

**State of Kansas
Department of Health and Environment**

Notice of Hearing on Proposed Administrative Regulations

The Kansas Department of Health and Environment (KDHE), Division of Public Health, Bureau of Health Promotion, will conduct a public hearing at 10:00 a.m. Wednesday, October 24, 2018, in the Azure Conference Room, fourth floor, Curtis State Office Building, 1000 SW Jackson, Topeka, Kansas, to consider the adoption of proposed amended cancer registry reporting requirements regulation K.A.R. 28-70-2.

A summary of the proposed amended regulation and estimated economic impact follows:

Summary of Regulation:

K.A.R. 28-70-2. Reporting requirements. This amended regulation specifies the cancer screening data for collection and the requirements for reporting when and by what method cancer screening data is to be reported to the Kansas Cancer Registry. The proposed amendments add two types of cancer screening data to be collected and clarify the method of electronic data transfer to the Kansas Cancer Registry. The proposed amendments comply with the national standards from the Centers for Disease Control and Prevention and the National Cancer Institute in regard to routine cancer screenings that provide the opportunity to identify cancers in early stages or before cancers become malignant. The long-term impact of having cancer screening data is to reduce screenable cancers and prolong survivorship.

Economic Impact:

Cost to the agency: There is no additional cost to the agency associated with the amendments to this regulation regarding data collection and reporting.

Cost to reporting parties: There is no additional cost to reporting parties.



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Costs to other governmental agencies or units: The amendments to this regulation will not result in additional costs to other government agencies.

The time period between the publication of this notice and the scheduled hearing constitutes a 60-day public comment period for the purpose of receiving written public comments on the proposed regulation. All interested parties may submit written comments prior to 5:00 p.m. on the day of the hearing to Julie Sergeant, Cancer Prevention and Control Program, Bureau of Health Promotion, Kansas Department of Health and Environment, 1000 SW Jackson, Suite 230, Topeka, KS 66612-1274, by email to julie.sergeant@ks.gov, or by fax to 785-559-4234. During the hearing, all interested parties will be given a reasonable opportunity to present their views orally on the proposed regulation as well as an opportunity to submit their written comments. In order to give each individual an opportunity to present their views, it may be necessary for the hearing officer to request that each presenter limit an oral presentation to an appropriate time frame.

Complete copies of the proposed regulation and the corresponding economic impact statement may be obtained from the KDHE Bureau of Health Promotion website, at <http://www.kdheks.gov/bhp/index.html> or by contacting julie.sergeant@ks.gov, 785-296-5868 or fax 785-559-4234. Questions pertaining to the proposed regulation should be directed to Julie Sergeant at the contact information above.

Any individual with a disability may request accommodation in order to participate in the public hearing and may request the proposed regulation and the economic impact statement in an accessible format. Requests for accommodation to participate in the hearing should be made at least five working days in advance of the hearing by contacting Julie Sergeant.

Jeff Andersen
Secretary

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28-70-2. Reporting requirements. (a)(1) Each administrator of a hospital, an ambulatory surgery center, a radiology oncology center, or a pathology laboratory shall, within six months of the date of diagnosis, report to the registry each case of cancer diagnosed or treated, unless exempted under subsection (d) of this regulation.

(2) Each report shall provide all required information available in the medical or administrative records that are under the direct control of the reporting administrator. No administrator shall be required to contact the patient, the patient's family, or another health care provider to obtain additional information not contained in the medical or administrative records.

(b) Each person who is either licensed to practice medicine and surgery or licensed to practice dentistry and who practices in a clinic or physician's office and each administrator of a hospice or adult care home shall provide the following to the registry:

(1) If used to confirm each cancer diagnosis, a list of in-state and out-of-state pathologists, or pathology laboratories and dermatopathologists; and

(2) for each patient for whom a cancer diagnosis has been confirmed, pathologically or clinically, a list that includes the name, social security number, date of birth, and cancer site. The social security number shall be used only for confirmation of patient identity.

(c) Upon receipt of any written request for information from the registry regarding a patient, each reporting party specified in subsection (a) or (b) shall provide the requested information that is contained in medical or administrative records under the direct control of the reporting party. The requested information may consist of either of the following:

(1) Any information specified in subsection (c), even if the patient's cancer has not been diagnosed or treated by the hospice or adult care home or by the health care provider or licensee

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specified in subsection (a) or (b); or

(2) annual follow-up information, including tumor recurrence and follow-up treatment.

(d) The reports specified in this regulation shall not be required for the following types of cancer:

(1) Squamous cell carcinoma of the skin, unless located on a lip of the face or in the genital area; or unless spread beyond local tissues at the time of diagnosis;

(2) basal cell carcinoma of the skin, unless located on a lip of the face or in the genital areas; or unless spread beyond local tissues at the time of diagnosis; and

(3) carcinoma in situ of the uterine cervix.

(e) Each report from any reporting party specified in subsection (a) or (b) shall include the following information, if available:

(1) Patient identifiers and demographics;

(2) cancer screening history;

(3) cancer diagnosis, including the cancer site and histology;

~~(3)~~ (4) personal and family history;

(4) ~~(5)~~ vital status, including the date of death and cause of death, if applicable;

~~(5)~~ (6) cancer-related treatment information;

~~(6)~~ (7) follow-up information, including the date of last contact with the patient; and

~~(7)~~ (8) third-party payer information; and

(9) risk factors for cancer.

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(f) Each report to the registry shall be submitted in one of the following formats:

(1) American standard code for information interchange (ASCII) file in the North

American association of central cancer registries (NAACCR) format;

(2) electronic or paper forms provided by the registry;

(3) any other format equivalent to any format specified in ~~paragraph (f)(1) or (2)~~ this subsection that is acceptable to the cancer registry director.

(g) All data transferred to the registry shall be secure and confidential.

(1) All paper data transferred to the registry shall be sealed in an envelope marked "CONFIDENTIAL" and addressed to the cancer registry director.

(2) Electronic data transfer ~~may~~ shall be made by ~~one of the following means:~~

~~(A) Diskette mailed in a sealed envelope marked "CONFIDENTIAL" and addressed to the cancer registry director; or~~

~~(B) a secured electronic transmission, if encrypted, according to prior instructions from the cancer registry director. (Authorized by and implementing K.S.A. 2004 2017 Supp. 65-1,169; implementing K.S.A. 2004 Supp. 65-1,168 and 65-1,169; effective Feb. 27, 1998; amended Aug. 5, 2005; amended P-_____.)~~

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**Kansas Administrative Regulations
Economic Impact Statement
For the Kansas Division of the Budget**

Kansas Department of Health and Environment
Agency

Susan Vogel
Agency Contact

785-296-1291
Contact Phone Number

28-70-2
K.A.R. Number(s)

Submit a hard copy of the proposed rule(s) and regulation(s) and any external documents that the proposed rule(s) and regulation(s) would adopt, along with the following to: Division of the Budget
900 SW Jackson, Room 504-N
Topeka, KS 66612

I. Brief description of the proposed rule(s) and regulation(s).

KAR 28-70-2. Reporting requirements. This regulation specifies the reporting requirements including who, what and when cancer-related information is to be reported to the Kansas Cancer Registry (KCR). The KCR is the agent of the Kansas Department of Health and Environment (KDHE) for the purpose of receiving and processing confidential cancer reports and other information related to the incidence of cancer in the state. The KCR is located at the University of Kansas Medical Center, Department of Preventive Medicine and Public Health and is managed by the Cancer Registry Director who is a faculty at the Department of Preventive Medicine and Public Health. The proposed amendments require that each report from a reporting party specified in subsections (a) and (b) of the regulation contains the cancer screening history and risk factors for cancer. An amendment eliminates an obsolete method for data transfer.

II. Statement by the agency if the rule(s) and regulation(s) is mandated by the federal government and a statement if approach chosen to address the policy issue is different from that utilized by agencies of contiguous states or the federal government. (If the approach is different, then include a statement of why the Kansas rule and regulation proposed is different)

Statewide cancer registries are mandated by the Cancer Registries Amendment Act Public Health Service Act (42 USC 280e -280e4; Public Law 102-515) and are in existence in all 50 states and in the United States territories. The proposed amendments are needed to comply with the federal standards related to cancer screening from the Center for Disease Control and Prevention (CDC) and the National Cancer Institute (NCI).

III. Agency analysis specifically addressing following:

A. The extent to which the rule(s) and regulation(s) will enhance or restrict business activities and growth;

The proposed regulation will neither enhance or restrict business activities and growth.

B. The economic effect, including a detailed quantification of implementation and compliance costs, on the specific businesses, sectors, public utility ratepayers, individuals, and local governments that would be affected by the proposed rule and regulation and on the state economy as a whole;

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The proposed regulation will have no implementation and compliance costs for businesses, sectors, public utility ratepayers, individuals and local government or on the state economy as a whole.

The proposed regulation adds no additional costs to the reporting parties or to the KCR. Costs will be absorbed within existing resources.

C. Businesses that would be directly affected by the proposed rule and regulation;

Subsections (a) and (b) of the regulation specify the required reporting parties. The proposed regulation will affect the required reporting parties including health care providers that provide cancer screening related services such as hospitals, laboratories and mammography stations. However, there will be no additional costs to reporting parties. Costs will be absorbed within existing resources because all of the reporting parties currently report cancer cases to the KCR.

D. Benefits of the proposed rule(s) and regulation(s) compared to the costs;

The filing of a report by a reporting party to the KCR of the cancer screening history and risk factors for cancer will not add any additional costs to the reporting party and costs will be absorbed within existing resources. The long-term impact of screening data will extend beyond reduction in screenable cancers and prolonging survivorship and will also improve quality of life and significantly reduce personal and societal economic costs.

E. Measures taken by the agency to minimize the cost and impact of the proposed rule(s) and regulation(s) on business and economic development within the State of Kansas, local government, and individuals;

The measures taken to minimize the cost to businesses, local government, individuals and any detrimental impact on economic development are to conduct linkages of the KCR database with electronic health records, including pathology, cytology, billing, claims, and medical records disease indices (MRDIs), that already contain screening related information. Records linkage will minimize the needs and/or costs resulting from direct abstraction. The electronic health records will be provided by reporting parties, while linkage cost will be covered by the funding obtained by the KCR from the CDC.

F. An estimate, expressed as a total dollar figure, of the total annual implementation and compliance costs that are reasonably expected to be incurred by or passed along to business, local governments, or members of the public.

\$0. There are no annual implementation and compliance costs expected to be incurred by or passed along to businesses, local governments or the public.

An estimate, expressed as a total dollar figure, of the total implementation and compliance costs that are reasonably expected to be incurred by or passed along to business, local governments, or members of the public.

\$0. There are no total implementation and compliance costs expected to be incurred by or passed along to businesses, local governments or the public. There will be no additional implementation and compliance costs for the reporting parties and the KCR and costs will be absorbed within existing resources.

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- 1) The case-finding sources that include MRDIs and billing records are in electronic format and have been sent routinely to the KCR for case-finding and/or quality audit purpose.
- 2) The screening-related codes already have been included in the cancer-finding lists. Therefore, there is no additional work/cost that is expected from producing the lists of patients who have received screening.
- 3) The CDC and the KCR currently target screening in women diagnosed with breast and/or cervical cancers of which there are about 2500 patients in Kansas annually, or six or less patients per reporting party. Many reporting parties will have no cases, while large reporting parties will have more patients.
- 4) The KCR will provide record linkage of all case-finding sources and send the patient list to the reporting party that provided the screening. The reporting party will send the electronic file to the KCR using the KCR secured file transfer portal, which is a secured free service to all reporting parties. There is no mailing cost to reporting parties. Further, the KCR will abstract the required data using the pertinent electronic reports that are transmitted to the KCR.
- 5) A reporting party has the option to abstract data if they choose to do so and will absorb personnel costs within existing resources. Costs for the KCR personnel will be obtained from the CDC grant funding.

Do the above total implementation and compliance costs exceed \$3.0 million over any two-year period?

YES ☐ NO ☒

Give a detailed statement of the data and methodology used in estimating the above cost estimate.

The cost estimate methodology is described in paragraph IIIE. The approach is to perform linkages between the KCR database with various sources of electronic health records that are already in existence. Many of these electronic health records have been transmitted to the KCR and are part of the current/standard data sources in cancer registration operation.

Prior to the submission or resubmission of the proposed rule(s) and regulation(s), did the agency hold a public hearing if the total implementation and compliance costs exceed \$3.0 million over any two-year period to find that the estimated costs have been accurately determined and are necessary for achieving legislative intent? If applicable, document when the public hearing was held, those in attendance, and any pertinent information from the hearing.

YES ☐ NO ☒

- G. If the proposed rule(s) and regulation(s) increases or decreases revenues of cities, counties or school districts, or imposes functions or responsibilities on cities, counties or school districts that will increase expenditures or fiscal liability, describe how the state agency consulted with the League of Kansas Municipalities, Kansas Association of Counties, and/or the Kansas Association of School Boards.**

The proposed amended regulation will have no effect on the cities, counties or school districts within the state. However, when the notice of hearing for this regulation was published in the *Kansas Register*, standard agency procedure was followed and the two organizations were contacted electronically for comment with attached copies of the regulation, economic impact statement and published notice of hearing.

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- H. Describe how the agency consulted and solicited information from businesses, associations, local governments, state agencies, or institutions and members of the public that may be affected by the proposed rule(s) and regulation(s).**

KDHE consulted with and solicited information from the Department of Preventative Medicine and Public Health at the University of Kansas Medical Center. KDHE requested comment from the three organizations listed in paragraph IIIG.

- I. For environmental rule(s) and regulation(s) describe the costs that would likely accrue if the proposed rule(s) and regulation(s) are not adopted, as well as the persons would bear the costs and would be affected by the failure to adopt the rule(s) and regulation(s).**

Not applicable.

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