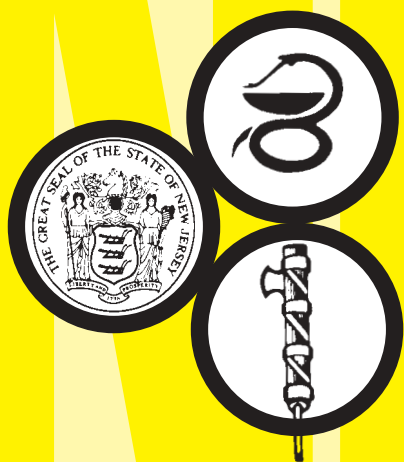


July 2003



New Jersey Board of Pharmacy

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124 Halsey St, 6th Floor
Newark, NJ 07101
www.state.nj.us/lps/ca/boards.htm

Published to promote voluntary compliance of pharmacy and drug law.

New Continuing Education Regulations

On March 17, 2003, new continuing education (CE) regulations were adopted. The new regulations became effective with the license renewal period beginning May 1, 2003. Key changes include a requirement that at least 10 of the CE credits shall be obtained through didactic instruction, and provisions for CE credit for activities such as preceptor participation in an externship program and graduate course work relevant to the practice of pharmacy.

Full text of the adoption follows:

N.J.A.C. 13:39-3A.1 Continuing education credit hour requirements

- (a) Each applicant for biennial license renewal shall complete a minimum of 30 credits of continuing education during the preceding biennial period, except that the Board shall not require completion of continuing education credits for an applicant's initial license renewal. At least 10 of the continuing education credits shall be obtained through didactic instruction. For purposes of this paragraph, "didactic instruction" means in-person instruction and may include telephonic or electronic instruction that is interactive, but shall not include videotaped instruction.
- (b) Ten credits of continuing education may be carried over into a succeeding biennial period only if such credits were earned during the last six months of the preceding biennial period and were not previously reported.

N.J.A.C. 13:39-3A.2 Criteria for continuing education credit

- (a) A licensee may obtain continuing education credit from the following categories:

1. Programs or courses offered by American Council on Pharmaceutical Education approved providers;
2. Programs and courses that have received prior Board approval pursuant to N.J.A.C. 13:39-3A.6;
3. Graduate course work relevant to the practice of pharmacy, taken at an accredited college or university, beyond that required for professional licensure;
4. Participation in teaching and/or research appointments;
5. Participation as a preceptor in externship programs;
6. Participation as a preceptor in internship programs; and
7. Publication of an article related to the practice of pharmacy in a peer-reviewed professional journal.

N.J.A.C. 13:39-3A.3 Continuing education credit hour calculations

- (a) Credit for continuing education shall be granted as follows for each biennial license period:
 1. Attendance at approved programs or courses shall be granted one credit for each hour of attendance. Credit shall not be granted for programs or courses which are less than one contact hour in duration, which is defined as 50 minutes of actual attendance in a program or course of study. One half credit shall be granted for each 30 minute segment of a program or course that is more than one contact hour in duration. Completion of an entire program or course is required in order to receive any continuing education credit for the program or course.
 2. Successful completion of graduate course work related to the practice of pharmacy at an accredited college or university beyond that which is required for professional licensure shall be granted three continuing education credits for each course credit awarded.

3. Teaching and research appointments related to the practice of pharmacy shall be granted three continuing education credits for each new program or course taught or subject matter researched by a licensee, to a maximum of six credits. "New," in this paragraph, means a program, course or subject matter which the licensee has never taught or researched before in any educational or practice setting. A licensee who is employed as a teacher and/or as a researcher on a full-time basis shall not be eligible to obtain continuing education credit for such activities.
 4. Participation as a preceptor in an externship program, upon prior approval by a college of pharmacy, shall be granted three continuing education credits per student to a maximum of six credits.
 5. Participation as a preceptor in an internship program shall be granted three continuing education credits per 160 hours of work performed by the intern(s) and supervised by the licensee, to a maximum of six credits.
 6. Publication of an article related to the practice of pharmacy in a peer-reviewed professional journal shall be granted three continuing education credits per article to a maximum of six credits.
- (b) The Board shall not grant credit for, or approve as a component of a continuing education program, participation in the routine business portion of any meeting of a pharmaceutical organization or any presentation that is offered to sell a product or promote a business enterprise.

N.J.A.C. 13:39-3A.4 Continuing education credit hour reporting procedure

- (a) A licensee shall specify on his or her application for biennial license renewal the number of continuing education credits completed. Falsification of any information contained in the renewal application may result in an appearance before the Board and the assessment of penalties and/or license suspension pursuant to N.J.S.A. 45:1-21 et seq.
- (b) A licensee shall maintain all documentation concerning the completion of continuing education requirements for a period of five years from the completion of the credit hours and shall submit such documentation to the Board upon request. Such documentation shall consist of:
 1. For programs offered by American Council on Pharmaceutical Education approved providers, a certificate of completion from the course or program;
 2. For programs and courses approved by the Board, the sponsors' written verification of attendance;
 3. For teaching or research appointments in an academic setting, a statement from the chairperson

of the department verifying completion of the assignment;

4. For research appointments in an industrial setting, a statement from the project coordinator verifying completion of the assignment;
 5. For participation as a preceptor in an externship program, a certificate from the college of pharmacy;
 6. For participation as a preceptor in an internship program, a certificate from the Board; and
 7. For publications in a peer-reviewed professional journal, submission of the published article.
- (c) The Board shall audit licensees on a random basis at the end of each biennial period to determine compliance with continuing education requirements.

N.J.A.C. 13:39-3A.5 Waiver of continuing education requirements

- (a) The Board may waive continuing education requirements on an individual basis for reasons of military service, hardship, illness or disability.
- (b) A licensee seeking a waiver of continuing education requirements shall apply to the Board in writing and set forth with specificity the reasons for requesting the waiver. The licensee shall also provide the Board with such additional information as the Board may request in support of the application for waiver.
- (c) A waiver of continuing education requirements granted pursuant to this section shall be effective only for the biennial period in which such waiver is granted. If the condition(s) which necessitated the waiver continues into the next biennial period, a licensee shall apply to the Board for a renewal of such waiver for the new biennial period.

N.J.A.C. 13:39-3A.6 Responsibilities of continuing education sponsors

- (a) A continuing education sponsor shall receive prior Board approval for a program or course if the sponsor provides, in writing on a form provided by the Board, information which demonstrates that the program or course meets the following requirements:
 1. The program or course is offered in a subject matter relevant to the practice of pharmacy;
 2. The program or course is at least one contact hour in length; and
 3. The program or course is conducted by a qualified instructor or discussion leader who submits a curriculum vitae and who is:
 - i. A pharmacist with a B.S. in Pharmacy or a Pharm. D. with at least five years of experience;
 - ii. A pharmacist with a B.S. in Pharmacy or a Pharm. D. with expertise in the program or course subject area;

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- iii. A pharmacist with a B.S. in Pharmacy or a Pharm. D. who is certified by a nationally recognized board or association; or
 - iv. A licensed health care professional who demonstrates special expertise in the lecture subject area.
- (b) A continuing education sponsor may request approval for a program or course conducted by an individual who possesses expertise in a subject area relevant to the practice of pharmacy, provided that the program or course to be conducted by that individual satisfies the requirements of (a)1 and 2 above.
 - (c) Applications for pre-approval of continuing education programs or courses shall be submitted by the continuing education sponsor on a form provided by the Board at least 45 days prior to the date the program or course is to be offered. Incomplete applications shall be returned to the sponsor.
 - (d) The Board shall approve only such continuing education programs and courses as are available and advertised on a reasonable nondiscriminatory basis to all persons licensed to practice pharmacy in the State. The Board shall maintain a list of all approved programs and courses at the Board office and shall furnish the list to licensees upon request.
 - (e) A continuing education sponsor shall not make substantive changes to an approved program or course, such as a change in program or course content or instructor, without prior Board approval.
 - (f) The continuing education sponsor shall monitor attendance at, or ensure completion of, each approved program or course and furnish to each enrollee a verification of attendance which shall include at least the following information:
 1. The title, date and location of the program or course offering;
 2. The name of the program or course presenter;
 3. The name and certificate number of the program or course presented;
 4. The number of continuing education credits awarded; and
 5. The name, address, telephone number and signature of the sponsor, or if the sponsor is an association or organization, the signature of an officer or responsible party of the association or organization.
 - (g) The continuing education sponsor shall submit the fee set forth at N.J.A.C. 13:39-1.3(a)1xii for each submission of program or course offerings.
 - (h) The continuing education sponsor shall maintain a list of all attendees who completed each approved program or course for a period of five years from the date the program or course was offered.

N.J.A.C. 13:39-3A.7 Monitoring of continuing education programs or courses

A Board member or a Board representative may monitor an approved program or course without prior notification to the continuing education sponsor.

Dispensing Multiple Strength Product Formulations

Enforcement Bureau inspection reports reflect that many pharmacists are not properly ascertaining what strength medication the prescriber intended when multi-strength and/or combination product formulations such as APAP with codeine, APAP with oxycodone, APAP with hydrocodone, and ASA with oxycodone are presented for filling with no strength(s) indicated. For example, prescriptions presented for Percocet® and Endocet® without the amount of oxycodone and APAP indicated require the pharmacist to contact the prescriber, then notate on the prescription the information obtained. Dispensing the most commonly prescribed strength without consulting the prescriber could harm the patient, and it subjects the pharmacist to fines for violation of several pharmacy statutes.

Changes Pharmacists Can Make to a Schedule II Prescription

The majority of changes to a Schedule II prescription can be made only after the pharmacist contacts the prescribing practitioner. The pharmacist is permitted to change the patient's address, drug strength, drug quantity, drug dosage form, and directions for use. The pharmacist may add information such as the patient's address. The pharmacist is never permitted to make changes to the patient's name, controlled substance prescribed (except to substitute a generic), or the prescriber's signature. These types of changes challenge the necessity of the original prescription and would require a new prescription from the prescribing physician. After consulting with the prescriber, the pharmacist must document any changes made including the time, date, and his/her signature. Documentation on the prescription is the pharmacist's account of the changes made. These changes should match what appears in the patient's chart at the prescriber's practice site if the address, dosage form, drug strength, quantity, or the directions for use are changed.

DATA and Buprenorphine

The Drug Addiction Treatment Act of 2000 (DATA) is an amendment to the Controlled Substance Act, and allows certain physicians to prescribe and dispense a schedule III, IV, or V opioid treatment drug, approved by Food and Drug Administration (FDA), for maintenance or detoxification treatment.

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Buprenorphine is a semi-synthetic opiate and has been available since 1985 (Buprenex[®]) as an injectable for the treatment of moderate to severe pain. Because of its agonist effects, buprenorphine is abusable, particularly by individuals who are not physically dependent on opioids. In 2002 Drug Enforcement Administration (DEA) reclassified buprenorphine from a Schedule V to Schedule III narcotic due to evidence regarding potential for abuse, diversion, dependence, and side effects.

Buprenex[®], Temgesic[®], and other generic formulations of buprenorphine are not approved for opiate addiction treatment. Only buprenorphine formulated for oral use has been approved by FDA for use under DATA. Two formulations, **Subutex[®]** (buprenorphine HCL sublingual tablet) and **Suboxone[®]** (buprenorphine HCL/naloxone HCL dihydrate sublingual tablet) were approved in October 2002, and are now available for office-based treatment of opioid dependence. The naloxone/buprenorphine combination is designed to decrease the potential for abuse by injection by actively using opioid users.

DATA imposes limits on patients and eligible physicians. For physicians, the total number of opioid-dependent patients for a practitioner or group cannot exceed 30. Physicians must meet special training criteria and be able to provide appropriate services. Physicians are required to obtain waivers to prescribe buprenorphine (Subutex and Suboxone) for opioid ad-

diction. Physicians should include their DATA waiver identification (ID) number on all opioid addiction treatment medications. The ID number is similar to the prescriber DEA number. The waiver number begins with an X rather than an A (ie, XB1234569). If the waiver number does not appear on the prescription pharmacists can go online to www.buprenorphine.samhsa.gov and check the physician locator or call 1-866/287-2728 to verify that the physician is authorized to prescribe buprenorphine for opioid addiction. (Note: The physician locator does not list every physician with a waiver, only those who have agreed to be listed on the site.)

For more information about buprenorphine, visit www.buprenorphine.samhsa.gov.

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The *New Jersey Board of Pharmacy News* is published by the New Jersey Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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