30:4D-17.17a
LEGISLATIVE HISTORY CHECKLIST
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LAWS OF: 2021 **CHAPTER:** 285

NJSA: 30:4D-17.17a (Requires public members of Drug Utilization Review Board to disclose financial interests and benefits received from and investment interests held in pharmaceutical distributors, pharmaceutical manufacturers, or pharmacy benefits managers.)

BILL NO: A277 (Substituted for S2035 (1R))

SPONSOR(S) Armato, John and others

DATE INTRODUCED: 1/14/2020

COMMITTEE: **ASSEMBLY:** Health

SENATE: Health, Human Services & Senior Citizens

AMENDED DURING PASSAGE: Yes

DATE OF PASSAGE: **ASSEMBLY:** 7/30/2020

SENATE: 6/3/2021

DATE OF APPROVAL: 11/8/2021

FOLLOWING ARE ATTACHED IF AVAILABLE:

FINAL TEXT OF BILL (First Reprint enacted) Yes

A277

INTRODUCED BILL (INCLUDES SPONSOR'S STATEMENT): Yes

COMMITTEE STATEMENT: **ASSEMBLY:** Yes

SENATE: Yes

(Audio archived recordings of the committee meetings, corresponding to the date of the committee statement, ***may possibly*** be found at www.njleg.state.nj.us)

FLOOR AMENDMENT STATEMENT: No

LEGISLATIVE FISCAL ESTIMATE: No

S2035 (1R)

INTRODUCED BILL (INCLUDES SPONSOR'S STATEMENT): Yes

COMMITTEE STATEMENT: **ASSEMBLY:** No

SENATE: Yes

(Audio archived recordings of the committee meetings, corresponding to the date of the committee statement, ***may possibly*** be found at www.njleg.state.nj.us)

FLOOR AMENDMENT STATEMENT: No

LEGISLATIVE FISCAL ESTIMATE: No

VETO MESSAGE: No

GOVERNOR'S PRESS RELEASE ON SIGNING: Yes

FOLLOWING WERE PRINTED:

To check for circulating copies, contact New Jersey State Government Publications at the State Library (609) 278-2640 ext.103 or mailto:refdesk@njstatelib.org

REPORTS: No

HEARINGS: No

NEWSPAPER ARTICLES: No

RWH/JA

§2
Note

P.L. 2021, CHAPTER 285, ***approved November 8, 2021***
Assembly, No. 277 ***(First Reprint)***

AN ACT concerning the Drug Utilization Review Board and amending P.L.1998, c.41.

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

1. Section 2 of P.L.1998, c.41 (C.30:4D-17.17a) is amended to read as follows:

2. a. There is established the Drug Utilization Review Board in the department to advise the department on the implementation of a drug utilization review program pursuant to P.L.1993, c.16 (C.30:4D-17.16 et seq.) and this section. The board shall establish a Senior Drug Utilization Review Committee to address the specific prescribing needs of the elderly and an AIDS/HIV Drug Utilization Review Committee to address the specific prescribing needs of persons with AIDS/HIV, in addition to such other committees as it deems necessary. It shall be the responsibility of each committee to evaluate the specific prescribing needs of its beneficiary population, and to submit recommendations to the board in regard thereto.

The board shall consist of 17 members, including the Commissioners of Human Services and Health or their designees, who shall serve as nonvoting ex officio members, and 15 public members. The public members shall be appointed by the Governor with the advice and consent of the Senate. The appointments shall be made as follows: six persons licensed and actively engaged in the practice of medicine in this State, including one who is a psychiatrist and at least two who specialize in geriatric medicine and two who specialize in AIDS/HIV care, one of whom who is a pediatric AIDS/HIV specialist, four of whom shall be appointed upon the recommendation of the Medical Society of New Jersey and two upon the recommendation of the New Jersey Association of Osteopathic Physicians and Surgeons; one person licensed as a physician in this State who is actively engaged in academic medicine; four persons licensed in and actively practicing or teaching pharmacy in this State, who shall be appointed from a list of pharmacists recommended by the New Jersey Pharmacists Association, the New Jersey Council of Chain Drug Stores, the Garden State Pharmacy Owners, Inc., the New Jersey Society of Hospital Pharmacists, the Academy of Consultant Pharmacists and the College of Pharmacy of Rutgers, The State University; one additional health care professional; two persons

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]Assembly AHE committee amendments adopted March 5, 2020.

certified as advanced practice nurses in this State, who shall be appointed upon the recommendation of the New Jersey State Nurses Association; and one member to be appointed upon the recommendation of the Pharmaceutical Research and Manufacturers of America.

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

At the time of appointment, each public member shall submit a written disclosure to the Department of Human Services and to the Office of the Attorney General detailing any financial interest or benefit furnished to the member by or through a pharmaceutical [1]distributor, pharmaceutical[1] manufacturer [1], or pharmacy benefits manager[1] within the preceding three years, including, but not limited to, any meals, payments, gifts, stocks, or salary furnished to the member by the manufacturer and any stock or other investment interest held in a pharmaceutical [1]distributor, pharmaceutical[1] manufacturer [1], or pharmacy benefits manager[1] by the member. Thereafter, each public member shall submit an updated disclosure on a quarterly basis for the duration of the member's term as a board member concerning any financial interest or benefit furnished to the member by or through a pharmaceutical [1]distributor, pharmaceutical[1] manufacturer [1], or pharmacy benefits manager[1] and any investment interest in a pharmaceutical [1]distributor, pharmaceutical[1] manufacturer [1], or pharmacy benefits manager[1] acquired or held by the member in the period following the date of the member's last written disclosure. An individual who fails to submit a written disclosure pursuant to this subsection shall be ineligible to serve as a board member and, if currently serving on the board, shall be immediately removed from the board. In addition, any individual who submits a written disclosure that is materially false, misleading, inaccurate, or incomplete shall be liable to a civil penalty of up to $20,000, which shall be collected and enforced by summary proceedings pursuant to the provisions of the "Penalty Enforcement Law of 1999," P.L.1999, c.274 (C.2A:58-10 et seq.). Written disclosures submitted pursuant to this subsection shall be made available to the public on the Internet websites of the Department of Human Services and the Office of the Attorney General.

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 two-year terms and shall serve until a successor is appointed and qualified, and are eligible for reappointment; except that of the public members first appointed, eight shall be appointed for a term of two years and five 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 but for the unexpired term only. Members of the board shall serve with compensation for the time and expenses incurred in the performance of

their duties as board members, as determined by the Commissioners of Human Services and Health, subject to the approval of the Director of the Division of Budget and Accounting in the Department of the Treasury.

d. The board shall select a chairman from among the public members, who shall serve a one-year term, and a secretary. The chairman may serve consecutive terms. The board shall adopt bylaws. The board shall meet at least quarterly and may meet at other times at the call of the chairman. The board shall in all respects comply with the provisions of the "Senator Byron M. Baer Open Public Meetings Act," P.L.1975, c.231 (C.10:4-6 et seq.). No motion to take any action by the board shall be valid except upon the affirmative vote of a majority of the authorized membership of the board.

e. The duties of the board shall include the development and application of the criteria and standards to be used in retrospective and prospective drug utilization review. The criteria and standards shall be based on the compendia and developed with professional input in a consensus fashion. There shall be provisions for timely reassessments and revisions as necessary and provisions for input by persons acting as patient advocates. The drug utilization review standards shall reflect the local practices of prescribers, 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;

(7) duration of drug treatment; and

(8) clinical drug abuse or misuse.

The board shall recommend to the department criteria for denials of claims and establish standards for a medical exception process. The board shall also consider relevant information provided by interested parties outside of the board and, if appropriate, shall make revisions to the criteria and standards in a timely manner based upon this information.

f. The board, with the approval of the department, shall be responsible for the development, selection, application, and assessment of interventions or remedial strategies for prescribers, pharmacists, and beneficiaries that are educational and not punitive in nature to improve the quality of care, including:

(1) Information disseminated to prescribers and pharmacists to ensure that they 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 prescriber, pharmacist, and beneficiary confidentiality, and suggested changes in the prescribing or dispensing practices designed to improve the quality of care;

(3) The development of an educational program, 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 section. 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 whether the interventions have improved the quality of care; and

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

(cf: P.L.2012, c.17, s.370)

2. The Commissioner of Human Services and the Attorney General may, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.) adopt rules and regulations as may be necessary to implement the provisions of this act.

3. This act shall take effect immediately.

Requires public members of Drug Utilization Review Board to disclose financial interests and benefits received from and investment interests held in pharmaceutical distributors, pharmaceutical manufacturers, or pharmacy benefits managers.

ASSEMBLY, No. 277

STATE OF NEW JERSEY

219th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2020 SESSION

Sponsored by:
Assemblyman JOHN ARMATO
District 2 (Atlantic)
Assemblyman ROBERT J. KARABINCHAK
District 18 (Middlesex)

SYNOPSIS

Requires public members of Drug Utilization Review Board to disclose financial interests and benefits received from and investment interests held in pharmaceutical manufacturers.

CURRENT VERSION OF TEXT

Introduced Pending Technical Review by Legislative Counsel.

AN ACT concerning the Drug Utilization Review Board and amending P.L.1998, c.41.

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

1. Section 2 of P.L.1998, c.41 (C.30:4D-17.17a) is amended to read as follows:

2. a. There is established the Drug Utilization Review Board in the department to advise the department on the implementation of a drug utilization review program pursuant to P.L.1993, c.16 (C.30:4D-17.16 et seq.) and this section. The board shall establish a Senior Drug Utilization Review Committee to address the specific prescribing needs of the elderly and an AIDS/HIV Drug Utilization Review Committee to address the specific prescribing needs of persons with AIDS/HIV, in addition to such other committees as it deems necessary. It shall be the responsibility of each committee to evaluate the specific prescribing needs of its beneficiary population, and to submit recommendations to the board in regard thereto.

The board shall consist of 17 members, including the Commissioners of Human Services and Health or their designees, who shall serve as nonvoting ex officio members, and 15 public members. The public members shall be appointed by the Governor with the advice and consent of the Senate. The appointments shall be made as follows: six persons licensed and actively engaged in the practice of medicine in this State, including one who is a psychiatrist and at least two who specialize in geriatric medicine and two who specialize in AIDS/HIV care, one of whom who is a pediatric AIDS/HIV specialist, four of whom shall be appointed upon the recommendation of the Medical Society of New Jersey and two upon the recommendation of the New Jersey Association of Osteopathic Physicians and Surgeons; one person licensed as a physician in this State who is actively engaged in academic medicine; four persons licensed in and actively practicing or teaching pharmacy in this State, who shall be appointed from a list of pharmacists recommended by the New Jersey Pharmacists Association, the New Jersey Council of Chain Drug Stores, the Garden State Pharmacy Owners, Inc., the New Jersey Society of Hospital Pharmacists, the Academy of Consultant Pharmacists and the College of Pharmacy of Rutgers, The State University; one additional health care professional; two persons certified as advanced practice nurses in this State, who shall be appointed upon the recommendation of the New Jersey State Nurses Association; and one member to be appointed upon the recommendation of the Pharmaceutical Research and Manufacturers of America.

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 <u>thus</u> is new matter.

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

At the time of appointment, each public member shall submit a written disclosure to the Department of Human Services and to the Office of the Attorney General detailing any financial interest or benefit furnished to the member by or through a pharmaceutical manufacturer within the preceding three years, including, but not limited to, any meals, payments, gifts, stocks, or salary furnished to the member by the manufacturer and any stock or other investment interest held in a pharmaceutical manufacturer by the member. Thereafter, each public member shall submit an updated disclosure on a quarterly basis for the duration of the member's term as a board member concerning any financial interest or benefit furnished to the member by or through a pharmaceutical manufacturer and any investment interest in a pharmaceutical manufacturer acquired or held by the member in the period following the date of the member's last written disclosure. An individual who fails to submit a written disclosure pursuant to this subsection shall be ineligible to serve as a board member and, if currently serving on the board, shall be immediately removed from the board. In addition, any individual who submits a written disclosure that is materially false, misleading, inaccurate, or incomplete shall be liable to a civil penalty of up to $20,000, which shall be collected and enforced by summary proceedings pursuant to the provisions of the "Penalty Enforcement Law of 1999," P.L.1999, c.274 (C.2A:58-10 et seq.). Written disclosures submitted pursuant to this subsection shall be made available to the public on the Internet websites of the Department of Human Services and the Office of the Attorney General.

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 two-year terms and shall serve until a successor is appointed and qualified, and are eligible for reappointment; except that of the public members first appointed, eight shall be appointed for a term of two years and five 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 but for the unexpired term only. Members of the board shall serve with compensation for the time and expenses incurred in the performance of their duties as board members, as determined by the Commissioners of Human Services and Health, subject to the approval of the Director of the Division of Budget and Accounting in the Department of the Treasury.

d. The board shall select a chairman from among the public members, who shall serve a one-year term, and a secretary. The chairman may serve consecutive terms. The board shall adopt bylaws. The board shall meet at least quarterly and may meet at

other times at the call of the chairman. The board shall in all respects comply with the provisions of the "Senator Byron M. Baer Open Public Meetings Act," P.L.1975, c.231 (C.10:4-6 et seq.). No motion to take any action by the board shall be valid except upon the affirmative vote of a majority of the authorized membership of the board.

e. The duties of the board shall include the development and application of the criteria and standards to be used in retrospective and prospective drug utilization review. The criteria and standards shall be based on the compendia and developed with professional input in a consensus fashion. There shall be provisions for timely reassessments and revisions as necessary and provisions for input by persons acting as patient advocates. The drug utilization review standards shall reflect the local practices of prescribers, 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;

(7) duration of drug treatment; and

(8) clinical drug abuse or misuse.

The board shall recommend to the department criteria for denials of claims and establish standards for a medical exception process. The board shall also consider relevant information provided by interested parties outside of the board and, if appropriate, shall make revisions to the criteria and standards in a timely manner based upon this information.

f. The board, with the approval of the department, shall be responsible for the development, selection, application, and assessment of interventions or remedial strategies for prescribers, pharmacists, and beneficiaries that are educational and not punitive in nature to improve the quality of care, including:

(1) Information disseminated to prescribers and pharmacists to ensure that they 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 prescriber, pharmacist, and beneficiary confidentiality, and suggested changes in the prescribing or dispensing practices designed to improve the quality of care;

(3) The development of an educational program, 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 section. 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 whether the interventions have improved the quality of care; and

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

(cf: P.L.2012, c.17, s.370)

2. The Commissioner of Human Services and the Attorney General may, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.) adopt rules and regulations as may be necessary to implement the provisions of this act.

3. This act shall take effect immediately.

STATEMENT

This bill requires the public members of the New Jersey Drug Utilization Review Board to, at the time of their appointment, submit a written disclosure to the Department of Human Services and to the Office of the Attorney General detailing any financial interest or other benefit furnished to the member by a pharmaceutical manufacturer within the preceding three years, including, but not limited to, any meals, payments, gifts, stocks, or salary, as well as any investment interest held in any pharmaceutical manufacturer by the member. Thereafter, each public member will be required update the written disclosure on a quarterly basis throughout the member's term of service on the board. The written disclosures will be made available to the public on the Internet websites of the Department of Human Services and the Office of the Attorney General.

An individual who fails to submit a written disclosure pursuant to the bill will be ineligible to serve as a board member and, if currently serving on the board, will be immediately removed from the board. In addition, any individual who submits a written disclosure that is materially false, misleading, inaccurate, or incomplete will be liable to a civil penalty of up to $20,000.

The Drug Utilization Review Board conducts an ongoing review of drugs prescribed under the Medicaid and NJ FamilyCare programs to ensure that patients have access to effective, affordable forms of treatment while avoiding the use of ineffective, redundant, or unnecessary therapies. The goals of this review are to maximize

patient safety, prevent waste, and reduce overall program costs. The Drug Utilization Review Board determines which drugs may be prescribed under the Medicaid and NJ FamilyCare programs without the need for additional authorization; inclusion on the list increases the likelihood the drug will be prescribed to program beneficiaries, which provides a competitive advantage to the maker of the drug.

Recent investigations suggest there has been a comprehensive effort by pharmaceutical manufacturers to influence drug utilization review boards throughout the country by providing board members with meals, gifts, paid consulting jobs, all-expenses-paid conferences, and direct compensation, among other items of value. These efforts present a significant risk that board decisions will not reflect the best interests of the State and the best interests of Medicaid and NJ FamilyCare enrollees. It is the sponsor's belief that requiring full disclosure of any items of value furnished to a board member by a pharmaceutical manufacturer will help ensure the board can serve its fundamental purpose in maximizing the effectiveness and efficiency of the prescription drug therapies covered under the Medicaid and NJ FamilyCare programs.

ASSEMBLY HEALTH COMMITTEE

STATEMENT TO

ASSEMBLY, No. 277

with committee amendments

STATE OF NEW JERSEY

DATED: MARCH 5, 2020

The Assembly Health Committee reports favorably and with committee amendments Assembly Bill No. 277.

As amended, this bill requires the public members of the New Jersey Drug Utilization Review Board to, at the time of their appointment, submit a written disclosure to the Department of Human Services and to the Office of the Attorney General detailing any financial interest or other benefit furnished to the member by a pharmaceutical distributor, pharmaceutical manufacturer, or pharmacy benefits manager within the preceding three years, including, but not limited to, any meals, payments, gifts, stocks, or salary, as well as any investment interest held in any pharmaceutical distributor, pharmaceutical manufacturer, or pharmacy benefits manager by the member. Thereafter, each public member will be required update the written disclosure on a quarterly basis throughout the member's term of service on the board. The written disclosures will be made available to the public on the Internet websites of the Department of Human Services and the Office of the Attorney General.

An individual who fails to submit a written disclosure pursuant to the bill will be ineligible to serve as a board member and, if currently serving on the board, will be immediately removed from the board. In addition, any individual who submits a written disclosure that is materially false, misleading, inaccurate, or incomplete will be liable to a civil penalty of up to $20,000.

The Drug Utilization Review Board conducts an ongoing review of drugs prescribed under the Medicaid and NJ FamilyCare programs to ensure that patients have access to effective, affordable forms of treatment while avoiding the use of ineffective, redundant, or unnecessary therapies. The goals of this review are to maximize patient safety, prevent waste, and reduce overall program costs. The Drug Utilization Review Board determines which drugs may be prescribed under the Medicaid and NJ FamilyCare programs without the need for additional authorization; inclusion on the list increases the likelihood the drug will be prescribed to program beneficiaries, which provides a competitive advantage to the maker of the drug.

This bill was pre-filed for introduction in the 2020-2021 session pending technical review. As reported, the bill includes the changes required by technical review, which has been performed.

COMMITTEE AMENDMENTS:

The committee amendments require disclosure of any financial interest or other benefit furnished by a pharmaceutical distributor or pharmacy benefits manager and make a technical change to the synopsis.

SENATE HEALTH, HUMAN SERVICES AND SENIOR CITIZENS COMMITTEE

STATEMENT TO

[First Reprint]
ASSEMBLY, No. 277

STATE OF NEW JERSEY

DATED: FEBRUARY 9, 2021

The Senate Health, Human Services and Senior Citizens Committee reports favorably Assembly Bill No. 277 (1R).

This bill requires the public members of the New Jersey Drug Utilization Review Board to, at the time of their appointment, submit a written disclosure to the Department of Human Services and to the Office of the Attorney General detailing any financial interest or other benefit furnished to the member by a pharmaceutical distributor, pharmaceutical manufacturer, or pharmacy benefits manager within the preceding three years, including, but not limited to, any meals, payments, gifts, stocks, or salary, as well as any investment interest held in any pharmaceutical distributor, pharmaceutical manufacturer, or pharmacy benefits manager by the member. Thereafter, each public member will be required to update the written disclosure on a quarterly basis throughout the member's term of service on the board. The written disclosures will be made available to the public on the Internet websites of the Department of Human Services and the Office of the Attorney General.

An individual who fails to submit a written disclosure pursuant to the bill will be ineligible to serve as a board member and, if currently serving on the board, will be immediately removed from the board. In addition, any individual who submits a written disclosure that is materially false, misleading, inaccurate, or incomplete will be liable to a civil penalty of up to $20,000.

The Drug Utilization Review Board conducts an ongoing review of drugs prescribed under the Medicaid and NJ FamilyCare programs to ensure that patients have access to effective, affordable forms of treatment while avoiding the use of ineffective, redundant, or unnecessary therapies. The goals of this review are to maximize patient safety, prevent waste, and reduce overall program costs. The Drug Utilization Review Board determines which drugs may be prescribed under the Medicaid and NJ FamilyCare programs without the need for additional authorization; inclusion on the list increases the likelihood the drug will be prescribed to program beneficiaries, which provides a competitive advantage to the maker of the drug.

Recent investigations suggest there has been a comprehensive effort by pharmaceutical manufacturers to influence drug utilization review boards throughout the country by providing board members with meals, gifts, paid consulting jobs, all-expenses-paid conferences, and direct compensation, among other items of value. These efforts present a significant risk that board decisions will not reflect the best interests of the State and the best interests of Medicaid and NJ FamilyCare enrollees.

As reported by the committee, Assembly Bill No. 277 (1R) is identical to Senate Bill No. 2035, which was also reported by the committee on this date, with amendments.

This bill was pre-filed for introduction in the 2020-2021 session pending technical review. As reported, the bill includes the changes required by technical review, which has been performed.

SENATE, No. 2035

STATE OF NEW JERSEY

219th LEGISLATURE

INTRODUCED MARCH 16, 2020

Sponsored by:
Senator TROY SINGLETON
District 7 (Burlington)
Senator SHIRLEY K. TURNER
District 15 (Hunterdon and Mercer)

SYNOPSIS

Requires public members of Drug Utilization Review Board to disclose financial interests and benefits received from and investment interests held in pharmaceutical manufacturers.

CURRENT VERSION OF TEXT

As introduced.

(Sponsorship Updated As Of: 2/9/2021)

AN ACT concerning the Drug Utilization Review Board and amending P.L.1998, c.41.

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

1. Section 2 of P.L.1998, c.41 (C.30:4D-17.17a) is amended to read as follows:

2. a. There is established the Drug Utilization Review Board in the department to advise the department on the implementation of a drug utilization review program pursuant to P.L.1993, c.16 (C.30:4D-17.16 et seq.) and this section. The board shall establish a Senior Drug Utilization Review Committee to address the specific prescribing needs of the elderly and an AIDS/HIV Drug Utilization Review Committee to address the specific prescribing needs of persons with AIDS/HIV, in addition to such other committees as it deems necessary. It shall be the responsibility of each committee to evaluate the specific prescribing needs of its beneficiary population, and to submit recommendations to the board in regard thereto.

The board shall consist of 17 members, including the Commissioners of Human Services and Health or their designees, who shall serve as nonvoting ex officio members, and 15 public members. The public members shall be appointed by the Governor with the advice and consent of the Senate. The appointments shall be made as follows: six persons licensed and actively engaged in the practice of medicine in this State, including one who is a psychiatrist and at least two who specialize in geriatric medicine and two who specialize in AIDS/HIV care, one of whom who is a pediatric AIDS/HIV specialist, four of whom shall be appointed upon the recommendation of the Medical Society of New Jersey and two upon the recommendation of the New Jersey Association of Osteopathic Physicians and Surgeons; one person licensed as a physician in this State who is actively engaged in academic medicine; four persons licensed in and actively practicing or teaching pharmacy in this State, who shall be appointed from a list of pharmacists recommended by the New Jersey Pharmacists Association, the New Jersey Council of Chain Drug Stores, the Garden State Pharmacy Owners, Inc., the New Jersey Society of Hospital Pharmacists, the Academy of Consultant Pharmacists and the College of Pharmacy of Rutgers, The State University; one additional health care professional; two persons certified as advanced practice nurses in this State, who shall be appointed upon the recommendation of the New Jersey State Nurses Association; and one member to be appointed upon the recommendation of the Pharmaceutical Research and Manufacturers of America.

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 <u>thus</u> is new matter.

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

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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 two-year terms and shall serve until a successor is appointed and qualified, and are eligible for reappointment; except that of the public members first appointed, eight shall be appointed for a term of two years and five 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 but for the unexpired term only. Members of the board shall serve with compensation for the time and expenses incurred in the performance of their duties as board members, as determined by the Commissioners of Human Services and Health, subject to the approval of the Director of the Division of Budget and Accounting in the Department of the Treasury.

d. The board shall select a chairman from among the public members, who shall serve a one-year term, and a secretary. The chairman may serve consecutive terms. The board shall adopt bylaws. The board shall meet at least quarterly and may meet at

other times at the call of the chairman. The board shall in all respects comply with the provisions of the "Senator Byron M. Baer Open Public Meetings Act," P.L.1975, c.231 (C.10:4-6 et seq.). No motion to take any action by the board shall be valid except upon the affirmative vote of a majority of the authorized membership of the board.

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(1) therapeutic appropriateness;

(2) overutilization or underutilization;

(3) therapeutic duplication;

(4) drug-disease contraindications;

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(6) incorrect drug dosage;

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The board shall recommend to the department criteria for denials of claims and establish standards for a medical exception process. The board shall also consider relevant information provided by interested parties outside of the board and, if appropriate, shall make revisions to the criteria and standards in a timely manner based upon this information.

f. The board, with the approval of the department, shall be responsible for the development, selection, application, and assessment of interventions or remedial strategies for prescribers, pharmacists, and beneficiaries that are educational and not punitive in nature to improve the quality of care, including:

(1) Information disseminated to prescribers and pharmacists to ensure that they 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 prescriber, pharmacist, and beneficiary confidentiality, and suggested changes in the prescribing or dispensing practices designed to improve the quality of care;

(3) The development of an educational program, 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 section. 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 whether the interventions have improved the quality of care; and

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

(cf: P.L.2012, c.17, s.370)

2. The Commissioner of Human Services and the Attorney General may, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.) adopt rules and regulations as may be necessary to implement the provisions of this act.

3. This act shall take effect immediately.

STATEMENT

This bill requires the public members of the New Jersey Drug Utilization Review Board to, at the time of their appointment, submit a written disclosure to the Department of Human Services and to the Office of the Attorney General detailing any financial interest or other benefit furnished to the member by a pharmaceutical manufacturer within the preceding three years, including, but not limited to, any meals, payments, gifts, stocks, or salary, as well as any investment interest held in any pharmaceutical manufacturer by the member. Thereafter, each public member will be required update the written disclosure on a quarterly basis throughout the member's term of service on the board. The written disclosures will be made available to the public on the Internet websites of the Department of Human Services and the Office of the Attorney General.

An individual who fails to submit a written disclosure pursuant to the bill will be ineligible to serve as a board member and, if currently serving on the board, will be immediately removed from the board. In addition, any individual who submits a written disclosure that is materially false, misleading, inaccurate, or incomplete will be liable to a civil penalty of up to $20,000.

The Drug Utilization Review Board conducts an ongoing review of drugs prescribed under the Medicaid and NJ FamilyCare programs to ensure that patients have access to effective, affordable forms of treatment while avoiding the use of ineffective, redundant, or unnecessary therapies. The goals of this review are to maximize

patient safety, prevent waste, and reduce overall program costs. The Drug Utilization Review Board determines which drugs may be prescribed under the Medicaid and NJ FamilyCare programs without the need for additional authorization; inclusion on the list increases the likelihood the drug will be prescribed to program beneficiaries, which provides a competitive advantage to the maker of the drug.

Recent investigations suggest there has been a comprehensive effort by pharmaceutical manufacturers to influence drug utilization review boards throughout the country by providing board members with meals, gifts, paid consulting jobs, all-expenses-paid conferences, and direct compensation, among other items of value. These efforts present a significant risk that board decisions will not reflect the best interests of the State and the best interests of Medicaid and NJ FamilyCare enrollees. It is the sponsor's belief that requiring full disclosure of any items of value furnished to a board member by a pharmaceutical manufacturer will help ensure the board can serve its fundamental purpose in maximizing the effectiveness and efficiency of the prescription drug therapies covered under the Medicaid and NJ FamilyCare programs.

SENATE HEALTH, HUMAN SERVICES AND SENIOR CITIZENS COMMITTEE

STATEMENT TO

SENATE, No. 2035

with committee amendments

STATE OF NEW JERSEY

DATED: FEBRUARY 9, 2021

The Senate Health, Human Services and Senior Citizens Committee reports favorably and with committee amendments Senate Bill No. 2035.

As amended by the committee, this bill requires the public members of the New Jersey Drug Utilization Review Board to, at the time of their appointment, submit a written disclosure to the Department of Human Services and to the Office of the Attorney General detailing any financial interest or other benefit furnished to the member by a pharmaceutical distributor, pharmaceutical manufacturer, or pharmacy benefits manager within the preceding three years, including, but not limited to, any meals, payments, gifts, stocks, or salary, as well as any investment interest held in any pharmaceutical distributor, pharmaceutical manufacturer, or pharmacy benefits manager by the member. Thereafter, each public member will be required to update the written disclosure on a quarterly basis throughout the member's term of service on the board. The written disclosures will be made available to the public on the Internet websites of the Department of Human Services and the Office of the Attorney General.

An individual who fails to submit a written disclosure pursuant to the bill will be ineligible to serve as a board member and, if currently serving on the board, will be immediately removed from the board. In addition, any individual who submits a written disclosure that is materially false, misleading, inaccurate, or incomplete will be liable to a civil penalty of up to $20,000.

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Recent investigations suggest there has been a comprehensive effort by pharmaceutical manufacturers to influence drug utilization review boards throughout the country by providing board members with meals, gifts, paid consulting jobs, all-expenses-paid conferences, and direct compensation, among other items of value. These efforts present a significant risk that board decisions will not reflect the best interests of the State and the best interests of Medicaid and NJ FamilyCare enrollees.

As reported by the committee with amendments, Senate Bill No. 2035 is identical to Assembly Bill No. 277(1R) which was also reported by the committee on this date.

COMMITTEE AMENDMENTS:

The committee amendments revise the bill to require disclosure of any financial interest or other benefit furnished to a member of the Drug Utilization Board by a pharmaceutical distributor, pharmaceutical manufacturer, or pharmacy benefits manager; as introduced, the bill only required disclosures related to pharmaceutical manufacturers.

Governor Murphy Signs Legislation Promoting Transparency on the New Jersey Drug Utilization Review Board

11/8/2021

TRENTON – Governor Phil Murphy today signed legislation (A-277/S-2035) that requires public members of the New Jersey Drug Utilization Review Board to submit disclosures of financial interests and involvement in pharmaceutical distributors, manufacturers, or benefits managers. The bill continues the Murphy Administration's efforts to promote transparency and integrity in health care.

"New Jerseyans have the right to know about the financial interests of those reviewing medications provided through state programs," **said Governor Murphy.** "This law will help to protect the integrity of the Drug Utilization Review Board and instill confidence in the Board's recommendations."

Primary sponsors of the legislation include Assemblymembers John Armato and Robert Karabinchak, and Senators Troy Singleton and Shirley Turner.

"The Drug Utilization Board's purpose is to maximize the efficacy of prescription drug therapies covered by Medicaid and New Jersey FamilyCare. Their work should always be in the best interest of the State and the people who rely on these medications for relief, not the big drug companies," said **Assemblymen John Armato and Robert Karabinchak**. "It's only fair that we ask public Board members to disclose any financial ties to pharmaceutical companies so that we may be confident their service is truly to benefit the people of New Jersey."

"The Drug Utilization Review Board evaluates different drugs and therapies for people under the Medicaid and New Jersey FamilyCare programs to decide what can be prescribed to patients. Equally as important, they are charged with determining what the best options are for patients. However, that is not always the case because pharmaceutical companies may try to influence board members to prioritize their drugs," **said Senator Troy Singleton.** "With this new law, we are bringing transparency to the review process by requiring members of the review board to disclose any ties they have to pharmaceutical companies. Their role on this board is for the betterment of lower-income residents and not personal gain."

"Our taxpayers deserve the peace of mind that decisions that are being made by the New Jersey Drug Utilization Review Board are being made in the public interest and not for the benefit of any private individuals or corporations," **said Senator Shirley Turner.** "Full transparency is imperative for protecting our taxpayers and the residents who rely on the prescription drugs that the Board recommends."

This legislation requires the public members of the New Jersey Drug Utilization Review Board to, at the time of their appointment, submit a written disclosure to the Department of Human Services and to the Office of the Attorney General detailing any financial interest or other benefit provided to the member by a pharmaceutical distributor, pharmaceutical manufacturer, or pharmacy benefits manager within the preceding three years, including, but not limited to, any meals, payments, gifts, stocks, or salary, as well as any investment interest held in any pharmaceutical distributor, pharmaceutical manufacturer, or pharmacy benefits manager by the member. Each public member will be required to update the written disclosure on a quarterly basis throughout the member's term of service on the board. The written disclosures will be made available to the public on the websites of the Department of Human Services and the Office of the Attorney General. Individuals who fail to comply with the law will be ineligible to serve on the board and will be subject to removal.

The Drug Utilization Review Board is responsible for reviewing and recommending drug utilization review protocols for medications provided by NJ FamilyCare (NJFC), the Pharmaceutical Assistance to the Aged and Disabled (PAAD) Program, the Senior Gold Prescription Discount (Senior Gold) Program, as well as the Aids Drug Distribution Program (ADDP).