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State/Territory Name: Massachusetts

State Plan Amendment (SPA) #: 19-0001

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/Summary Form (with 179-like data)
- 3) Approved SPA Pages

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850



Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

July 31, 2019

Marylou Sudders, Secretary
Executive Office of Health and Human Services
One Ashburton Place, Room 1109
Boston, Massachusetts 02108

Dear Ms. Sudders:

We have reviewed Massachusetts State Plan Amendment (SPA) 19-0001 received in the Boston Regional Operations Group on March 12, 2019. This SPA proposes to authorize the state to enter value- or outcome-based supplemental rebate agreements with drug manufacturers for drugs provided to the Medicaid program.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 19-0001 is approved with an effective date of January 1, 2019. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into Massachusetts state plan will be forwarded by the Boston Regional Operations Group.

If you have any questions regarding this amendment, please contact Whitney Swears at (410) 786-6543 or Whitney.Swears@cms.hhs.gov.

Sincerely,

/s/

Cynthia R. Denemark, RPh,
Deputy Director
Division of Pharmacy

cc: Daniel Tsai, Assistant Secretary for MassHealth, Medicaid Director
Kaela Konefal, Federal Authority Policy Analyst/State Plan Coordinator
Francis T. McCullough, Director, CMS Division of Medicaid Field Operations East (Boston)
Julie McCarthy, CMS Division of Medicaid Field Operations East (Boston)



Boston Regional Operations Group

July 31, 2019

Marylou Sudders, Secretary
Executive Office of Health and Human Services
One Ashburton Place, Room 1109
Boston, Massachusetts 02108

Dear Secretary Sudders:

On July 31, 2019 the CMS Division of Pharmacy approved your proposed State Plan Amendment (SPA) No. 19-0001, effective January 1, 2019. This letter conveys the Transmittal and Notice of Approval of State Plan Material (CMS-179) and the approved State plan pages. SPA No. 19-0001 amends the State's approved Title XIX State plan to allow the State to enter into State-specific value- or outcome-based supplemental rebate agreements with drug manufacturers for drugs provided to the Medicaid Program.

Enclosed are copies of the following approved State plan pages.

- Supplement to Attachment 3.1-A, pages 3a1a and 3a1b; and
- Supplement to Attachment 3.1-B, pages 3a1a and 3a1b.

If you have any questions regarding this matter you may contact Julie McCarthy at (781) 961-1070 or by e-mail at Julie.McCarthy@cms.hhs.gov.

Sincerely,

/s/

Francis T. McCullough, Director
Division of Medicaid Field Operations East (Boston)

Enclosure/s

cc: Daniel Tsai, Assistant Secretary for MassHealth, Medicaid Director
Kaela Konefal, Federal Authority Policy Analyst/State Plan Coordinator

**TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL**

FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES

1. TRANSMITTAL NUMBER

1 9 — 0 0 1

2. STATE

MA

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
CENTERS FOR MEDICARE & MEDICAID SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE

01/01/2019

5. TYPE OF PLAN MATERIAL (*Check One*)

NEW STATE PLAN

AMENDMENT TO BE CONSIDERED AS NEW PLAN

AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (*Separate transmittal for each amendment*)

6. FEDERAL STATUTE/REGULATION CITATION

42 U.S.C. 1396r-8

7. FEDERAL BUDGET IMPACT

a. FFY 2019 \$ 0

b. FFY 2020 \$ 0

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

Supplement to Attachment 3.1-A pages 3a1a-3a1b
Supplement to Attachment 3.1-B pages 3a1a-3a1b

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (*If Applicable*)

Supplement to Attachment 3.1-A pages 3a1a-3a1b
Supplement to Attachment 3.1-B pages 3a1a-3a1b

10. SUBJECT OF AMENDMENT

Value-Based Supplemental Rebate

11. GOVERNOR'S REVIEW (*Check One*)

GOVERNOR'S OFFICE REPORTED NO COMMENT

COMMENTS OF GOVERNOR'S OFFICE ENCLOSED

NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

OTHER, AS SPECIFIED

Not required under 42 CFR 430.12(b)(2)(i)

12. SIGNATURE OF STATE AGENCY OFFICIAL

/s/

13. TYPED NAME

Marylou Sudders

14. TITLE

Secretary

15. DATE SUBMITTED

03/12/2019

16. RETURN TO

Kaela Konefal
State Plan Coordinator
Executive Office of Health and Human Services
Office of Medicaid
One Ashburton Place, 11th Floor
Boston, MA 02108

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED

03/12/2019

18. DATE APPROVED

07/31/2019

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL

01/01/2019

20. SIGNATURE OF REGIONAL OFFICIAL

/s/

21. TYPED NAME

Francis T. McCullough

22. TITLE Director, Division of Medicaid Field Operations
East (Boston)

23. REMARKS

**State Plan under Title XIX of the Social Security Act
State: Massachusetts
Amount, Duration and Scope of Medical
And Remedial Care and Services Provided to the Categorically Needy**

2. A rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on March 31, 2016, and entitled, “State of Massachusetts Supplemental Rebate Agreement” has been authorized by CMS, and a value-based rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on March 12, 2019, and entitled, “State of Massachusetts Value-Based Supplemental Rebate Agreement” has been authorized by CMS.
3. Manufacturers with supplemental rebate agreements are allowed to audit utilization data. Supplemental rebates received by the state in excess of those required under the National Drug Rebate Agreement (NDRA) will be shared with the federal government on the same percentage basis as applied under the NDRA.
4. The unit rebate amount under the NDRA is confidential and cannot be disclosed in accordance with Section 1927(b)(3)(D) of the Social Security Act. No substantial changes will be made to the supplemental rebate agreement without CMS authorization. Supplemental rebates received pursuant to these agreements are only for the MassHealth program.
5. All drugs covered by the program, irrespective of a supplemental rebate agreement, will comply with the provisions of the NDRA.
6. The prior authorization process for covered outpatient drugs conforms to Section 1927(d)(5) of the Social Security Act. The prior authorization process provides for a turnaround response by either telephone or other telecommunications device within twenty-four hours of receipt of a prior authorization request. In emergency situations, providers may dispense at least a seventy-two hour supply of medication.
7. The state may agree within the terms of a supplemental rebate agreement that the covered drug(s) may or may not be subject to prior authorization, for as long as the agreement is in effect, and that the state may obtain supplemental drug rebates in either case. This may include instances in which the state imposes prior authorization on a drug or drugs for clinical purposes, instances in which the state imposes prior authorization on a drug or drugs as part of a “step-edit” approach, and instances in which the state imposes prior authorization on a drug or drugs (which may include a generic drug) when the application of the supplemental rebate on the preferred drug or drugs results in a lower net cost to the state. The state may also enter value- or outcome-based agreements.
8. Only drugs supplied to MassHealth members will be covered under these agreements. In addition to collecting supplemental rebates for fee-for-service claims, the state may, at its option, also collect supplemental rebates for MassHealth member utilization through MCE(s) under an agreement.
9. The state may continue to collect supplemental rebates under agreements that are currently in process or effect based on the form of agreement approved by CMS as part of MA-TN-012-005 until those agreements are otherwise terminated or amended to align with the CMS-approved forms referred to in paragraph 2, above.

Effective January 1, 2006, the Medicaid agency will not cover any Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.

**State Plan under Title XIX of the Social Security Act
State: Massachusetts
Amount, Duration and Scope of Medical
And Remedial Care and Services Provided to the Categorically Needy**

The Medicaid agency provides coverage for the following excluded or otherwise restricted drugs or classes of drugs, or their medical uses to all Medicaid recipients, including full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit –Part D.

The following excluded drugs are covered:

- (a) agents when used for anorexia, weight loss, weight gain (for medically necessary appetite stimulants only)
- (b) agents when used to promote fertility
- (c) agents when used for the symptomatic relief cough and colds (covered only when dispensed to members residing in a nursing facility).
- (d) prescription vitamins and mineral products, except prenatal vitamins and fluoride-containing products

**State Plan under Title XIX of the Social Security Act
State: Massachusetts
Amount, Duration and Scope of Medical
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2. A rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on March 31, 2016, and entitled, “State of Massachusetts Supplemental Rebate Agreement” has been authorized by CMS, and a value-based rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on March 12, 2019, and entitled, “State of Massachusetts Value-Based Supplemental Rebate Agreement” has been authorized by CMS..
3. Manufacturers with supplemental rebate agreements are allowed to audit utilization data. Supplemental rebates received by the state in excess of those required under the National Drug Rebate Agreement (NDRA) will be shared with the federal government on the same percentage basis as applied under the NDRA.
4. The unit rebate amount under the NDRA is confidential and cannot be disclosed in accordance with Section 1927(b)(3)(D) of the Social Security Act. No substantial changes will be made to the supplemental rebate agreement without CMS authorization. Supplemental rebates received pursuant to these agreements are only for the MassHealth program.
5. All drugs covered by the program, irrespective of a supplemental rebate agreement, will comply with the provisions of the NDRA.
6. The prior authorization process for covered outpatient drugs conforms to Section 1927(d)(5) of the Social Security Act. The prior authorization process provides for a turnaround response by either telephone or other telecommunications device within twenty-four hours of receipt of a prior authorization request. In emergency situations, providers may dispense at least a seventy-two hour supply of medication.
7. The state may agree within the terms of a supplemental rebate agreement that the covered drug(s) may or may not be subject to prior authorization, for as long as the agreement is in effect, and that the state may obtain supplemental drug rebates in either case. This may include instances in which the state imposes prior authorization on a drug or drugs for clinical purposes, instances in which the state imposes prior authorization on a drug or drugs as part of a “step-edit” approach, and instances in which the state imposes prior authorization on a drug or drugs (which may include a generic drug) when the application of the supplemental rebate on the preferred drug or drugs results in a lower net cost to the state. The state may also enter value- or outcome-based agreements.
8. Only drugs supplied to MassHealth members will be covered under these agreements. In addition to collecting supplemental rebates for fee-for-service claims, the state may, at its option, also collect supplemental rebates for MassHealth member utilization through MCE(s) under an agreement.
9. The state may continue to collect supplemental rebates under agreements that are currently in process or effect based on the form of agreement approved by CMS as part of MA-TN-012-005 until those agreements are otherwise terminated or amended to align with the CMS-approved forms referred to in paragraph 2, above.

Effective January 1, 2006, the Medicaid agency will not cover any Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.

The Medicaid agency provides coverage for the following excluded or otherwise restricted drugs or classes of drugs, or their medical uses to all Medicaid recipients, including full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit –Part D.

OFFICIAL

Supplement to Attachment 3.1-B
Page 3a1b

State Plan under Title XIX of the Social Security Act
State: Massachusetts
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The following excluded drugs are covered:

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- (b) agents when used to promote fertility
- (c) agents when used for the symptomatic relief cough and colds (covered only when dispensed to members residing in a nursing facility)
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