

California State Board of Pharmacy

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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



To: Board Members

Subject: Discussion of and Possible Action to Initiate a Rulemaking to Amend California Code of Regulations, Title 16, Section 1793.65 Related to Pharmacy Technician Certification Programs Approved by the Board

Relevant Law

<u>Business and Professions Code (BPC) section 4202</u> generally establishes the requirements for a pharmacy technician license and includes four pathways to licensure. One of these pathways is certification by a pharmacy technician certifying organization offering a pharmacy technician certification program accredited by the National Commission for Certifying Agencies that is approved by the Board. (See BPC section 4202(a)(4).)

California Code of Regulations (CCR), title 16, section 1793.65(a) specifies that the pharmacy technician certification programs approved by the Board are those offered by the Pharmacy Technician Certification Board (PTCB) and the National Healthcareer Association. Section 1793.65(b) establishes a sunset date for these program approvals, which is currently June 30, 2026.

<u>BPC section 139</u> requires DCA to develop a policy regarding examination development and validation, and occupational analysis. The section further requires that every board within DCA have a method for ensuring that every licensing examination administered by or pursuant to contract with the board is subject to periodic evaluation, which must include:

- 1. A description of the occupational analysis serving as the basis for the examination:
- 2. Sufficient item analysis data to permit a psychometric evaluation of the items;
- 3. An assessment of the appropriateness of prerequisites for admittance to the examination; and
- 4. An estimate of the costs and personnel required to perform these functions.

<u>Background</u>

The DCA Licensure Examination Validation Policy (which has been established to meet the mandate of BPC section 139) provides in part that, generally, an occupational analysis and examination outline should be updated every five years to be considered current.

Statutory changes effective January 1, 2017, updated the provisions for authorized pharmacy technician certification programs by expanding

authorization to programs accredited by the National Commission for Certifying Agencies. (Prior provisions of the law limited the authorization to certification by the Pharmacy Technician Certification Board.) In response to the change, the Board promulgated regulations to identify the Board approved programs. Although the Board initiated the rulemaking in 2017, the regulation (i.e., 16 CCR section 1793.65) did not become effective until January 1, 2023.

In 2024, the Board initiated and completed a rulemaking to amend section 1793.65 of Article 11 of Division 17 of Title 16 of the CCR to extend the sunset date of the Board's approval of the programs until June 30, 2026, to allow for the DCA Office of Professional Examination Services (OPES) to evaluate the two pharmacy technician certification programs to ensure compliance with the provisions of BPC section 139.

In Fiscal Year 2023-24, the Board contracted with DCA OPES to evaluate the Pharmacy Technician Certification Board's Pharmacy Technician Certification Exam (PTCE) and National Healthcareer Association's Exam for the Certification of Pharmacy Technicians (ExCPT) for compliance with BPC section 139. As part of this compliance check, an occupational analysis was performed, and it was anticipated that the findings would be released in 2025. In 2024, the PTCB conducted a comprehensive occupational analysis study resulting in a change of the PTCE Content Outline and CPhT Knowledge Reference, to be implemented in 2026. As a result, DCA OPES' review of the PTCE was delayed due to the implementation date of 2026 for the changes being made to the PTCE. The Board now anticipates receiving DCA OPES' findings in early 2026. With the current June 30, 2026 sunset date, Board staff recommend pursuing a regulatory change to extend the sunset date to June 2027, which would allow time for the Board to consider the findings of the DCA OPES reports before updating the approved programs subsequent to the DCA OPES' evaluation of the two pharmacy technician programs to ensure compliance with the provisions of BPC section 139. Should members agree this change is appropriate, the following motion could be used to initiate the formal rulemaking process:

Possible Motion: Initiate a rulemaking to amend California Code of Regulations, Title 16, section 1793.65 [either "as proposed" or "consistent with the Board's discussion"]. Direct staff to submit the text to the Director of the Department of Consumer Affairs and the Business, Consumer Services, and Housing Agency for review, and authorize the executive officer to take all steps necessary to initiate the rulemaking process, make any technical or nonsubstantive changes to the package, and set the matter for hearing, if requested. If, during the 45-day comment period, the Board does not receive any comments providing objections or adverse recommendations specifically directed at the proposed action or to the procedures followed by the Board in proposing or adopting the action, and no hearing is

requested, authorize the executive officer to take all steps necessary to complete the rulemaking and adopt the proposed regulation at Section 1793.65.

Following this memo is a copy of the DCA Licensure Examination Validation Policy and draft regulation language.

Department of Consumer Affairs Title 16. Board of Pharmacy

Proposed Regulation Text Pharmacy Technician Certification Programs

Proposed changes made to the current regulation language are shown by strikethrough for deleted language and underline for added language.

Amend section 1793.65 to Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

- § 1793.65. Pharmacy Technician Certification Programs Approved by the Board.
- (a) Pursuant to Business and Professions Code section 4202(a)(4), the Board approves the pharmacy technician certification program offered by:
 - (1) The Pharmacy Technician Certification Board, and
 - (2) The National Healthcareer Association.
- (b) Approval of these programs is valid through June 30, 2026. June 30, 2027.

NOTE: Authority cited: Sections 4005 and 4202, Business and Professions Code. Reference: Sections 4038 and 4202, Business and Professions Code.





TITLE	LICENSURE EXAMINATION VALIDATION POLICY			
POLICY OWNER	OFFICE OF PROFESSIONAL EXAMINATION SERVICES			
POLICY NUMBER	OPES 22-01		SUPERSEDES	OPES 18-02
ISSUE DATE	November 23, 2022		EFFECTIVE	IMMEDIATELY
DISTRIBUTE TO	ALL EMPLOYEES			
ORIGINAL APPROVED BY	*Original Signature on File Kimberly Kirchmeyer Director			
NUMBER OF PAGES	1 of 11	ATTACH	MENTS	NONE

POLICY

It is the policy of the Department of Consumer Affairs (DCA) that occupational analyses and examination development studies are fundamental components of licensure programs. Licensure examinations with substantial validity evidence are essential in preventing unqualified individuals from obtaining professional licenses. To that end, licensure examinations must be:

- Developed according to an examination outline that is based on a current occupational analysis.
- Regularly evaluated.
- Updated when tasks performed or prerequisite knowledge in a profession change, or to prevent overexposure of test questions.
- Reported annually, in terms of validation activities, to the Legislature.

APPLICABILITY

This policy applies to all employees, governmental officials, contractors, consultants, and temporary staff of DCA; and any of its divisions, bureaus, boards, and other constituent agencies. Within this policy, the generic acronym "DCA" applies to all of these entities. For purposes of this policy, "board" shall refer to all boards, bureaus, or committees.

PURPOSE

The purpose of this policy is to meet the mandate of Business and Professions (B&P) Code section 139 (a) and (b) directing DCA to develop a policy regarding examination development and validation, and occupational analyses; and B&P Code section 139 (c) and (d) directing DCA to evaluate and report annually to the Legislature the methods used by each regulatory entity for ensuring that their licensing examinations are subject to periodic evaluations.

On September 30, 1999, the Office of Professional Examination Services (OPES) completed and distributed to its clients an internal publication "Examination Validation Policy" in compliance with B&P Code section 139 (a) and (b). In 2000, DCA policy "Licensing Examinations – Reporting Requirements" (OER-00-01) was established to meet the mandate of B&P Code section 139 (c) and (d). OER-00-01 has since been abolished. This new policy addresses the provisions of all four subsections of B&P Code section 139: (a), (b), (c), and (d).

AUTHORITY

- Business and Professions Code section 139 (a), (b), (c), and (d).
- Business and Professions Code section 101.6.
- Government Code section 12944 (a) of the Fair Employment and Housing Act.
- Uniform Guidelines on Employee Selection Procedures (1978), adopted by the Equal Employment Opportunity Commission, Civil Service Commission (EEOC), Department of Labor, and Department of Justice.
- Civil Rights Act of 1964, as amended.

DEFINITIONS

Content domain is the realm of behaviors, knowledge, skills, abilities, or other characteristics that a particular test is intended to measure, as reflected by its examination outline, and about which the scores are generally intended to be generalized.

Content-related evidence of validity is the evidence that shows the extent to which the content of a selection procedure is a representative sample of work-related personal characteristics, work performance, or other work activities or outcomes.

Criterion-referenced passing score is a specified point in a distribution of scores at or above which candidates are considered successful in the selection process. By definition, the criterion-referenced passing score is related to a minimally acceptable competence criterion and is the same for all applicant groups.

Entry level in licensure testing refers to newly licensed individuals. In relation to examination development workshops, licensees 0-5 years post-licensure are generally considered sufficiently close to "entry level" to provide substantive information about this area.

Examination development specialists are individuals who are trained, experienced, and skilled in licensure-related occupational analysis; licensure-related examination planning, development, validation, administration, scoring, and analysis; and the professional and technical standards, laws, and regulations related to these tasks.

Examination outline is organized around the content domains drawn directly from the results of an occupational analysis. The content domains are comprised of the knowledge, skills, and abilities that have been determined to be the essential elements of competency for the occupation being assessed. In addition to the listing of content domains, the examination outline specifies the number or proportion of items that are planned to be included on each test form for each content domain. These proportions reflect the relative importance of each content domain to competency in the occupation. They are sometimes also referred to as test specifications, test plans, or test blueprints.

Minimum acceptable competence is the minimum level of knowledge, skill, and ability required of newly licensed individuals that, when the profession is performed at this level, would not cause harm to the public health, safety, or welfare.

Occupational analysis is a method used to gain an understanding of the work behaviors and activities required, or the worker requirements (i.e., knowledge, skills, abilities, and other personal characteristics), and the context or environment in which an organization and individual may operate. For occupational licensing, the term occupational analysis is preferred over job analysis or practice analysis because the scope of analysis is across a profession, not an individual job.

Reciprocity review of a licensure examination is an analysis of an occupational licensure examination accepted by another state. The purposes of the review are (1) to evaluate whether professional testing standards are being met and (2) to determine whether the examination is comparable (i.e., substantially similar) to the examination(s) used in California to meet initial licensure requirements. If an examination meets technical standards and professional guidelines, and if the examination is comparable to California examination(s), licensees who pass that examination may be deemed competent to practice in California.

Reliable measurement/reliability is the degree to which scores for a group of candidates are consistent over one or more potential sources of error (e.g., time, raters, items, conditions of measurement, etc.) in the application of a measurement procedure.

Review (Audit) of a national licensure examination is an analysis of a nationally developed and administered licensure examination for a profession. The goals of the review are (1) an assessment of whether professional testing standards are being met and (2) the identification of any critical aspects of the profession that are practiced in California and should be (but is not) tested nationally.

Subject matter experts (SMEs) are licensees who have a thorough knowledge of the work behaviors, activities, and responsibilities of job incumbents and the knowledge, skills, abilities and other characteristics needed for effective performance on the job. To participate in examination development workshops, SMEs should be practitioners currently possessing an active license in good standing and who are active in their profession. When contracting for their services, DCA refers to SMEs as Expert Consultants.

Validation is the process by which evidence of content accuracy is gathered, analyzed, and summarized.

Validity is the "degree to which accumulated evidence and theory support specific interpretations of test scores entailed by proposed uses of a test." Validity is not a property inherent in a test; it is the degree to which the decisions based on that test are accurate. For licensing examinations, validity is interpreted as correctly differentiating between persons who are qualified to competently and safely practice a profession from those who are not.

PROVISIONS

A. VALIDATION TOPICS

B&P Code section 139 (b) requires OPES to address eight specific topics, plus any other topics necessary to ensure that licensing examinations conducted on behalf of DCA are validated according to accepted technical and professional standards.

1. AN APPROPRIATE SCHEDULE FOR EXAMINATION VALIDATION AND OCCUPATIONAL ANALYSIS AND CIRCUMSTANCES UNDER WHICH MORE FREQUENT REVIEWS ARE APPROPRIATE

Occupational Analysis Schedule

Generally, an occupational analysis and examination outline should be updated every 5 years to be considered current; however, many factors are taken into consideration when determining the need for a different interval. For instance, an occupational analysis and examination outline must be updated whenever there are significant changes in a profession's job tasks and/or demands, scope of practice, equipment, technology, required knowledge, skills and abilities, or laws and regulations governing the profession. The board is responsible for promptly notifying the examination development specialist of any significant changes to the profession. This is true both for California-specific and national licensure examination-related occupational analyses.

Examination Validation Schedule

New forms of a licensure examination assist in the legal defensibility of the examination, prevent overexposure of test items, and keep the examination current. The decision to create an examination, or new forms of an examination, is made by the board responsible for the license in consultation with the examination development specialist. The creation of new examination forms depends on the needs of the testing program and the number of people taking the examination.

2. MINIMUM REQUIREMENTS FOR PSYCHOMETRICALLY SOUND EXAMINATION VALIDATION, EXAMINATION DEVELOPMENT, AND OCCUPATIONAL ANALYSES, INCLUDING STANDARDS FOR SUFFICIENT NUMBER OF TEST ITEMS

Boards have the ultimate responsibility to ensure that a licensure examination meets technical, professional, and legal standards and protects the health, safety, and welfare of the public by assessing a candidate's ability to practice at or above the level of minimum acceptable competence.

The inferences made from the resulting scores on a licensing examination are continuously validated. Gathering evidence in support of an examination and the resulting scores is an ongoing process. Each examination is created from an examination outline that is based upon the results of a current occupational analysis that identifies the job-related critical tasks, and related knowledge, skills, and abilities necessary for safe and competent practice. Examinations are designed to assess those knowledge, skills, and abilities. To ensure that examinations are job-related, SMEs must participate in all phases of examination development.

All aspects of test development and test use, including occupational analysis, examination development, and validation, should adhere to accepted technical and professional standards to ensure that all items on the examination are psychometrically sound, job-related, and legally defensible. These standards include those found in *Standards for Educational and Psychological Testing*, referred to in this policy as the *Standards*; and the *Principles for Validation and Use of Personnel Selection Procedures*, referred to in this policy as the *Principles*.

The *Standards* and *Principles* are used as the basis of all aspects of the policies contained in this document. The EEOC *Uniform Guidelines on Employee Selection Procedures* (1978) provide direction on the legal defensibility of selection-related examinations.

Other professional literature that defines and describes testing standards and influences professionals is produced by the following organizations:

- American Educational Research Association (AERA)
- American Psychological Association (APA)
- Council on Licensure, Enforcement, and Regulation (CLEAR)
- Equal Employment Opportunity Commission (EEOC)
- Institute for Credentialing Excellence (ICE)
- National Council of Measurement in Education (NCME)
- Society for Industrial and Organizational Psychology (SIOP)

Minimum Requirements for Psychometrically Sound Occupational Analysis

The minimum requirements for a psychometrically sound occupational analysis are as follows:

- Adhere to a content validation strategy or other psychometrically sound examination development method as referenced in a recognized professional source.
- Develop an examination outline from the occupational analysis.

 Gather data from a sample of current licensees in the State of California that represents the geographic, professional, and other relevant categories of the profession.

Minimum Requirements for Psychometrically Sound Examination Development and Validation

The minimum requirements for psychometrically sound examination development and validation are as follows:

- Adhere to the Standards and Principles.
- Document the process following recommendations in the *Standards* and *Principles*.
- Conduct with a trained examination development specialist in consultation with SMEs.
- Use an examination outline and psychometrically sound item-writing guidelines.
- Follow established security procedures.

Standards for Sufficient Number of Test Items

The number of items in an examination should be sufficient to ensure content coverage and provide reliable measurement. Both empirical data and the judgment and evaluation by SMEs should be used to establish the number of items within an examination. The empirical data should include results from an occupational analysis, item analysis, and test analysis.

The item bank for a licensure examination should contain a sufficient number of items such that: 1) at least one new form of the examination could be generated if a security breach occurred; and 2) items are not exposed too frequently to repeating examinees. Boards should develop an examination retake policy that minimizes the overexposure of test items.

3. SETTING PASSING STANDARDS

Passing score standards for licensure examinations must:

- Follow a process that adheres to accepted technical and professional standards.
- Adhere to a criterion-referenced passing score methodology that uses minimum competence at an entry level to the profession.

An arbitrary fixed passing score or percentage, such as 70%, does not represent minimally acceptable competence. Arbitrary passing scores are not legally defensible.

If a board has an appeals process for candidates who are not successful in their examination, once a criterion-referenced passing score has been determined for a multiple-choice examination, the board shall not change a candidate's score without consultation with the examination development specialist.

4. STANDARDS FOR REVIEW OF STATE AND NATIONAL EXAMINATIONS

All licensure examinations appropriated for use in California professions regulated by DCA should be validated according to accepted technical and professional standards, as described elsewhere in these provisions. At a minimum, the following factors must be considered in a review of state and national examination programs:

- Right to access information from all studies and reports from test vendors (local or national).
- Right of state agency to review recent examination.
- Description of methodology used to establish content-related validity.
- Occupational analysis report and frequency of updates.
- Method to ensure standards are set for entry level practice.
- Examination outline and method to link to the occupational analysis.
- Information about the sample of practitioners surveyed.
- Item development process (experts used, editing methods, etc.).
- · Sufficient size of item banks.
- · Pass-point setting methodology.
- Examination security methods; examination administration processes.
- Examination reliability.
- Pass-fail ratio.
- Statistical performance of examinations.

The suitability of an occupational analysis conducted on a national level to validate a national exam that is/could be used in California and for use in examination development in California for a California-only examination must be determined by: (1) a review of the methodology of the occupational analysis, including the demographics of the practitioners upon which it is based to ensure California practice is appropriately represented; and (2) a comparison study between a current California occupational analysis of the profession and the national occupational analysis to assess the validity of the national examination content for California practice.

Reciprocity

Reciprocity refers to the mutual recognition, endorsement, and acceptance by the State of California of licenses granted by other jurisdictions. Reciprocity agreements often include a waiver of certain California licensing requirements, such as a practice-based examination. Licensure examinations accepted in California as part of reciprocity agreements are not used for licensure in California, but individuals passing them may be qualified to practice in California without fulfilling all California licensure requirements. These examinations should be validated according to technical and professional standards to ensure that they are legally defensible. Before a licensure examination is accepted under a reciprocity

agreement, a comparison study must be performed to verify that the examination meets professional standards for validity, that the scope of practice measured by the examination is substantially similar to the California scope of practice, and that the examination is a sufficient measure of the critical competencies required for practice in California. The study should carefully evaluate differences in the scope of practice or competencies measured by the examination, and the study should determine whether waiving the California licensure examination would endanger the public. The board should consult with OPES to conduct this study.

Additional Considerations for Reciprocity

In addition to conducting a comparison study of the licensure examination, the board should evaluate the equivalency of education and experience requirements set by the jurisdiction for initial licensure within the license category requesting reciprocity. The board should set other relevant criteria, such as requiring a minimum number of years licensed and that the license must be in good standing. The board should also determine whether licensees seeking reciprocity should be required to pass a California-specific examination, e.g., a jurisprudence examination.

5. APPROPRIATE FUNDING SOURCES FOR EXAMINATION VALIDATIONS AND OCCUPATIONAL ANALYSES

Budget line items should be designated exclusively for examination development and occupational analyses projects. To assure validity, maintain consistency, preserve security, and ensure the integrity of the examination program, the budget line items need to be continuous appropriations.

Boards should budget for costs associated with examination and occupational analysis development; contracting with a computer-based testing vendor for electronic examination administration; and projecting for expenses associated with travel and per diem for SMEs who participate in examination development and occupational analysis workshops. Boards that administer examinations by paper and pencil should also consider the expense of examination proctors, including their travel and per diem expenses; examination site rental; additional security resources; and printing costs for the preparation guides and examination booklets.

Boards must have the budgetary flexibility to adapt to unexpected or additional program needs. For example, the potential for catastrophic incidents such as a security breach and the cost to replace the compromised examination should be considered in determining overall examination-related costs.

Boards contract via intra-agency contracts (IACs) with OPES for examination-related services. Currently, boards request OPES' services and submit a Budget Change Proposal (BCP) to obtain expenditure authority if they do not already have a budget line item for these expenditures. Boards are then charged, and OPES is reimbursed through the IACs for occupational

analyses, national examination reviews, and ongoing examination development, evaluation, construction, and publication services. Consulting and psychometric expertise and test scoring and item analysis (TSIA) services, among others, continue to be funded by distributed administrative costs (pro rata).

6. CONDITIONS UNDER WHICH BOARDS SHOULD USE INTERNAL AND EXTERNAL ENTITIES TO CONDUCT THESE REVIEWS

A board may choose to use external and/or internal resources for licensure examination development and/or review of state and national licensure examinations, and must determine the most logical application of those resources.

OPES is the internal resource for examination review and California-specific examination development services for DCA. OPES also conducts reviews of national examination programs to ensure compliance with California requirements.

If OPES is unable to provide the requested service, external development and review may occur. External examination development or review of a national licensure examination occurs when the board contracts with a qualified private testing firm.

7. STANDARDS FOR DETERMINING APPROPRIATE COSTS OF REVIEWS OF DIFFERENT TYPES OF EXAMINATIONS, MEASURED IN TERMS OF HOURS REQUIRED

The *Standards* provide "a basis for evaluating the quality of testing practices." These criteria can be used to identify tasks that must be performed in the development and validation of a licensure examination. Costs are applied to the performance of each task, based on its difficulty, available technology, and the complexity of the profession.

OPES has a defined fee schedule that is based on the number of hours to complete each phase of the project. An occupational analysis and an examination development project will require different tasks to be performed; therefore, the number of hours varies from one phase to another. The time and tasks required depends on the profession, type of exam, number of forms, frequency of administration, technology resources, and other factors.

8. CONDITIONS UNDER WHICH IT IS APPROPRIATE TO FUND PERMANENT AND LIMITED-TERM POSITIONS WITHIN A BOARD TO MANAGE THESE REVIEWS

Because examinations are critical to the mandate for consumer protection, it is necessary that if a board provides an examination, it should maintain examination support staff. The number of support staff needed is determined by each board's examination requirements and secured through the budget process.

Factors that may affect change in the number of needed staff support include, but are not limited to the following:

- An increase in the number of times an examination is offered.
- A change of method by which an examination is administered, for example:
 - o From paper to computer-based testing administration.
 - o From oral panel to written examination format.
 - o From written-only to the addition of a practical examination.
- A change of examination administration, for example:
 - From a national to a California-based examination, or vice versa.
 - o A change in examination administration vendors.
- A unique circumstance such as a breach of examination security.
- A change in legislative mandates.

B. YEARLY REPORTING REQUIREMENTS

B&P Code section 139 (c) specifies that every regulatory board shall submit to DCA on or before December 1 of each year its method for ensuring that every licensing examination is subject to periodic evaluation. These evaluations must include four components:

- 1. A description of the occupational analysis serving as the basis for the examination.
- 2. Sufficient item analysis data to permit a psychometric evaluation of the items
- 3. An assessment of the appropriateness of prerequisites for admittance to the examination.
- 4. An estimate of the costs and personnel required to perform these functions.

B&P Code section 139 (d) states that the evaluation specified in section 139 (c) may be conducted either by the Board, Bureau, Committee, OPES, or a qualified private testing firm.

OPES compiles this information annually into a report for the appropriate fiscal, policy, and review committees of the Legislature. This report is consolidated into DCA's Annual Report.

VIOLATIONS

Validation ensures that licensing examinations are psychometrically sound, job-related, and legally defensible. Failure to follow the provisions of this policy may result in licensing persons who do not meet the minimum level of competency required for independent and safe practice, exposing California consumers and DCA's regulatory entities to considerable risk of harm by unqualified licensees.

REVISIONS

OPES is responsible for determining whether this policy needs revision; questions regarding revision should be directed to OPES at (916) 575-7240. Specific questions regarding the status or maintenance of this policy should be directed to the Division of Programs & Policy Review at DPPR@dca.ca.gov.

RELATED DOCUMENTS

Departmental Policy Memorandum "Examination Security": OPES 22-01 Departmental Policy "Participation in Examination Workshops": OPES 20-01