STATE OF NEW YORK

4123

2021-2022 Regular Sessions

IN ASSEMBLY

February 1, 2021

Introduced by M. of A. RODRIGUEZ, AUBRY, ABBATE, BENEDETTO, ABINANTI, MAGNARELLI, PERRY, PAULIN, PEOPLES-STOKES, GOTTFRIED, STECK -- Multi-Sponsored by -- M. of A. J. A. GIGLIO, GLICK, LAVINE, LUPARDO, SIMON, THIELE -- read once and referred to the Committee on Health

AN ACT to amend the social services law and the public health law, relation to prescription drugs in Medicaid managed care programs; and to repeal certain provisions of the social services law, relating to payments for prescription drugs

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

- Section 1. The social services law is amended by adding a new section 2 365-i to read as follows:
- § 365-i. Prescription drugs in Medicaid managed care programs. 1. 3 Definitions. As used in this section, unless the context clearly 5 requires otherwise:
- (a) "Article" means title eleven of article five of this chapter with 7 respect to the medical assistance program, and title one-A of article twenty-five of the public health law with respect to the child health 8 insurance plan.
- 10 (b) "Clinical drug review program" means the clinical drug review 11 program under section two hundred seventy-four of the public health law.
- (c) "Emergency condition" means a medical or behavioral condition as 12 determined by the prescriber or pharmacist, the onset of which is 13 sudden, that manifests itself by symptoms of sufficient severity, 14 including severe pain, and for which delay in beginning treatment 15 16 prescribed by the patient's health care practitioner would result in:
- 17 (i) placing the health or safety of the person afflicted with such 18 condition or other person or persons in serious jeopardy;
- (ii) serious impairment to such person's bodily functions; 19
- 20 (iii) serious dysfunction of any bodily organ or part of such person;
- 21 (iv) serious disfigurement of such person; or
 - (v) severe discomfort.

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(d) "Managed care provider" means a managed care provider under 23 section three hundred sixty-four-j of this title, a managed long term 24

EXPLANATION--Matter in italics (underscored) is new; matter in brackets [-] is old law to be omitted.

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care plan or other care coordination model under section forty-four hundred three-f of the public health law, an approved organization under title one-A of article twenty-five of the public health law (child health insurance plan), or any other entity that provides or arranges for the provision of medical assistance services and supplies to participants directly or indirectly (including by referral), including case management, including the managed care provider's authorized agents.

- (e) "Non-preferred drug" means a prescription drug that requires prior authorization under the participant's managed care provider.
- (f) "Participant" means a medical assistance recipient who receives, is required to receive or elects to receive his or her medical assistance services from a managed care provider.
- (g) "Preferred drug" means a prescription drug that is not a non-preferred drug under the patient's managed care provider. "Preferred drug list" means a list of a managed care provider's preferred drugs.
- (h) "Preferred drug program" means the preferred drug program established under section two hundred seventy-two of the public health law.
- (i) "Prescriber" means a health care professional authorized to prescribe prescription drugs for a participant of the managed care provider, acting within his or her lawful scope of practice.
- (j) "Prescription drug" or "drug" means a drug defined in subdivision seven of section sixty-eight hundred two of the education law, for which a prescription is required under the federal food, drug and cosmetic act. Any drug that does not require a prescription under such act, but which would otherwise be eligible for reimbursement under this article when ordered by a prescriber and the prescription is subject to the applicable provisions of this article and paragraph (a) of subdivision four of section three hundred sixty-five-a of this title.
- (k) "Prior authorization" means a process requiring the prescriber or the dispenser to verify with the participant's managed care provider that the drug is appropriate for the needs of the specific patient.
- (1) "Qualified prescription drug system" or "system" means a process under this section, approved by the commissioner, through which a managed care provider approves payment for a non-preferred drug for a participant based on prior authorization.
- 2. Payment for prescription drugs under capitation. (a) Payment for prescription drugs shall be included in the capitation payments for services or supplies provided to a managed care provider's participants, provided that the managed care provider pays for prescription drugs under a qualified prescription drug system. Every prescription drug eligible for reimbursement under this article prescribed in relation to a service provided by the managed care provider shall be either a preferred or non-preferred drug under the qualified prescription drug system. The commissioner shall approve a managed care provider's qualified prescription drug system if it conforms to the provisions of this section.
- (b) If the managed care provider does not pay for prescription drugs under a qualified prescription drug system, then payment for prescription drugs for the managed care provider's patients shall not be included in such capitation payments and prescription drugs shall be provided for the managed care provider's participants under the preferred drug program.
- 3. Qualified prescription drug system; criteria. (a) A qualified prescription drug system shall promote access to the most effective prescription drugs while reducing the cost of prescription drugs under

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this article. This subdivision and subdivision four of this section apply to qualified prescription drug systems.

- (b) When a prescriber prescribes a non-preferred drug for a participant, reimbursement may be denied unless prior authorization is obtained, unless no prior authorization is required under this section. When a prescriber prescribes a preferred drug for a participant, no prior authorization shall be required for reimbursement, unless prior authorization is required under the clinical drug review program.
- 9 <u>(c) The commissioner shall establish performance standards for systems</u>
 10 <u>that, at a minimum, ensure that systems provide sufficient technical</u>
 11 <u>support and timely responses to consumers, prescribers and pharmacists.</u>
 - (d) The commissioner shall adopt criteria for qualified prescription drug systems after considering recommendations and comments received from prescribers, pharmacists, participants, and organizations representing them.
 - (e) The managed care provider shall develop its preferred drug list based initially on an evaluation of the clinical effectiveness, safety, and patient outcomes, followed by consideration of the cost-effectiveness of the drugs. In each therapeutic class, the managed care provider shall determine whether there is one drug that is significantly more clinically effective and safe, and that drug shall be included on the preferred drug list without consideration of cost. If, among two or more drugs in a therapeutic class, the difference in clinical effectiveness and safety is not clinically significant, then cost-effectiveness may also be considered in determining which drug or drugs shall be included on the preferred drug list.
 - 4. Prior authorization. (a) A qualified prescription drug system shall make available a twenty-four hour per day, seven days per week telephone call center that includes a tollfree telephone line and dedicated facsimile line to respond to requests for prior authorization. The call center shall include qualified health care professionals who shall be available to consult with prescribers concerning prescription drugs that are non-preferred drugs. A prescriber seeking prior authorization shall consult with the program call line to reasonably present his or her justification for the prescription and give the program's qualified health care professional a reasonable opportunity to respond.
 - (b) When a patient's health care provider prescribes a non-preferred drug, the prescriber shall consult with the system to confirm that in his or her reasonable professional judgment, the patient's clinical condition is consistent with the criteria for approval of the non-preferred drug. Such criteria shall include:
 - (i) the preferred drug has been tried by the patient and has failed to produce the desired health outcomes;
- 44 <u>(ii) the patient has tried the preferred drug and has experienced</u> 45 <u>unacceptable side effects;</u>
 - (iii) the patient has been stabilized on a non-preferred drug and transition to the preferred drug would be medically contraindicated; or
 - (iv) other clinical indications identified by the commissioner or the managed care provider for the patient's use of the non-preferred drug, which shall include consideration of the medical needs of special populations, including children, elderly, chronically ill, persons with mental health conditions, and persons affected by HIV/AIDS or Hepatitis C.
- 54 (c) In the event that the patient does not meet the criteria in para-55 graph (b) of this subdivision, the prescriber may provide additional 56 information to the managed care provider to justify the use of a non-

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 preferred drug. The system shall provide a reasonable opportunity for a prescriber to reasonably present his or her justification of prior authorization. If, after consultation with the managed care provider, the prescriber, in his or her reasonable professional judgment, determines that the use of a non-preferred drug is warranted, the prescriber's determination shall be final.

- (d) If a prescriber meets the requirements of paragraph (b) or (c) of this subdivision, the prescriber shall be granted prior authorization under this section.
- (e) In the instance where a prior authorization determination is not completed within twenty-four hours of the original request, solely as the result of a failure of the system (whether by action or inaction), prior authorization shall be immediately and automatically granted with no further action by the prescriber and the prescriber shall be notified of this determination. In the instance where a prior authorization determination is not completed within twenty-four hours of the original request for any other reason, a seventy-two hour supply of the medication shall be approved by the system and the prescriber shall be notified of this determination.
- (f) When, in the judgment of the prescriber or the pharmacist, an emergency condition exists, and the prescriber or pharmacist notifies the managed care provider that an emergency condition exists, a seventy-two hour emergency supply of the drug prescribed shall be immediately authorized by the managed care provider.
- (q) In the event that a patient presents a prescription to a pharmacist for a prescription drug that is a non-preferred drug and for which the prescriber has not obtained a prior authorization, the pharmacist shall, within a prompt period based on professional judgment, notify the prescriber. The prescriber shall, within a prompt period based on professional judgment, either seek prior authorization or shall contact the pharmacist and amend or cancel the prescription. The pharmacist shall, within a prompt period based on professional judgment, notify the patient when prior authorization has been obtained or denied or when the prescription has been amended or cancelled.
- (h) Once prior authorization of a prescription for a drug that is not on the preferred drug list is obtained, prior authorization shall not be required for any refill of the prescription.
- (i) No prior authorization under a qualified prescription drug system shall be required for: (i) atypical anti-psychotics; (ii) anti-depressants; (iii) anti-retrovirals used in the treatment of HIV/AIDS or Hepatitis C; (iv) anti-rejection drugs used in the treatment of organ and tissue transplants; and (v) any other therapeutic class for the treatment of mental illness, HIV/AIDS or Hepatitis C, approved by the commissioner.
- 5. Clinical drug review program. In the case of a drug for which prior authorization is required under the clinical drug review program, prior authorization shall be obtained under the clinical drug review program and not under this section.
- 6. Prescriber conduct. The managed care provider and the department shall monitor the prior authorization process under a qualified prescription drug system for prescribing patterns which are suspected of endangering the health and safety of the patient or which demonstrate a likelihood of fraud or abuse. The managed care provider and the department shall take any and all actions otherwise permitted by law to investigate such prescribing patterns, to take remedial action and to enforce applicable federal and state laws.

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7. Use of preferred drug program. The commissioner may contract with a managed care provider for the provider to use the preferred drug program to provide prior authorization under the managed care provider's qualified prescription drug system. The contract shall include terms required by the commissioner to maximize savings to the Medicaid program and protect the health and interests of the managed care provider's participants. The contract shall provide whether the preferred drug program shall use the managed care provider's lists of preferred and non-preferred drugs or the preferred drug list under the preferred drug program, with respect to whether prior authorization is required.

- § 2. Subdivisions 25 and 25-a of section 364-j of the social services law are REPEALED.
- § 3. Section 2511 of the public health law is amended by adding a new subdivision 22 to read as follows:
- 22. Payment for prescription drugs. Payment for prescription drugs shall be included in the payments for services or supplies provided by the approved organization, provided that the plan pays for prescription drugs under a qualified prescription drug system under section three hundred sixty-five-i of the social services law. Every prescription drug eligible for reimbursement under this article prescribed in relation to a service provided by the approved organization shall be either a preferred or non-preferred drug under the qualified prescription drug system. If the approved organization does not pay for prescription drugs under a qualified prescription drug system, then payment for prescription drugs for the approved organization's patients shall not be included in such payments and prescription drugs shall be provided for the approved organization's participants under the preferred drug program.
- § 4. Subdivision 11 of section 270 of the public health law, as amended by section 2-a of part C of chapter 58 of the laws of 2008, is amended to read as follows:
- "State public health plan" means the medical assistance program established by title eleven of article five of the social services law (referred to in this article as "Medicaid"), the elderly pharmaceutical insurance coverage program established by title three of article two of the elder law (referred to in this article as "EPIC"), [and the family health plus program established by section three hundred sixty-nine-ee of the social services law to the extent that section provides that the program shall be subject to this article], and the child health insurance plan under title one-A of article twenty-five of this chapter.
- § 5. Section 272 of the public health law is amended by adding a new subdivision 12 to read as follows:
- 12. No prior authorization shall be required under the preferred drug program for:
- (a) atypical anti-psychotics; (b) anti-depressants; (c) anti-retrovirals used in the treatment of HIV/AIDS or Hepatitis C; (d) anti-rejection drugs used in the treatment of organ and tissue transplants; and (e) any other therapeutic class for the treatment of mental illness, HIV/AIDS or Hepatitis C, recommended by the board and approved by the commissioner under this section.
- § 6. This act shall take effect on the one hundred eightieth day after it shall become a law; provided, however, that section two of this act shall take effect one year after this act shall become a law. Effective 54 immediately the commissioner of health is authorized to promulgate any 55 regulation or rule necessary to implement this act on or before such 56 effective date.