

**STATE OF WISCONSIN
PHARMACY EXAMINING BOARD**

**IN THE MATTER OF RULE-MAKING : REPORT TO THE LEGISLATURE
PROCEEDINGS BEFORE THE : ON CLEARINGHOUSE RULE 09-019
PHARMACY EXAMINING BOARD : (s. 227.19 (3), Stats.)**

I. THE PROPOSED RULE:

The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS:

No new or revised forms are required by these rules.

III. FISCAL ESTIMATES:

The department estimates that the proposed rule will have no significant fiscal impact. The department finds that this rule has no significant fiscal effect on the private sector.

IV. DETAILED STATEMENT EXPLAINING THE BASIS AND PURPOSE OF THE PROPOSED RULE, INCLUDING HOW THE PROPOSED RULE ADVANCES RELEVANT STATUTORY GOALS OR PURPOSES:

Under the current rule, the Pharmacy Examining Board administers a practical examination to determine an applicant's competence in compounding and dispensing medications, which includes consultation of patients. The board has determined that this examination is no longer needed because the competencies tested in the examination are also tested in two other national examinations that applicants are required to take in order to obtain a license in Wisconsin.

It was the board's custom over time to review examination performance at each full board meeting for the examination that occurred the day before its meetings. As a result of apparent trends that emerged from these post-examination reviews, the board undertook an analysis of aggregate examination pass rates as it discussed the ongoing need for a practical examination and found rates to be significantly higher for graduates of the University of Wisconsin-Madison than for other pharmacy schools. The board also reviewed experience in other states and found that Wisconsin is one of only four states in the nation that continues to require a practical examination. One of the implications suggested by the board as a result of its review is that the examination creates a barrier to licensure in Wisconsin, and that the benefits of the examination do not justify its costs.

V. NOTICE OF PUBLIC HEARING:

A public hearing was held on April 8, 2009.

The following individuals appeared and spoke in support of the proposed rule-making:

Ken Schaefer, R.Ph., Wausau, WI

Jeremy Levin, Director of Advocacy, Rural Wisconsin Health Cooperative, Sauk City, WI

The following individuals appeared in support of the proposed rule-making:

JoAnne Preston, Rural Wisconsin Health Cooperative

Hilary Maxfield, Appleton, WI

Written comments in support of the proposed rule-making were received from the following:

Prati Wojtal, MS, R.Ph., Manager, Ambulatory Pharmacy Services, Aurora Health Care
Katherine A. Benson, R.Ph. (State of Michigan), Zone Operations Director, Cardinal Health-NPS

Tom Woller, MS, FASHP, Vice President, Pharmacy Services, Aurora Health Care

Ashley Feldt, Pharm.D., Health-System Pharmacy Administration Resident, Aurora Health Care

Sarah Ray, Pharm.D. BCPS, Clinical Coordinator, Ambulatory Care Services, Dept. of Pharmaceutical Services, Aurora Health Care, Milwaukee, WI

Susan K. Bird, Wisconsin Department of Regulation and Licensing, Office of Education and Examinations, Madison, WI, submitted written comments relating to other provisions in ch. Phar 2 that relate specifically to the practical examination and should be included in this proposed rule-making order.

Matthew Mabie, R.Ph., DeForest, WI, appeared to obtain information.

The following individuals appeared and spoke, and also provided written comments, in opposition to the proposed rule-making:

Paul Baum, Group Health Cooperative of South Central Wisconsin, Madison, WI

Cindy Benning, R.Ph., Pharmacy Operations Manager, Columbia-St. Mary's east-side campuses, Milwaukee, WI

Ted Grabarczyk, DPH-3, Wisconsin Society of Pharmacy Students, Student Political Advocacy Network Coordinator, and Leiha Gavin, DPH-3, Wisconsin Society of Pharmacy Students, President, Madison, WI

Bonnie Svarstad, Ph.D., Professor Emerita, UW-Madison School of Pharmacy, WI

Beth A. Martin, R.Ph., Ph.D., Assistant Professor (CHS), University of Wisconsin School of Pharmacy, Madison, WI

Betty Chewning, Ph.D., F.APh.A., Professor, Director Sonderegger Research Center, University of Wisconsin School of Pharmacy, Madison, WI

Kurt Holm, Morton Pharmacy, Neenah, WI, appeared and spoke in opposition to the proposed rule-making.

Written comments in opposition to the proposed rule-making were received from:

Jeanette C. Roberts, Ph.D., M.P.H., Dean and Professor, Pharmaceutical Sciences Division, University of Wisconsin School of Pharmacy, Madison, WI
Patrick Cory, B.S., Pharm.D., Pharmacy Program Director, Unity Health Insurance, Deputy Director, UW-Hospital & Clinics Center for Drug Policy, Sauk City, WI

Tom Engels and Sarah Boyce, Pharmacy Society of Wisconsin, Madison, WI, appeared and took no position on the proposed rule-making.

The Board's Response to Public Comments in Opposition to the Rule

The following is a summary of the major concerns expressed by individuals who submitted comments in opposition to the proposed rules and the board's response:

A. Public Comments

1. Paul Baum, Group Health Cooperative of South Central Wisconsin, Madison, WI

Mr. Baum stated that he believes it is inappropriate to de-emphasize consultation skills when those skills are becoming more important than ever. Eliminating the consultation exam is removing a public safety net at a time when the safety net is more important than ever. There must be assurance of some minimum level of consultation skill.

2. Cindy Benning, R.Ph., Pharmacy Operations Manager, Columbia-St. Mary's Milwaukee, WI

First, Ms. Benning stated that the Multistate Pharmacy Jurisprudence Examination (MPJE) and the North American Pharmacist Licensure Examination (NAPLEX), which are computer adaptive tests, only test knowledge, not skills. They in no way test the communication, interpersonal and interaction skills necessary in a good consultation. Second, the argument that eliminating the exam will bring more pharmacists into the state in rural and underserved city neighborhoods is a guess at best. There is no evidence to suggest or prove that the consultation exam discouraged pharmacists from entering the state to practice.

In addition, data for 2008 from the National Association of Boards of Pharmacy (NABP) shows that more than twice the number of candidates requested transfer of their pharmacy licenses into Wisconsin as requested transfer out. It was noted that Wisconsin had one of the highest levels of unmet demand, which would explain the 118% increase in requests to transfer into the state. Nothing can guarantee that any health care practitioner will choose to practice in

rural or underserved areas of the state. Testimony was given that this is a national problem with many health care professionals and by no means a reflection of the use of the board's consultation exam.

3. Ted Grabarczyk, DPH-3, Wisconsin Society of Pharmacy Students, Student Political Advocacy Network Coordinator, and Leiha Gavin, DPH-3, Wisconsin Society of Pharmacy Students, President, Madison, WI

Mr. Grabarczyk and Ms. Gavin stated, in part, that they believe complete, careful and proper consultation on every prescription works towards the public's best interest by guiding patients how to use their medications safely and effectively. They believe it is important that the board verify competency in this area prior to licensure as a pharmacist.

4. Bonnie Svarstad, Ph.D., Professor Emerita, UW-Madison School of Pharmacy, WI

Dr. Svarstad stated, in part, that the NAPLEX and MPJE examinations do not provide valid or reliability assessment of oral communication skills. An FDA study found that in the 6 states that rely solely on the NAPLEX and MPJE, only 42% of the patients received any oral information. In states that have a separate counseling exam, all patients received some oral counseling and most patients received some discussion of side effects or risks.

Note: No evidence was provided that this increase in communication improved the patient's medication therapy outcome.

5. Beth A. Martin, R.Ph., Ph.D., Assistant Professor (CHS), University of Wisconsin School of Pharmacy, Madison, WI

Dr. Martin opposed the repeal of the practical examination for two reasons. First, although passing the examination does not guarantee adequate and effective consultations during the course of daily practice, it does establish a minimum standard of practice for Wisconsin licensees in a way that cannot be established by using any multiple choice exam. There is significant literature that suggests that direct observation is an effective method to assess professional competency and the ability to translate that skill into practice in comparison to multiple choice exams. She is also concerned about the message that eliminating the consultation exam will send to Wisconsin citizens and the legislators. Will it send the message that consultation is unnecessary? Second, creating an emergency rule claiming that the consultation exam is an impediment to pharmacists seeking careers in Wisconsin seems confounded. Plenty of workforce studies have examined practice behaviors and none, to her knowledge, have identified state regulations and licensure requirements as a reason for workforce shortages.

6. Betty Chewning, Ph.D., F.APhA., Professor, Director Sonderegger Research Center, University of Wisconsin School of Pharmacy, Madison, WI

Dr. Chewning expressed concern that the board was considering repealing the practical examination requirement without input from experts in the field. She also stated that to evaluate

communication skills requires observation exams where the student's actual behavior can be observed. The MPJE and NAPLEX can assess certain knowledge levels, but not the consultation skills needed to promote patient safety. In addition, there is a major paradigm shift for pharmacists to provide more medication therapy monitoring and management as part of Medicare Part D. The communication skills of pharmacists have never been more critical for the safety of our most vulnerable patients. In reference to the shortage of pharmacists, Dr. Chewning stated that invoking the Finding of Emergency seems particularly improper in light of some pharmacy corporations having just laid off about 1,000 pharmacists nationally.

Finally, Dr. Chewning stated that the justification for invoking the Finding of Emergency is inaccurate and insufficient. The Scope Statement formally states, "The board believes that consultation competency is effectively developed in the pharmacy school." Dr. Chewning said that this statement is false. She offered as formal evidence the work of Dr. Carole Kimberlin, professor at the University of Florida who spent her sabbatical at the American Association of Colleges of Pharmacy evaluating curricula on patient consultation and communication of 90 schools of pharmacy. This included site visits, surveys, and interviews. Dr. Kimberlin found that out of 90 schools of pharmacy only 49 (54%) had a course with a focus on patient communication. Of those who integrated communication into their pharmaceutical skills labs, the number of lecture hours devoted to patient communication skills ranged from 0 to 20 with 19 schools reporting 5 or fewer hours.

7. Kurt Holm, Director of Pharmacy, Morton Pharmacy, Neenah, WI

In reference to the practical examination, Mr. Holm stated that Wisconsin is special and he does not want to lose that. He stated that demonstrating knowledge of drugs on a test does not correlate to being a good pharmacist. One cannot measure on a piece of paper how someone will communicate in the real world.

In addition, Mr. Holm stated that if there are problems with the examination, in terms of validity and/or pass rate, the solution is to fix the problems, not eliminate the examination.

8. Jeanette C. Roberts, Ph.D., M.P.H., Dean and Professor, Pharmaceutical Sciences Division, University of Wisconsin School of Pharmacy, Madison, WI

Dean Roberts opposes the proposal to repeal the practical examination. First, in reference to the argument that the current examination is difficult to administer and has not been appropriately developed and validated, she agrees with this assessment. That is the reason she initiated interaction with several experts to assist the Department and overcome those barriers. That effort was unexpectedly and suddenly terminated.

Second, in reference to the argument that the MPJE and NAPLEX assess competency in patient consultation, she does not believe this is an educationally sound conclusion. While there may be questions that relate to consultation on these examinations, assessment of competency in such areas cannot be adequately accomplished without a face-to-face interaction involving a complex case and interpersonal communication.

Third, in reference to the argument that Wisconsin is one of only four states that requires a practical examination for pharmacist licensure, she believes this decline mainly grew out of the diminishing need to assess compounding and dispensing, which is appropriate, but interestingly, remains in the language governing the practical examination in Wisconsin. However, the practice of pharmacy is evolving more and more rapidly toward providing drug and disease state information and therapy management rather than product, necessitating a higher level of competence in the skills examined in the consultation examination.

Finally, Dean Roberts questioned the board invoking the Findings of Emergency because it appears to preclude public input and debate.

9. Patrick Cory, B.S., Pharm.D., Pharmacy Program Director, Unity Health Insurance, Deputy Director, UW-Hospital & Clinics Center for Drug Policy, Sauk City, WI

Dr. Cory states that the board's decision to repeal the practical examination requirement is of great concern to him for two reasons. First, he is concerned because of the ramifications for patient care and the profession of pharmacy. The ability of pharmacists to interact with patients in a meaningful way to improve the quality of their care provides tremendous value to the dispensing process and to his health plan's members. Eliminating the practical examination requirement will undermine this competency within community pharmacies. This decision has taken place at a time when dispensing technology is improving at a rapid pace and patient consultation has been pushed to the forefront of pharmacy practice.

Dr. Cory further stated that if the rationale for eliminating the examination relates to the inadequacy of the examination, he would prefer to see the examination revised rather than eliminated. In reference to the belief that the standardized examinations (NAPLEX and MPJE) assess patient consultation competency, some students are "book smart," but are not able to effectively communicate with patients. These students will likely do very well on the standardized tests; however, he does not believe they should be licensed as pharmacists until they learn the skills necessary to communicate directly with patients.

In addition, Dr. Cory stated that it is true that most other states do not require the practical examination, but Wisconsin has always been a leader in the practice of pharmacy. His vote would be to maintain the high standard that has always set Wisconsin apart.

Finally, Dr. Cory is concerned about the process used by the board to arrive at the "emergency" decision without the opportunity for public input. His expectation is that the board would not only accept public comments during the decision-making process, but would view public input as an essential ingredient used in forming effective policy decisions.

B. The Board's Response

The board's response to the public comments received in opposition to the elimination of the practical examination is as follows:

1. The Board provided ample opportunity for public input.

The procedures followed by the board in revising its rules to eliminate the practical examination provided more than an ample opportunity for public input.

First, the board discussed its intent to eliminate the practical examination at three board meetings prior to the effective date of the emergency rules on February 28, 2009. Several of the individuals who appeared at the public hearing on the rules, also submitted written comments in opposition to the rule at the meetings when the board discussed its intent to eliminate the examination. In addition, all three board meetings had “Public Comments” as an agenda item. No comments were offered at any of the board meetings.

Second, the public hearing on the proposed rules, which was held on April 8, 2009, provided an opportunity for public input. The public hearing is part of the procedure adopted by the Legislature, which is codified in Wis. Stats. ch. 227, to ensure public input in the rule-making process. In addition, the comment period for submission of public comments was held open until April 13, 2009.

2. Colleges and schools of pharmacy are responsible for testing communication and patient consultation skills.

There were two major concerns raised by opponents to the elimination of Wisconsin’s practical examination requirement, commonly referred to as the consultation exam. First, the need for the Pharmacy Examining Board to test a candidate’s communication skills. Second, the need for the board to test a candidate's patient consultation skills.

A. The role of the Board

Under the current rule, the board administers a practical examination to determine a candidate's competence in compounding and dispensing medications, which includes consultation of patients. The board has determined that this examination is no longer needed because the competencies tested in the examination are also tested in two other examinations that applicants are required to take in order to obtain a license in Wisconsin.

B. The role of Colleges and Schools of Pharmacy

It is the opinion of the board that the colleges and schools of pharmacy are responsible for ensuring that graduates have adequate communication and patient consultation skills prior to granting a Doctor of Pharmacy degree.

State boards of pharmacy require that licensure applicants from the United States have graduated from an accredited pharmacy degree program to be eligible to sit for the North American Pharmacist Licensure Examination (NABP’s NAPLEX®). Colleges and schools of pharmacy are required to meet the standards and guidelines established by the Accreditation Council For Pharmacy Education (ACPE) in order to be accredited. The following are relevant

provisions taken from ACPE's Standards and Guidelines For The Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree, effective July 1, 2007:

Standard No. 12 and 13 read, in part, as follows:

Standard No. 12: Professional Competencies and Outcome Expectations

Excerpts from Guideline 12.1

Graduates must possess the basic knowledge, skills, attitudes, and values to practice pharmacy independently at the time of graduation.

Pharmacy graduates must be able to:

- communicate and collaborate with patients, care givers, physicians, nurses, and other health care providers, policy makers, members of the community, and administrative and support personnel to engender a team approach to patient care.
- retrieve, analyze, and interpret the professional, lay, and scientific literature to provide drug information and counseling to patients, their families or care givers, and other involved health care providers.

Standard No. 13: Curricular Core - Knowledge, Skills, Attitudes, and Values

Excerpts from Guideline 13.3

The college or school curriculum should address issues that cut across a number of topics, such as communication skills, professionalism, critical thinking, problem solving, health and wellness, patient safety, teamwork, mathematical skills, and information management.

3. Protection of the Public

The board's primary function is to provide protection to the public. This function is accomplished in several ways.

First, the board requires all applicants to take and pass two examinations that are designed to establish their competence to practice pharmacy in the state of Wisconsin. Wis. Stats. § 450.04 (3) and Wis. Admin. Code, ch. Phar 4.

In Wis. Admin. Code § Phar 4.02, the board has determined that the following examinations test the competency of applicants to engage in the practice of pharmacy:

Phar 4.02 Competencies tested. Competencies are tested by examination as follows:

- (1) The multi-state pharmacy jurisprudence examination shall determine an applicant's competence to practice

within federal laws and regulations and Wisconsin laws and rules governing the practice of pharmacy.

(2) The practical examination shall determine an applicant's competence in compounding and dispensing medications, which includes consultation of patients.

(3) NAPLEX shall determine an applicant's competence in the basic principles and professional areas within the practice of pharmacy.

Based upon its review of the contents of the Multistate Pharmacy Jurisprudence Examination (MPJE) and the North American Pharmacist Licensure Examination (NAPLEX), the board concluded that both of these examinations test competencies that relate to subject areas that are also tested in the practical examination. This conclusion is also supported by the Department's Examination Specialist who opined that the NAPLEX meets all the necessary patient consultation criteria.

Second, the board provides protection to the public by requiring all pharmacists to provide a patient consultation for all new and refill prescriptions dispensed. Refer to Wis. Admin. Code § Phar 7.01 (1) (e). Violations of this provision may constitute unprofessional conduct under Wis. Admin. Code § Phar 10.03. This requirement will remain in effect even after the practical examination is eliminated.

4. The board's attempt to improve the consultation exam

The board recognized the patient consultation exam needed improvement as early as December 2004. Over the course of two plus years the board, with the support of UW-Madison School of Pharmacy and UW-Madison Medical School staff, attempted to improve the exam. A new exam format was created, tested and ultimately used in a "live" exam. The new format, even after revision, produced unacceptable failure rates.

Between December 2004 and February 2008, there was a complete turnover of board members. New board members questioned the need for the patient consultation exam like past board members had. Over time the board moved to eliminate the practical examination requirement.

5. Wisconsin's pharmacist shortage

There is a pharmacist shortage in Wisconsin.

One of the four key findings of The Wisconsin Hospital Association's 2008 Workforce Report states, "Pharmacist positions remain difficult to fill in Wisconsin hospitals. Increasing use of medications and the need for professional assistance with managing medication regimens increases the need for pharmacists, while the long educational timeline reduces supply."

The National Association of Chain Drug Stores' 2008 Chain Pharmacy Employment Survey Results documented Wisconsin's pharmacist shortage ranked ninth nationally. On a scale of 1-5 where 1 equals large shortage, 3 equals about right and 5 equals large oversupply, Wisconsin scored 1.75. The pharmacist shortage was less severe in all states bordering Wisconsin (Minnesota 2.28, Iowa 2.36, Illinois 2.51 and Michigan 2.67). None of the states that border Wisconsin have a practical examination requirement.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 2. It is assumed that the rule is intended, when it becomes effective, to apply to an applicant for licensure regardless at what stage the applicant is in the application process. For example, if an applicant is scheduled to take the practical examination but the rule takes effect before the date of the examination, the applicant will not be required to take the scheduled exam. If that is not the intent, an "initial applicability" provision should be considered.

Response: The assumption is correct. When the rule becomes effective it will apply to an applicant for licensure regardless of what stage the applicant is in the application process. Therefore, it is not necessary for the board to consider including an "initial applicability" provision in the rule or to make any changes to the rule.

VII. FINAL REGULATORY FLEXIBILITY ANALYSIS:

These rules will have no significant economic impact on small businesses, as defined in s. 227.114 (1), Stats.