

State of Kansas
Board of Pharmacy

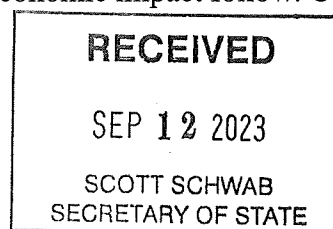
**Notice of Public Hearing on Proposed Administrative
Regulation**

A public hearing will be conducted on Thursday, December 7, 2023, at 8:30 a.m. at the Office of Administrative Hearings, 1020 S. Kansas Ave., Topeka, Kansas, to review and consider the adoption of a proposed permanent regulation of the Kansas State Board of Pharmacy.

This 60-day notice of the public hearing shall constitute a public comment period for the purpose of receiving written public comments on the proposed regulation. All interested parties may submit written comments prior to the public hearing to Alexandra Blasi, Executive Secretary, 800 S.W. Jackson, Suite 1414, Topeka, Kansas 66612-1244, or by e-mail to pharmacy@ks.gov. All interested parties will be given a reasonable opportunity to present their views orally regarding the adoption of the proposed regulation during the public hearing. In order to provide all parties an opportunity to present their views, it may be necessary to request that each participant limit any oral presentation to five minutes.

Any individual with a disability may request an accommodation in order to participate in the public hearing and may request the regulation and economic impact statement in an accessible format. Requests for accommodation to participate in the public hearing should be made at least 10 business days in advance of the hearing by contacting Alexandra Blasi, Executive Secretary, 800 S.W. Jackson, Suite 1414, Topeka, Kansas 66612-1244 or by phone at (785) 296-4056. Handicapped parking is located at the north entrance to the building. Curbs at the north entrance are accessible to individuals with disabilities.

A summary of the proposed regulation and its economic impact follow. Copies of the



regulation and economic impact statement may be viewed at <https://pharmacy.ks.gov/statutes-regs/proposed-changes>. (Note: Statements indicating that “The Board anticipates that the proposed new regulation will have minor to no economic impact” are intended to indicate that no economic impact on the Board, other state agencies, state employees, or the general public have been identified.)

K.A.R. 68-20-33. 6-(2-chlorophenyl)-1-methyl-8-nitro-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine included in schedule I. Pursuant to the Board’s emergency scheduling authority, the proposed permanent regulation would place clonazepam in schedule I of the Kansas Uniform Controlled Substances Act until July 1, 2024, giving the Kansas legislature sufficient time to consider the drug for permanent scheduling. This schedule is reserved for drugs that have no known medicinal use. Any economic impact would be related to the prosecution of alleged criminals for possession or sale of clonazepam and any resultant conviction.

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68-20-33. 6-(2-chlorophenyl)-1-methyl-8-nitro-4*H*-benzo[*f*] [1,2,4]triazolo[4,3-*a*][1,4]diazepine included in schedule I. (a) 6-(2-chlorophenyl)-1-methyl-8-nitro-4*H*-benzo[*f*] [1,2,4]triazolo[4,3-*a*][1,4]diazepine (other name: clonazepam), including its salts, isomers, and salts of isomers, shall be classified as a schedule I controlled substance.

(b) This regulation shall expire on July 1, 2024. (Authorized by and implementing K.S.A. 65-4102; effective, T-_____, _____; effective P-_____.)

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**Kansas Administrative Regulations
Economic Impact Statement (EIS)**

Kansas Board of Pharmacy
Agency

Alexandra Blasi
Agency Contact

785-296-8419 (direct)
Contact Phone Number

68-20-33
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).

Based on the Board's emergency scheduling authority for controlled substances under K.S.A. 65-4102(e), the proposed regulation will classify clonazepam as a Schedule I substance until July 1, 2024. Chemical name: 6-(2-chlorophenyl)-1-methyl-8-nitro-4*H*-benzo[*f*] [1,2,4]triazolo[4,3-*a*][1,4]diazepine.

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.)*

The regulation does not exceed the requirements of applicable federal law, as the DEA issued temporary emergency scheduling of this substance in December 2022. The proposed Kansas regulation is consistent with federal emergency scheduling related to controlled substances. Proposed new regulation is consistent with current standards of pharmacy practice. Furthermore, the Board received notification from law enforcement of identification of the substance in Kansas, and the Board made a finding of an imminent hazard to the public safety based on the criteria set forth in K.S.A. 65-4102, and amendments thereto.

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;

No business impact is anticipated. The regulation is consistent with federal steps to protect public safety and any business opportunity is outweighed by the risk to the public associated with sale/use of this substance, as it has no known medical use.

- 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;

Unknown or impossible to estimate. Any economic impact would be related to the prosecution of alleged criminals for possession or sale of clonazepam and the resulting conviction.

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

None

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

Clonazepam is a triazole analogue to clonazepam, which is currently a Schedule IV controlled substance in Kansas. Clonazepam has no known medical use and its availability and use is an imminent danger to the public. The Board believes scheduling is necessary to protect the public health and safety in Kansas.

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- 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 Board is seeking a temporary regulation for emergency scheduling to avoid unnecessary delay, followed by a permanent regulation which will expire July 1, 2024. The Board plans to bring this substance to the attention of the Kansas Legislature during the 2024 session for permanent statutory scheduling through its mandatory annual report and voluntary introduction of legislation.

- 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

Costs to Local Governmental Units – \$Unknown

Costs to Members of the Public – \$0

Total Annual Costs – \$Unknown

(sum of above amounts)

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

Reviewed with Board in public meeting on May 17, 2023. Outreach to KBI and local law enforcement for any concerns; none expressed.

- ☐ 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

If applicable, click here to enter public hearing information.

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.

0

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.

Unknown, see above related to criminal prosecution

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- 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.

Not applicable

- 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).

Reviewed with Board in public meeting on July 27, 2023. Outreach to KBI and local law enforcement for any concerns; none expressed. The Board did not pursue other avenues because time is of the essence in emergency scheduling processes and steps by the Federal Government suggest necessity and public safety outweigh potential costs.

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.

- 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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