

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 Family Health, will conduct a public hearing at 9:00 a.m. Friday, September 9, 2022, in Room 530, Curtis State Office Building, 1000 SW Jackson, Topeka, Kansas, to consider the adoption of proposed amended maternal and child health regulations K.A.R. 28-4-520 and 28-4-521, regarding the start and implementation of the Kansas Birth Defects Program.

A summary of the proposed regulations and estimated economic impact follows:

Summary of Regulations:

K.A.R. 28-4-520. Definitions. Removes behavioral disorders from the definition of abnormal condition. Removes outdated ICD-9 references and defined ICD-9 codes. Adds the defined term notifiable condition. Removes the defined term primary diagnosis.

K.A.R. 28-4-521. Reporting notifiable conditions. Changes the reporting of abnormal conditions and congenital anomalies to the reporting only of notifiable conditions. Removes reporting requirements, method of reporting, and removal of reported information. Adopts department document "Kansas Birth Defects Surveillance Reporting Manual."

Economic Impact:

Cost to the agency: The proposed regulations will not result in increased costs to the agency.

Cost to the public and regulated community: The proposed regulations will not result in increased costs to the public and regulated community.

Costs to other governmental agencies or units: The proposed regulations will not result in increased costs to other governmental agencies or units.

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A detailed economic impact is provided in the economic impact statement that is available from the designated KDHE contact staff person or at the Kansas Birth Defects Program website, as listed below.

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 regulations. All interested parties may submit written comments prior to 5:00 p.m. on the day of the hearing to Alyson Dalrymple, Kansas Department of Health and Environment, Bureau of Family Health, Screening and Surveillance Section, 1000 SW Jackson, Suite 220, Topeka, KS 66612, by email to alyson.dalrymple@ks.gov, or by fax to 785-559-4280. Interested parties are encouraged to participate in the public hearing by submitting written comments.

During the hearing, all interested parties will be given a reasonable opportunity to present their views orally on the proposed regulations as well as an opportunity to submit their written comments. It is requested that each individual giving oral comments also provide a written copy of the comments for the record. 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 regulations and the corresponding economic impact statement may be obtained from the Kansas Birth Defects Program website at <https://www.kdhe.ks.gov/678/Birth-Defects-Program>, or by contacting Alyson Dalrymple at alyson.dalrymple@ks.gov, 785-296-6134, or fax 785-559-4280. Questions pertaining to the proposed regulations should be directed to Alyson Dalrymple at the contact information above.

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Any individual with a disability may request accommodation in order to participate in the public hearing and may request the proposed regulations 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 Alyson Dalrymple.

Janet Stanek
Secretary

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28-4-520. Definitions. In addition to the definitions terms defined in K.S.A. 65-1,241 and K.S.A. 65-2401 and amendments thereto, each of the following terms, as used in this regulation and in K.A.R. 28-4-521, shall have the meaning assigned specified in this regulation:

(a) "Abnormal condition" means any condition established at conception or acquired in utero that results in a morphologic, metabolic, or functional, ~~or behavioral~~ disorder requiring medical or other intervention.

(b) "Birth defects information system" means the Kansas birth defects reporting system, which collects, maintains, analyzes, and disseminates information regarding abnormal conditions, birth defects, and congenital anomalies of each stillbirth and of each ~~child from birth to five years of age with a birth defect~~ children from live birth to five years of age pursuant to K.S.A. 65-101, and amendments thereto.

(c) "Congenital anomaly" means an error of morphogenesis that is established at conception or acquired during intrauterine life, ~~which is also referred to as a birth defect.~~

(d) "ICD-9-CM" means the clinical modification of the "international classification of diseases," ninth revision, published by Ingenix inc., which is used to code and classify morbidity data ~~from inpatient and outpatient records, physician offices, and most surveys from the national center for health statistics.~~ The following portions of volume one of this document are hereby adopted by reference:

(1) ~~"Genetic and metabolic conditions," codes 243 through 279.2 on pages 49 through 60;~~

(2) ~~"sickle cell anemia and other hemoglobinopathies," codes 282.4 through 282.7 on pages 61 and 62;~~

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K.A.R. 28-4-520, page 2

(3) ~~“congenital anomalies,” codes 740 through 759 on pages 227 through 240; and~~

(4) ~~“fetal alcohol syndrome,” code 760.71 on page 241~~ “Notifiable condition” means any abnormal condition or congenital anomaly diagnosed by a physician in a child from live birth to five years of age or stillbirth.

(e) ~~“Primary diagnosis” means the principal disease or condition assigned to an infant by a licensed physician based on the history of the disease process, signs and symptoms, laboratory data, and special tests. (Authorized by and implementing K.S.A. 2009 Supp. 65-1,245; effective Dec. 3, 2010; amended P-~~_____.)

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28-4-521. Reporting abnormal conditions and congenital anomalies notifiable conditions.

(a) ~~Reporting requirements. Each physician, hospital, and freestanding birthing center shall report to the birth defects information system, pursuant to K.S.A. 65-1,241 and amendments thereto, the abnormal conditions and congenital anomalies listed in the portions of ICD-9 CM adopted by reference in K.A.R. 28-4-520~~ The requirements for reporting notifiable conditions shall be those specified in the department's "Kansas birth defects surveillance reporting manual," dated April 18, 2022, which is hereby adopted by reference.

(b) ~~Method of reporting. Each abnormal condition and congenital anomaly that is required to be reported under this regulation shall be reported to the birth defects information system on a form approved by the secretary.~~

(c) ~~Removal of reported information. Any parent or legal guardian may request the removal of reported information from the birth defects information system by using the removal form in accordance with K.S.A. 65-1,244, and amendments thereto. (Authorized by K.S.A. 2009 Supp. 65-1,245; implementing K.S.A. 2009 Supp. 65-1,241, 65-1,244, and 65-1,245; effective Dec. 3, 2010; amended P-~~_____.)

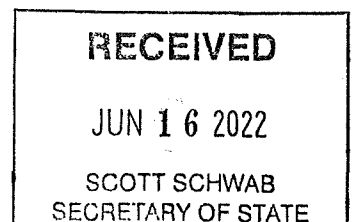
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Kansas Administrative Regulations Economic Impact Statement (EIS)

Kansas Department of Health and Environment
Agency

Susan Vogel
Agency Contact

(785) 296-1291
Contact Phone Number

28-4-520; 28-4-521
K.A.R. Number(s)

☒ Permanent ☐ Temporary

Is/Are the proposed rule(s) and regulation(s) mandated by the federal government as a requirement for participating in or implementing a federally subsidized or assisted program?

☐ Yes If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.

☒ No If no, do the total annual implementation and compliance costs for the proposed rule(s) and regulation(s), calculated from the effective date of the rule(s) and regulation(s), exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024 (as calculated in Section III, F)?

☐ Yes If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration, the Attorney General, AND the Division of the Budget. The regulation(s) and the EIS will require Budget approval.

☒ No If no, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.

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Section I

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

K.A.R. 28-4-520 and K.A.R. 28-4-521 are regulations set in place to support K.S.A. 65-1,241 et. seq. regarding the start and implementation of the Kansas Birth Defects Program.

The proposed changes of K.A.R. 28-4-520 reflect 2 (two) major updates:

1. The list of mandated disorders to be reported to the Kansas Birth Defects Information System was changed from ICD-9-CM diagnosis codes to a more generalized, standard set of disorder categories. This change eliminates the need to amend regulations in the event the International Classification of Disease codes are updated/changed or when additional disorders that our federal, state and local stakeholders deem necessary to track have been identified. Additionally, within this new generalized, standard set of disorder categories, Neonatal Abstinence Syndrome (NAS) is now included, as it is a specific disorder of interest with our stakeholders to identify and track.

2. The change of the definition for “abnormal condition” to exclude the reporting of metabolic and behavioral disorders, as metabolic disorders are now being monitored by the Kansas Newborn Screening Program and birth defects do not include strictly behavioral disorders per guidance from the Centers for Disease Control and Prevention as well as the National Birth Defects Prevention Network.

The proposed changes of K.A.R. 28-4-521 reflect 2 (two) major changes:

1. To better align with our entire regulations set (K.A.R. 28-4-501 et. seq.), the verbiage of who is mandated to report birth defects is changed.

2. The creation of a department document allows the Birth Defects Program to remove specific reporting instructions and the directions for how to remove patient information from the Birth Defects Program from the regulation itself and instead provide a specific list of most current ICD-10-CM codes with these reporting and patient removal instructions on one document that can easily be edited and sent to our healthcare providers. The new department document also changes how the Birth Defects Information System can receive birth defects data.

Section II

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

These regulations are not mandated by the federal government. The amendment of these regulations will, however, allow us to better align with the recommendations provided by our federal and national stakeholders. All 4 contiguous states monitor for the birth defects listed in the proposed amended regulations, and do not include metabolic or behavioral disorders as a part of their Birth Defects Programs.

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Section III

Agency analysis specifically addressing the following:

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

The proposed amended regulations will neither enhance nor 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(s) and regulation(s) and on the state economy as a whole;

The proposed amended regulations will have no implementation and compliance costs for businesses, sectors, public utility ratepayers, individuals and local governments or for the state economy. The existing regulations will only be changed to update how the Birth Defects Information System can receive data as well as what disorders are to be reported. Any trainings, education and outreach pertaining to any changes in the list of conditions to be reported will be offered free of charge.

- C. Businesses that would be directly affected by the proposed rule(s) and regulation(s);

Hospitals, birthing facilities, midwives or physician's offices that report birth defects data will be required to change the list of conditions they are reporting to the Birth Defects Program. The addition of any new disorders may require education and training with will be offered at no cost to these businesses.

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

There are no additional costs. The benefits of updating the current list of reportable birth defects to include 37 new disorders added, under recommendations by the National Birth Defects Prevention Network (NBDPN), since the condition list was last updated in Kansas. This will allow Kansas to better use data to understand these birth defects and provide more robust education, outreach and coordination of referral services. Kansas has been missing valuable data for the disorders that were not previously tracked simply due to outdated regulations that did not allow for revisions as the recommended list of disorders changed. These changes will keep Kansas in compliance with recommendations made by the Centers for Disease Control and Prevention as well as the NBDPN, but providing education, outreach and referral information will also improve the lives of Kansas children and their families affected by the new, updated list of birth defects. The change of information regarding the two additional methods of reporting will allow the reporting of birth defects to be more accessible, resulting in more complete and accurate data, a critical component to having a robust and dependable surveillance program. Regarding the revision to exclude metabolic and behavioral disorders will reduce duplicate and confusing reporting expectations. At the time the metabolic disorders were added to the Kansas reportable birth defect list, the

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Newborn Screening (NBS) Program was only screening for limited metabolic disorders. Since then, the NBS has expanded and reporting for birth defects is duplicative of the NBS process. Additionally, it is not recommended to be monitored under the Birth Defects by NBDPN. Lastly, behavioral disorders are also not recommended as they are a separate section of medical disorders entirely and, while behavioral disorders may accompany some birth defects, these disorders are not recommended for inclusion into reporting practices by the NPBDPN. Removing metabolic and behavioral disorders allows the birth defects program to function as intended by the legislation with a sole focus on birth defects to provide outreach and surveillance to identify potential environmental or health factors that cause birth defects, with the goal of reducing the number of preventable defects and improving the health of infants and families in Kansas.

- 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;

No measures are taken as there is no additional cost or impact on businesses or economic development within the state or local governments and individuals associated with the amendments to this regulation.

- F. An estimate of the total annual implementation and compliance costs that are reasonably expected to be incurred by or passed along to businesses, local governments, or members of the public.

Note: Do not account for any actual or estimated cost savings that may be realized.

Costs to Affected Businesses – \$0.00

Costs to Local Governmental Units – \$0.00

Costs to Members of the Public – \$0.00

Total Annual Costs – \$0.00

(sum of above amounts)

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

There are no additional costs for changing the disorders that are to be reported to the Kansas Birth Defects Information System or the method of reporting the data.

- ☐ Yes If the total implementation and compliance costs exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024, and prior to the submission or resubmission of the proposed rule(s) and regulation(s), did the agency hold a public hearing 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.
- ☐ No
- ☒ Not Applicable

N/A

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Provide an estimate to any changes in aggregate state revenues and expenditures for the implementation of the proposed rule(s) and regulation(s), for both the current fiscal year and next fiscal year.

There are no total implementation and compliance costs expected to be incurred by or passed along to businesses, local governments or members of the public.

Provide an estimate of any immediate or long-range economic impact of the proposed rule(s) and regulation(s) on any individual(s), small employers, and the general public. If no dollar estimate can be given for any individual(s), small employers, and the general public, give specific reasons why no estimate is possible.

There are no total implementation and compliance costs expected to be incurred by or passed along to businesses, local governments or members of the public.

- 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 regulations will have no effect on the cities, counties or school districts within the state. However, when a notice of hearing for a set of regulations is published in the *Kansas Registrar*, standard agency procedure is followed and the three organizations are contacted electronically for comment with attached copies of the regulation, economic impact statement and published notice of hearing.

- 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).

The Kansas Perinatal Quality Collaborative (KPQC) was consulted in 2018. KDHE did not consult with or solicit information from businesses, associations, local governments, state agencies, institutions or members of the public. This amended regulation will not have a direct effect on or add additional costs to those entities. KDHE will request comment from the three organizations listed in paragraph III.G.

Section IV

Does the Economic Impact Statement involve any environmental rule(s) and regulation(s)?

- ☐ Yes If yes, complete the remainder of Section IV.
☒ No If no, skip the remainder of Section IV.

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- A. Describe the capital and annual costs of compliance with the proposed rule(s) and regulation(s), and the persons who would bear the costs.

Click here to enter agency response.

- B. Describe the initial and annual costs of implementing and enforcing the proposed rule(s) and regulation(s), including the estimated amount of paperwork, and the state agencies, other governmental agencies, or other persons who would bear the costs.

Click here to enter agency response.

- C. Describe the costs that would likely accrue if the proposed rule(s) and regulation(s) are not adopted, as well as the persons who would bear the costs and would be affected by the failure to adopt the rule(s) and regulation(s).

Click here to enter agency response.

- D. Provide a detailed statement of the data and methodology used in estimating the costs used.

Click here to enter agency response.

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