Regulatory Analysis Form

(Completed by Promulgating Agency)

(All Comments submitted on this regulation will appear on IRRC's website)

INDEPENDENT REGULATORY REVIEW COMMISSION

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IRRC

(1) Agency

Department of Health

(2) Agency Number: 10
Identification Number: 193

IRRC Number: 3099

(3) PA Code Cite:

28 Pa. Code § 25.72

(4) Short Title:

Schedules of controlled substances

(5) Agency Contacts (List Telephone Number and Email Address):

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(6) Type of Rulemaking (check applicable box): ☐ Proposed Regulation ☐ Final Regulation ☒ Final Omitted Regulation	X No ☐ Emergency Certification Regulation; ☐ Certification by the Governor ☐ Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

The Department of Health (Department) is amending the schedule of controlled substances at 28 Pa. Code § 25.72 (relating to schedules of controlled substances). This regulation contains five schedules of controlled substances that categorize substances according to differing potentials for abuse and medical use. The amendment reschedules the substance Clobazam from Schedule I (high potential for abuse and no currently accepted medical use) to Schedule IV (low potential for abuse, as compared to substances in Schedule III, and current accepted medical use). *See* 35 P.S. § 780-104 and 28 Pa. Code § 25.72. The amendment to the schedules of controlled substances effectuates the order of the Secretary of the Department of Health following authorization from the Pennsylvania Drug, Device and Cosmetic Board, published in the *Pennsylvania Bulletin* on April 7, 2012, and follows similar action by the U.S. Food and Drug Administration (FDA) approving clobazam for legitimate medical use in the United States.

(8) State the statutory authority for the regulation. Include specific statutory citation.

The amendment to the schedules of controlled substances is adopted pursuant to authority under Sections 3 and 4 of the act, (35 P.S. §§ 780-103 and 780-104). The amendment is also adopted pursuant to Section 2012(g) of the Administrative Code of 1929, 71 P.S. § 532(g).

Section 3 of the act provides that the Secretary may control all substances listed in Schedules I throughV of the act. Section 3(c) (35 P.S. § 780 – 103(c)) provides that the Secretary shall not reschedule any controlled substance unless specifically authorized by the Pennsylvania Drug, Device and Cosmetic Board (Board) to do so. The Board authorized the Secretary to reschedule clobazam.

(9) Is the regulation mandated by any Federal or state law or court order, or Federal regulation? Are there any relevant state or Federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

No. While the rescheduling of clobazam is not mandated by Federal law or regulation, it follows similar changes at the Federal level as described in detail in the answer to question 10.

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

The rescheduling of clobazam from a Schedule I controlled substance to a Schedule IV controlled substance in the Commonwealth of Pennsylvania was effectuated by order of the Secretary,

following authorization from the Board, published in the *Pennsylvania Bulletin* on April 7, 2012. The rescheduling, that will be reflected in the Department's regulations upon publication of this final omitted regulation, resolves a conflict between State and Federal law.

Until recently, there was no legitimate medical use in the United States for the use of clobazam. In October of 2011, the U.S. Food and Drug Administration (FDA) approved clobazam (Onfi ®) tablets for use as an adjunctive (add-on) treatment for seizures associated with Lennox-Gastaut syndrome in adults and children 2 years of age and older. Onfi ® was granted orphan drug designation by the FDA because the intended population to be treated for a disease or condition affects fewer than 200,000 people in the United States. Therefore, as of October 2011, at the Federal level, clobazam has a legitimate medical use in the United States as a schedule IV controlled substance.

As long as the substance remained a Schedule I drug at the state level, serious problems existed relating to the inability of physicians and other licensed (or authorized) practitioners to prescribe clobazam and the manner in which law enforcement officials were required to prosecute. Patients using and physicians prescribing clobazam benefit from the drug having been rescheduled. Patients in need of the drug are able to obtain it more readily and physicians are not subject to criminal prosecution for prescribing it.

(11) Are there any provisions that are more stringent than Federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

No. Rescheduling ensures conformance with Federal scheduling parameters and amendment of the regulation ensures that the regulation reflects the current scheduling for the drug.

(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?

The amendment follows similar action by the Federal government. The amendment does not put Pennsylvania at a competitive disadvantage with other states.

(13) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

No.

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)

The Board did not solicit input from the public for the rescheduling of clobazam other than holding a meeting open to the public.

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

Persons:

1. Patients

As a result of clobazam being rescheduled, patients now have access to the drug with orphan drug designation that is prescribed for the treatment of a rare but severe form of epilepsy in adults and in children ages two and older. The population affected is less than 200,000 people in the United States.

2. Physicians and other practitioners with prescribing authority

Physicians and other practitioners with prescription authority are able to prescribe clobazam. As of March 12, 2015, the Bureau of Professional and Occupational Affairs active license counts provide the following number of licensed practitioners who have authority to prescribe clobazam:

Medicine	
Medical Physician and Surgeon	46,034
Medical Physician Assistant	6,755
Nurse-Midwife Prescriptive Authority	283
Osteopathic Medicine	
Osteopathic Physician and Surgeon	7,766
Osteopathic Physician Assistant	1,306

In 2010, the majority of "Family and General Practitioners" were employed in Offices of Physicians (58.1%). A number of family and general practitioners were also employed in General Medical and Surgical Hospitals (26.1%) while 10.0% were self-employed. Other industries that employed family and general practitioners were Outpatient Care Centers and Home Health Care Services.

In 2010, the majority of "Physician Assistants" were employed in Offices of Physicians (58.4%). A number of physician assistants were also employed in General Medical and Surgical Hospitals (23.0%) and Outpatient Care Centers (5.1%). Other industries that employed physician assistants were Offices of Dentists and Psychiatric and Substance Abuse Hospitals.

In 2010, the majority of "Registered Nurses" were employed in General Medical and Surgical Hospitals (53.0%). A number of registered nurses were employed in Offices of Physicians (9.8%), Home Health Care Services (6.1%), Nursing Care Facilities (5.6%), and Outpatient Care Centers (4.2%).

Prescribing a scheduled drug requires record keeping, but the record keeping mechanism will already be in place for other controlled substances.

3. Pharmacists:

As of March 12, 2015, the Board of Pharmacy had record of 22,195 actively licensed pharmacists. In 2010, the majority of "Pharmacists" were employed in Health and Personal Care Stores

(46.5%). A number of pharmacists were also employed in General Medical and Surgical Hospitals (22.6%) and Grocery Stores (6.4%). Other industries that employed pharmacists included Department Stores, Other General Merchandise Stores, and Druggists' Goods Merchant Wholesalers. Pharmacists are affected by the rescheduling of clobazam to a Schedule IV controlled substance only to the extent dispensing controlled substances is subject to record keeping, which should already be in place for other controlled substances.

Businesses:

1. Manufacturers of prescription drugs:

Currently, in Pennsylvania, there are 469 registered manufacturers of prescription drugs. Clobazam (Onfi) is currently manufacturd by Catalent Pharma Solutions LLC in Winchester, Kentucky, for Lundbeck, Inc. of Deerfield, Illinois. Under 21 C.F.R. 316.31, the FDA will not approve a marketing application from another manufacturer before the expiration of 7 years from the date of approval given to the manufacturer that was initially approved via the application for orphan drug designation. Therefore, at this time, there is no effect on any in-state manufacturer as a result of the rescheduling.

If the Federal classification changes, it is possible that an in-state manufacturer could manufacture this substance, but the only impact even at that point would be with regard to recordkeeping, which is already in place for other controlled substances.

2. Distributors of prescription drugs:

Currently, in Pennsylvania, there are 728 licensed distributors that may distribute clobazam. If a Pennsylvania licensed distributor chooses to carry the product, the only impact of the rescheduling would be on recordkeeping, which is already in place for other controlled substances.

3. Pharmacies:

As of March 12, 2015, the Board of Pharmacy had record of 3,415 actively licensed pharmacies. Pharmacies are affected by the rescheduling of clobazam to a Schedule IV controlled substance, only to the extent dispensing controlled substances is subject to recordkeeping requirements, which is already in place for other controlled substances.

Small Businesses:

Small business has been defined in Section 3 of Act 76 of 2012 (71 P.S. § 745.3) as follows:

> **As defined in accordance with the size standards described by the United States Small Business Administration's Small Business Size Regulations under 13 CFR Ch. 1 Part 121 (relating to Small Business Size Regulations) or its successor regulation.**

Pursuant to 13 CFR § 121.201, the United State Small Business Administration has defined size

standards as identified by North American Industry Classification System (NAICS) codes as follows:

The size standards described in this section apply to all SBA programs unless otherwise specified in this part. The size standards themselves are expressed either in *number of employees or annual receipts in millions of dollars*, unless otherwise specified. The number of employees or annual receipts indicates the maximum allowed for a concern and its affiliates to be considered small.

In applying the NAICS standards to the types of businesses that would be impacted with the rescheduling of clobazam from a Schedule I controlled substances to a Schedule IV controlled substance in the Commonwealth of Pennsylvania, the following applies:

Small Business Size Standards by NAICS Industry

NAICS codes	NAIC U.S. Industry Title	Size standards in millions of dollars	Size standards in number of employees
Subsector 325 – Chemical Manufacturing			
325412	Pharmaceutical Preparation Manufacturing		750
The NAICS Standard for a small business is 750 employees or less if related to Pharmaceutical Preparation Manufacturing			
Subsector 424 – Merchant Wholesalers, Nondurable Goods			
424210	Drugs and Druggists Sundries Merchant Wholesalers		100
The NAIC Standard for a small business is 100 employees or less if related to Druggists' Sundries Merchant Wholesalers			

The number of small Pharmaceutical Preparation Manufacturing businesses, as defined above, in Pennsylvania is 62, and the number of small Drugs and Druggists' Sundries Merchant Wholesalers in Pennsylvania is 161. This information was supplied by the Center for Workforce Information and Analysis in the Department of Labor and Industry.

(16) List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.
See response to (15)

(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

The individuals and entities identified in section (15) will benefit from the rescheduling of clobazam from a Schedule I controlled substance to a Schedule IV controlled substance. There is no fiscal impact, and the general public benefits from the rescheduling of clobazam. Also, the rescheduling of clobazam to Schedule IV allows for better enforcement and control of the drug

abuse problems in the Commonwealth. Patients in need of clobazam for treatment now have access to it through their physicians.

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

No adverse effects or costs have been associated with the rescheduling of clobazam to a Schedule IV controlled substance.

(19) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

The amendment does not significantly affect costs or savings by the regulated community. The amendment to reschedule clobazam to a Schedule IV controlled substance does not require any new legal, accounting, or consulting procedures not already being undertaken by the regulated community.

(20) Provide a specific estimate of the costs and/or savings to the **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

The amendment has no measurable fiscal impact on local government because a system already exists for the oversight of controlled substances.

(21) Provide a specific estimate of the costs and/or savings to the **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

The amendment has no measurable fiscal impact on state government because a system already exists for the oversight of controlled substances.

(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

The rescheduling of clobazam does not require any additional recordkeeping or other paperwork requirements since such persons or entities as identified in response to question 10 are already required to comply with current regulations. Thus, while there may be some change associated with moving a substance from one schedule to another, there is no measurable change in existing reporting, record keeping or other paperwork requirements.

(23) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year

SAVINGS:	$	$	$	$	$	$
Regulated Community						
Local Government						
State Government						
Total Savings	$0	$0	$0	$0	$0	$0
COSTS:						
Regulated Community						
Local Government						
State Government						
Total Costs	$0	$0	$0	$0	$0	$0
REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses	$0	$0	$0	$0	$0	$0

(23a) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3	FY -2	FY -1	Current FY
N/A				

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

(a) An identification and estimate of the number of small businesses subject to the regulation.

(b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.
(c) A statement of probable effect on impacted small businesses.
(d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

As noted in the answers to question 10, 15, and 17, this regulation does not have an adverse impact on small businesses.

(25) List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.

There are no special needs of any person or entity identified in response to question 10.

(26) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

There are no alternative regulatory approaches.

(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

a) The establishment of less stringent compliance or reporting requirements for small businesses;
b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
c) The consolidation or simplification of compliance or reporting requirements for small businesses;
d) The establishment of performing standards for small businesses to replace design or operational standards required in the regulation; and
e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

As noted in the answers to question 10, 15, 17 and 24, this regulation will have no adverse impact on small businesses. Any impact will be a deminimus impact on existing record keeping methodologies.

(28) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

This rulemaking is not based upon any scientific date, studies, or references. The rulemaking aligns Pennsylvania law with Federal law.

(29) Include a schedule for review of the regulation including:

A. The date by which the agency must receive public comments: **N/A**

B. The date or dates on which public meetings or hearings will be held: **N/A**

C. The expected date of promulgation of the proposed regulation as a final-form regulation: **N/A**

D. The expected effective date of the final-form regulation: **Upon publication**

E. The date by which compliance with the final-form regulation will be required: **Upon publication**

F. The date by which required permits, licenses or other approvals must be obtained: **N/A**

The Department has dispensed with notice of proposed rulemaking and procedures for adopting final form regulations pursuant to Section 204(3) of the Commonwealth Documents Law, 45 P.S. § 1204(3), because the procedures relating to proposed rulemaking as specified in Section 201 and 202 of the Commonwealth Documents Law, 45 P.S. §§ 1201 and 1202, are unnecessary and contrary to the public interest in this circumstance. Rescheduling was effective upon the Secretary's directive following authorization from the Pennsylvania Drug, Device and Cosmetic Board and notice of the rescheduling was published on Saturday, April 7, 2012. *See* 42 Pa.B. 1929. This amendment ensures that the regulation conforms to the Secretary's directive.

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

The Department continually monitors and updates the schedules of controlled substances as needed.

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(Pursuant to Commonwealth Documents Law)

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Copy below is hereby approved as to form and legality. Attorney General.	Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:	Copy below ~~is~~ hereby approved as to form and legality. ~~Executive or independent~~ Agencies.
BY _____ DEPUTY ATTORNEY GENERAL	DEPARTMENT OF HEALTH (AGENCY)	BY _____
_____ DATE OF APPROVAL	DOCUMENT/FISCAL NOTE NO. 10-193	5/7/15 DATE OF APPROVAL
	DATE OF ADOPTION: _____	(Deputy General Counsel) ~~(Chief Counsel, Independent Agency)~~ (~~Strike inapplicable title~~)
	BY: Karen M. Murphy, PhD, RN	
	TITLE: Acting Secretary of Health	
☐ Check if applicable. Copy not approved. Objections attached.		☐ Check if applicable. No Attorney General approval or objection within 30 days after submission.

NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

TITLE 28. HEALTH AND SAFETY

PART III. PREVENTION OF DISEASES

CHAPTER 25. CONTROLLED SUBSTANCES, DRUGS, DEVICES AND COSMETICS

Subchapter A. CONTROLLED SUBSTANCES, DRUGS, DEVICES AND COSMETICS SCHEDULES OF CONTROLLED SUBSTANCES

The Department of Health (Department) hereby amends the schedules of controlled substances under the powers and duties contained in the Controlled Substances, Drug, Device and Cosmetic Act (Act) (P.L. 233, No. 64)(35 P.S. §§ 780-101 – 780-144). The Department amends 28 Pa. Code § 25.72 (relating to schedules of controlled substances) to reschedule the substance clobazam from a Schedule I substance to a Schedule IV substance, as set forth in Annex A hereto.

A. PURPOSE OF THE AMENDMENTS

The regulation amends 28 Pa. Code § 25.72 (§ 25.72) and reschedules the substance clobazam from a Schedule I substance to a Schedule IV substance in accordance with controlled substance scheduling requirements of *The Controlled Substances, Drug Device and Cosmetic Act* (35 P.S. §§ 780-201 – 780-144) (Act). The Act recognizes the fact that there is a need to control substances that have potential for abuse while also recognizing that some of those substances have medical uses. The Act provides for a system of five schedules of controlled substances as a means of grouping potentially dangerous substances based on their differing potentials for abuse and on their potential for medical use. Penalties for illegal use of the controlled substances vary according to the schedule on which the substance is listed. The health and safety of the public is protected by having a substance placed on the proper schedule. Additionally, proper scheduling ensures appropriate enforcement when a substance is abused or otherwise used illegally.

The Act requires that a controlled substance be placed in Schedule I when there is: (1) a high potential for abuse; (2) no currently accepted medical use in the United States; and (3) a lack of accepted safety for use under medical supervision.

The Act requires that a controlled substance be placed in Schedule IV when there is: (1) a low potential for abuse relative to substances listed in Schedule III; (2) currently accepted medical use in the United States; and (3) limited physical dependence or psychological dependence liability or both relative to the substances listed in Schedule III.

The Act provides that the Secretary of Health shall control all substances listed in Schedules I through V and may, by regulation, upon his own motion or on the petition of any interested party, add a substance as a controlled substance, after requesting the advice of the Pennsylvania Drug, Device and Cosmetic Board (Board). The Act prohibits the Secretary from removing any substance from control unless authorized by the General Assembly and from rescheduling any controlled substance unless specifically authorized by the Board. 35 P.S. § 780-103 (relating to authority to control).

Until recently, there was no legitimate medical use in the United States for clobazam. Accordingly, Clobazam was listed as a Schedule I controlled substance, and as such, it was illegal to possess, administer, dispense, prescribe or distribute.

On October 21, 2011, the U.S. Food and Drug Administration (FDA) approved the drug Onfi™ (chemical name: clobazam) for the treatment of a rare but severe form of epilepsy in adults and in children ages two and older. When the Department learned of the action of the FDA to approve the use of Onfi™ to treat certain forms of epilepsy, the Secretary acted as chair to convene a meeting of the Board. The purpose of the meeting on Tuesday, March 27, 2012, was to determine whether, in consideration of the FDA's action regarding Onfi™, clobazam should be rescheduled as a Schedule IV controlled substance instead of a Schedule I controlled substance. The Board voted unanimously to authorize the rescheduling of clobazam as a

Schedule IV controlled substance. The Secretary, upon being authorized by the Board, directed that the substance clobazam be rescheduled. The rescheduling was effective immediately upon the Secretary's action and the Department published notice of the rescheduling in the *Pennsylvania Bulletin* on April 7, 2012. The purpose of these amendments is to revise 28 Pa. Code § 25.72 to conform to the action taken by the Secretary under section 103(c) of the Act to reschedule clobazam as a Schedule IV controlled substance.

Pursuant to § 204 of the Commonwealth Documents Law, 45 P.S. § 1204, notice of proposed rulemaking may be omitted if the agency for good cause finds that the procedures specified in §§ 201 and 202, 45 P.S. §§ 1201-1202, are, under the circumstances, impracticable, unnecessary, or contrary to the public interest. Based on the above, the Department finds justification for omitting notice of proposed rulemaking to reschedule clobazam from a Schedule I substance to a Schedule IV substance, because, under the circumstances, it is unnecessary and contrary to the public interest. *See* 45 P.S. § 1204(3).

B. AFFECTED PERSONS

Patients using and physicians and other practitioners prescribing clobazam are affected by its rescheduling. Patients in need of the drug will be able to obtain it more readily and physicians and other practitioners will not be subject to criminal prosecutions for prescribing or dispensing it.

Pharmacies and pharmacist in this Commonwealth, physicians, drug distributors, manufacturers and distributors will also be affected.

The general public will be affected and will benefit from the rescheduling of clobazam to Schedule IV classification. Patients in need of clobazam for treatment will have access to it through their physicians.

C. FISCAL IMPACT

This amendment to the schedules of controlled substances has no measurable fiscal impact on the Commonwealth, local government, the private sector or the general public. This amendment does not significantly affect costs or savings by the regulated community. This amendment does not require any new legal, accounting or consulting procedures not already being undertaking by the regulated community. There is no measurable fiscal impact on local governments or State government because a system exists for the oversight of controlled substances.

D. PAPERWORK REQUIREMENTS

A system already exists for the handling of controlled substances under the act and this final rule-making, with proposed rule-making omitted, does not increase paperwork.

E. STATUTORY AUTHORITY

The amendments to the schedules of controlled substances are being adopted pursuant to authority under sections 3 and 4 of the act (35 P.S. §§ 780-103 and 780-104). The amendments are also being adopted pursuant to authority under section 2012(g) of The Administrative Code of 1929 (71 P.S. § 532(g)).

Section 3 of the act provides that the Secretary may control all substances listed in Schedules I through V of the act. Section 3(c) (35 P.S. § 780 – 103(c)) provides that the Secretary shall not

reschedule any controlled substance unless specifically authorized by the Board to do so. The Board has authorized the Secretary to reschedule clobazam.

F. EFFECTIVE DATE/SUNSET DATE

The amendments will become effective upon publication as final rulemaking. There is no sunset date; the regulations will be continually monitored and updated as needed.

G. REGULATORY REVIEW

Under section 5.1(a) of the Regulatory Review Act (71 P.S. § 745.5), on May 7, 2015, the Department submitted a copy of the regulation with proposed rulemaking omitted to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House Health and Human Services Committee and the Senate Public Health and Welfare Committee. On the same date, the regulation was submitted to the Office of Attorney General for review and approval pursuant to the Commonwealth Attorneys Act. In addition to submitting the regulation, the Department has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

In accordance with Section 5.1(d) of the Act, 71 P.S. § 745.5.1(d), the regulation was (deemed) approved by the House Health and Human Services Committee on _____ and (deemed) approved by the Senate Public Health and Welfare Committee on _____. IRRC met on _____ and approved the regulation.

H. *Contact Person*

Questions or comments regarding the final-form rulemaking may be submitted to Susan Coble, Director, Bureau of Community Program Licensure and Certification, Department of Health, 132 Kline Plaza, Suite A, Harrisburg, PA 17104, (717) 783-1379.

Persons with a disability who require an alternative format of this notice (for example, large print, audiotape, Braille) should contact the Department of Health, Bureau of Community Program Licensure and Certification, Division of Home Health via the Drug, Device and Cosmetic Program, 132A Kline Plaza, Harrisburg, PA 17104, (717) 783-1379 or for speech and/or hearing impaired persons, V/TT (717) 783-6514 or the Pennsylvania AT&T Relay Services at (800) 654-5984.

The Department will accept comments in response to these amendments at any time following the effective date of the amendments.

I. FINDINGS

The Department finds that:

(1) These regulatory revisions satisfy the requirements of 45 P.S. § 1204 for submission of regulations in final rulemaking with proposed rulemaking omitted format. Under the circumstances, notice is impractical, unnecessary or contrary to the public interest.

(2) The adoption of the final-form rulemaking in the manner provided by this order is necessary and appropriate for the administration of the authorizing statutes and is in the public interest.

J. ORDER

The Department, acting under the authorizing statutes, orders that:

(a) The regulations of the Department, 28 Pa. Code § 25.72, be amended to read as set forth in Annex A.

(b) The Secretary shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for approval as to form and legality as required by law.

(c) The Secretary shall submit this order, Annex A and a Regulatory Analysis Form to IRRC, the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare for review and action as required by law.

(d) The Secretary shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(e) This order shall take effect upon publication in the *Pennsylvania Bulletin.*

Karen M. Murphy, PhD, RN,

Secretary

Annex A

TITLE 28. HEALTH AND SAFETY

PART III. PREVENTION OF DISEASES

CHAPTER 25. CONTROLLED SUBSTANCES, DRUGS, DEVICES AND COSMETICS

Subchapter A. CONTROLLED SUBSTANCES, DRUGS, DEVICES AND COSMETICS

SCHEDULES OF CONTROLLED SUBSTANCES

§ 25.72 Schedules of controlled substances.

* * * * *

(b) *Schedule I.* In determining that a substance comes within this schedule, the Secretary will find: a high potential for abuse; no currently accepted medical use in the United States; and a lack of accepted safety for use under medical supervision. The following controlled substances are included in this schedule:

* * * * *

(6) Unless specifically excepted or unless listed in another schedule, a material, compound, mixture or preparation which contains any quantity of the following substances including the salts, isomers and salts of isomers:

* * * * *

[(vi)		Clobazam.
(vii)]	(vi)	Clotiazepam.
[(viii)]	(vii)	Cloxazolam.
[(ix)]	(viii)	Delorazepam.
[(x)]	(ix)	Ethyl loflazepate.
[(xi)]	(x)	Fludiazepam.
[(xii)]	(xi)	Flunitrazepam.
[(xiii)]	(xii)	Haloxazolam.

[(xiv)] (xiii) Ketazolam.

[(xv)] (xiv) Loprazolam.

[(xvi)] (xv) Lormetazepam.

[(xvii)] (xvi) Medazepam.

[(xviii)] (xvii) Nimetazepam.

[(xix)] (xvii) Nitrazepam.

[(xx)] (xix) Nordiazepam.

[(xxi)] (xx) Oxazolam.

[(xxii)] (xxi) Pinazepam.

[(xxiii)] (xxii) Tetrazepam.

[(xxiv)] (xxiii) 3, 4-Methylenedioxymethamphetamine (MDMA)

[(xxv)] (xxiv) 4-methylaminorex.

[(xxvi)] (xxv) Cathinone.

[(xxvii)] (xxvi) Methcathinone HCL.

[(xxviii)](xxvii) Dimethylamphetamine.

[(xxix)] (xxviii) 1-(3-trifluoromethylphenyl) Piperazine (TFMPP)

[(xxx)] (xxix) N-Benzylpiperazine (BZP)

[(xxxi)] (xxx) Alpha-Methyltryptamine (AMT)

[(xxxii)] (xxxi) 2-5 Dimethoxy-4-(N)-Propylthiophenethylamine (2C-T-7)

[(xxxiii)](xxxii) 5-Methoxy-N, N-Diisopropyltryptamine (5-MEO-DIPT)

* * * * *

(e) *Schedule IV*

In determining that a substance comes within this schedule, the Secretary will find: a low potential for abuse relative to substances in Schedule III; currently accepted medical use in the United States; and limited physical or psychological dependence liability relative to the substances listed in Schedule III. The following controlled substances are included in this schedule:

(1) A material, compound, mixture or preparation, unless specifically excepted or unless listed in another schedule, which contains a quantity of the following substances:

* * * * *

(xxvii) Clobazam. (added March 27, 2012)

* * * * *

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF HEALTH

May 7, 2015

David Sumner
Executive Director
Independent Regulatory Review Commission
14th Floor, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Department of Health – Final Rulemaking, Proposed Rulemaking Omitted (No. 10-193)
28 Pa. Code § 25.72 (Schedules of Controlled Substances)

Dear Mr. Sumner:

Enclosed is a final-form regulation with proposed rulemaking omitted for review by your Committee in accordance with the Regulatory Review Act (71 P.S. §§ 745.1 – 745.15). This regulation amends 28 Pa. Code § 25.72 and reschedules the substance clobazam from a Schedule I substance to a Schedule IV substance in accordance with controlled substance scheduling requirements of the *The Controlled Substances, Drug Device and Cosmetic Act* (35 P.S. §§ 780-201 – 780-144) (Act).

Pennsylvania's Schedules of Controlled Substances at 28 Pa. Code § 25.72 are authorized by *The Controlled Substances, Drug, Device and Cosmetic Act* (35 P.S. §§ 780-201 – 780-144). Until recently, clobazam was listed as a Schedule I controlled substance because there was no legitimate medical use for the drug, In 2011, the U.S. Food and Drug Administration (FDA) approved the drug Onfi™ (chemical name: clobazam) for the treatment of a rare but severe form of epilepsy in adults and in children ages two and older. In March 2012, the Secretary convened a meeting of the Pennsylvania Drug, Device and Cosmetic Board (Board) which voted unanimously to authorize the rescheduling of clobazam as a Schedule IV substance. The Secretary, upon being authorized by the Board, directed that the substance clobazam be rescheduled. As provided by law, the rescheduling was effective immediately upon the Secretary's action and publication of notice in the *Pennsylvania Bulletin* on April 7, 2012.

Publication of this amendment to §25.72 will ensure that the Department's regulations reflect the rescheduling of clobazam from a Schedule I controlled substance to a Schedule IV controlled substance effected by order of the Secretary of Health. Pursuant to section 204 of the Commonwealth Document Law, 45 P.S. § 1204, the Department is omitting proposed rulemaking, having for good cause found that the procedures specified in section 201 and 202 of the Commonwealth Documents Law, 45 P.S. §§ 1201 – 1202, are in these circumstances unnecessary and contrary to the public interest.

Section 5.1(e) of the Act provides that within 10 days following the expiration of the Standing Committee review period, or at its next regularly scheduled meeting, the Commission shall approve or disapprove the final-form regulation with proposed rulemaking omitted.

If you have any questions, please contact Neil Malady, Director of the Office of Legislative Affairs, at (717) 787-6436.

Sincerely,

Karen Murphy, PhD, RN

Karen Murphy, PhD, RN
Acting Secretary of Health

Enclosures

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	**10-193**
SUBJECT:	**Controlled Substances, Drugs, Devices and Cosmetics – Schedules of Controlled Substances**
AGENCY:	**Department of Health**

TYPE OF REGULATION

RECEIVED
IRRC
2015 MAY -7 PM 3:38

Proposed Regulation

X Final Regulation

X Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
5/7/15	Honorable Matthew E. Baker	House Committee on Health – **Majority Chairperson**
5/7/15	Honorable Florindo J. Fabrizo	House Committee on Health – **Minority Chairperson**
5/7/15	Honorable Gene DiGirolamo	House Committee on Human Services –**Majority Chairperson**
5-7-15	Honorable Angel Cruz	House Committee on Human Services – **Minority Chairperson**
5/7/15	Honorable Patricia H. Vance	Senate Committee on Public Health & Welfare - **Majority Chairperson**
5/7/15	Honorable Shirley M. Kitchen	Senate Committee on Public Health & Welfare - **Minority Chairperson**
5/7/15	K Cooper	Independent Regulatory Review Commission
5/7/15		Attorney General (for Final Omitted only)
		Legislative Reference Bureau (for Proposed only)