

Regulatory Analysis Form (Completed by Promulgating Agency)		INDEPENDENT REGULATORY REVIEW COMMISSION RECEIVED	
(All Comments submitted on this regulation will appear on IRRC's website)		SEP - 2 2021 Independent Regulatory Review Commission	
(1) Agency: Department of State, Bureau of Professional and Occupational Affairs, State Board of Medicine			
(2) Agency Number: 16A Identification Number: 4948		IRRC Number: 3313	
(3) PA Code Cite: 49 Pa. Code §§ 16.1, 17.11, 17.12 and 17.12c			
(4) Short Title: Examinations			
(5) Agency Contacts (List Telephone Number and Email Address): Primary Contact: Dana M. Wucinski, Board Counsel, State Board of Medicine, Department of State, P.O. Box 69523, Harrisburg, PA 17106-5923 (phone 717-783-7200) (fax 787-0251); dwucinski@pa.gov . Secondary Contact: Jacqueline A. Wolfgang, Acting Senior Regulatory Counsel, P.O. Box 69523, Harrisburg, PA 17106-5923 (phone 717-783-7200) (fax 787-0251) jawolfgang@pa.gov .			
(6) Type of Rulemaking (check applicable box):		<input type="checkbox"/> Emergency Certification Regulation; <input type="checkbox"/> Certification by the Governor <input type="checkbox"/> Certification by the Attorney General	
<input checked="" type="checkbox"/> Proposed Regulation <input type="checkbox"/> Final Regulation <input type="checkbox"/> Final Omitted Regulation			
(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)			
<p>The United States Medical Licensing Examination (USMLE) is the examination co-sponsored and administered by the Federation of State Medical Boards (FSMB) and the National Board of Medical Examiners (NBME). USMLE was created in response to the need for one path to medical licensure for allopathic physicians in the United States. Before USMLE, multiple examinations (the NBME Parts Examination and the Federation Licensing Examination (FLEX)) offered paths to medical licensure. It was desirable to create one examination system accepted in every state, to ensure that all licensed medical doctors (MDs) pass same assessment standards regardless of where individuals received education and training. Today, all State medical boards in the United States utilize the USMLE. USMLE is used for licensure of graduates of accredited MD-granting medical schools in the United States and graduates of International Medical Schools recognized by the Education Commission for Foreign Medical Graduates (ECFMG).</p> <p>To ensure that all licensed MDs have passed the same assessment standards, following the same rules, the Board has adopted the USMLE and has determined that accepting FSMB and NBME criteria for passing the USMLE will ensure that Pennsylvania examination standards are consistent with National standards. Thus, the Board intends to rely on the FSMB and NBME established USMLE eligibility</p>			

requirements, including the order in which the steps may be taken, the number of attempts permitted for any one step of USMLE, the time required in between attempts and the score necessary to pass each step.

In addition to updating its regulations to conform to the current National examination for medical licensure, the Board also considered existing regulatory provisions related to former medical licensure examinations and determined that some updates were necessary. While the Board's existing regulations refer to examinations that are no longer administered, the Board proposes updates to those provisions to ensure that the regulations appropriately reflect examination standards for those former examinations so that MDs who have taken those older examinations or combinations of the older examinations may apply for licensure or participate in graduate medical training in this Commonwealth.

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

Section 24(a) of the Medical Practice Act (act) (63 P.S. § 422.24(a)) gives the Board authority to require an applicant to take and pass an examination to the satisfaction of the Board. Under section 24(d) of the act, when the Board accepts an examination given by an examining agency, the Board may establish the criteria for passing, or may accept the criteria for passing established by the examining agency.

Section 8 of the act (63 P.S. § 422.8) authorizes the Board to adopt such regulations as are reasonably necessary to carry out the purposes of the act, including the licensure of qualified individuals as physicians.

(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, the regulation is not mandated by any federal or state law or court order or regulation. However, the regulation is necessary to conform the Board's existing regulations to National standards.

(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 proposed rulemaking is required to conform to the Board's regulations to National standards and to reflect the current examination (USMLE) accepted by the Board. The proposed rulemaking also updates and clarifies requirements and standards for examinations that are no longer administered but are still valid examinations for licensure.

This rulemaking will benefit all medical doctor applicants in that examination standards will be clearly set forth in the Board's regulations. The Board's proposed regulations accept FSMB and NBME's criteria for passing the USMLE. The proposed regulations relies on FSMB and NBME for the individual USMLE eligibility requirements, including the order in which the steps may be taken,

the number of attempts permitted for any one step of USMLE, the time required in between attempts and the score necessary to pass each step, the Board will not have to amend its regulations when USMLE standards are modified or updated. Instead of amending the Board's regulations and definitions and having the continuing need to monitor and amend regulatory definitions that set forth details of the Board adopted examination, the proposed regulations will automatically reflect updated USMLE standards. This will be beneficial to the Board and to applicants because examination standards will be standardized, clarified and automatically updated.

(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. The USMLE is the licensing examination for medical doctors used in all 50 states.

(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 USMLE standards are identical in all 50 states. The Board's proposed regulations will ensure that USMLE standards are current and up to date. Having current and up to date regulations can only improve Pennsylvania's ability to compete 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.

The regulation will not affect other regulations of the Board or other state agencies.

(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 discusses its regulatory proposals at regularly scheduled public meetings of the Board. Representatives of the professional associations representing the regulated community routinely attend those meetings. In drafting the proposal, the Board solicited comments from stakeholders and interested parties by providing an exposure draft of the regulation to stakeholders on February 25, 2020. The Board did not receive any comments from stakeholders.

(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?

According to the Small Business Administration (SBA), as of 2018, there were approximately one million businesses in Pennsylvania of which 99.6% are small businesses. Most businesses in Pennsylvania are therefore considered small businesses. Applicants of the Board will be affected by the regulation, including those that are or work for small businesses. On an annual basis, the Board receives approximately 3,500 applications for a license to practice as a medical physician and surgeon. The Pennsylvania Department of Labor and Industry reports that in 2019, the vast majority of physicians work in offices of physicians and in hospitals. Others work in academia and in government.

For the businesses listed above, small businesses are defined in Section 3 of the Regulatory Review Act, (71 P.S. § 745.3) which provides that a small business is defined by the SBA's Small Business Size Regulations under 13 CFR Ch. 1 Part 121. These size standards have been established for types of businesses under the North American Industry Classification System (NAICS). In applying the NAICS standards to the types of businesses where physicians may work, a small business under NAICS Code 622110 (General Medical and Surgical Hospitals) are considered small businesses if they have \$41.5 million or less in average annual receipts; offices of physicians (NAICS code 621111) are considered small businesses if they have \$12 million or less in average annual receipts; educational services including colleges, universities and professional schools (NAICS code 611310) are considered small businesses if they have \$30 million or less in average annual receipts.

Many of the hospitals and health systems in Pennsylvania would not be considered small businesses under these thresholds. The Board does not collect information on the size of the businesses where its applicants or licensees are employed but believes that many applicants and licensees would be employed by hospitals and health systems in Pennsylvania. For purposes of determining the economic impact on small businesses, the Board also assumes that many of its applicants would work for small businesses as that term is defined by the SBA and Pennsylvania's Regulatory Review Act.

Regardless of where applicants work, this proposed rulemaking would not have a negative fiscal impact on small businesses or any other business. This proposed regulation will positively impact businesses in Pennsylvania because it clarifies examination standards and ensures that examination standards are standardized and automatically updated.

(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.

All individuals who are applying for initial licensure as a medical physician and surgeon in this Commonwealth must comply with examination standards, including the USMLE testing policies. The Board receives approximately 3,500 applications each year for initial licensure to practice as a medical physician and surgeon.

(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 Board does not anticipate any financial, economic or social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. This proposed regulation will positively impact individuals, small businesses, businesses and labor communities and other public and private organizations in Pennsylvania because it would clarify examination standards and will ensure that examination standards are standardized and automatically updated.

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

There are no costs or adverse effects to the regulation.

(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.

There are neither costs nor savings to the regulated community associated with this rulemaking.

(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.

There are neither costs nor savings to local governments associated with this rulemaking.

(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.

There are no costs or savings to State government with this rulemaking. Additionally, operations of the Board are supported entirely from fees paid by licensees, so there are no costs to state government from the Board's operations.

(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.

There are no legal, accounting or consulting procedures related to the proposed rulemaking.

(22a) Are forms required for implementation of the regulation?

No forms are required for implementation of the proposed regulation.

(22b) If forms are required for implementation of the regulation, **attach copies of the forms here.** If your agency uses electronic forms, provide links to each form or a detailed description of the information required to be reported. **Failure to attach forms, provide links, or provide a detailed description of the information to be reported will constitute a faulty delivery of the regulation.**

N/A

(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	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Savings	0	0	0	0	0	0
COSTS:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Costs	0	0	0	0	0	0
REVENUE LOSSES:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
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 2017-2018	FY 2018-2019	FY 2019-2020	Current FY 2020-2021 (Budgeted)
State Board of Medicine	\$7,182,568	\$8,193,843	\$8,013,596	\$8,440,000

(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.

The regulation has no 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.

The Board has not identified any particular needs or affected groups or persons which would require special provisions. The USMLE is the examination required for medical doctor licensure across the United States.

(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.

Because these are National standards, no alternative provisions were considered.

(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.

There are no particular compliance or reporting requirements for small businesses. Small businesses could not be exempt from the regulation.

(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 data, studies or references.

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

- A. The date by which the agency must receive public comments: **30 days**
- B. The date or dates on which public meetings or hearings will be held: **The Board meets in public session 10 times a year.**
- C. The expected date of delivery of the final-form regulation: **Winter 2022**
- D. The expected effective date of the final-form regulation: **Upon final publication**
- E. The date by which compliance with the final-form regulation will be required: **Upon final publication**
- F. The date by which required permits, licenses or other approvals must be obtained: **N/A**

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

The Board continually reviews the efficacy of its regulations, as part of its annual review process under Executive Order 1996-1. The Board reviews its regulatory proposals at regularly scheduled public meetings, typically in the morning of the board meetings. The Board is scheduled to meet in 2021 on the following dates: May 25, June 22, July 27, September 14, October 26 and December 14, 2021. More information can be found on the Board's website (www.dos.pa.gov/medicine).

DL-1

**FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU**

(Pursuant to Commonwealth Documents Law)

RECEIVED
SEP - 2 2021
Independent Regulatory
Review Commission

DO NOT WRITE IN THIS SPACE

<p>Copy below is hereby approved as to form and legality. Attorney General</p> <p>BY: <u>Amy M. Elliott</u> (DEPUTY ATTORNEY GENERAL)</p> <p><u>8/12/21</u> DATE OF APPROVAL</p> <p><input type="checkbox"/> Check if applicable. Copy not approved. Objections attached.</p>	<p>Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by</p> <p><u>State Board of Medicine</u> (AGENCY)</p> <p>DOCUMENT/FISCAL NOTE NO. <u>16A-4948</u></p> <p>DATE OF ADOPTION _____</p> <p>BY: <u>Mark B. Woodland</u> Mark B. Woodland, MS, MD Board Chair</p> <p>TITLE _____ (EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)</p>	<p>Copy below is hereby approved as to form and legality. Executive or Independent Agencies.</p> <p>BY: <u>Marisa H. Z. Lehr</u> (Deputy General Counsel) (Chief Counsel, Independent Agency) (Strike inapplicable title)</p> <p><u>July 19, 2021</u> DATE OF APPROVAL</p> <p><input type="checkbox"/> Check if applicable. No Attorney General approval or objection within 30 days after submission.</p>
---	---	--

NOTICE OF PROPOSED RULEMAKING

**COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS**

STATE BOARD OF MEDICINE

49 PA. CODE CHAPTER 16 & 17

§§ 16.1, 17.11, 17.12 and 17.12c

EXAMINATIONS

The State Board of Medicine (Board) proposes to amend §§ 16.1 (relating to definitions), 17.11 (relating to examination information for license without restriction), 17.12 (relating to failure on FLEX I or FLEX II) and 17.12c (relating to failure on USMLE), to read as set forth in Annex A.

Effective Date

The amendments will be effective upon publication of the final-form rulemaking in the *Pennsylvania Bulletin*.

Statutory Authority

Section 24(a) of the Medical Practice Act (act) (63 P.S. § 422.24(a)) gives the Board authority to require an applicant to take and pass an examination to the satisfaction of the Board. Under section 24(d) of the act, when the Board accepts an examination given by an examining agency, the Board may establish the criteria for passing, or may accept the criteria for passing established by the examining agency.

Section 8 of the act (63 P.S. § 422.8) authorizes the Board to adopt such regulations as are reasonably necessary to carry out the purposes of the act, including the licensure of qualified individuals as physicians.

Background and Need for Amendments

The Federation of State Medical Boards (FSMB) is a national non-profit organization representing all 71 state medical and osteopathic boards within the United States and its territories that license and discipline allopathic and osteopathic physicians and, in some jurisdictions, other health care professionals. FSMB membership provides state medical boards, board members and staff with a variety of opportunities to expand their professional networks; gain access to valuable resources and relationships; and develop leadership roles in the field of medical regulation. The Board is a FSMB member board. The United States Medical Licensing Examination (USMLE) is the national examination co-sponsored and administered by FSMB and the National Board of Medical Examiners (NBME).

USMLE was created in response to the need for one path to medical licensure for allopathic physicians in the United States. Before USMLE, multiple examinations (the NBME Parts Examination and the Federation Licensing Examination (FLEX)) offered paths to medical licensure. It was desirable to create one examination system accepted in every state, to ensure that all licensed medical doctors (MDs) pass same assessment standards regardless of where individuals received education and training. Today, all State medical boards in the United States utilize the USMLE. USMLE is used for licensure of graduates of accredited MD-granting medical schools in the United States and graduates of International Medical Schools recognized by the Education Commission for Foreign Medical Graduates (ECFMG).

While section 24(d) of the act authorizes the Board to establish, by regulation, a time period in which the entire examination must be successfully completed and a maximum number of examination attempts it will recognize for the purpose of receiving a passing score on an examination recognized but not given by the Board, it also authorizes the Board to accept the criteria for passing established by the examining agency (FSMB and NBME). The Board has adopted the USMLE and has determined that accepting FSMB and NBME criteria for passing the USMLE will ensure that Pennsylvania examination standards are consistent with National standards. Thus, the Board intends to rely on the FSMB and NBME established USMLE eligibility requirements, including the order in which the steps may be taken, the number of attempts permitted for any one step of USMLE, the time required in between attempts and the score necessary to pass each step.

In addition to updating its regulations to conform to the current National examination for medical licensure, the Board also considered existing regulatory provisions related to former medical licensure examinations and determined that some updates were necessary. While the Board's existing regulations refer to examinations that are no longer administered, the Board proposes updates to those provisions to ensure that the regulations appropriately reflect examination standards for those former examinations so that MDs who have taken those older examinations or combinations of the older examinations may apply for licensure or participate in graduate medical training in this Commonwealth.

Description of Proposed Amendments

In § 16.1, the Board proposes to amend the definition of FLEX and delete the definitions for FLEX I and FLEX II. The FLEX examination has not been offered since 1993; therefore, detailed definitions of the FLEX examination are no longer necessary. The Board also proposes to amend the definition of the USMLE to clarify that USMLE includes a three-step examination, which replaced the two-component FLEX examination and National Boards parts examination. The Board proposes to delete the definitions of each of the three steps of the USMLE (Step 1; USMLE, Step 2; and USMLE, Step 3). The steps of the USMLE are subject to change and are established through FSMB and NBME. For example, recently, in January of 2021, the two component Step 2, which formerly consisted of Step 2 Clinical Knowledge and Step 2 Clinical Skills, was modified by FSMB and NBME to permanently discontinue the Step 2 Clinical Skills component.

The Board proposes to amend § 17.11(a) to delete the detailed description of the FLEX examination and to clarify that a passing score on a previously taken FLEX I and FLEX II, as outlined in § 17.1(a)(1)(ii), satisfies the requirement for a license without restriction. FLEX I and FLEX II have not been offered since 1993 and has since been replaced with the nationally accepted USMLE examination. The FLEX examination, which consisted of two components and required a passing score on each component, remains a valid examination for licensure for those physicians who passed the examination prior to 1993, the date it was discontinued.

The Board proposes amendments to § 17.11(b) to delete details about the Federation of State Medical Boards licensing examination, which was offered from June 1968 through

December 1984. The Board proposes to add language to clarify that this licensing examination, also called FLEX, was the forerunner to FLEX I and FLEX II since no name for this examination is otherwise specified in the regulations. The FLEX forerunner remains a valid examination for licensure for those physicians who passed the three-part examination during June 1968 through December 1984, the dates it was administered. The Board proposes to add a cross reference to § 17.1 (a)(1)(iii) to clarify passing scores for this examination and to specify that a passing score on the FLEX forerunner satisfies the examination requirement for a license without restriction.

The Board further proposes amendments to update examination requirements for the USMLE. In § 17.11(d), the Board proposes to clarify that the USMLE consists of Steps 1, 2 and 3 and that the USMLE is given throughout the year by FSMB and NBME. The Board also proposes to delete outdated USMLE requirements, including the eligibility requirements to take each step of USMLE. As set forth in the “Eligibility for the USMLE Requirements” in the USMLE Bulletin of Information, which may be found at <https://www.usmle.org/bulletin>, if an examinee does not pass Steps 1 and 2 of USMLE, they are not eligible to sit for Step 3. The only eligibility requirement for Steps 1 and 2, which can be taken in any order, is that the examinee be officially enrolled in, or a graduate of, a U.S. or Canadian Medical School leading to an M.D. degree that is accredited by the Liaison Committee on Medical Education (LCME) or a medical school that is outside of the U.S. and Canada that meets ECFMG eligibility requirements. Additionally, under USMLE eligibility requirements, currently examinees become ineligible to take a step or step component if they have six or more prior attempts on that step or step component, including incomplete attempts. In July of 2021, the USMLE eligibility requirements will be modified. Under the updated requirements, an examinee will be ineligible to take a step or step component if the examinee has made four or more prior attempts on that step or step component, including incomplete attempts. This policy change will reduce the total number of attempts an examinee may take per step or step component from six to four.

The Board proposes to delete § 17.12, which relates to failure on FLEX I or FLEX II because information relating to failures on the FLEX I and FLEX II is no longer necessary since the examination has not been offered since 1993.

The Board proposes to delete § 17.12c (related to failure on USMLE) in its entirety because the language is outdated and addressed in other sections of the Board’s current regulations and proposed regulations. Section 17.12c(a) relates the retaking of USMLE and the time period for passing the entire examination. The 7-year period is currently outlined in § 17.1(a)(1)(ii) (relating to license without restriction) and it is not necessary to repeat it here. Section 17.12c (b) relates to number of attempts for Step 3 of USMLE. This information is outdated and has been updated in § 17.11(d). Section 17.12c(c) is also outdated. The Board has determined that it is not necessary to update this provision because the Board already outlines which step of USMLE must be successfully completed before advancing in graduate medical training as outlined in § 17.5 (related to graduate license). For example, under § 17.5(d), to participate in graduate medical training at a second-year level, the licensee shall secure a passing score on Step 1 and Step 2 of USMLE. Under § 17.5(e), to participate in graduate medical training at a third-year level or higher, the licensee shall secure a passing score on Steps 1, 2 and 3 of USMLE (or a combination of previously

administered examinations) The Board relies on § 17.5 as it relates to passing examination scores and advancing in graduate training. Therefore, it is unnecessary to repeat this information here.

Fiscal Impact and Paperwork Requirements

The regulation will not have any fiscal impact on licenses, the Board or the Commonwealth, nor is any additional paperwork anticipated.

Sunset Date

The Board continuously monitors its regulations; therefore, no sunset date has been assigned.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on September 2, 2021, the Board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC), and the House Professional Licensure Committee (HPLC). A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria that have not been met. The Regulatory Review Act specifies detailed procedures for review of comments, recommendations and objections by the Board, the General Assembly, and the Governor, prior to final publication of the rulemaking.

Public Comment

Interested persons are invited to submit written comments, recommendations or objections regarding this proposed rulemaking to Board Counsel, State Board of Medicine, P.O. Box 69523, Harrisburg, Pennsylvania, 17106-5923, RA-STRegulatoryCounsel@pa.gov within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Reference 16A-4948 (Examinations) when submitting comments.

Mark B. Woodland, M.S., M.D.
Chair, State Board of Medicine

ANNEX A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 16. STATE BOARD OF MEDICINE—GENERAL PROVISIONS

Subchapter A. BASIC DEFINITIONS AND INFORMATION

§ 16.1. Definitions.

The following words and terms, when used in this chapter and Chapters 17 and 18 (relating to State Board of Medicine-medical doctors; and State Board of Medicine-practitioners other than medical doctors), have the following meanings, unless the context clearly indicates otherwise:

ECFMG—The Educational Commission for Foreign Medical Graduates.

FLEX—[This examination provided by the Federation of State Medical Boards of the United States, Inc., comprised of FLEX I and FLEX II, was used by the Board to test applicants for a license to practice medicine and surgery without restriction. This uniform examination was administered simultaneously in most of the states, territories and possessions of the United States.]

The Federation Licensing Examination, which was used by the Board to test applicants for a license to practice medicine and surgery without restriction. The examination was comprised of two components—FLEX I and FLEX II. The last regular administration of FLEX I and FLEX II was December of 1993.

[*FLEX I*—The examination component of the FLEX designed to evaluate measurable aspects of knowledge and understanding of basic and clinical science principles and mechanisms underlying disease and modes of therapy. This component will be last regularly administered in December 1993.

FLEX II—The examination component of the FLEX designed to measure a core of competence involved in the diagnosis and management of selected clinical problems frequently encountered by a physician engaged in the independent practice of medicine. This component will be last regularly administered in December 1993.]

Federation—The Federation of State Medical Boards of the United States, Inc.

Treatment regimen—The provision of care and practice of a component of the healing arts by a Board-regulated practitioner.

USMLE—The United States Medical Licensing Examination, a single, uniform examination for medical licensure consisting of three steps. The examination is provided by the Federation of State Medical Boards (FSMB) and the National Board of Medical Examiners (NBME) and replaces the FLEX examination and the NBME National Boards Parts examination.

[*USMLE, Step 1*—Assesses whether an examinee understands and can apply key concepts of basic biomedical science, with an emphasis on principles and mechanisms of health, disease and modes of therapy.

USMLE, Step 2—Assesses whether an examinee possesses the medical knowledge and understanding of clinical science considered essential for the provision of patient care under supervision, including emphasis on health promotion and disease prevention.

USMLE, Step 3—Assesses whether an examinee possesses the medical knowledge and understanding of biomedical and clinical science considered essential for the unsupervised practice of medicine.]

CHAPTER 17. STATE BOARD OF MEDICINE—MEDICAL DOCTORS

* * * * *

Subchapter B. EXAMINATION INFORMATION

§ 17.11. Examination information for license without restriction.

(a) *FLEX*. [This is the examination offered by the Board for a license without restriction. The last regular administration of FLEX I and FLEX II was December of 1993. The examination is comprised of two components—FLEX I and FLEX II. Both components are given every December and June. FLEX I may be taken after graduating from a medical college but, beginning July 1, 1986, shall be passed prior to commencing a second-year level of graduate medical training if the medical doctor has not already passed Parts I and II of the National Boards or a licensing examination acceptable to the Board under § 17.1(a)(1)(iii), (viii) and (ix) (relating to license without restriction), or secured a license without restriction in this Commonwealth or an equivalent license issued by a state, territory or possession of the United States or the Dominion of Canada. FLEX II may be taken after graduating from a medical college but, for a medical doctor to begin a third-year level of graduate medical training he shall first pass FLEX I and FLEX II or a licensing examination acceptable to the Board under § 17.1(a)(1)(iii), (viii) and (ix), or have secured a license without restriction in this Commonwealth or an equivalent license issued by another state, territory or possession of the United States or the Dominion of Canada. Both FLEX I and FLEX

II may be taken by a student in a medical college if the student is in the last semester or a similar school term, the dean of the medical college certifies to the Board that the student's graduation is imminent and the semester or similar school term will conclude shortly after the administration of FLEX I and FLEX II.] A passing score on [this examination] FLEX I and FLEX II as outlined in § 17.1(a)(1)(ii) satisfies the examination requirement for a license without restriction.

(b) *Licensing examination of Federation from June 1968 through December 1984.* [This examination is the forerunner of the present FLEX.] This three-part examination, also called the FLEX, is the forerunner of the two-component FLEX examination in subsection (a). A passing score on this three-part examination, as outlined in § 17.1 (a)(1)(iii), satisfies the examination requirement for a license without restriction. [This examination is no longer offered as a licensing examination by the Board. A passing score on this examination shall have been achieved in an individual attempt, that is, a passing score cannot be achieved by combining scores received on separate parts of the examination obtained in more than one examination attempt.]

(c) *National Boards.* This examination comprised of Parts I, II and III was given in most accredited medical colleges. A passing score on this examination satisfies the examination requirement for a license without restriction.

(d) *USMLE.* This examination is a uniform examination for licensure which replaces the National Boards Parts I, II and III and FLEX I and FLEX II. [Each step is given twice a year.] Steps 1, 2 and 3 of USMLE are given throughout the year at times and places designated by FSMB and NBME. [To be eligible for Step 1 or 2 of the examination, an individual shall be a medical student officially enrolled in, or a graduate of, an accredited medical school or a graduate of an

unaccredited medical school. Steps 1 and 2 may be taken in any sequence. To be eligible for Step 3 of the USMLE, the individual shall have obtained a medical doctor degree or equivalent, shall have achieved a passing score on both Step 1 and Step 2 or equivalent, and shall be enrolled in a graduate medical training program. Additionally, a graduate of an unaccredited school shall be currently certified by ECFMG or shall have successfully completed a “Fifth Pathway” program. All Steps of the examination shall be completed within 7 years.] USMLE eligibility requirements for each step or step component of the USMLE are jointly set by FSMB and NBME. A passing score on all three steps of USMLE, as determined by FSMB and NBME and as outlined in § 17.1(a)(1)(i), [this examination] satisfies the examination requirement for a license without restriction.

(e) *Examination of the Medical Council of Canada.* This is an examination offered in Canada which has been adopted as a licensing examination in most of the provinces of Canada. A passing score on this examination, as determined by the Medical Council of Canada, satisfies the examination requirement for a license without restriction if the examination was taken in English in or after May 1970.

(f) *State Board Examination.* This is an examination for a license to practice medicine and surgery without restriction, other than USMLE, FLEX or the forerunner of FLEX, which is used by a licensing authority in another state, territory or possession of the United States. A passing score on this examination, as determined by the licensing authority in the other jurisdiction, satisfies the examination requirement for a license without restriction if the examination was taken in English prior to December 1973.

§ 17.12. [Failure on FLEX I or FLEX II.] Reserved.

[(a) *Retaking examination.* An individual who fails either FLEX I or FLEX II is permitted to retake that component of the FLEX in this Commonwealth after the expiration of 6 months and within 2 years from the prior examination date.

(b) *Repeating year of graduate medical training.* If an individual fails to secure a passing grade on FLEX I in a second attempt, the individual shall repeat a year of graduate medical training at a first-year level before retaking FLEX I in this Commonwealth. If the individual fails to secure a passing grade on FLEX II in a second attempt, the individual shall repeat a year of graduate medical training at a first or second-year level before retaking FLEX II in this Commonwealth.

(c) *Awaiting examination results.* Effective July 1, 1986, if an individual scheduled to go into a second-year level of graduate medical training is awaiting the FLEX I score, the individual may not begin training at a second-year level until the individual has notified the Board that FLEX I has been passed, and the Board has issued the appropriate license, but may continue to train at a first-year level until that time, if the individual has renewed the first-year level license. An individual scheduled to go into a third-year level of graduate medical training who is awaiting the FLEX II score, may not begin training at a third-year level until the individual has notified the Board that FLEX II has been passed, and the Board has issued the appropriate license, but may continue to train at a first or second-year level until that time, if the individual has renewed the first or second-year level license.]

* * * * *

§ 17.12c. [Failure on USMLE.] Reserved.

(a) *Retaking examination.* An individual is permitted to retake any component of the USMLE. Steps 1, 2 and 3 shall be completed within a 7-year period. Because Steps 1 and 2 may be taken in any sequence, the 7-year period begins with the passage of the first step taken.

(b) *Repeating year of graduate medical training.* If an individual fails to secure a passing score on Step 3 in a third attempt, the individual shall repeat a year of graduate medical training at a first or second-year level before retaking Step 3.

(c) *Awaiting examination results.* If an individual scheduled to go into a second-year level of graduate medical training is awaiting examination scores, the individual may not begin training at a second-year level, but may continue to train at a first-year level, if the individual has renewed the first-year level license, until the individual has notified the Board that Steps 1 and 2 have been passed and the Board has issued the appropriate license. If an individual scheduled to go into a third-year level of graduate medical training is awaiting examination scores, the individual may not begin training at a third-year level, but may continue to train at a first or second-year level, if the individual has renewed the first or second-year level license, until the individual has notified the Board that Step 3 has been passed and the Board has issued the appropriate license.]



COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE
Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649
(717) 783-1400

September 2, 2021

The Honorable George D. Bedwick, Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Proposed Regulation
State Board of Medicine
16A-4948: Examinations

Dear Chairman Bedwick:

Enclosed is a copy of a proposed rulemaking package of the State Board of Medicine pertaining to Examinations.

The Board will be pleased to provide whatever information the Commission may require during the course of its review of the rulemaking.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark B. Woodland".

Mark B. Woodland, M.S., M.D., Chairperson
State Board of Medicine

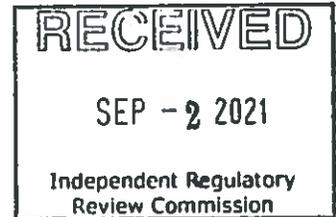
MBW/dmw:bmz
Enclosure

cc: K. Kalonji Johnson, Commissioner of Professional and Occupational Affairs
Pamela Iovino, Deputy Secretary of Regulatory Programs
Marc Farrell, Deputy Director of Policy, Department of State
Cynthia Montgomery, Deputy Chief Counsel, Department of State
Jacqueline A. Wolfgang, Regulatory Unit Counsel, Department of State
Dana M. Wucinski, Counsel, State Board of Medicine
State Board of Medicine

From: [Smeltz, Jennifer](#)
To: [Zappasodi, Brittany](#); [Blauch, Tammy](#)
Subject: RE: DELIVERY: REGULATIONS 16A-4948 & 16A-5218
Date: Thursday, September 2, 2021 9:06:40 AM

Received.

Jen Smeltz
Executive Director
Consumer Protection and Professional Licensure Committee
Office of Senator Robert M. Tomlinson
Phone: (717) 787-5072



From: Zappasodi, Brittany <bzappasodi@pa.gov>
Sent: Thursday, September 2, 2021 8:59 AM
To: Smeltz, Jennifer <jmsmeltz@pasen.gov>; Blauch, Tammy <tblauch@pasen.gov>
Subject: DELIVERY: REGULATIONS 16A-4948 & 16A-5218
Importance: High

Ⓢ CAUTION : External Email Ⓢ

Please provide written (email) confirmation of receipt of the delivery of the attached rulemaking.

Please be advised that the State Board of Medicine and State Board of Optometry are delivering the following proposed rulemakings:

- State Board of Medicine 16A-4948 Examinations
- State Board of Optometry: 16A-5218 License by Endorsement

Brittany Zappasodi | *Legal Assistant II*
Department of State | Counsel Division Legal Office
2601 North Third Street, P.O. Box 69523
Harrisburg, PA 17106-9523
Phone: 717.783.7200 | Fax: 717.787-0251
www.dos.pa.gov

PRIVILEGED AND CONFIDENTIAL COMMUNICATION

The information transmitted is intended only for the person or entity to whom it is addressed and may contain confidential and/or privileged material. Any use of this information other than by the intended recipient is prohibited. If you receive this message in error, please send a reply e-mail to the sender and delete the material from any and all computers. Unintended transmissions shall not constitute a waiver of the attorney-client or any other privilege.

From: [Emily Hackman](#)
To: [Zappasodi, Brittany](#)
Cc: [Nicole Sidle](#)
Subject: RE: DELIVERY: REGULATIONS 16A-4948 & 16A-5218
Date: Thursday, September 2, 2021 9:34:50 AM

Received.

EMILY EPLER HACKMAN | ADMINISTRATIVE ASSISTANT II

David S. Hickernell, Majority Chairman

Professional Licensure Committee

98th Legislative District

Room 43, East Wing

Harrisburg, PA 17120-2098

717-783-2076

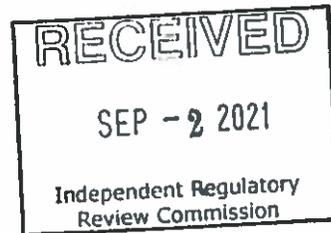
Representative Mindy Fee

37th Legislative District

Room 47, East Wing

Harrisburg, PA 17120-2037

717-772-5290



From: Zappasodi, Brittany <bzappasodi@pa.gov>

Sent: Thursday, September 2, 2021 9:02 AM

To: Nicole Sidle <nsidle@pahousegop.com>; Emily Hackman <Eepler@pahousegop.com>

Subject: DELIVERY: REGULATIONS 16A-4948 & 16A-5218

Importance: High

Please provide written (email) confirmation of receipt of the delivery of the attached rulemaking.

Please be advised that the State Board of Medicine and State Board of Optometry are delivering the following proposed rulemakings:

- State Board of Medicine 16A-4948 Examinations
- State Board of Optometry: 16A-5218 License by Endorsement

Brittany Zappasodi | Legal Assistant II

Department of State | Counsel Division Legal Office

2601 North Third Street, P.O. Box 69523

Harrisburg, PA 17106-9523

Phone: 717.783.7200 | Fax: 717.787-0251

www.dos.pa.gov

PRIVILEGED AND CONFIDENTIAL COMMUNICATION

The information transmitted is intended only for the person or entity to whom it is addressed and may contain confidential and/or privileged material. Any use of this information other than by the intended recipient is prohibited. If you receive this message in error, please send a reply e-mail to the sender and delete the material from any and all

computers. Unintended transmissions shall not constitute a waiver of the attorney-client or any other privilege.

The information transmitted is intended only for the person or entity to which it is addressed and may contain confidential and/or privileged material. Any review, retransmission, dissemination or other use of, or taking of any action in reliance upon, this information by persons or entities other than the intended recipient is prohibited. If you received this information in error, please contact the sender and delete the message and material from all computers.

From: [Livingston, Jerry](#)
To: [Zappasodi, Brittany](#)
Subject: Read: DELIVERY: REGULATIONS 16A-4948 & 16A-5218
Date: Thursday, September 2, 2021 9:37:06 AM
Attachments: [Read DELIVERY REGULATIONS 16A-4948 16A-5218.msg](#)
Importance: High

This message and any attachment may contain privileged or confidential information intended solely for the use of the person to whom it is addressed. If the reader is not the intended recipient then be advised that forwarding, communicating, disseminating, copying or using this message or its attachments is strictly prohibited. If you receive this message in error, please notify the sender immediately and delete the information without saving any copies.

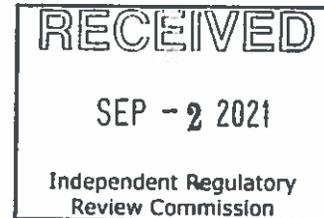


From: [Wilson, Marlene](#)
To: [Zappasodi, Brittany](#)
Subject: RE: DELIVERY: REGULATIONS 16A-4948 & 16A-5218
Date: Thursday, September 2, 2021 10:17:09 AM
Attachments: [image001.png](#)

Received. Thank you.



Marlene Wilson, Esquire
Senior Committee Executive Director
House Professional Licensure Committee
Rep. Jake Wheatley, Jr., Chairman
Phone: (717) 787-4032
Internal Phone: 6253
Email - mwilson@pahouse.net



From: Zappasodi, Brittany <bzappasodi@pa.gov>
Sent: Thursday, September 2, 2021 9:01 AM
To: Wilson, Marlene <MWilson@pahouse.net>
Subject: DELIVERY: REGULATIONS 16A-4948 & 16A-5218
Importance: High

Please provide written (email) confirmation of receipt of the delivery of the attached rulemaking.

Please be advised that the State Board of Medicine and State Board of Optometry are delivering the following proposed rulemakings:

- State Board of Medicine 16A-4948 Examinations
- State Board of Optometry: 16A-5218 License by Endorsement

Brittany Zappasodi | *Legal Assistant II*
Department of State | Counsel Division Legal Office
2601 North Third Street, P.O. Box 69523
Harrisburg, PA 17106-9523
Phone: 717.783.7200 | Fax: 717.787-0251
www.dos.pa.gov

PRIVILEGED AND CONFIDENTIAL COMMUNICATION

The information transmitted is intended only for the person or entity to whom it is addressed and may contain confidential and/or privileged material. Any use of this information other than by the intended recipient is prohibited. If you receive this message in error, please send a reply e-mail to the sender and delete the material from any and all computers. Unintended transmissions shall not constitute a waiver of the attorney-client or any other privilege.

From: [Bulletin](#)
To: [Zappasodi, Brittany](#)
Subject: [External] RE: DELIVERY: REGULATIONS 16A-4948 & 16A-5218
Date: Thursday, September 2, 2021 9:24:56 AM

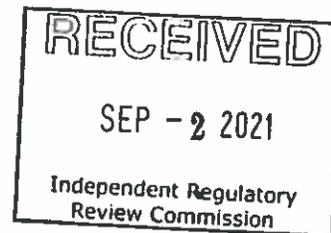
ATTENTION: This email message is from an external sender. Do not open links or attachments from unknown sources. To report suspicious email, forward the message as an attachment to CWOPA_SPAM@pa.gov.

Good morning Brittany:

Thank you for sending Proposed Rulemakings #16A-4948 and 16A-5218. Someone from our office will contact you regarding publication in the Pennsylvania Bulletin.

Thank you and have a nice day.

Coleen P. Engvall | Legal Assistant
cengvall@palrb.us | 717.783.1531
Legislative Reference Bureau
Code and Bulletin Office



From: Zappasodi, Brittany <bzappasodi@pa.gov>
Sent: Thursday, September 2, 2021 9:15 AM
To: Bulletin <bulletin@palrb.us>
Subject: DELIVERY: REGULATIONS 16A-4948 & 16A-5218
Importance: High

Please provide written (email) confirmation of receipt of the delivery of the attached rulemaking.

Please be advised that the State Board of Medicine and State Board of Optometry are delivering the following proposed rulemakings:

- State Board of Medicine 16A-4948 Examinations
- State Board of Optometry: 16A-5218 License by Endorsement

Brittany Zappasodi | Legal Assistant II
Department of State | Counsel Division Legal Office
2601 North Third Street, P.O. Box 69523
Harrisburg, PA 17106-9523
Phone: 717.783.7200 | Fax: 717.787-0251
www.dos.pa.gov

PRIVILEGED AND CONFIDENTIAL COMMUNICATION

The information transmitted is intended only for the person or entity to whom it is addressed and may contain

confidential and/or privileged material. Any use of this information other than by the intended recipient is prohibited. If you receive this message in error, please send a reply e-mail to the sender and delete the material from any and all computers. Unintended transmissions shall not constitute a waiver of the attorney-client or any other privilege.