

45:14-15.1

LEGISLATIVE HISTORY CHECKLIST
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(Pharmacists--review of
new prescriptions)

NJSA: 45:14-15.1

LAWS OF: 1993 **CHAPTER:** 120

BILL NO: S793

SPONSOR(S) Cardinale and others

DATE INTRODUCED: May 14, 1992

COMMITTEE: **ASSEMBLY:** ---
SENATE: Commerce

AMENDED DURING PASSAGE: Yes Amendments during passage
First reprint enacted denoted by superscript numbers

DATE OF PASSAGE: **ASSEMBLY:** November 30, 1992 Re-enacted 5-20-93
SENATE: June 18, 1992 Re-enacted 5-13-93

DATE OF APPROVAL: May 27, 1993

FOLLOWING STATEMENTS ARE ATTACHED IF AVAILABLE:

SPONSOR STATEMENT: Yes

COMMITTEE STATEMENT: **ASSEMBLY:** No
SENATE: Yes

FISCAL NOTE: No

VETO MESSAGE: Yes

MESSAGE ON SIGNING: No

FOLLOWING WERE PRINTED:

REPORTS: No

HEARINGS: No

See newspaper clipping-attached:
"New law will require all druggists to counsel patients," 5-28-93 Star
Ledger.

KBG:pp

STATE OF NEW JERSEY

INTRODUCED MAY 14, 1992

By Senators CARDINALE, HAINES,
Assemblymen Moran and Impreveduto

1 AN ACT concerning certain responsibilities of pharmacists and
2 supplementing chapter 14 of Title 45 of the Revised Statutes.

3

4 BE IT ENACTED *by the Senate and General Assembly of the*
5 *State of New Jersey:*

6 1. a. A pharmacist shall conduct a prospective drug review
7 before each new prescription is dispensed or delivered to a
8 patient or a person acting on behalf of the patient. The review
9 shall include screening for potential drug therapy problems due to:

10 (1) therapeutic duplication;

11 (2) drug-disease contraindications ¹to the extent the diagnosis
12 information is available¹ ;

13 (3) drug-drug interactions, including serious interactions with
14 nonprescription or over-the-counter drugs;

15 (4) incorrect drug dosage or duration of drug treatment;

16 (5) drug-allergy interactions; and

17 (6) clinical abuse or misuse.

18 b. A pharmacist may conduct a prospective drug review in
19 accordance with the provisions of this section before refilling a
20 prescription to the extent he deems appropriate in his
21 professional judgment.

22 2. a. A pharmacist shall offer to counsel any person who
23 presents a new prescription for filling. The offer to counsel may
24 be made in any manner the pharmacist deems appropriate in his
25 professional judgment, and ¹[may] shall¹ include any one or a
26 combination of the following:

27 (1) Face-to-face communication with the pharmacist;

28 (2) ¹[A sign posted in such a manner that it can be seen by
29 patients or customers;

30 (3) A notation affixed to or written on the bag in which the
31 prescription is delivered;

32 (4) A notation affixed to or written on the prescription
33 container; or

34 (5) Face-to-face communication with ancillary personnel; or

35 (3)¹ By telephone.

36 For the purpose of Medicaid or other third-party
37 reimbursement or payment programs, any of the above methods,
38 or a combination of them, shall constitute an acceptable offer to
39 provide counseling except to the extent this subsection is
40 inconsistent with regulations promulgated by the federal Health
41 Care Financing Administration pursuant to 42 U.S.C. §1396r-8
42 (g)(2)(A)(ii).

EXPLANATION--Matter enclosed in bold-faced brackets [thus] in the
above bill is not enacted and is intended to be omitted in the law.

Matter underlined thus is new matter.

Matter enclosed in superscript numeral's has been adopted as follows:

¹ Senate amendments adopted in accordance with Governor's
recommendations March 20, 1993.

1 b. ¹If, in the professional judgment of the pharmacist, it is
2 inappropriate to verbally make the offer to counsel, the offer to
3 counsel may be made in a written communication.

4 c.¹ A pharmacist may offer to counsel any person who
5 receives a refill prescription in accordance with the provisions of
6 this section to the extent he deems appropriate in his professional
7 judgment.

8 ¹[c.] d.¹ If the offer to counsel is accepted, the pharmacist
9 shall counsel the person presenting the prescription to the extent
10 the pharmacist deems appropriate in his professional judgment.
11 Counseling shall be performed by the pharmacist himself and
12 may, but need not, include the following:

13 (1) The name and description of the medication;

14 (2) The dosage form, dosage, route of administration, and
15 duration of drug therapy;

16 (3) Special directions and precautions for preparation,
17 administration, and use by the patient;

18 (4) Common adverse or severe side effects or interactions and
19 therapeutic contraindications that may be encountered, including
20 their avoidance, and the action required if they occur;

21 (5) Techniques for self-monitoring drug therapy;

22 (6) Proper storage;

23 (7) Prescription refill information; and

24 (8) Action to be taken in the event of a missed dose.

25 ¹[d.] e.¹ Nothing in this section shall be construed as requiring
26 a pharmacist to provide counseling when the person presenting
27 the prescription fails to accept the pharmacist's offer to
28 counsel. If the prescription is filled for a person residing outside
29 of the local telephone calling area of the pharmacy, the
30 pharmacist shall either provide a toll-free telephone number or
31 accept reasonable collect calls from the person.

32 3. a. ¹[A pharmacist shall make reasonable efforts to obtain.
33 record and maintain the following patient information generated
34 at the individual pharmacy:

35 (1) Name, address, telephone number, date of birth or age, and
36 gender;

37 (2) Individual history where significant, including known
38 allergies and drug reactions, and a comprehensive list of
39 medications and relevant devices; and

40 (3) Any additional comments relevant to the patient's drug use,
41 including any failure to accept the pharmacist's offer to counsel.

42 b.] A patient profile system must be maintained by all
43 pharmacies for persons for whom prescriptions are dispensed.
44 The patient profile record system shall be devised so as to enable
45 the immediate retrieval of information necessary to enable the
46 dispensing pharmacist to identify previously dispensed medication
47 at the time a prescription is presented for dispensing. One
48 profile record may be maintained for members of a family living
49 at the same address and possessing the same family name.

50 b. The following information generated at the individual
51 pharmacy shall be recorded in the patient profile system:

52 (1) The family name and the first name of the person for whom
53 the medication is intended (the patient);

54 (2) The address and telephone number of the patient;

- 1 (3) Indication of the patient's age, birth date or age group
2 (infant, child, adult) and gender;
3 (4) The original or refill date the medication is dispensed and
4 the initials of the dispensing pharmacist, if said initials and such
5 date are not recorded on the back of the original prescription or
6 in any other record approved by the New Jersey State Board of
7 Pharmacy;
8 (5) The number or designation identifying the prescription;
9 (6) The prescriber's name;
10 (7) The name, strength and quantity of the drug dispensed;
11 (8) Individual history where significant, including known
12 allergies and drug reactions, and a comprehensive list of
13 medications and relevant devices; and
14 (9) Any additional comments relevant to the patient's drug use,
15 including any failure to accept the pharmacist's offer to counsel.

16 c.¹ The information obtained shall be recorded in the patient's
17 manual or electronic profile, or in the prescription signature log,
18 or in any other system of records, and may be considered by the
19 pharmacist in the exercise of his professional judgment
20 concerning both the offer to counsel and content of counseling.
21 The absence of any record of a failure to accept the pharmacist's
22 offer to counsel shall be presumed to signify that the offer was
23 accepted and that the counseling was provided.

24 4. The provisions of this act shall not apply to any drug
25 dispensed to an inpatient of a hospital or nursing home, except to
26 the extent required by regulations promulgated by the federal
27 Health Care Financing Administration implementing 42 U.S.C. §
28 1396r-8 (g)(2)(A).

29 5. This act shall take effect on the 90th day following the date
30 of enactment.

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35 Establishes standards for drug review program by pharmacists in
36 compliance with federal Medicaid requirements.

1 counsel the person presenting the prescription to the extent the
2 pharmacist deems appropriate in his professional judgment.
3 Counseling shall be performed by the pharmacist himself and
4 may, but need not, include the following:

- 5 (1) The name and description of the medication;
- 6 (2) The dosage form, dosage, route of administration, and
7 duration of drug therapy;
- 8 (3) Special directions and precautions for preparation,
9 administration, and use by the patient;
- 10 (4) Common adverse or severe side effects or interactions and
11 therapeutic contraindications that may be encountered, including
12 their avoidance, and the action required if they occur;
- 13 (5) Techniques for self-monitoring drug therapy;
- 14 (6) Proper storage;
- 15 (7) Prescription refill information; and
- 16 (8) Action to be taken in the event of a missed dose.

17 d. Nothing in this section shall be construed as requiring a
18 pharmacist to provide counseling when the person presenting the
19 prescription fails to accept the pharmacist's offer to counsel. If
20 the prescription is filled for a person residing outside of the local
21 telephone calling area of the pharmacy, the pharmacist shall
22 either provide a toll-free telephone number or accept reasonable
23 collect calls from the person.

24 3. a. A pharmacist shall make reasonable efforts to obtain,
25 record and maintain the following patient information generated
26 at the individual pharmacy:

- 27 (1) Name, address, telephone number, date of birth or age, and
28 gender;
- 29 (2) Individual history where significant, including known
30 allergies and drug reactions, and a comprehensive list of
31 medications and relevant devices; and
- 32 (3) Any additional comments relevant to the patient's drug use,
33 including any failure to accept the pharmacist's offer to counsel.

34 b. The information obtained shall be recorded in the patient's
35 manual or electronic profile, or in the prescription signature log,
36 or in any other system of records, and may be considered by the
37 pharmacist in the exercise of his professional judgment
38 concerning both the offer to counsel and content of counseling.
39 The absence of any record of a failure to accept the pharmacist's
40 offer to counsel shall be presumed to signify that the offer was
41 accepted and that the counseling was provided.

42 4. The provisions of this act shall not apply to any drug
43 dispensed to an inpatient of a hospital or nursing home, except to
44 the extent required by regulations promulgated by the federal
45 Health Care Financing Administration implementing 42 U.S.C. §
46 1396r-8 (g)(2)(A).

47 5. This act shall take effect on the 90th day following the date
48 of enactment.

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51 STATEMENT

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53 This bill establishes the standards for a drug use review
54 program to be carried out by pharmacists in order to meet

1 federal requirements for continued participation in the Medicaid
2 outpatient prescription program. Changes made to the federal
3 law by the "Omnibus Budget Reconciliation Act of 1990" ("OBRA
4 '90") require that, no later than January 1, 1993, states must
5 provide for a drug use review program to assure that
6 prescriptions are appropriate, medically necessary and are not
7 likely to result in adverse medical results. While the bill is a
8 result of this federal mandate, it is not limited in scope to
9 persons receiving Medicaid benefits and would supplement State
10 law regulating the practice of pharmacy to apply generally to all
11 prescriptions filled on an outpatient basis by a pharmacist.

12 The bill provides that a pharmacist shall conduct a prospective
13 drug review before each new prescription is dispensed or
14 delivered to a patient or a person acting on behalf of the patient,
15 which review shall include screening for potential drug therapy
16 problems due to therapeutic duplication, drug-disease
17 contraindications and interaction with other prescription or
18 over-the-counter drugs which the individual may be taking. The
19 bill further provides that a pharmacist shall offer to counsel any
20 person who presents a new prescription for filling in any one of
21 several ways, including face-to-face communication, a notation
22 affixed to or written on the bag in which the prescription is
23 delivered, or by telephone. If the prescription is filled for a
24 person residing outside of the local telephone calling area of the
25 pharmacy, the pharmacist shall either provide a toll-free
26 telephone number or accept reasonable collect calls from the
27 person.

28 If the offer to counsel is accepted, counseling shall be
29 performed by the pharmacist himself and may include such
30 matters as: the name and description of the medication; the
31 dosage and duration of drug therapy; common or severe side
32 effects or interactions and the action required if they occur;
33 proper storage; refill information; and action to be taken in the
34 event of a missed dose.

35 Finally, the bill requires pharmacists to maintain relevant
36 patient information profiles to be considered in both the offer to
37 counsel and the content of any counseling provided.

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42 Establishes standards for drug review program by pharmacists in
43 compliance with federal Medicaid requirements.

SENATE COMMERCE COMMITTEE

STATEMENT TO

SENATE, No. 793

STATE OF NEW JERSEY

DATED: JUNE 1, 1992

The Senate Commerce Committee reports favorably Senate Bill No. 793.

This bill requires a pharmacist to conduct a prospective drug review before a new prescription is dispensed or delivered to a patient, which review must include screening for potential drug therapy problems due to therapeutic duplication; drug-disease contraindications; drug-drug interactions, including serious interactions with nonprescription or over-the-counter drugs; incorrect drug dosage or duration of drug treatment; drug-allergy interactions; and clinical abuse or misuse. A pharmacist may also conduct a prospective drug review before refilling a prescription.

The bill further requires that a pharmacist must offer to counsel a person who presents a new prescription for filling in any one of several ways, including face-to-face communication, a sign in the pharmacy, a notation on the bag in which the prescription is delivered, or by telephone. If the offer to counsel is accepted, counseling must be performed by the pharmacist himself and may include: the name and description of the medication; dosage form, dosage, route of administration, and duration of drug therapy; special directions and precautions for preparation, administration and use by the patient; common adverse or severe side effects or interactions and the action required if they occur; techniques for self-monitoring drug therapy; proper storage; refill information; and action to be taken in the event of a missed dose. A pharmacist may also offer to counsel a person who receives a refill prescription. If the prescription is filled for a person residing outside of the local telephone calling area of the pharmacy, the pharmacist must either provide a toll-free telephone number or accept reasonable collect calls from the person.

Finally, the bill requires a pharmacist to make reasonable efforts to obtain and maintain relevant patient information profiles to be considered in both the offer to counsel and the content of any counseling provided.

The provisions of the bill do not apply to any drug dispensed to an inpatient of a hospital or nursing home.

SENATE BILL NO. 793

To the Senate:

Pursuant to Article V., Section I, Paragraph 14 of the New Jersey Constitution, I herewith return Senate Bill No. 793 with my recommendations for reconsideration.

The federal Omnibus Budget Reconciliation Act of 1990 (OBRA 90) requires every state to establish standards for a drug use review program and for pharmacist counseling for Medicaid recipients in order to meet requirements for continued participation in the Medicaid outpatient prescription program. This bill would supplement the Pharmacy Act (N.J.S.A. 45:14-1 et seq.) by mandating that a pharmacist conduct a prospective drug review for all patients before each new prescription is dispensed to screen for potential drug therapy problems.

In the case of a prescription to be refilled, the bill allows the pharmacist to use his professional judgment to determine whether a prospective review is appropriate. In addition, this bill provides that a pharmacist shall "offer to counsel" any person who presents a new prescription for filling in any one of several ways, including face-to-face communication, a notation affixed to or written on the bag in which the prescription is delivered, or by telephone. Under the bill, if a prescription is delivered to a person residing outside of the local telephone calling area of the pharmacy, the pharmacist shall make the "offer to counsel" by affixing a note to or writing a note on the bag in which the prescription is delivered. The pharmacist must also provide a toll-free telephone number or accept reasonable collect calls from

any person desiring counseling. The bill does not require a pharmacist to provide such counseling if the customer fails to accept the offer. If, however, the "offer to counsel" is accepted, the bill requires that the counseling be performed by the pharmacist himself. The bill requires pharmacists to maintain relevant patient information profiles to be considered in both the offer to counsel and the content of any counseling provided. Finally, the bill exempts hospitals and nursing homes from mandatory pharmacist counseling.

The current New Jersey Board of Pharmacy regulations (Board regulations) are generally consistent with OBRA 90 requirements for prospective drug reviews and patient counseling. I am, however, pleased to see that this bill supplements State law by requiring drug use review programs and patient counseling for all individuals and not just those receiving Medicaid benefits. This expansion of State law will ensure a consistent level of care for all patients.

Although I strongly agree with the intent of this bill to establish standards for a drug use review program and for pharmacist counseling of all patients, I believe that this bill weakens present pharmacy practice as governed by existing State Board of Pharmacy regulations (Board regulations). For this reason, there are several aspects of this legislation with which I must take exception.

First, State Board regulations currently require a pharmacist to maintain a Patient Profile System for the purpose of recording significant individual history, i.e., known allergies drug reactions and a comprehensive list of medications and relevant devices for all whom prescriptions are dispensed. This bill would relax the Board's regulations because it would not require a pharmacist to maintain as much information on each patient as the Board's regulations require. This bill therefore would benefit if it were amended to require pharmacists to record in the Patient Profile Record System, the same patient information that the Board's current regulations require be recorded in the Patient Profile Record System.

Second, OBRA 90 would allow ancillary personnel to extend to the patient the offer to receive counseling if the pharmacist chooses

not to make the offer to the patient directly. Under OBRA 90 the actual counseling, however, can only be performed by a pharmacist. This bill limits the "offer to counsel" to the pharmacist only and needs to be expanded to include ancillary personnel.

Third, the bill does not provide for situations where it is inappropriate or unnecessary to verbally make the offer to counsel. This bill would benefit by an amendment to include language to: (a) take into account the delivery of prescriptions to the home by delivery persons and not the pharmacist; (b) handle language barriers experienced in many neighborhoods by providing written "offers to counsel" in various foreign languages; and (c) provide for the mail order prescription "offer to counsel."

Finally, as written, the bill makes it appear that the information recorded in the Patient Profile System by the dispensing pharmacist will be able to be retrieved by any pharmacist at any pharmacy location. The bill should be amended to clarify that the information recorded by the dispensing pharmacist in the Patient Profile System will only be able to be retrieved from the pharmacy where the information was originally recorded.

I believe that these amendments will ensure Board compliance with OBRA 90 requirements on drug use review and patient counseling and will have a positive impact on patient care and practice standards for pharmacists in New Jersey.

Accordingly, for the reasons stated above, I herewith return Senate Bill No. 793 and recommend that it be amended as follows:

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|----------------------------------------|-------------------------------------------------------------------------------------------------------------------|
| <u>Page 1, Section 1, Line 11:</u> | After "contraindications" insert "to the extent the diagnosis information is available" |
| <u>Page 1, Section 2, Line 24:</u> | After "and" delete "may" insert "shall" |
| <u>Page 1, Section 2, Lines 27-33:</u> | Delete in entirety. Insert:
"(2) Face to face communication with ancillary personnel; or
(3) By telephone." |
| <u>Page 1, Section 2, Lines 41-44:</u> | Insert: "b. If, in the professional judgment of the pharmacist, it is inappropriate to verbally |

make the offer to counsel,
the offer to counsel may be
made in a written
communication."

Page 1, Section 2, Line 41:

Delete "b." insert "c."

Page 1, Section 2, Line 45:

Delete "c." insert "d."

Page 2, Section 2, Line 17:

Delete "d." insert "e."

Page 2, Section 3, Lines 24-33:

After "3", delete in entirety
insert:

"a. A patient profile system
must be maintained by all
pharmacies for persons for
whom prescriptions are
dispensed. The patient
profile record system shall
be devised so as to enable
the immediate retrieval of
information necessary to
enable the dispensing
pharmacist to identify
previously dispensed
medication at the time a
prescription is presented for
dispensing. One profile
record may be maintained for
members of a family living at
the same address and
possessing the same family
name.

b. The following information
generated at the individual
pharmacy shall be recorded in
the patient profile system:

(1) The family name and the
first name of the person for
whom the medication is
intended (the patient);

(2) The address and telephone
number of the patient;

(3) Indication of the
patient's age, birth date or
age group (infant, child,
adult) and gender;

(4) The original or refill
date the medication is
dispensed and the initials of
the dispensing pharmacist, if
said initials and such date
are not recorded on the back
of the original prescription
or in any other record
approved by the New Jersey
State Board of Pharmacy;

(5) The number or designation
identifying the prescription;

(6) The prescriber's name;

(7) The name, strength and quantity of the drug dispensed;

(8) Individual history where significant, including known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and

(9) Any additional comments relevant to the patient's drug use, including any failure to accept the pharmacist's offer to counsel."

Page 2, Section 3, Line 34:

Delete "b." insert "c."

Respectfully,

GOVERNOR

Attest:

Chief Counsel to the Governor