30:4D-1

LEGISLATIVE HISTORY CHECKLIST

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(Medicaid Drug Utilization Review--establish)

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LAWS OF: 1993 CHAPTER: 16

BILL NO: S1373

SPONSOR(S) Bassano

DATE INTRODUCED: November 23, 1992

COMMITTEE: ASSEMBLY: ---

SENATE: Health & Human Services

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DATE OF PASSAGE: ASSEMBLY: December 21, 1992

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FOLLOWING STATEMENTS ARE ATTACHED IF AVAILABLE:

SPONSOR STATEMENT: Yes

COMMITTEE STATEMENT: ASSEMBLY: No

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FOLLOWING WERE PRINTED:

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HEARINGS: No

KBG:pp

[FIRST REPRINT]

SENATE, No. 1373

STATE OF NEW JERSEY

INTRODUCED NOVEMBER 23, 1992

By Senator BASSANO

AN ACT establishing the Medicaid Drug Utilization Review Board and supplementing P.L.1968, c.413 (C.30:4D-1 et seq.).

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

1. As used in this act:

"Board" means the Medicaid Drug Utilization Review Board established pursuant to this act.

"Compendia" means those resources widely accepted by the medical profession in the efficacious use of drugs which is based on, but not limited to, these sources: the "American Hospital Formulary Services Drug Information," the "U.S. Pharmacopeia-Drug Information," the "American Medical Association Drug Evaluations," the peer-reviewed medical literature, and information provided from the manufacturers of drug products.

"Criteria" means those explicit and predetermined elements that are used to assess or measure drug use on an ongoing basis to determine if the use is appropriate, medically necessary, and not likely to result in adverse medical outcomes.

"Division" means the Division of Medical Assistance and Health Services in the Department of Human Services.

"Drug interactions" means the occurence when two or more drugs taken by a recipient lead to clinically significant toxicity that is characteristic of one or any of the drugs present or that leads to the interference with the effectiveness of one or any of the drugs.

"Drug-disease contraindication" means the occurrence when the therapeutic effect of a drug is adversely altered by the presence of another disease or condition.

"Intervention" means a form of educational communication utilized by the board with a prescriber or pharmacist to inform about or to influence prescribing or dispensing practices.

"Medicaid" means the program established pursuant to P.L.1968, c.413 (C.30:4D-1 et seq.).

"Overutilization or underutilization" means the use or non-use of a drug in quantities such that the desired therapeutic goal is not achieved.

"Prospective drug utilization review" means that part of the drug utilization review program that occurs before the drug is dispensed and is designed to screen for potential drug therapy problems based on knowledge of the patient, the patient's

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 numerals has been adopted as follows:
[1] Senate SHH committee amendments adopted December 10, 1992.

continued drug use and the drug-use criteria and standards developed by the board.

"Retrospective drug utilization review" means that part of the drug utilization review program that assesses or measures drug use based on an historical review of drug use data against criteria and standards developed by the board on an ongoing basis with professional input.

"Standards" means the acceptable range of deviation from the criteria that reflects local medical practice and that is tested on [1]the[1] Medicaid [1][recipients] recipient database[1].

"Therapeutic appropriateness" means drug prescribing and dispensing based on rational drug therapy that is consistent with the criteria and standards developed pursuant to this act.

"Therapeutic duplication" means the prescribing and dispensing of the same drug or of two or more drugs from the same therapeutic class when overlapping time periods of drug administration are involved and when the prescribing or dispensing is not medically indicated.

2. a. There is established the Medicaid Drug Utilization Review Board in the Division of Medical Assistance and Health Services in the Department of Human Services to administer the Medicaid drug utilization review program pursuant to this act.

The board shall consist of 12 members, including the Commissioner of Human Services or his designee, who shall serve as a nonvoting ex officio member, and 11 public members to be appointed by the Governor, with the advice and consent of the Senate, no more than [1][five] six[1] of whom shall be members of the same political party, as follows: four persons licensed and actively engaged in the practice of medicine in this State, three to be appointed upon the recommendation of the Medical Society of New Jersey and one upon the recommendation of the New Jersey Osteopathic Association; one person licensed as a physician in this State who is actively engaged in academic medicine; one person licensed and actively engaged in the practice of dentistry, to be appointed upon the recommendation of the New Jersey Dental Association; four persons licensed and actively practicing [1][retail] or teaching[1] pharmacy in this State, to be appointed [1][upon the recommendation of] from a list of pharmacists recommended by[1] the New Jersey Pharmaceutical Association[1], the New Jersey Council of Chain Drug Stores, the Garden State Pharmacy Owners, Inc., the New Jersey Society of Hospital Pharmacists, and the College of Pharmacy of Rutgers, The State University[1]; and one person who shall represent pharmaceutical manufacturers, to be appointed upon the recommendation of the Pharmaceutical Manufacturers Association.

Each of the physician and pharmacist members of the board shall have expertise in the clinically appropriate prescribing and dispensing of outpatient drugs.

In appointing the public members of the board, the Governor shall give consideration to geographic diversity.

b. All appointments to the board shall be made no later than the 60th day after the effective date of this act. The public members shall be appointed for three-year terms and are eligible

for reappointment, except that of the members first appointed, four shall be appointed for a term of three years, four for a term of two years, and three for a term of one year.

c. Vacancies in the membership of the board shall be filled in the same manner as the original appointments were made. Members of the board shall serve without compensation but shall be reimbursed for the necessary expenses incurred in the performance of their duties as members of the board, within the limits of available funds.

d. The board shall select a chairman from among the public members, who shall serve a one-year term, and a secretary who need not be a member of the board. The chairman may serve consecutive terms.

e. The division shall provide such staff and other resources as the board requires to carry out its responsibilities pursuant to this act.

3. The board shall be responsible for:

a. The adoption of regulations, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), to carry out its responsibilities pursuant to this act.

b. The implementation of a Medicaid drug utilization review program to ensure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical outcomes, including the approval of the provisions of any contractual agreement between the Medicaid program and other entities processing and reviewing Medicaid drug claims and profiles for the drug utilization review program.

The program shall include both retrospective and prospective drug utilization review. Retrospective drug utilization review shall include an analysis of drug claims processing data in order to identify patterns of fraud, abuse or gross overuse, and inappropriate or medically unnecessary care, and to assess data on drug use against standards that are based on the compendia and other sources. Prospective drug utilization review shall include a review conducted by the pharmacist at the point of sale.

c. The development and application of the criteria and standards to be used in retrospective and prospective drug utilization review in such a manner as to ensure that the criteria and standards are based on the compendia and are developed with professional input in a consensus fashion with provisions for timely reassessments and revisions as necessary, and with provisions for input by persons acting as consumer advocates[1][, and that the]. The board shall also consider relevant clinical information provided by interested parties outside of the board and, if appropriate, shall make revisions to the criteria and standards based upon this information in a timely manner. The[1] drug utilization review standards shall reflect the local practices of physicians, in order to monitor:

(1) therapeutic appropriateness;

(2) overutilization or underutilization;

(3) therapeutic duplication;

(4) drug-disease contraindications;

(5) drug-drug interactions;

(6) incorrect drug dosage or duration of drug treatment; and

(7) clinical drug abuse or misuse.

d. The development, selection, application, and assessment of interventions or remedial strategies for physicians, pharmacists, and recipients that are educational and not punitive in nature to improve the quality of care, including:

(1) Information disseminated to physicians and pharmacists to ensure that physicians and pharmacists are aware of the duties and powers of the board;

(2) Written, oral, or electronic reminders of patient-specific or drug-specific information that are designed to ensure recipient, physician, and pharmacist confidentiality, and suggested changes in the prescribing or dispensing practices designed to improve the quality of care;

(3) The development of an educational program, administered directly by the board or through a contract with another entity, using data provided through drug utilization review as a part of active and ongoing educational outreach activities to improve prescribing and dispensing practices as provided in this act. These educational outreach activities shall include accurate, balanced and timely information about drugs and their effect on a patient. If the board contracts with another entity to provide this program, that entity shall publicly disclose any financial interest or benefit that accrues to it from the products selected or used in this program;

(4) Use of face-to-face discussion between experts in drug therapy and the prescriber or pharmacist who has been designated by the board for educational intervention;

(5) Intensified reviews or monitoring of selected prescribers or pharmacists;

(6) The timely evaluation of interventions to determine if the interventions have improved the quality of care; and

(7) The review of case profiles prior to the conducting of an intervention.

e. The [1][publication] <u>submission</u>[1] of an annual report, which shall be subject to public comment prior to its issuance, to the federal Department of Health and Human Services by December 1st of each year. The annual report shall also be submitted to the Governor, the Legislature, the New Jersey Pharmaceutical Association and the New Jersey Medical Society by December 1st of each year. The report shall include the following information:

(1) An overview of the activities of the board and the drug utilization review program;

(2) Interventions used and their ability to improve the quality of care; however, this information shall not disclose the identities of individual physicians, pharmacists, or recipients, but shall specify whether the intervention was a result of underutilization or overutilization of drugs;

(3) The costs of administering the drug utilization review program;

(4) Any cost impact to other areas of the Medicaid program resulting from the drug utilization review program, such as hospitalization rates or changes in long-term care;

(5) A quantitative assessment of how drug utilization review has improved Medicaid recipients' quality of care;

(6) A review of the total number of prescriptions reviewed by drug therapeutic class;

(7) An assessment of the impact of the educational program established pursuant to subsection d. of this section and interventions on prescribing or dispensing practices, total program costs, quality of care and other pertinent patient patterns[1]; and[1]

(8) Recommendations for improvement of the drug utilization review program.

f. The development of a working agreement between the board and other boards or agencies, including, but not limited to: the board of pharmacy of the State of New Jersey and the State Board of Medical Examiners, in order to clarify any overlapping areas of responsibility.

g. The establishment of an appeal process for physicians or pharmacists pursuant to this act.

h. The publication and dissemination of medically correct and balanced educational information to physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists and recipients, including:

(1) potential or actual reactions to drugs;

(2) therapeutic appropriateness;

(3) overutilization or underutilization;

(4) appropriate use of generic drugs;

(5) therapeutic duplication;

(6) drug-disease contraindications;

(7) drug-drug interactions;

(8) incorrect drug dosage or duration of drug treatment;

(9) drug allergy interactions; and

(10) clinical abuse or misuse.

i. The development and publication, with the input of the board of pharmacy of the State of New Jersey, of the guidelines to be used by pharmacists, including mail order pharmacies, in their counseling of Medicaid recipients.

j. The adoption and implementation of procedures designed to ensure the confidentiality of any information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or contractors to the Medicaid drug utilization review program, that identifies individual physicians, pharmacists, or Medicaid recipients. The board may have access to identifying information for purposes of carrying out intervention activities, but the identifying information may not be released to anyone other than a member of the board, except that the board may release cumulative nonidentifying information for purposes of legitimate research. The improper release of identifying information in violation of this act may subject that person to criminal or civil penalties.

k. The determination of whether nursing or long-term care facilities under 42 CFR 483.60 are exempt from the provisions of this act.

4. This act shall take effect on January 1, 1993 or immediately, whichever date is sooner.

Establishes Medicaid Drug Utilization Review Board.

Board of Medical Examiners, in order to clarify any overlapping areas of responsibility.

g. The establishment of an appeal process for physicians or pharmacists pursuant to this act.

h. The publication and dissemination of medically correct and balanced educational information to physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists and recipients, including:

(1) potential or actual reactions to drugs;

(2) therapeutic appropriateness;

(3) overutilization or underutilization;

(4) appropriate use of generic drugs;

(5) therapeutic duplication;

(6) drug-disease contraindications;

(7) drug-drug interactions;

(8) incorrect drug dosage or duration of drug treatment;

(9) drug allergy interactions; and

(10) clinical abuse or misuse.

i. The development and publication, with the input of the board of pharmacy of the State of New Jersey, of the guidelines to be used by pharmacists, including mail order pharmacies, in their counseling of Medicaid recipients.

j. The adoption and implementation of procedures designed to ensure the confidentiality of any information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or contractors to the Medicaid drug utilization review program, that identifies individual physicians, pharmacists, or Medicaid recipients. The board may have access to identifying information for purposes of carrying out intervention activities, but the identifying information may not be released to anyone other than a member of the board, except that the board may release cumulative nonidentifying information for purposes of legitimate research. The improper release of identifying information in violation of this act may subject that person to criminal or civil penalties.

k. The determination of whether nursing or long-term care facilities under 42 CFR 483.60 are exempt from the provisions of this act.

4. This act shall take effect on January 1, 1993 or immediately, whichever date is sooner.

STATEMENT

This bill establishes a Medicaid Drug Utilization Review Board in the Division of Medical Assistance and Health Services of the Department of Human Services to develop and administer the Medicaid drug utilization review program in accordance with the provisions of this bill.

This bill is intended to comply with the requirements of the federal "Omnibus Budget Reconciliation Act of 1990," Pub.L.101-508, which mandates that each state Medicaid program establish a drug utilization review board by January 1, 1993.

SENATE HEALTH AND HUMAN SERVICES COMMITTEE

STATEMENT TO

SENATE, No. 1373

with committee amendments

STATE OF NEW JERSEY

DATED: DECEMBER 10, 1992

The Senate Health and Human Services Committee favorably reports Senate Bill No. 1373 with committee amendments.

As amended by the committee, this bill establishes a Medicaid Drug Utilization Review Board in the Division of Medical Assistance and Health Services of the Department of Human Services to develop and administer the Medicaid drug utilization review program.

The bill provides that the board is to consist of 12 members, including the Commissioner of Human Services or his designee, as a nonvoting ex officio member, and 11 public members appointed by the Governor, with the advice and consent of the Senate, no more than six of whom shall be members of the same political party, as follows: four persons licensed and actively engaged in the practice of medicine in this State, three to be appointed upon the recommendation of the Medical Society of New Jersey and one upon the recommendation of the New Jersey Osteopathic Association; one person licensed as a physician in this State who is actively engaged in academic medicine; one person licensed and actively engaged in the practice of dentistry, to be appointed upon the recommendation of the New Jersey Dental Association; four persons licensed and actively practicing or teaching pharmacy, to be appointed from a list of pharmacists recommended by the New Jersey Pharmaceutical Association, the New Jersey Council of Chain Drug Stores, the Garden State Pharmacy Owners, Inc., the New Jersey Society of Hospital Pharmacists, and the College of Pharmacy of Rutgers, The State University; and one person representing pharmaceutical manufacturers, to be appointed upon the recommendation of the Pharmaceutical Manufacturers Association.

The board is to be responsible for implementing a Medicaid drug utilization review program to ensure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical outcomes. The program shall include both retrospective and prospective drug utilization review. Retrospective drug utilization review includes an analysis of drug claims processing data in order to identify patterns of fraud, abuse or gross overuse, and inappropriate or medically unnecessary care, and to assess data on drug use against standards that are based on the compendia and other sources. Prospective drug utilization review includes a review conducted by the pharmacist at the point of sale.

The criteria and standards to be used in retrospective and prospective drug utilization review shall be designed to monitor:

(1) therapeutic appropriateness;

(2) overutilization or underutilization;

(3) therapeutic duplication;
(4) drug-disease contraindications;
(5) drug-drug interactions;
(6) incorrect drug dosage or duration of drug treatment; and
(7) clinical drug abuse or misuse.

The Medicaid drug utilization review program shall also develop and utilize interventions or remedial strategies for physicians, pharmacists, and recipients that are educational and not punitive in nature to improve the quality of care.

In addition, the Medicaid Drug Utilization Review Board shall:

- publish an annual report on the activities of the board and the drug utilization review program, which shall be submitted to the federal Department of Health and Human Services, the Governor, the Legislature, the New Jersey Pharmaceutical Association and the Medical Society of New Jersey;
- develop a working agreement with other boards or agencies, including, but not limited to: the State board of pharmacy and the State Board of Medical Examiners, in order to clarify any overlapping areas of responsibility;
- establish an appeal process for physicians or pharmacists;
- publish and disseminate medically correct and balanced educational information to physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists and recipients;
- develop and publish, with the input of the State board of pharmacy, guidelines to be used by pharmacists, including mail order pharmacies, in their counseling of Medicaid recipients;
- adopt and implement procedures to ensure the confidentiality of information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or contractors to the Medicaid drug utilization review program, that identifies individual physicians, pharmacists, or Medicaid recipients; and
- determine whether nursing or long-term care facilities under 42 CFR 483.60 are exempt from the provisions of this bill.

This bill is intended to comply with the requirements of the federal "Omnibus Budget Reconciliation Act of 1990," Pub.L.101-508, which mandates that each state Medicaid program establish a drug utilization review board by January 1, 1993.

The committee amended the bill to provide that the four pharmacist members of the Medicaid Drug Utilization Review Board shall be licensed and actively practicing or teaching pharmacy in this State, to be appointed from a list of pharmacists recommended by the New Jersey Pharmaceutical Association, the New Jersey Council of Chain Drug Stores, the Garden State Pharmacy Owners, Inc., the New Jersey Society of Hospital Pharmacists, and the College of Pharmacy of Rutgers, The State University, rather than being four persons actively practicing retail pharmacy appointed solely upon the recommendation of the New Jersey Pharmaceutical Association.

Other committee amendments provide that the board, in its development of the criteria and standards to be used in drug utilization review, shall consider relevant clinical information provided by interested parties outside of the board and, if appropriate, shall make revisions to the criteria and standards based

upon this information in a timely manner. Other committee amendments are technical.

A similar bill, Assembly Bill No. 2024 [1R] (Colburn/Haytaian), is currently pending before the General Assembly.