SENATE BILL NO. 321–SENATOR SHAFFER

MARCH 17, 2003

Referred to Committee on Human Resources and Facilities

SUMMARY—Makes various changes concerning coverage of prescription drugs by Medicaid fee-for-service program. (BDR 38-763)

FISCAL NOTE: Effect on Local Government: No.
Effect on the State: Yes.

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EXPLANATION – Matter in ***bolded italics*** is new; matter between brackets **[**~~omitted material~~**]** is material to be omitted.

AN ACT relating to public welfare; creating a Drug Utilization Review Board within the Department of Human Resources to develop drug utilization review programs for any Medicaid fee-for-service program that provides coverage for prescription drugs to outpatients; setting forth requirements for any program that requires prior authorization for a prescription drug within a Medicaid fee-for-service program; and providing other matters properly relating thereto.

THE PEOPLE OF THE STATE OF NEVADA, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. Chapter 422 of NRS is hereby amended by adding thereto the provisions set forth as sections 2 to 9, inclusive, of this act.

Sec. 2. ***As used in sections 2 to 9, inclusive, of this act, "Review Board" means the Drug Utilization Review Board established by section 3 of this act.***

Sec. 3. ***1. There is hereby created within the Department a Drug Utilization Review Board to develop and assess a retrospective drug utilization review program and a prospective drug utilization review program for any Medicaid fee-for-service program established in the State of Nevada that provides coverage for prescription drugs to outpatients.***

2. The Review Board consists of the following 11 members appointed by the Director:

(a) Three active physicians licensed pursuant to chapter 630 of NRS appointed from a list of not less than six names submitted by the Board of Medical Examiners;

(b) One active osteopathic physician licensed pursuant to chapter 633 of NRS appointed from a list of not less than two names submitted by the State Board of Osteopathic Medicine;

(c) Five active registered pharmacists registered pursuant to chapter 639 of NRS appointed from a list of not less than seven names submitted by the State Board of Pharmacy;

(d) One member of the public representing recipients of services provided pursuant to a Medicaid fee-for-service program who is a resident of this state; and

(e) One person representing the pharmaceutical industry who is a resident of this state appointed from a list of not less than two names submitted by the Pharmaceutical Research and Manufacturers of America.

3. To the extent practicable, the members of the Review Board must be representative of the various geographic areas of this state.

4. Of the members of the Review Board first appointed, one physician licensed pursuant to chapter 630 of NRS, one registered pharmacist and the member of the public must be appointed for initial terms of 2 years. All other appointments must be for a term of 3 years. A member may, if he still possesses the requisite qualifications for appointment, be reappointed for not more than three additional terms of 3 years and one partial term if the partial term is the result of being appointed to fill a vacancy of a member of the Review Board in accordance with subsection 6.

5. The Review Board shall elect from its members a Chairman and Vice Chairman. The Chairman and Vice Chairman shall serve a term of 1 year and may be reelected.

6. A vacancy occurring in the membership of the Review Board must be filled in the same manner as the original appointment except, if applicable, that such appointments must be made from a new list submitted by the relevant board or entity.

7. The Review Board shall meet at least twice a year and at the times and places specified by the call of the Chairman of the Review Board.

Sec. 4. *Any meeting of the Review Board must be conducted in accordance with the provisions of chapter 241 of NRS. Any documents relating to a decision made by the Review Board must be made available to any interested person. The Review Board shall provide the opportunity for any person present at a meeting*

of the Review Board to comment on the information presented to the Review Board or any decisions of the Review Board made during the meeting.

Sec. 5. *1. The Review Board shall, with assistance from professionals in the field of prescription drug use, develop and recommend to the Department a retrospective drug utilization review program and a prospective drug utilization review program for any Medicaid fee-for-service program that provides coverage for prescription drugs to outpatients to ensure that the drugs prescribed pursuant to the Medicaid fee-for-service program are appropriate, medically necessary and not likely to result in adverse medical outcomes.*

2. The retrospective drug utilization review program must assess and measure on an ongoing basis, and with input from professionals, the use of prescription drugs based on a historical review of data concerning the actual use of prescription drugs as compared to predetermined and explicit criteria and standards for the use of prescription drugs to determine whether the use of prescription drugs by outpatients in the Medicaid fee-for-service program is appropriate, medically necessary and not likely to result in an adverse medical outcome. The retrospective drug utilization review program must include, without limitation, the periodic examination of data from claims of pharmacies which provide services to outpatients receiving benefits pursuant to the Medicaid fee-for-service program and other available information to:

(a) Identify patterns of fraud, abuse, gross overuse or underuse of prescription drugs, or inappropriate or medically unnecessary care in the provision of services to outpatients pursuant to the Medicaid fee-for-service program;

(b) Monitor, in the Medicaid fee-for-service program:

(1) The therapeutic appropriateness of prescription drugs;

(2) The overutilization or underutilization of a prescription drug which results in the therapeutic goal of the drug not being achieved;

(3) The use of generic prescription drugs;

(4) Whether the therapeutic effect of a prescription drug duplicates the effect of another prescription drug or treatment;

(5) The possibility of the therapeutic effect of a prescription drug being adversely altered by the presence of a disease or condition other than the disease or condition for which the drug was prescribed;

(6) The possibility of two or more prescription drugs that are taken by a patient leading either to clinically significant

toxicity that is uncharacteristic of any one of the drugs or to interference with the effectiveness of one or more of the drugs;

(7) Any clinically significant adverse medical effect that may result from the use of two or more prescription drugs together;

(8) Any prescription for an incorrect dosage of a prescription drug or an incorrect duration of treatment with a prescription drug; and

(9) Any clinical abuse or misuse of prescription drugs; and

(c) Develop remedial strategies to improve the quality of care provided to outpatients pursuant to the Medicaid fee-for-service program and to conserve money expended for prescription drugs by both the outpatients and the Medicaid fee-for-service program.

3. The prospective drug utilization review program must require a registered pharmacist who provides services to outpatients receiving benefits pursuant to the Medicaid fee-for-service program, before filling or delivering a prescription drug, to review the prescription to screen for potential drug therapy problems, including, without limitation:

(a) Whether the therapeutic effect of the prescription drug duplicates the effect of another prescription drug or treatment being taken or received by the patient;

(b) The possibility of two or more prescription drugs that are taken by a patient leading either to clinically significant toxicity that is uncharacteristic of any one of the drugs or to interference with the effectiveness of one or more of the drugs;

(c) Any clinically significant adverse medical effect that may result from the use of two or more prescription drugs together;

(d) Any potential interactions between the prescription drug and an allergy of the patient;

(e) A prescription for an incorrect dosage of a prescription drug or an incorrect duration of treatment with a prescription drug; and

(f) Any clinical abuse or misuse of prescription drugs.

4. A drug utilization review program developed pursuant to this section must be based on:

(a) The American Hospital Formulary Services Drug Information;

(b) The United States Pharmacopoeia Drug Information;

(c) Peer-reviewed medical and clinical literature;

(d) Information provided by persons involved in the provision of health care; and

(e) Drug labeling that is approved by the United States Food and Drug Administration.

Sec. 6. *The Review Board shall:*

1. Advise the Department concerning the drug utilization review programs developed pursuant to section 5 of this act, and make recommendations concerning any regulations which relate to the programs;

2. Oversee contractual agreements between the Department and any entity involved in establishing policies or making decisions which affect the drug utilization review programs developed pursuant to section 5 of this act, and make recommendations to the Department concerning such agreements;

3. Provide providers of health care who provide services to outpatients covered under a Medicaid fee-for-service program with educational opportunities concerning the use of prescription drugs;

4. Develop and make recommendations to the Department regarding programs for the prior authorization of prescription drugs in accordance with the provisions of sections 7 and 8 of this act;

5. Develop a procedure for a person to appeal a recommendation made by the Review Board to include a prescription drug in the program requiring prior authorization pursuant to sections 7 and 8 of this act after which a person may receive a hearing by the Department on the recommendation; and

6. Reassess and revise the drug utilization review programs developed pursuant to section 5 of this act when necessary.

Sec. 7. *1. Any program that requires prior authorization for a prescription drug within a Medicaid fee-for-service program established in the State of Nevada must be approved by the Review Board. The Review Board must observe a policy of avoiding a requirement for prior authorization for a prescription drug other than to address problems of abuse, misuse or inappropriate use of the prescription drug. The Review Board shall consider any information provided by interested persons concerning the program requiring prior authorization for prescription drugs, including, without limitation, information provided by:*

(a) Physicians licensed pursuant to chapter 630 of NRS;

(b) Osteopathic physicians licensed pursuant to chapter 633 of NRS;

(c) Registered pharmacists registered pursuant to chapter 639 of NRS; and

(d) Pharmaceutical manufacturers.

2. The Review Board shall not recommend for inclusion in the program requiring prior authorization for prescription drugs:

(a) A drug or compound that has been approved by the Federal Drug Administration, is newly released, has never before

been marketed and which pharmacies in this state that dispense prescription drugs for the Medicaid fee-for-service program can readily obtain in commercial quantities;

(b) A drug that has been approved by the Federal Drug Administration for a new condition or as a new treatment which pharmacies in this state that dispense prescription drugs for the Medicaid fee-for-service program can readily obtain in commercial quantities; or

(c) A drug that has not been included in the Medicaid fee-for-service program for at least 12 months, unless the class of therapeutic prescription drug of which the drug is a member is included in the program requiring prior authorization for prescription drugs.

3. A prescription drug may not be included in the program requiring prior authorization for prescription drugs unless:

(a) The Review Board has analyzed data from the retrospective drug utilization review program developed pursuant to section 5 of this act to identify the classes of therapeutic prescription drugs whose use is not likely to be medically appropriate or medically necessary, or is likely to result in adverse medical outcomes;

(b) The Review Board includes the entire class of therapeutic prescription drugs of which the drug is a member in the program requiring prior authorization;

(c) If the drug is the only member in its class of therapeutic prescription drugs, the decision of the Review Board to include the drug in the program requiring prior authorization applies to the entire class of therapeutic prescription drugs and not to the drug which is the only member of the class at the time that the decision to include the class in the program is made;

(d) The Review Board considers the potential impact on patient care and the potential fiscal impact of including the class of therapeutic prescription drugs of which the drug is a member in the program requiring prior authorization;

(e) Any consideration by the Review Board of the cost of the drug reflects the total cost of treating the conditions for which the class of therapeutic prescription drugs of which the drug is a member is prescribed, including, without limitation, non-pharmaceutical costs and costs incurred by other sectors of the health care system in this state that may be affected by the availability of the drug for treating recipients of the Medicaid fee-for-service program;

(f) The Review Board considers all other alternatives to requiring prior authorization for the class of therapeutic prescription drugs of which the drug is a member, including, without limitation, educating providers of health care who provide

services to patients covered under the Medicaid fee-for-service program and patients who receive such services;

(g) The Review Board makes a formal written recommendation to the Department that the class of therapeutic prescription drugs of which the drug is a member be included in the program requiring prior authorization and that recommendation is supported by an analysis of data from the prospective and retrospective drug utilization review programs developed pursuant to section 5 of this act that demonstrates:

(1) The expected impact of the inclusion of the class of therapeutic prescription drugs in the program on the clinical care received by recipients of the Medicaid fee-for-service program for whom the class of therapeutic prescription drugs is medically necessary;

(2) The expected impact of the inclusion of the class of therapeutic prescription drugs in the program on physicians who provide services to patients covered under the Medicaid fee-for-service program for whom the class of therapeutic prescription drugs is medically necessary; and

(3) The expected fiscal impact of the inclusion of the class of therapeutic prescription drugs in the program on the Medicaid fee-for-service program;

(h) The Department accepts the recommendation of the Review Board made pursuant to paragraph (g) and makes a written decision that the class of therapeutic prescription drugs of which the drug is a member should be included in the program requiring prior authorization, without adding to or detracting from the recommendation of the Review Board concerning the specific drug, taking into consideration any additional clarifying information provided by any interested person; and

(i) The Department notifies the manufacturers of all of the drugs which are included in the class of therapeutic prescription drugs of which the drug is a member that the drug has been accepted for inclusion in the program requiring prior authorization.

4. Within 180 days after receiving a notice pursuant to paragraph (i) of subsection 3, a manufacturer may propose a plan of drug utilization to the Review Board to educate persons who prescribe or dispense prescription drugs to patients covered under the Medicaid fee-for-service program concerning criteria and standards that are designed to identify and prevent the potential abuse, misuse or inappropriate use of the class of therapeutic prescription drugs of which the drug accepted for inclusion in the program requiring prior authorization is a member. If a manufacturer proposes a plan of drug utilization that is acceptable

to the Department pursuant to this subsection, the drug may not be included in the program requiring prior authorization.

5. Written notice of each decision of the Department concerning the program that requires prior authorization for prescription drugs within the Medicaid fee-for-service program must be provided to the public, and the Department must provide a period of at least 30 days after each decision during which the public may provide comments concerning the decision to the Department. No decision of the Department concerning the program that requires prior authorization for prescription drugs within the Medicaid fee-for-service program is effective until the end of the period provided for public comment.

6. The Review Board shall review the need for any prescription drug to be included within a program requiring prior authorization not later than 12 months after the original inclusion of the prescription drug within the program.

Sec. 8. *1. Any program that requires prior authorization for a prescription drug within a Medicaid fee-for-service program established in the State of Nevada must provide for the approval or denial of the use of the prescription drug via telephone, facsimile or electronic transmission within 24 hours after the receipt of a request for the prior authorization for the prescription drug.*

2. In an emergency situation, including, without limitation, a situation in which an approval or denial of the use of a prescription drug is unavailable, the program of prior authorization must provide for the approval of:

(a) A 72-hour supply of the prescription drug; or

(b) At the discretion of the Review Board, a supply of the prescription drug that is greater than the amount set forth in paragraph (a) and that is sufficient to assure a minimum effective duration of therapy for an acute intervention,

paid for by the Medicaid fee-for-service program.

3. The program of prior authorization must authorize a prescription for:

(a) A dose, duration or refill of a prescription drug;

(b) A prescription drug that duplicates the effect of another prescription drug or treatment;

(c) A prescription drug whose therapeutic effect might be adversely altered by the presence of a disease or condition other than the disease or condition for which the drug was prescribed;

(d) A prescription drug which might when taken with another prescription drug prescribed to the patient lead either to clinically significant toxicity that is uncharacteristic of any one of the drugs or to interference with the effectiveness of one or more of the drugs; or

(e) A prescription drug which might when taken with another prescription drug prescribed to the patient result in a clinically significant adverse medical effect,
that is not authorized by the program if the person who prescribed the prescription knows of and accepts the potential complications involved in such a prescription.

4. The program of prior authorization shall work with persons who prescribe prescription drugs to patients covered under the Medicaid fee-for-service program to develop an efficient process for the submission of a request for prior authorization. To the extent possible, the process must be directly related to the interaction between the person who is prescribing the prescription drug and the patient, and must not consist of separate tasks required by the person who is prescribing the prescription drug.

Sec. 9. ***To ensure that the use of prescription drugs is appropriate, medically necessary and not likely to result in adverse medical outcomes in any Medicaid fee-for-service program that provides coverage for prescription drugs, the Department must implement the retrospective drug utilization review program and the prospective drug utilization review program developed by the Review Board pursuant to section 5 of this act.***

Sec. 10. NRS 422.240 is hereby amended to read as follows:

422.240 1. Money to carry out the provisions of NRS 422.001 to 422.410, inclusive, ***and sections 2 to 9, inclusive, of this act*** and 422.580, including, without limitation, any federal money allotted to the State of Nevada pursuant to the program to provide Temporary Assistance for Needy Families and the Program for Child Care and Development, must be provided by appropriation by the Legislature from the State General Fund.

2. Disbursements for the purposes of NRS 422.001 to 422.410, inclusive, ***and sections 2 to 9, inclusive, of this act*** and 422.580 must be made upon claims duly filed, audited and allowed in the same manner as other money in the State Treasury is disbursed.

Sec. 11. This act becomes effective on July 1, 2003.