ARKANSAS REGISTER

Proposed Rule Cover Sheet

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Agency or Division Name Center for Public Health Practice

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RULES PERTAINING TO THE ARKANSAS CANCER REGISTRY

CENTER FOR PUBLIC HEALTH PRACTICE

(Effective upon Legislative approval)

Arkansas Department of Health
José R. Romero, MD, FAAP, FIDSA, FPIDS, FAAAS
Secretary and State Health Officer

RULES PERTAINING TO THE ARKANSAS CANCER REGISTRY

Table of Contents

SECTION I. AUTHORITY

The following Rules Pertaining to the Arkansas Cancer Registry are duly adopted and promulgated by the Arkansas State Board of Health and implemented by the Arkansas Department of Health ("Department"), pursuant to the authority expressly conferred by the laws of the State of Arkansas, specifically Ark. Code Ann. §§ 20-15-201 - 205.

SECTION II. PURPOSE

The purpose of these rules ~~and regulations~~ is to clarify the cancer-reporting responsibilities of medical care professionals, hospitals, laboratories and institutions, pursuant to Arkansas law. In addition, it contains intervention for noncompliance, reinforces the confidentiality requirements, authorizes the exchange of cancer incidence data with other states and for the data to be made available to the public. In carrying out this mandate, ~~T~~the Department's Arkansas Central Cancer Registry ("ACCR") collaborates with the National Cancer Institute, the Centers for Disease Control and Prevention, medical research institutions, ~~and~~ national and international cancer surveillance programs designated by the ACCR, the Arkansas Cancer Coalition, and public health agencies. The importance of cancer registration was reinforced by the passage of federal legislation in 1992 (Public Law 102-515) establishing the National Program of Cancer Registries, in which Arkansas participates.

SECTION III. DEFINITIONS

A. "Arkansas Cancer Coalition (ACC)" means the statewide comprehensive cancer control partnership, which is a network of members and organizations that strive to provide an overview of cancer control in Arkansas, strengthen and sustain the cancer control partnership and support network, and direct goals and strategies in the Arkansas Cancer Plan.

B. "Benign neoplasms" means a benign tumor that does not grow in an unlimited, aggressive manner and does not invade surrounding tissues and does not metastasize.

C. "Borderline tumor" means a neoplasm with many histologic criteria of malignancy, but future behavior is uncertain.

D. "Cancer" means cellular abnormalities with widely variable courses, some grow rapidly, others grow slowly, others stop growing completely and some regress.

E. "Casefinding" means a systematic process of locating cases eligible for inclusion in the cancer registry to include but not limited to pathology reports and disease indices.

F. "Casefinding Audit" means a systematic process of reviewing facility based documents and information to ensure that all eligible/reportable cancer cases were identified, abstracted and reported by facilities to the ACCR.

~~G. "Hospital Reporting Manual" means the manual containing guidelines and requirements to assist hospital registries in reporting cancer cases to the Arkansas Central Cancer Registry. The Hospital Reporting Manual is attached hereto as Appendix A.~~

H. "In Situ (in place) cancer" means a cancer that involves only the place in which it began and that has not spread, or invaded and may regress.

I. "Invasive cancer" means a tumor that grows in an uncontrolled manner and invades surrounding tissues and is capable of metastasizing.

~~J.~~ "New Primary" means a very basic definition is a first time diagnosed cancer. ~~Multiple Primary and Histology Coding Rules must be applied to determine a new primary.~~

~~K. "Non-Hospital Reporting Manual" means the manual containing requirements and guidelines to assist non-hospital facilities in reporting cancer cases to the Arkansas Central Cancer Registry. The Non-Hospital Reporting Manual is attached hereto as Appendix.~~

L. "Qualified researcher" means a researcher from a recognized institution, including without limitation an academic, state or federal government, or nonprofit nongovernmental institution, and who is adequately trained about conditions where names and identities of individuals are appropriately protected while conducting research for the purposes of cancer prevention, control, and treatment.

A. "Re-Abstracting (Quality Assurance) Audit" means a systematic process of reviewing specific data items and codes, to help ensure quality and accurate coding is being submitted by facilities to the ACCR.

B. "Registry" means the system for the reporting, collection, and analysis of cancer cases by the Arkansas Department of Health.

C. "Reporting" means the notification furnished to the ~~Arkansas~~ Department ~~of Health~~ of

cases of in situ or invasive neoplasms of the human body, not including squamous cell and basal cell carcinoma of the skin.

SECTION IV. PARTICIPATION IN THE PROGRAM

A. All licensed health care facilities and providers including, but not limited to: hospitals, pathology laboratories, health care practitioners, radiation treatment facilities, specialty clinics (~~ex.~~ e.g. dermatology, oncology, urology clinics, etc.), surgery centers/clinics, and dental offices shall participate in the program.

B. All participants shall designate specific staff member(s) to be responsible for reporting required cancer data and shall notify the ACCR of the name(s), title, work telephone number and e-mail address of the designated staff member(s).

SECTION V. CANCER CASE REPORTING

A. Reportable Cancer Cases

1. Any newly diagnosed in-situ or invasive cancer or reportable benign and borderline conditions as specified ~~defined~~ by the ACCR. ~~Hospital Manual (page 12) and Non- Hospital Reporting Manual (appendix F of the manual) is considered a reportable diagnosis.~~ If a patient subsequently develops a new primary cancer, it shall be reported separately. In addition, health care facilities and providers shall furnish follow-up data on each cancer patient when requested.

B. Format for reporting

1. The format for reporting, the required ~~codes~~ coding guidelines, and the standards for completeness and quality are specified ~~defined in~~ by the ACCR. ~~Hospital and Non-Hospital Reporting Manuals~~. Text is required for specified variables and shall be adequate to permit quality assurance evaluation of coding decisions.

C. Data Items to be reported

1. The standardized report of cancer shall include as a minimum those data items required by the ACCR. ~~a list of which is maintained in the ACCR Hospital and Non-Hospital reporting manuals.~~ The report of cancer shall include the listed demographic, diagnostic, and treatment data as defined by the ACCR. ~~department~~.

D. Deadline for Reporting

1. Reporting shall occur no later than six months after the date of diagnosis of cancer and/or initial treatment of cancer.

E. Failure to Report

1. If a hospital, laboratory, facility or health care practitioner fails to provide the required information in the format or time specified by the ACCR or if the data are of unacceptable quality, personnel from the ACCR staff may enter the facility, or access the information electronically, to abstract the information.

F. Quality Assurance

1. Staff members from the ACCR shall perform periodic quality assurance activities on all reporting facilities. These activities shall include:

a. Casefinding to ensure that all reportable cancer cases have been accessioned; and

b. Reabstracting the records of cancer patients to ensure accurate and complete coding of all data.

2. Reporting facilities shall assist the ACCR staff by providing the necessary casefinding documents, medical records and office space for conducting quality assurance activities.

3. In order to improve the quality of the data, the ACCR or their appointees shall offer training to reporting facility personnel if deemed necessary.

SECTION VI. CONFIDENTIALITY

A. All information reported to the ACCR shall be confidential and shall not be disclosed under any circumstances except:

1. To other state cancer registries or federal organizations with which the Ddepartment has data sharing agreements that ensure confidentiality;

2. To Ddepartment ~~of health~~ officials and its agents who are obligated to keep such information confidential; and

3. For Department-approved cancer research under specific conditions where names and identities of the individuals are appropriately protected, and when such research is conducted for the purpose of cancer prevention, control and treatment.

B. Protection of Patient Identifying Information Obtained by Special Studies and Other Research Studies.

1. All identifying information such as records of interviews, questionnaires, reports, statements, notes and memoranda that are procured or prepared by employees or agents of the Arkansas Central Cancer Registry shall be used solely for statistical, scientific and medical research purposes and shall be held strictly confidential by the ACCR. This applies also to identifying information procured by any other person, agency, or organization, including public or private colleges and universities acting jointly with the ACCR in connection with special cancer studies and health research investigations.

SECTION VII. RELEASE OF DATA

A. Release of non-identifying information

1. To Federal Agencies: The ACCR is authorized to collaborate with the National Program of Cancer Registries (NPCR), the Centers for Disease Control and Prevention (CDC), and the National Cancer Institute (NCI) to provide cancer incidence statistics and

participate in cancer studies.

2. To the Arkansas Department of Health: The ACCR shall work closely with the Arkansas Department of Health in investigating cancer-related issues and in evaluating programs. Because the ACCR data are an integral part of the Arkansas Department of Health cancer prevention and control programs, the use of registry data by public health officials shall be considered an in-house activity. Data required by the Arkansas Department of Health for responding to concerns expressed about threats to the public shall receive priority in determining the order of processing requests.

3. To the general public: Public reports published by the ACCR shall include aggregate, not patient identifying information or facility identifying information. Information that would potentially identify a cancer patient shall not be published.

4. To Others: The ACCR is authorized to collaborate with the North American Association of Central Cancer Registries (NAACCR) to provide cancer incidence statistics and participate in cancer studies.

5. To Qualified Cancer Researchers: The ACCR is authorized to collaborate with the Arkansas Cancer Coalition to provide cancer statistics and participate in cancer studies with qualified researchers.

B. Release of identifying information

~~1.~~ Identifying information collected from any hospital, laboratory, facility or health care practitioner may be released to qualified persons for the purposes of cancer prevention, control and research, ~~provided that each request for identifying information follows the established procedure outlined in the ACCR Policies and Procedures Manual and receives prior approval~~ as approved by the D~~d~~epartment ~~and the Board of Health.~~

2. ~~Data linkages with ACCR files shall be performed only by the ACCR staff, and the Registry may require the removal of identifiers to protect the identity of cases.~~ The actual costs of the data linkage shall be borne by the qualified researcher.

C. Interstate Exchange of Data

~~1.~~ Because cancer patients may be diagnosed or receive treatment in another state, the ACCR is authorized to sign agreements with other states to acquire cancer data concerning Arkansas residents and, in return, to provide those states with data relating to their residents. Each signatory state shall agree in writing to keep all patient data confidential and privileged as defined in the contract for data exchange. ~~, a copy of which is included in the ACCR Policies and Procedures Manual.~~

SECTION VIII. VIOLATIONS AND PENALTIES

Every firm, person, or corporation who violates this rule may be assessed a civil penalty by the B~~b~~oard of Health. The penalty shall not exceed one thousand dollars ($1,000) for each violation. Each day of a continuing violation may be deemed a separate violation for purposes of penalty assessments. However, no single fine levied by the Board shall exceed ten thousand dollars ($10,000).

SECTION IX. EFFECTIVE DATE

The initial effective date of a version of these Rules ~~and Regulations shall be~~ was March 1, 2012. Any further revisions to these Rules will be effective upon compliance with the Administrative Procedure Act and only after legislative approval.

SECTION X. SEVERABILITY

If any provision of these Rules ~~and Regulations~~, or the application thereof to any person or circumstances is held invalid, such invalidity shall not affect other provisions or applications of these Rules ~~and Regulations~~ which can give effect without the invalid provisions or applications, and to this end the provisions hereto are declared to be severable.

SECTION XI. REPEAL

All Rules ~~Regulations~~ and parts of Rules ~~Regulations~~ in conflict herewith are hereby repealed.

CERTIFICATION

This is to certify that the foregoing Rules Pertaining to the Arkansas Cancer Registry were adopted by the Arkansas State Board of Health at a regular meeting of the Board held in Little Rock, Arkansas on January 23, 2020.

_____

José R. Romero, MD, FAAP, FIDSA, FPIDS, FAAAS
Secretary of Health
Arkansas Board of Health

QUESTIONNAIRE
FOR FILING PROPOSED RULES WITH THE
ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT/AGENCY Arkansas Department of Health
DIVISION Center for Public Health Practice
DIVISION DIRECTOR Shirley Louie
CONTACT PERSON Center for Public Health Practice
ADDRESS 4815 West Markham, Little Rock Arkansas 72205
PHONE NO. (501) 661-2297 **FAX NO.** (501) 661-2357 **E-MAIL** Laura.Shue@arkansas.gov
NAME OF PRESENTER AT COMMITTEE MEETING Laura Shue
PRESENTER E-MAIL Laura.Shue@arkansas.gov

INSTRUCTIONS

A. Please make copies of this form for future use.
B. Please answer each question completely using layman terms. You may use additional sheets if necessary.
C. If you have a method of indexing your rules, please give the proposed citation after "Short Title of this
D. Rule" below.
E. Submit two (2) copies of the Questionnaire and Financial Impact Statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to:

Jessica C. Sutton
Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
One Capitol Mall, 5th Floor
Little Rock, AR 72201

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1. What is the short title of this rule? Rules Pertaining to the Arkansas Cancer Registry

2. What is the subject of the proposed rule? To clarify the cancer-reporting responsibilities of medical care professionals, hospitals, laboratories and institutions, pursuant to Arkansas law

3. Is this rule required to comply with a federal statute, rule, or regulation? Yes ☐ No ☑

If yes, please provide the federal rule, regulation, and/or statute citation.

4. Was this rule filed under the emergency provisions of the Administrative Procedure Act?

Yes ☐ No ☑

If yes, what is the effective date of the emergency rule? _____

When does the emergency rule expire? _____

Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act? Yes ☐ No ☐

5. **Is this a new rule? Yes ☐ No ☑ If yes, please provide a brief summary explaining the rule.**

Does this repeal an existing rule? Yes ☐ No ☑ If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does.

Is this an amendment to an existing rule? Yes ☑ No ☐ If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled "mark-up."

Board of Health approval would no longer be required for the Central Cancer Registry to disclose statistical information for purposes of on-going research.

6. **Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation.**

Ark. Code Ann. §§ 20-15-201 - 205

7. **What is the purpose of this proposed rule? Why is it necessary?**

This change would allow the Board of Health to approve data requests for the entire length of a grant.

8. **Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b).**

https://www.healthy.arkansas.gov/proposed-amendment-to-existing-rules

9. **Will a public hearing be held on this proposed rule? Yes ☐ No ☑ If yes, please complete the following:**

Date: 08/11/2021

Time: 10:00 am -11:00am

Place: Department of Health, 4815 West Markham Street, Room 2508, Little Rock, Arkansas

10. **When does the public comment period expire for permanent promulgation? (Must provide a date.)**

08/11/2021

11. **What is the proposed effective date of this proposed rule? (Must provide a date.)**

01/30/2022

12. **Please provide a copy of the notice required under Ark. Code Ann. § 25-15-204(a), and proof of the publication of said notice.** _____

13. **Please provide proof of filing the rule with the Secretary of State as required pursuant to Ark. Code Ann. § 25-15-204(e).** _____

14. **Please give the names of persons, groups, or organizations that you expect to comment on these rules? Please provide their position (for or against) if known.**

No known opponents.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas Department of Health
DIVISION Center for Public Health Practice
PERSON COMPLETING THIS STATEMENT Laura Shue, General Counsel
TELEPHONE NO. (501) 661-2297 **FAX NO.** (501) 661-2357 **EMAIL:** Laura.Shue@arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file two (2) copies with the Questionnaire and proposed rules.

SHORT TITLE OF THIS RULE Rules Pertaining to the Arkansas Cancer Registry

1. **Does this proposed, amended, or repealed rule have a financial impact? Yes☐ No☑**

2. **Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule?**
   Yes☑ No☐

3. **In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered? Yes☑ No☐**
   If an agency is proposing a more costly rule, please state the following:
   a) **How the additional benefits of the more costly rule justify its additional cost;**
   b) **The reason for adoption of the more costly rule;**
   c) **Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and**
   d) **Whether the reason is within the scope of the agency's statutory authority, and if so, please explain.**

4. If the purpose of this rule is to implement a federal rule or regulation, please state the following:

a) What is the cost to implement the federal rule or regulation?

Current Fiscal Year		Next Fiscal Year	
General Revenue		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	$ 0.00	Total	$ 0.00

b) What is the additional cost of the state rule?

Current Fiscal Year		Next Fiscal Year	
General Revenue		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	$ 0.00	Total	$ 0.00

5. What is the total estimated cost by fiscal year to any private individual, entity and business subject to the proposed, amended, or repealed rule? Identify the entity(ies) subject to the proposed rule and explain how they are affected.

Current Fiscal Year	Next Fiscal Year
$	$

6. What is the total estimated cost by fiscal year to state, county, and municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.

Current Fiscal Year	Next Fiscal Year
$	$

7. **With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars ($100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?**
Yes ☐ **No** ☑

If YES, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously with the financial impact statement and shall include, without limitation, the following:

(1) a statement of the rule's basis and purpose;

(2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;

(3) a description of the factual evidence that:
(a) justifies the agency's need for the proposed rule; and
(b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;

(4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;

(5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;

(6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and

(7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
(a) the rule is achieving the statutory objectives;
(b) the benefits of the rule continue to justify its costs; and
(c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.

Arkansas Department of Health

4815 West Markham Street • Little Rock, Arkansas 72205-3867 • Telephone (501) 661-2000
Governor Asa Hutchinson
José R. Romero, MD, Secretary of Health

Summary of Changes to

Rules Pertaining to the Arkansas Cancer Registry

- Amendments to the Rule implement Act 345 of 2021, which removed the requirement for Board of Health approval to release statistical information from the Arkansas Central Cancer Registry and added a definition of “qualified researcher.”
- Amendments to the Rule implement Act 315 of 2019, which removes unnecessary usage of the term “regulation.”
- Amendments revise the Rule to remove the definition of “Hospital and Non-Hospital Reporting manuals.”