DRAFT LBDC

A BUDGET BILL submitted by the Governor
in accordance with Article VII of the Constitution

AN ACT to amend the social services law, the public health law and the insurance law, in relation to creating a single preferred-drug list for medication assisted treatment; to amend chapter 57 of the laws of 2015, amending the social services law and other laws relating to supplemental rebates, in relation to the effectiveness thereof; to amend chapter 165 of the laws of 1991, amending the public health law and other laws relating to establishing payments for medical assistance, in relation to the effectiveness thereof; to amend chapter 710 of the laws of 1988, amending the social services law and the education law relating to medical assistance eligibility of certain persons and providing for managed medical care demonstration programs, in relation to the effectiveness thereof; and providing for the repeal of certain provisions upon expiration thereof (Part _ );

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

PART __

Section 1. Paragraph (e) of subdivision 7 of section 367-a of the social services law, as amended by section 5-a of part T of chapter 57 of the laws of 2018, is amended to read as follows:

(e) During the period from April first, two thousand fifteen through March thirty-first, two thousand [twenty] twenty-three, the commissioner may, in lieu of a managed care provider, negotiate directly and enter into an agreement with a pharmaceutical manufacturer for the provision of supplemental rebates relating to pharmaceutical utilization by enrollees of managed care providers pursuant to section three hundred sixty-four-j of this title and may also negotiate directly and enter into such an agreement relating to pharmaceutical utilization by medical assist-

ance recipients not so enrolled. Such rebates shall be limited to drug utilization in the following classes: antiretrovirals approved by the FDA for the treatment of HIV/AIDS, opioid dependence agents and opioid antagonists listed in a statewide formulary established pursuant to subparagraph (vii) of this paragraph and hepatitis C agents for which the pharmaceutical manufacturer has in effect a rebate agreement with the federal secretary of health and human services pursuant to 42 U.S.C. § 1396r-8, and for which the state has established standard clinical criteria. No agreement entered into pursuant to this paragraph shall have an initial term or be extended beyond the expiration or repeal of this paragraph.

(i) The manufacturer shall not pay supplemental rebates to a managed care provider, or any of a managed care provider's agents, including but not limited to any pharmacy benefit manager on the [two] classes of drugs subject to this paragraph when the state is collecting supplemental rebates and standard clinical criteria are imposed on the managed care provider.

(ii) The commissioner shall establish adequate rates of reimbursement which shall take into account both the impact of the commissioner negotiating such rebates and any limitations imposed on the managed care provider's ability to establish clinical criteria relating to the utilization of such drugs. In developing the managed care provider's reimbursement rate, the commissioner shall identify the amount of reimbursement for such drugs as a separate and distinct component from the reimbursement otherwise made for prescription drugs as prescribed by this section.

(iii) The commissioner shall submit a report to the temporary president of the senate and the speaker of the assembly annually by December

thirty-first. The report shall analyze the adequacy of rates to managed care providers for drug expenditures related to the classes under this paragraph.

(iv) Nothing in this paragraph shall be construed to require a pharmaceutical manufacturer to enter into a supplemental rebate agreement with the commissioner relating to pharmaceutical utilization by enrollees of managed care providers pursuant to section three hundred sixty-four-j of this title or relating to pharmaceutical utilization by medical assistance recipients not so enrolled.

(v) All clinical criteria, including requirements for prior approval, and all utilization review determinations established by the state as described in this paragraph for [either] <u>any</u> of the drug classes subject to this paragraph shall be developed using evidence-based and peer-reviewed clinical review criteria in accordance with article two-A of the public health law, as applicable.

(vi) All prior authorization and utilization review determinations related to the coverage of any drug subject to this paragraph shall be subject to article forty-nine of the public health law, section three hundred sixty-four-j of this title, and article forty-nine of the insurance law, as applicable. Nothing in this paragraph shall diminish any rights relating to access, prior authorization, or appeal relating to any drug class or drug afforded to a recipient under any other provision of law.

<u>(vii) The department shall publish a statewide formulary of opioid dependence agents and opioid antagonists, which shall include all drugs in such classes, provided that:</u>

<u>(A) for all drugs that are included as of the date of the enactment of this subparagraph on a formulary of a managed care provider, as defined</u>

in section three hundred sixty-four-j of this title, or in the Medicaid fee-for-service preferred drug program pursuant to section two hundred seventy-two of the public health law, the cost to the department for such drug is equal to or less than the lowest cost paid for the drug by any managed care provider or by the Medicaid fee-for-service program after the application of any rebates, as of the date that the department implements the statewide formulary established by this subparagraph. Where there is a generic version of the drug approved by the Food and Drug Administration as bioequivalent to a brand name drug pursuant to 21 U.S.C. § 355(j)(8)(B), the cost to the department for both the brand and generic versions shall be equal to or less than the lower of the two maximum costs determined pursuant to the previous sentence; and

(B) for all drugs that are not included as of the date of the enactment of this subparagraph on a formulary of a managed care provider, as defined in section three hundred sixty-four-j of this title, or in the Medicaid fee-for-service preferred drug program pursuant to section two hundred seventy-two of the public health law, the department is able to obtain the drug at a cost that is equal to or less than the lowest cost to the department of other drugs in the class, after the application of any rebates. Where there is a generic version of the drug approved by the Food and Drug Administration as bioequivalent to a brand name drug pursuant to 21 U.S.C. § 355(j)(8)(B), the cost to the department for both the brand and generic versions shall be equal to or less than the lower of the two maximum costs determined pursuant to the previous sentence.

§ 2. Paragraph (a) of subdivision 3 of section 273 of the public health law, as added by section 10 of part C of chapter 58 of the laws

of 2005, is amended and a new paragraph (a-1) is added to read as follows:

(a) When a patient's health care provider prescribes a prescription drug that is not on the preferred drug list or the statewide formulary of opioid dependence agents and opioid antagonists established pursuant to subparagraph (vii) of paragraph (e) of subdivision seven of section three hundred sixty-seven-a of the social services law, the prescriber shall consult with the program 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;

(ii) the patient has tried the preferred drug and has experienced unacceptable side effects;

(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 [committee for the patient's use of the non-preferred drug] drug utilization review board established pursuant to section three hundred sixty-nine-bb of the social services law, 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, pregnant persons and persons with an opioid use disorder.

(a-1) When a patient's health care provider prescribes a prescription drug that is on the statewide formulary of opioid dependence agents and opioid antagonists established pursuant to subparagraph (vii) of paragraph (e) of subdivision seven of section three hundred sixty-seven-a of

the social services law, the department shall not require prior authorization unless required by the department's drug use review program established pursuant to section 1927(g) of the Social Security Act.

§ 3. Section 364-j of the social services law is amended by adding a new subdivision 38 to read as follows:

38. (a) When a patient's health care provider prescribes a prescription drug that is not on the statewide formulary of opioid dependence agents and opioid antagonists, the prescriber shall consult with the managed care plan 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 or non-formulary drug. Such criteria shall include:

(i) the preferred drug has been tried by the patient and has failed to produce the desired health outcomes;

(ii) the patient has tried the preferred drug and has experienced unacceptable side effects;

(iii) the patient has been stabilized on a non-preferred drug and transition to the preferred or formulary drug would be medically contraindicated; or

(iv) other clinical indications identified by the committee 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, persons affected by HIV/AIDS and pregnant persons with a substance use disorder.

(b) The managed care plan shall have a process for a patient, or the patient's prescribing health care provider, to request a review for a prescription drug that is not on the statewide formulary of opioid

dependence agents and opioid antagonists, consistent with 42 C.F.R. 438.210(d), or any successor regulation.

(c) A managed care plan's failure to comply with the requirements of this subdivision shall be subject to a one thousand dollar fine per violation.

§ 4. Subparagraph (A) of paragraph 7-a of subsection (l) of section 3221 of the insurance law, as added by chapter 748 of the laws of 2019, is amended to read as follows:

(A) Every policy that provides medical, major medical or similar comprehensive-type large group coverage shall provide immediate coverage for all buprenorphine products, methadone or long acting injectable naltrexone without prior authorization for the detoxification or maintenance treatment of a substance use disorder. Further, immediate coverage without prior authorization shall include methadone, when used for opioid use disorder and administered or dispensed in an opioid treatment program.

§ 5. Section 364-j of the social services law is amended by adding new subdivision 26-c to read as follows:

26-c. Managed care providers shall not require prior authorization for methadone, when used for opioid use disorder and administered or dispensed in an opioid treatment program.

§ 6. Subdivision 10 of section 273 of the public health law, as added by section 5 of part B of chapter 69 of the laws of 2016, is amended to read as follows:

10. Prior authorization shall not be required for an initial or renewal prescription for buprenorphine or injectable naltrexone for detoxification or maintenance treatment of opioid addiction unless the prescription is for a non-preferred or non-formulary form of such drug

as otherwise required by section 1927(k)(6) of the Social Security Act. Further, prior authorization shall not be required for methadone, when used for opioid use disorder and administered or dispensed in an opioid treatment program.

§ 7. Subdivision 1 of section 60 of part B of chapter 57 of the laws of 2015, amending the social services law and other laws relating to supplemental rebates, as amended by section 5-b of part T of chapter 57 of the laws of 2018, is amended to read as follows:

1. section one of this act shall expire and be deemed repealed March 31, [2023] 2026;

§ 8. Subdivision (c) of section 62 of chapter 165 of the laws of 1991, amending the public health law and other laws relating to establishing payments for medical assistance, as amended by section 16 of part Z of chapter 57 of the laws of 2018, is amended to read as follows:

(c) section 364-j of the social services law, as amended by section eight of this act and subdivision 6 of section 367-a of the social services law as added by section twelve of this act shall expire and be deemed repealed on March 31, [2024] 2026 and provided further, that the amendments to the provisions of section 364-j of the social services law made by section eight of this act shall only apply to managed care programs approved on or after the effective date of this act;

§ 9. Section 11 of chapter 710 of the laws of 1988, amending the social services law and the education law relating to medical assistance eligibility of certain persons and providing for managed medical care demonstration programs, as amended by section 18 of part Z of chapter 57 of the laws of 2018, is amended to read as follows:

§ 11. This act shall take effect immediately; except that the provisions of sections one, two, three, four, eight and ten of this act

shall take effect on the ninetieth day after it shall have become a law; and except that the provisions of sections five, six and seven of this act shall take effect January 1, 1989; and except that effective immediately, the addition, amendment and/or repeal of any rule or regulation necessary for the implementation of this act on its effective date are authorized and directed to be made and completed on or before such effective date; provided, however, that the provisions of section 364-j of the social services law, as added by section one of this act shall expire and be deemed repealed on and after March 31, [2024] 2026, the provisions of section 364-k of the social services law, as added by section two of this act, except subdivision 10 of such section, shall expire and be deemed repealed on and after January 1, 1994, and the provisions of subdivision 10 of section 364-k of the social services law, as added by section two of this act, shall expire and be deemed repealed on January 1, 1995.

§ 10. This act shall take effect immediately, provided however, that:

a. the amendments to paragraph (e) of subdivision 7 of section 367-a of the social services law made by section one of this act shall not affect the repeal of such paragraph and shall be deemed expired therewith;

b. the provisions of section two of this act shall expire March 31, 2026 when upon such date the provisions of such section shall be deemed repealed;

c. the amendments to section 364-j of the social services law made by sections three and five of this act shall not affect the repeal of such section and shall be deemed expired therewith; and

d. the statewide formulary of opioid dependence agents and opioid antagonists authorized by this act shall be implemented within six months after it shall have become a law.