous twelve (12) months or during the school year;

(2) in the ~~First~~ first grade, and the vision screening shall be completed within the previous (12) months, with certification provided to school personnel within thirty (30) days of the beginning of the school year; and

(3) in the ~~Third~~ third grade, and the vision screening shall be completed within the previous twelve (12) months, with certification provided to school personnel within thirty (30) days of the beginning of the school year.

(b) Vision screening must, at a minimum, utilize the following vision screening tests using standard screening procedures:

- (1) For relative distance acuity, the Snellen Letter Chart, HOTV Chart, or Lea Symbol Chart, at a distance of ten (10) feet; and, or any new vision screening tool determined by the Department to be a comparably effective and efficient screening tool; and
 - (2) For stereo acuity, the Random Dot E Stereo Test, at a distance according to the calibration of the manufacturer, or any new vision screening tool determined by the Department as being a comparably effective and efficient screening tool.
- (c) The following visual criteria shall be used as a basis for referring a child for further evaluation by an optometrist or ophthalmologist:
- (1) For relative distance acuity, worse than 20/40 in either or both eyes for children below the ~~First~~ first Grade grade or for new tools the equivalent, or worse than 20/30 in either or both eyes for children in the ~~First~~ first grade or above or, for new screening tools the equivalent, and for all children, a two or more line difference between either eye or, for new screening tools the equivalent; and,
 - (2) For relative stereo acuity, a child identifies the E correctly in less than four (4) consecutive responses out of ten (10) attempts or, for new vision screening tools the equivalent.

310:531-5-3. Approval of ~~Vision Screening Providers~~ vision screening providers

- (a) In order to become an approved vision screening provider, an individual must make application to the ~~Advisory Committee~~ Department and include documentation of successful completion of training conducted by an approved trainer using an approved training curriculum that includes the following:
- (1) common eye problems;
 - (2) the screening process;
 - (3) required screening tools;
 - (4) screening special populations; and,
 - (5) basic anatomy and physiology of the eye.
- (b) The ~~Advisory Committee~~ Department will review and ~~submit, a minimum of one time annually, a list of approved vision screening providers to the Department~~ approve vision screening providers.
- (c) The vision screening provider approval will be valid from the date of approval by the ~~Advisory Committee~~ Department and ends three years from the most recently approved training.
- (d) All approved vision screening providers will be added to the statewide registry on the Internet website maintained by the Department.
- (e) Unless otherwise provided by law, no person shall engage in vision screening as provided in 70 O.S. § 1210.284 without first being listed on the vision screening registry maintained by the Department.

310:531-5-5. Re-approval of vision screening providers

A vision screening provider currently approved by the ~~Advisory Committee~~ Department may renew his or her application by submitting documentation of successful completion of training, conducted by an approved trainer, using an approved curricula, prior to the end of his or her third year.

310:531-5-6. Approval of ~~trainers of vision screening providers~~ vision screening trainers

- (a) In order to become an approved ~~trainer of vision screening providers~~ vision screening trainer an individual must be an approved vision screening provider and make application to the ~~Advisory Committee~~ Department and include documentation of successful completion of training conducted by an approved trainer using an approved training curriculum that includes the following:
- (1) common eye problems;
 - (2) the screening process;
 - (3) required screening tools;
 - (4) screening special populations;
 - (5) basic anatomy and physiology of the eye; and,
 - (6) techniques for effective training of vision screening providers.

(b) The applicant must provide to the ~~Advisory Committee Department~~ documentation of successful completion of training, which is administered by a vision screening trainer of trainers approved by the ~~Advisory Committee Department~~ using training curricula for trainers approved by the ~~Advisory Committee Department~~.

(c) The ~~Advisory Committee Department~~ will review, ~~approve and submit to the Department, at a minimum of one time annually, a list of qualified and approve trainers of vision screening providers~~ vision screening trainers and the approved curricula used for training vision screening providers.

(d) The approval of a ~~trainer of vision screening providers~~ vision screening trainer ends three years from the most recently approved training.

310:531-5-7. Re-approval of ~~trainers of vision screening providers~~ vision screening trainers

A ~~trainer of vision screening providers~~ vision screening trainer currently approved by the ~~Advisory Committee Department~~ may renew his or her application by submitting documentation of successful completion of training, conducted by an approved vision screening trainer of trainers, using an approved curricula, prior to the end of his or her third year.

310:531-5-8. Approval of ~~trainers of vision screening trainers~~ vision screening trainers of trainers

(a) In order to become an approved ~~trainer of vision screening trainers~~ vision screening trainer of trainers, an individual must be an approved vision screening provider, an approved ~~trainer of vision screening providers~~ vision screening trainer, and make application to the ~~Advisory Committee Department~~ and include documentation of successful completion of training conducted by an approved trainer using an approved training curriculum that includes the following:

- (1) common eye problems;
- (2) the screening process;
- (3) required screening tools;
- (4) screening special populations;
- (5) basic anatomy and physiology of the eye;
- (6) techniques for effective training of vision screening providers; and,
- (7) techniques for effective training of ~~trainers of vision screening trainers~~ vision screening trainers of trainers.

(b) The applicant must provide to the ~~Advisory Committee Department~~ documentation of successful completion of training, ~~which~~ which is administered by a vision screening trainer of trainers approved by the ~~Advisory Committee Department~~ using training curricula for trainers approved by the ~~Advisory Committee Department~~.

(c) The ~~Advisory Committee Department~~ will review, ~~approve and submit to the Department, at a minimum of one time annually, a list of qualified and approve trainers of vision screening trainers~~ vision screening trainers of trainers and the approved curricula used for training vision screening trainers.

(d) The approval of a ~~trainer of vision screening trainers~~ vision screening trainers of trainers ends three years from most recently approved training.

310:531-5-9. Re-approval of ~~trainers of vision screening trainers~~ vision screening trainers of trainers

A ~~trainer of vision screening trainers~~ vision screening trainer of trainers currently approved by the ~~Advisory Committee Department~~ may renew his or her application by submitting documentation of successful completion of training conducted by an approved trainer and use of an approved curriculum prior to the end of his or her third year.

SUBCHAPTER 7. REGISTRY ENFORCEMENT FOR VISION SCREENING

310:531-7-2. Grounds for discipline

- (a) An approval of a vision screening provider may be modified, suspended, or terminated for one or more of the following reasons:
- (1) Failure to conduct vision screenings according to the procedures and referral criteria approved by the ~~Advisory Committee~~ Department, including but not limited to, deletion of one or more portions of the process outlined in the screening standards and training curriculum, or addition of one or more procedures not contained in the screening standards and training curriculum, in sections 310:531-5-2 and 310:531-5-3, respectively;
 - (2) Making referrals for ~~professional examinations~~ comprehensive eye examinations that indicate a conflict of interest, financial or otherwise;
 - (3) Failure to participate in a training curricula approved by the ~~Advisory Committee~~ Department upon expiration of his or her three year approval;
 - (4) Violations of a student's right of privacy in the student's education records pursuant to the Family Educational Rights and Privacy Act of 1974, 20 United States Code §§1232 *et seq.* and the rules promulgated thereunder; and
 - (5) Any act that harms, or threatens harm to, a child.
- (b) An approval of a ~~trainer of vision screening providers~~ vision screening trainer may be modified, suspended, or terminated for one or more of the following reasons:
- (1) Failure to conduct training workshops for vision screening providers utilizing curricula and/or procedures approved by the ~~Advisory Committee~~ Department;
 - (2) Failure to participate in a training curricula approved by the ~~Advisory Committee~~ Department upon expiration of the three year approval;
 - (3) Violations of a student's right of privacy in the student's education records pursuant to the Family Educational Rights and Privacy Act of 1974, 20 United States Code §1232 *et seq.* and the rules promulgated thereunder; and
 - (4) Any act that harms, or threatens to harm, a child.
- (c) An approval of a ~~trainer of trainers of vision screening providers~~ vision screening trainer of trainers may be modified, suspended, or terminated for one or more of the following reasons:
- (1) Failure to conduct training workshops for ~~trainers of vision screening trainers~~ vision screening trainers utilizing curricula and/or procedures approved by the ~~Advisory Committee~~ Department;
 - (2) Failure to participate in a training curricula approved by the ~~Advisory Committee~~ Department upon expiration of the three year approval;
 - (3) Violations of a student's right of privacy in the student's education records pursuant to the Family Educational Rights and Privacy Act of 1974, 20 United States Code §§ 1232 *et seq.* and the rules promulgated thereunder; and
 - (4) Any act that harms, or threatens harm to, a child.

310:531-7-3. Complaint investigation

- (a) **Reporting complaints.** Any person may report to the Department any complaint or allegations of non-compliance with 70 O.S. § 1210.284 or this Chapter by a vision screening provider or trainer by submitting the following:
- (1) the name, address, and telephone number, if known, of the vision screening ~~provider or~~ provider or trainer who is the subject of the complaint;
 - (2) the location(s) where the alleged non-compliance occurred;
 - (3) the date(s) of non-compliance;
 - (4) the reporting party's name, address and telephone number; and,
 - (5) the specific allegations against the vision screening provider or trainer, including but not limited to references to, or a copy of supporting documentation regarding, or any witnesses to, the alleged non-compliance.
- (b) **Process.** Upon receipt of a complaint against a vision screening provider or trainer alleging non-compliance with 70 O.S. § 1210.284 or this Chapter, the Department shall conduct an investigation. ~~Upon completion of the investigation, a written report will be prepared and presented to the Advisory~~

~~Committee for recommendation. If sufficient evidence exists to initiate an individual proceeding, the Advisory Committee shall recommend that the Department initiate disciplinary proceedings.~~

310:531-7-4. Summary removal

(a) If in the course of an investigation the Department determines that a vision screening provider has engaged in conduct of a nature that is, or is likely to be detrimental to the health, safety, or welfare of the public, and which conduct necessitates immediate action to prevent such harm, the Commissioner may order summary removal of the name of the vision screening provider from the registry for vision screening maintained by the Department pending the Department filing a petition to remove the name of the vision screening provider from the registry following an individual proceeding pursuant to the Oklahoma Administrative Procedures Act, 75 O.S. §§ 309 *et seq.* A presumption of imminent harm to the public shall exist if the Department determines that probable cause exists that a vision screening provider has harmed, or threatened harm to, a child while providing vision screening services. The order of summary removal from the registry must include the specific grounds for the summary removal, a citation of the statute or law allegedly violated, and inform the ~~visionscreening~~ vision screening provider of the process to request a hearing to contest the summary action.

(b) Any vision screening provider whose name has been summarily removed from the registry for vision screening may request a hearing to contest such summary action. The Department shall have the initial burden of persuasion to show that the provider has engaged in conduct that has caused, or is likely to cause, harm to a child. If the Department meets this burden of persuasion, the ~~visionscreening~~ vision screening provider has the burden to prove that the conduct of the provider in providing ~~visionscreening~~ vision screening services would not harm a child.

(c) If in the course of an investigation the Department determines that a vision screening trainer has engaged in conduct of a nature that is, or is likely to be detrimental to the health, safety, or welfare of the public, and which conduct necessitates immediate action to prevent such harm, the Commissioner may order summary removal of the name of the vision screening ~~provider~~ trainer from the list for vision screening trainers maintained by the Department pending the Department filing a petition to remove the name of the vision screening trainer from the list following an individual proceeding pursuant to the Oklahoma Administrative Procedures Act, 75 O.S. §§ 309 *et seq.* A presumption of imminent harm to the public shall exist if the Department determines that probable cause exists that a vision screening trainer has harmed, or threatened harm to, a child while providing vision screening services. The order of summary removal from the list must include the specific grounds for the summary removal, a citation of the statute or law allegedly violated, and inform the vision screening trainer of the process to request a hearing to contest the summary action.

(d) Any vision screening trainer whose name has been summarily removed from the list for vision screening trainers may request a hearing to contest such summary action. The Department shall have the initial burden of persuasion to show that the trainer has engaged in conduct that has caused, or is likely to cause, harm to a child. If the Department meets this burden of persuasion, the vision screening trainer has the burden to prove that the conduct of the trainer in providing vision screening services would not harm a child.

310:531-7-5. Appearance before the Advisory Committee

~~Except as provided for in section 310:531-7-4, if the Advisory Committee recommends that the status of a vision screening provider or trainer be modified, suspended, or terminated by these provisions the Committee shall first give a vision screening provider, or trainer, or applicant an opportunity to appear before the Advisory Committee at the next regularly scheduled meeting by providing written notice at least thirty (30) days in advance of the meeting. The vision screening provider, trainer, or applicant must advise in writing at least ten (10) days in advance of the next scheduled Advisory Committee meeting by postmarked notification to the Committee of his or her request to appear before the Committee. Failure to so notify may be deemed a waiver of the right to appear before the Advisory Committee.~~

310:531-7-6. Right to a hearing

Except as provided for in section 310:531-7-4, the name of a vision screening provider or trainer may not be removed from the vision screening registry or vision screening trainer's list until the Department provides notice to the vision screening provider or trainer and an opportunity for a hearing to contest the Department's allegations. The notice to the vision screening provider or trainer must comply with 75 O.S. § 309. The vision screening provider or trainer must request a hearing within twenty ~~(20) days~~ (20) days of receiving the notice from the Department or the sanction may be imposed by default.

SUBCHAPTER 9. SPORTS EYE SAFETY RESOURCE

310:531-9-1. Purpose

~~This subchapter identifies the role of the Advisory Committee in serving as a resource for sports eye safety.~~

310:531-9-2. Eye safety resource

~~(a) The Advisory Committee may serve as a sports eye safety resource for Oklahoma public school districts and nonprofit community sports organizations by:~~

- ~~(1) Developing and providing educational materials to reduce eye injuries associated with various sporting activities; and~~
- ~~(2) Developing and providing educational materials on the use of protective eyewear that reduces the risk of sports related eye injuries.~~

RULE COMMENT SUMMARY AND RESPONSE

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 531. Vision Screening**

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)]

No comments were received during the comment period or during the public hearing.

Agency Rule Contact:

Ann Benson, Administrative Program Manager, Child and Adolescent Health, phone (405) 271-4471, e-mail annrb@health.ok.gov.

**OKLAHOMA STATE BOARD OF HEALTH
COMMISSIONER'S REPORT**

Terry Cline, Ph.D., Commissioner
December 10, 2013

PUBLIC RELATIONS/COMMUNICATIONS

“Talk to your doctor” Press Conference, Tobacco Settlement Endowment Trust – attended
Oklahoma Watch Town Hall - panel member
National Safety Council – speaker
Focus PA Medicine – speaker
Administrative Rules Seminar – speaker
Tyler Media Public Service Announcements
Champions of Health – speaker
KTOK Radio Interview
Oklahoma Food Security Summit – speaker
Department of Human Services Awards Ceremony – speaker
American Public Health Annual Conference – speaker
Oklahoma City Leadership Class 32 – speaker
Tulsa County Medical Society Annual Meeting – speaker
College of Public Health, Public Health Policy class - speaker

SITE VISITS

Kingfisher County Health Department
Logan County Health Department
Pottawatomie County Health Department
Seminole County Health Department
Gateway to Recovery, Shawnee
Women, Infants and Children (WIC) office

STATE/FEDERAL AGENCIES/OFFICIALS

Chris Bruehl, Director of Appointments, Governor Fallin
Governor Fallin’s Cabinet Meeting
Preston Doerflinger, Secretary of Finance, Administration and Information Technology
Tracey Strader, Executive Director, TSET
Institute of Medicine Annual Conference
Million Hearts Core Team Meeting
Department of Tourism Movie Premier “Osage Autumn; Osage County”
OMES Budget Hearing
Nico Gomez, Executive Director, Oklahoma Health Care Authority
Terri White, Commissioner, OK Dept. of Mental Health & Substance Abuse Svs.
Gaylord Z. Thomas, Executive Director, OSBELTCA

OTHERS:

Gary Cox, Executive Director, Oklahoma City County Health Department

Bruce Dart, Executive Director, Tulsa Health Department

Reforming States Group Regional Meeting

Safe Communities American Luncheon

OHIP Full Team Meeting

Jonathan Small, Oklahoma Council of Public Affairs

Public-Private Partnership Meeting-OHIP workgroup

Oklahoma Turning Point Council Meeting

Opioid Prescribing Guidelines Workgroup

Drug Overdose Committee

Lyle Kelsey, Executive Director, Oklahoma State Board of Medical Association

Ted Haynes, CEO and Dr. Joseph Cunningham, Medical Director, Blue Cross Blue Shield

Monica Basu and Ken Leavitt, George Kaiser Family Foundation