EXHIBIT G

DEPARTMENT OF HEALTH, CENTER FOR PUBLIC HEALTH PRACTICE

SUBJECT: Cancer Registry

DESCRIPTION: A summary of the changes follows:

Section I. Authority

Delete the words "and Regulations"

Section II. Purpose

Purpose of rules and regulations expanded

Section III. Definitions

Additional definitions: Benign neoplasms, Borderline tumor, Cancer, Casefinding, Casefinding Audit, Hospital Reporting Manual, In Situ cancer, Invasive cancer, New primary, Non-Hospital Manual and Re-abstracting (Quality Assurance) Audit

Section IV. Participation in the Program

Replaces portion of Section IV General Requirements in present rule and regulation. New section - Specifies which facilities are to provide cancer data, notifying ACCR with contact information of person responsible for reporting cancer information.

Section V. Cancer Case Reporting

Replaces portion of Section IV General Requirements in present rule and regulation. Rewritten with specifics of reportable cancer cases, format for reporting, data items to be reported can be found in Hospital and Non-Hospital Manuals. Also included in this section – deadline for reporting, failure to report, and quality assurance activities.

Section VI. Confidentiality

Section V in present rule and regulations. Section rewritten, describes circumstances under which ACCR will disclose cancer information, including protection of patient identifying information used for special studies, research studies and used solely for statistical, scientific and medical research purposes.

Section VII. Release of Data

New section – Describes Collaborative Organizations ACCR is authorized to release non-identifying information, identifying formation, data linkages and interstate exchange data. Section VII(B) has been modified from the previous draft to include that approval by the Board is necessary before any release of identifying information from the registry.

Section VIII. Violations and Penalties

New section – Describes penalty for violation of rules. It has been modified from the previous draft to include a provision that no single fine levied by the Board will exceed $10,000.00.

PUBLIC COMMENT: Public hearings were held on July 14, 2011 and October 13, 2011. The public comment period originally expired on July 14, 2011, but after such time, an amendment was made to Section VIII providing for a maximum fine of $10,000. A new public comment period expired on October 13, 2011. No public comments were submitted to the agency.

The proposed effective date is January 1, 2012.

CONTROVERSY: This rule is expected to be controversial. Some health care professionals are opposed to the violations and penalty section.

FINANCIAL IMPACT:

Economic Impact Statement

1. Explain the need for the proposed changes.

The original rules pertaining to Arkansas Cancer Registry were adopted and approved by the Arkansas State Board of Health in 1994. Because of advancement in medicine and evolvement of medical practices, an update to the language and definitions better clarify the rules.

2. What are the top three benefits of the proposed rule?

1. Clarification on who is responsible for reporting cancer diagnoses to ACCR.
2. Clarification on what cancer diagnoses should be reported.
3. Assurance of confidentially of patients' private information.

3. What would be the consequence of taking no action, thereby maintaining the status quo?

Cases not being reported are missing from the state database system, obscuring the true burden of cancer for the state. This data is used to help produce statistics for such programs as breast and cervical, Prostate Cancer Foundation, and HIV/AIDS. This data is also shared with such state entities as the Arkansas Center for Health Improvement (ACHI).

Certification of the registry is in jeopardy. Arkansas's data will not be used in certain research projects, such as Geographical Association of Agriculture and Pancreatic Cancer. This project is exploring an association between residence in agriculture areas and the incidence of pancreatic cancer. Pediatric Brain Tumor Incidence study is comparing cancer incidence of Central Brain Tumor Registry of United States (CBTRUS) and the International Classification of Childhood Cancer. This project is using incidence data on all cases (at any age) of non-malignant (benign or borderline) and malignant primary brain tumors from U. S. Cancer registries that are included in Cancer in North America (CINA). If not certified, the data is not included in CINA.

A continued costly effort on the part of state Cancer Registry staff to maintain continuous contact with medical professionals regarding non-compliant issues as well as continue case ascertainment from facilities that are non-compliant.

Many quality assurance activities for Cancer Registry are incomplete.

The cancer registry cannot be fully used for what it was designed, which includes the monitoring of cancer trends over time, determining cancer patterns in various populations, helping to guide the planning and evaluation of cancer control programs (determine whether prevention, screening, and treatment efforts are making a difference), help set priorities for allocating health resources as well as advance clinical epidemiologic and health services research.

4. Describe market-based alternatives or voluntary standards that were considered in place of the proposed rule and state the reason for not selecting those alternatives.

Previous methods used to inform health care professionals of the reportability of certain cancers are as follows: Letters, providing educational materials, journal articles, and Cancer Registry staff presenting registry data to medical professionals in educational conferences, electronic mail, and facsimile.

Of the number of facilities in database that should report is approximately 880, not all are reporting. Of the ones that are reporting, 154 facilities reporting cases late 100% of the time, 53 report cases late 75-99% of the time, 16 reports late 25-49% of the time. The number of total cases reported late is 11,600. 57% of cases are late every year.

5. Estimate the cost to state government of collecting information, completing paperwork, filing, recordkeeping, auditing, and inspecting associated with this new rule.

Casefinding hours, case ascertainment, abstracting time as well as travel time, and abstracting time for State Cancer Registry abstractors results in an approximate cost of $378 per case. This is expected to decline once the proposed amendments are implemented.

6. What types of small businesses will be required to comply with the proposed rule?

All healthcare facilities that diagnose and/or treat patients with cancer. This could potentially affect approximately 800 small facilities.

7. Does the proposed rule create barriers to entry? If so, please describe those barriers and why those barriers are necessary.

No.

8. Explain the additional requirements with which small business owners will have to comply and estimate costs associated with compliance.

The cost of data collection should not be appreciably greater than what is currently required. However, there will be a cost to those entities currently not complying. The amendments to this rule clarify who must comply.

9. State whether the proposed rule contains different requirements for different sized entities, and explain why this is or is not necessary.

The requirements are the same for all entities.

10. Describe your understanding of the ability of small business owners to implement changes required by the proposed rule.

With initial guidance and training from the ADH/ACCR, and a willingness on the part of the facilities to comply with these rules, the process of implementing these changes are very manageable.

11. How does this rule compare to similar rules in other states or the federal government?

All surrounding states have comparable rules and regulations.

12. Summarize the input your agency has received from small business or small business advocates about the proposed rule.

Responses received: Six telephone calls, 2 electronic mails, one paper postal mail and one facsimile response. Five respondents were asking how they could become compliant with reporting, from those three wanted to be trained to use the free software and report cases. One hospital responded by hiring an additional person in the cancer registry. Two respondents made comments opposing many sections of the proposed changes. One respondent opposed the entire document.

LEGAL AUTHORIZATION: The Department of Health is directed to accumulate such data concerning cancer in Arkansas and its residents as is deemed appropriate for the purposes of describing the frequency of cancer, furnishing reports to health professionals and the public, and for planning and evaluating cancer prevention and control programs. The data shall be collected under the authority of regulations promulgated by the State Board of Health. Ark. Code Ann. § 20-15-201.

RULES PERTAINING TO THE ARKANSAS CANCER REGISTRY

SECTION I. AUTHORITY

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

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, The 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, 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. ~~Since cancer is one of the leading causes of death in Arkansas it is essential that specific information concerning this group of diseases be collected, analyzed and reported. All Arkansans will benefit from the epidemiological surveillance of this group of diseases.~~

SECTION III. DEFINITIONS

A. "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 .

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

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

D. "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.

E. "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.

F. "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.

G. "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.

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

I. "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.

J. "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 B.

K. "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.

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

~~B.~~M. "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. 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).

~~GENERAL REQUIREMENTS~~

~~A. Each hospital or other medical facility providing screening, diagnostic or therapeutic service, physicians, including surgeons, and all other health care practitioners or their designees shall report the following information concerning each case.~~

1.

1. Personal information.

a. Name.

b. Address.

c. Date of birth.

d. Place of birth.

e. Race and Spanish/Hispanic origin.

f. Sex.

g. Social security number.

h. County of residence.

i. Marital status.

j. Maiden name, if applicable.

k. Alias.

l. Occupational history, if available.

m. Tobacco use status, if available.

2. Diagnosis

a. Class of case.

b. Date of diagnosis.

c. Primary site.

d. Laterality

e. Histology.

3. Treatment

a. Grade.

b. Diagnostic confirmation.

c. Staging (American Joint Committee for Cancer - AJCC).

d. Reporting identification of the facility or person reporting.

4. Summary of Treatment.

a. Date first course started.

b. Name of physician.

c. First course of treatment, i.e., surgery, radiation, chemotherapy, hormone therapy.

5. Follow-up.

6. Recurrence.

B. In order to insure the accuracy and completeness of the cancer registry within the Department of Health, staff and agents shall be permitted access to records of hospitals, other medical

~~facilities, physicians (including surgeons), nursing homes and other individuals or agencies providing services wherein records concerning patients in which cases of cancer are identified are located.~~

~~C. All reporting shall be made on forms or in an acceptable manner in accordance with directives of the Department of Health. All cancer cases shall be reported within six months after the date of discharge or diagnosis is made or within six months after a cancer case is known, even if diagnosed elsewhere. Where appropriate cancer data will be in the format recognized by the American Association of Central Cancer Registries.~~

~~D. Each hospital licensed by the Department of Health shall designate a person who shall be responsible for accurate and timely reporting pursuant to this rule. Such hospital shall also adopt a policy which ensures the designation of such person and the hospital's reporting to the Registry.~~

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 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.

B. Format for reporting

1. The format for reporting, the required codes, and the standards for completeness and quality are defined in 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 department.

D. Deadline for Reporting

1. Reporting shall occur no later than six months after the date of diagnosis 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 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 department has data sharing agreements that ensure confidentiality;

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

3. For 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.

~~All information reported to the Department of Health shall be confidential and shall not be disclosed under any circumstances except (1) to other state cancer registries with which the Department of Health has agreements that insure confidentiality; (2) to other state health officials who are obligated to keep such information confidential; and (3) to approved cancer research centers under specific conditions where the names and identities of the individuals are appropriately protected, and when such research is conducted for the purpose of cancer prevention, control and treatment.~~

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

5. Is this a new rule? Yes ☐ No ☒

If yes, please provide a brief summary explaining the regulation.

n/a

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."**

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

Ark. Code Ann. §§ 20-15-201 - 205

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

Clarification of rules with an additional section of violations and penalty

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).

http://www.healthy.arkansas.gov/aboutADH/RulesRegs/CancerRegistry.pdf

9. Will a public hearing be held on this proposed rule? Yes ☒ No ☐

If yes, please complete the following:

Date: 10/13/11

Time: 10:00 PM

Place: Media Room, Fifth Floor, of the Arkansas Department of Health

10. When does the public comment period expire for permanent promulgation? (Must provide a date.) 10/13/11

11. What is the proposed effective date of this proposed rule? (Must provide a date.) 1/1/12

12. Do you expect this rule to be controversial? Yes ☒ No ☐

If yes, please explain. Some health care professionals are opposed to the violations and penalty section

13. 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.

Arkansas Medical Society - David Wroten, Executive Vice President; Peter Singer, M.D., Thomas Eans, M.D.

QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS WITH THE ARKANSAS LEGISLATIVE COUNCIL AND JOINT INTERIM COMMITTEE

DEPARTMENT/AGENCY Department of Health

DIVISION Center for Public Health Practice/Cancer Registry

DIVISION DIRECTOR John Senner

CONTACT PERSON Theressia Mitchell

ADDRESS 4815 W. Markham, #7

PHONE NO. 501-661-2463 **FAX NO.** 501-661-2891 **E-MAIL** theressia.mitchell@arkansas.gov

NAME OF PRESENTER AT COMMITTEE MEETING Robert Brech

PRESENTER E-MAIL robert.brech@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 Rule" below.
D. Submit two (2) copies of this questionnaire and financial impact statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to:

Donna K. Davis
Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
Room 315, State Capitol
Little Rock, AR 72201

****

1. What is the short title of this rule? Arkansas Cancer Registry Rules and Regulations

2. What is the subject of the proposed rule? The registration of required cancer cases in Arkansas.

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.

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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? N/A

   When does the emergency rule expire? N/A

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

SECTION IX. EFFECTIVE DATE

The effective date of these Rules and Regulations shall be January 1, ~~1996~~2012.

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. SECTION VIII. REPEAL

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

CERTIFICATION

This is to certify that the foregoing Rules Pertaining to the Arkansas Cancer Registry adopted by the Arkansas State Board of Health at a regular session of said Board held in Little Rock, Arkansas on the _____ day of _____, 20__.

_____

Paul Halverson, DrPH
Secretary
Arkansas State Board of Health

~~The foregoing Rules, copy having been filed in my office, are hereby approved on this ___ day of _____, 2010.~~

_____

~~Mike Beebe~~
~~Governor~~

(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.

~~1.~~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.

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 by the department 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 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 violating any of the provisions of this rule shall be deemed guilty of a misdemeanor and upon conviction thereof shall be punished by a fine of not less than one hundred dollars ($100) nor more than five hundred dollars ($500), or by imprisonment not exceeding one (1) month, or both. Each day of violation shall constitute a separate offense.~~

Every firm, person, or corporation who violates this rule may be assessed a civil penalty by the board. 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).