

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, September 19, 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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SECRETARY OF STATE**

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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 Manager, Special Health Services, Bureau of Family Health, Kansas Department of Health and Environment, 1000 SW Jackson, Suite 200, 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, 785-559-4245 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
Kansas Department of Health and Environment

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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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APPROVED

FEB 20 2018

ATTORNEY GENERAL

APPROVED

FEB 08 2018

DEPT. OF ADMINISTRATION

May 29, 2018

Kansas Department of Health and Environment
Economic Impact Statement

Pursuant to the requirements of K.S.A. 2017 Supp. 77-416, and amendments thereto, the Kansas Department of Health and Environment (KDHE) submits the following economic impact statement concerning an amended regulation for the Kansas Newborn Screening Program. The proposed amended regulation is needed to align with the national standards regarding newborn screening timeliness and addresses an ongoing need for specimen collection to occur during the most appropriate timeframe. Additionally, the earlier specimen collection time sets the stage for overall timeliness for newborn screening, from collection to reporting. The sooner the specimen processing occurs and follow-up takes place, the earlier the medical diagnosis can be obtained and the sooner interventions can begin, ultimately providing the best opportunity for minimal to no long-term health impacts.

1. **Regulation to be amended:**

K.A.R. 28-4-503. Timing of Specimen Collections

2. **Brief description of the regulation and what is intended to be accomplished by the amendment.**

K.A.R. 28-4-503. Timing of Specimen Collections.

The amendments to this regulation specify the timeframe that a newborn screening specimen must be collected including the 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.

3. **Is this regulation mandated by federal law as a requirement for participating in or implementing a federally subsidized or assisted program?**

Yes _____ No X

If yes, please explain.

4. **Does the proposed regulation exceed the requirements of applicable federal law?**

Yes _____ No X

5. **Description of Costs:**

(a) **Cost to the agency:**

There is no added cost to the agency associated with this amended regulation. The amendments simply change the acceptable timeframe for collection.

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- (b) **Cost to persons who will bear the costs and those who will be affected (i.e., private citizens and consumers of the products or services) and are subject to the proposed regulation or the enforcement:**

There is no added cost to the institution or others to collect the specimens in the amended timeframe required by this amended regulation. The amendments simply change the acceptable timeframe for collection.

- (c) **Costs to other governmental agencies or units:**

There is no added cost to any other governmental agency associated with this amended regulation.

6. **Description of any less costly or less intrusive methods that were considered by the agency for the purpose of the regulation and why such methods were rejected in favor of the proposed regulation.**

No less costly or intrusive methods were identified.

7. **Verification of economic impact statement with League of Kansas Municipalities, Kansas Association of Counties and the Kansas Association of School Boards.**

The above-mentioned regulation was determined as appropriate for consultation as to the economic impact with the League of Kansas Municipalities, Kansas Association of Counties and the Kansas Association of School Boards, pursuant to K.S.A. 77-416, and amendments thereto.

Yes _____

No X

If yes:

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