

Proposed

**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. 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 maternal and child health regulation K.A.R. 28-4-503.

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

Summary of Regulation:

K.A.R. 28-4-503. Timing of specimen collections. This amended regulation aligns the Kansas Newborn Screening Program with national standards for newborn screening timeliness and provides the earlier specimen collection timeframe during which a newborn screening specimen must be collected. Amendments specify the required specimen collection for an infant requiring a blood transfusion, for infants who require transfer to another institution, and for infants born outside of an institution.

Economic Impact:

Cost to the agency: There is no added cost to the agency associated with the amendments to this regulation that only change the required timeframe for specimen collection.

Cost to institutions: There is no added cost to institutions or others collecting specimens in the timeframe required by the amendments to this regulation.

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

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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 Shawn Manos, Newborn Screening Program Coordinator, Special Health Services, Bureau of Family Health, Kansas Department of Health and Environment, 1000 SW Jackson, Suite 220, Topeka, KS 66612-1274, by email to Shawn.M.Manos@ks.gov, or by fax to 785-559-4245. 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 newborn screening website, at http://www.kdheks.gov/newborn_screening/index.html or by contacting Shawn Manos at Shawn.M.Manos@ks.gov, 785-291-3363 or fax 785-559-4245. Questions pertaining to the proposed regulation should be directed to Shawn Manos 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 Shawn Manos.

Jeff Andersen
Secretary

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28-4-503. Timing of specimen collections. (a) The initial specimen from each infant born in an institution shall be obtained as follows:

(1) ~~(A) Before discharge but no later than at 72~~ When the infant is at least 24 hours of age but less than 48 hours of age; or

(B) if the infant is discharged from the institution of birth before 24 hours of age, before the infant is discharged;

(2) before ~~any transfer of the infant~~ is transferred from the institution of birth to another institution; and

(3) before the infant receives any blood transfusion.

(b) The initial specimen from each infant born outside of an institution shall be obtained as follows:

(1) ~~No later than at 72~~ When the infant is at least 24 hours of age but less than 48 hours of age; and

(2) before the infant receives any blood transfusion.

(c) A repeat specimen shall be obtained from each infant born in an institution or outside of an institution under any of the following conditions:

(1) The specimen is unsatisfactory as specified in K.A.R. 28-4-505.

(2) Follow-up recommendations have been issued by the department.

(3) The infant is less than 24 hours old when the initial specimen is taken. (Authorized by K.S.A. 65-101 and K.S.A. ~~2009~~ 2017 Supp. 65-180; implementing K.S.A. ~~2009~~ 2017 Supp. 65-180 and K.S.A. 65-181; effective, T-87-48, Dec. 19, 1986; effective May 1, 1987; amended April 14, 2000; amended Dec. 3, 2010; 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

28-4-503

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).

K.A.R. 28-4-503. Timing of Specimen Collections. This amended regulation specifies the following: 1) the revised timeframe that a newborn screening specimen is required to be collected; 2) the required collection for a well-baby, a baby born requiring a blood transfusion, and babies born who require transfer to another hospital or birthing facility; and 3) the circumstances that would require a repeat specimen collection.

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)*

This regulation is not mandated by the federal government. However, this regulation as amended will align Kansas with a national recommendation by the Department of Health and Human Services for timeliness of newborn screening specimens. All four of the contiguous states have policies in place recommending collection between 24-48 hours after birth. Kansas currently recommends collection between 24-72 hours after birth.

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 amended regulation will neither enhance nor restrict business activities and growth.

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- 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;**

The proposed amended regulation will have no implementation and compliance costs for businesses, sectors, public utility ratepayers, individuals and local governments or for the state economy as a whole. For hospitals and birthing facilities collecting the specimens, the proposed regulation only changes the required timeframe of collection and adds no additional costs. Costs will be absorbed within existing resources.

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

There is no additional costs to the hospitals and birthing facilities collecting the specimens in the changed timeframe required by the amended regulation. Costs will be absorbed within existing resources because hospitals and birthing facilities currently collect infant specimens.

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

There are no additional costs. Costs of the proposed amended regulation will be absorbed within existing resources because hospitals and birthing facilities currently collect infant specimens. The proposed regulation only changes the timeframe of collection. The benefits of increasing timely and effective screenings based on earlier specimen collection will allow the KDHE Newborn Screening Program to respond more rapidly to abnormal screenings. This rapid response may have a direct correlation in the reduction of unnecessary medical costs and may result in saving babies' lives.

- 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 were taken as there is no additional cost or impact on business or economic development within the state or on local governments and individuals associated with the amendments to this regulation that change the required timeframe of collecting infant specimens.

- 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 business, local governments or members of the public. Because hospitals and birthing facilities already collect infant specimens, there will be

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no additional costs for earlier collections. Costs will be absorbed within existing resources.

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.

There will be no additional costs for earlier infant specimen collections as hospitals and birthing facilities are currently collecting specimens and costs will be absorbed within existing resources.

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.

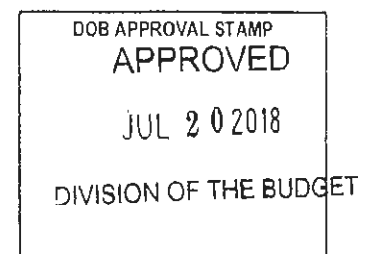
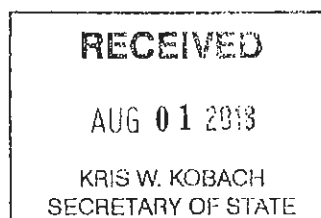
YES ☐ NO ☒

- 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 a notice of hearing for a set of regulations is published in the *Kansas Register*, 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).**

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 affect on or add additional costs to those entities. The regulation only changes the required timeframe for collection of infant specimens. The costs to KDHE will be absorbed within existing resources. KDHE will request comment from the three organizations listed in paragraph IIIG.



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- 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).

This is not an environmental regulation. However, if this regulation is not adopted, it could have a negative effect on the ability of the state of Kansas to provide timely notifications to primary care providers and specialists to effectively reduce disability, morbidity and mortality in newborns with time-critical disorders.

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