

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

Kansas Board of Pharmacy  
Agency

Alexandra Blasi  
Agency Contact

785-296-8419  
Contact Phone Number

68-7-15, 68-19-1, and 68-2-10  
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. 68-7-15 is being amended to allow packaging of drugs dispensed or supplied by the pharmacy or any other pharmacy engaged in a shared services agreement under K.A.R. 68-7-20, and to provide necessary limitations for prepackaging and repackaging of parenteral products.

K.A.R. 68-19-1 is being amended to require review of the Board's quarterly newsletter during the pharmacy's quarterly continuous quality improvement meetings.

K.A.R. 68-2-10 is being amended to require closed pharmacies to notify the Board and patients about the location and disposition of patient records, and creating requirements for pharmacies accepting records of closed pharmacies.

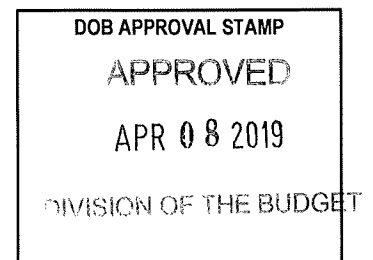
**II. Statement by the agency if the rule(s) and regulation(s) is mandated by the federal government and a statement if approach chosen to address the policy issue is different from that utilized by agencies of contiguous states or the federal government. (If the approach is different, then include a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

Regulations are not mandated by the federal government. Amendments are consistent with other state requirements; language was specifically modeled from similar regulations in Arkansas.

**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 Board anticipates no impact on business activities or 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;**

Any economic impact would stem only from K.A.R. 68-2-10 and would be specifically related to the closing pharmacy's new responsibility to notify patients of the closure and the disposition of patient records. Pharmacies are already required to maintain patient records for five years and, upon closure, are required to secure another pharmacy buyer or a permanent storage location for the files. The only new component is a notification to the patient about the disposition of the patient record. Notification may be made by mail or email, the economic effect of which may include the cost of paper, envelopes, and postage. This cost would be allocated to the closing pharmacy.

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

Pharmacies registered in Kansas

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

K.A.R. 68-7-15: Increased ability of pharmacies to capitalize on efficiencies and economies of scale in packaging and repackaging drugs for patients.

K.A.R. 68-19-1: Increased pharmacist, intern, and technician awareness and education; higher level of engagement with the Board; public safety and patient welfare.

K.A.R. 68-2-10: Patient access to previous medication records and future access to care.

**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;**

Utilization of existing Board forms, resources, and processes.

**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.**

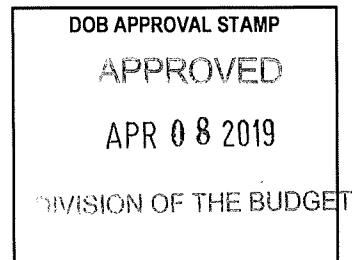
\$0

**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

**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.**

n/a

**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.**

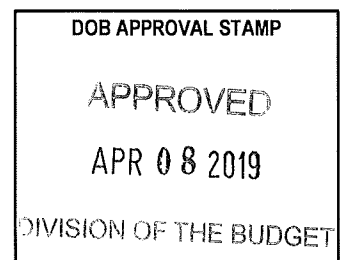
n/a

- 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).**

After a recent abrupt pharmacy closure, the Board discussed changes to K.A.R. 68-2-10 in an open meeting. Requested changes to K.A.R. 68-7-15 were brought to the Board's attention during a public comment period by a large Kansas health system. The Board also discussed changes to K.A.R. 68-19-1 based on regular publication of the Board newsletter containing relevant policy and compliance articles which are evidently not being utilized or reviewed by Kansas pharmacists.

- 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).**

n/a



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

Kansas Board of Pharmacy  
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Alexandra Blasi  
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785-296-8419  
Contact Phone Number

68-21-6  
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. 68-21-6 is being amended to allow the Board to share K-TRACS data with other relevant government entities that have established prescription drug monitoring programs, including the Missouri St. Louis County initiative, military health system via the department of defense, Indian health systems, and veteran health system.

**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)**

There are no federal mandates pertaining to these regulations. The Board currently shares data with 31 states and would like to expand this connectivity to share with federal health systems and Missouri which do not currently fit under the stated allowance for sharing with "state" programs. At the time the regulation was adopted, other data sharing was not conceived.

**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;**

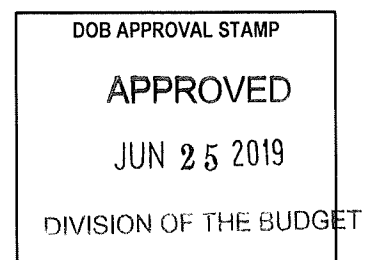
The Board anticipates no impact on business activities or growth.

**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;**

None. The Board has data sharing capabilities and will merely expand to these other entities. If there is any economic impact, it would be related to increased data sharing and increased program utilization which could positively benefit the health of patients.

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

These regulations are unlikely to affect businesses that employ prescribers and pharmacists (hospitals, clinics, pharmacies).



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

If there is any economic impact, it would be related to increased data sharing and increased program utilization which could positively benefit the health of patients and potentially decrease healthcare costs in the long run. Such impact is unknown to the Board and unquantifiable.

**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;**

None

**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

**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

**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.**

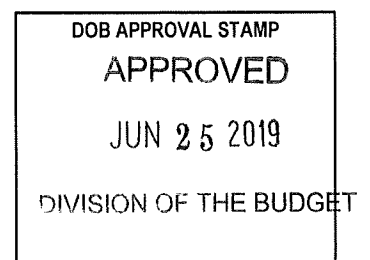
n/a

**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.**

n/a

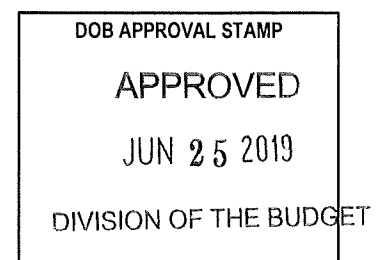


**H. Describe how the agency consulted and solicited information from businesses, associations, local governments, state agencies, or institutions and members of the public that may be affected by the proposed rule(s) and regulation(s).**

The Board discussed these regulatory changes in an open meeting of the Board of Pharmacy and consulted the PDMP Advisory Committee, which is composed of prescribers and pharmacists representing all relevant stakeholder organizations. Both groups agreed to move this regulation forward without opposition or objection. The Board also annually meets with other states regarding interstate data sharing and this model is consistent with successful models in other states.

**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).**

n/a



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68-14-1, 68-14-2, 68-14-3, 68-14-4, 68-14-5, 68-14-7, 68-14-7a, 68-14-7b  
K.A.R. Number(s)

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900 SW Jackson, Room 504-N  
Topeka, KS 66612

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

These regulations are proposed in response to 2017 HB 2055 to establish Kansas compliance with the Federal Drug Supply Chain Security Act (DSCSA), 21 U.S.C. 351 et seq. The law was amended at the federal level in 2014 to commence a 10-year process for updating requirements for those in the drug manufacturing and distribution chain, and to create an electronic, interoperable system to identify and trace prescription drugs from the manufacturer through distribution, to the ultimate consumer. These regulations align Board oversight of wholesale distributors, virtual wholesale distributors, third-party logistics providers, and outsourcing facilities with federal rules, including definitions, operational requirements, facilities, security, storage, and records. Kansas currently registers each of these facilities as a pharmacy, manufacturer, or distributor, but this is not how they are classified by the Federal Food and Drug Administration (FDA). Thus, new registration categories have been established and regulations are being adopted in response.

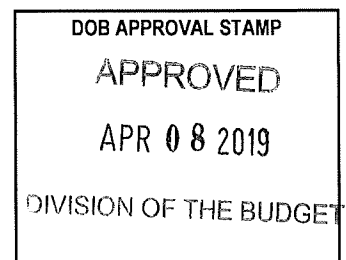
**II. Statement by the agency if the rule(s) and regulation(s) is mandated by the federal government and a statement if approach chosen to address the policy issue is different from that utilized by agencies of contiguous states or the federal government. *(If the approach is different, then include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

Regulations are not mandated by the federal government but are needed to allow facilities to be compliant on the state and national level and for consistency. Language is consistent with and was specifically modeled from similar regulations in other states.

**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;**

Aligning state requirements with the federal rules and other states should enhance business activity related to the manufacture, distribution, and compounding of prescription drugs and devices by allowing these facilities to more readily transact business with Kansas. The regulations are also designed to maintain necessary public protection mechanisms within these facilities and ensure compliance with recognized pharmacy standards.



- 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;**

Registration and renewal application fees have been set in a separate regulation. However, fees should have a null effect on revenue and expense because the Board is merely shifting registrants from one registration category to another. For the same reasons, there would not be any increased cost to the Board related to licensure or compliance. There could be an increase in the number of registered facilities in Kansas, which would result in an increase in revenue to the Board that is immeasurable.

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

Manufacturers, wholesale distributors, virtual wholesale distributors, third-party logistics providers, and outsourcing facilities of prescription drugs and devices.

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

These regulations benefit the aforementioned businesses that may be impacted by creating consistency with federal and state law, which will increase the level of compliance and the number of business transactions in Kansas related to the distribution of prescription drugs and devices. Furthermore, these regulations protect the public by ensuring these facilities meet recognized standards related to distribution of prescription drugs and devices, as well as outsourcing facilities which compound sterile preparations in bulk. Any costs are incidental and are related to routine operational costs of the Board.

- 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;**

Utilization of existing Board forms, resources, and processes. The Board also has planned a phased implementation to allow businesses with current registrations to shift categories without incurring additional expenses or application fees, and to minimize any impact on Board staff and resources.

- 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.**

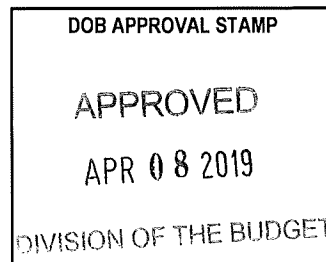
\$0 – costs to businesses may include time associated with completing necessary application forms and corresponding with the Board.

**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

**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.**

n/a

**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.**

n/a

**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 Board has discussed implementation with other states and plans to solicit information from businesses with current registrations after adoption of regulations but prior to commencing the phased implementation process. In addition, the Board consulted with businesses at the time of the implementing legislation (2017 HB 2055).

**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).**

n/a

