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State/Territory Name: Massachusetts

State Plan Amendment (SPA) #: 16-0002

This file contains the following documents in the order listed:

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

Disabled & Elderly Health Programs Group

May 12, 2016

Marylou Sudders
Secretary
Executive Office of Health and Human Services
Office of Medicaid
One Ashburton Place, 11th Floor
Boston, MA 02108

Attention: Daniel Cohen

Dear Ms. Sudders:

We have reviewed Massachusetts' State Plan Amendment (SPA) 16-002 received in the Boston regional office on March 31, 2016. This amendment proposed to update the terms upon which the state intends to collect supplemental rebates from drug manufacturers in order to authorize the state, at its option, to also include MassHealth member utilization through its MassHealth MCOs under an agreement.

We are pleased to inform you that the amendment is approved with an effective date of April 25, 2016. A copy of the CMS-179 form, as well as the page(s) approved for incorporation into the Massachusetts state plan, will be forwarded to you by the Boston regional office. If you have any questions regarding this amendment, please contact Emeka Egwim, PharmD at (410) 786-1092.

Sincerely,

/s/

John Coster, PhD, RPh
Director
Division of Pharmacy

cc: Richard D. Allen, ARA, Denver Regional Office
Julie McCarthy, Denver Regional Office

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
JFK Federal Building, Government Center
Room 2275
Boston, Massachusetts 02203

CENTERS FOR MEDICARE & MEDICAID SERVICES

Division of Medicaid and Children's Health Operations / Boston Regional Office

May 17, 2016

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

Dear Secretary Sudders:

On May 12, 2016 our Central Office sent you a letter approving your proposed State Plan Amendment (SPA) No. 16-002. This letter transmits the Transmittal and Notice of Approval of State Plan Material (CMS-179) and the approved State Plan pages and attachments.

SPA No. 16-002 proposed to amend the State's approved Title XIX State Plan to update the terms upon which the State intends to collect supplemental rebates from drug manufacturers in order to authorize the State, at its option, to also include MassHealth member utilization through its MassHealth managed care organizations under an agreement.. This SPA was approved effective April 25, 2016.

Changes are reflected in the following sections of your approved State Plan:

- Supplement to Attachment 3.1-A, page 3a1;
- Supplement to Attachment 3.1-B, page 3a1; and
- State of Massachusetts Supplemental Rebate Agreement.

If you have any questions regarding this matter you may contact Julie McCarthy at (617) 565-1244 or by e-mail at Julie.McCarthy@cms.hhs.gov.

Sincerely,

/s/

Richard R. McGreal
Associate Regional Administrator

Enclosure/s

cc: Daniel Tsai, Assistant Secretary for MassHealth, Medicaid Director
Daniel Cohen, State Plan Coordinator

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICIAD SERVICES

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES	1. TRANSMITTAL NUMBER: 016-002	2. STATE MA
	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR CENTERS FOR MEDICARE AND MEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE April 25, 2016	

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:	7. FEDERAL BUDGET IMPACT:
Section 1927 of the Social Security Act (42 USC 1396r-8)	**a. FFY16 $0** **b. FFY17 ($5 million)**
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
Supplement to Attachment 3.1-A page 3a1 a and 3a1b **Supplement to Attachment 3.1-B page 3a1** a and 3a1b	**Supplement to Attachment 3.1-A page 3a1** **Supplement to Attachment 3.1-B page 3a1**

10. SUBJECT OF AMENDMENT:

Supplemental Drug Rebate Agreement

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/	16. RETURN TO:
13. TYPED NAME: **Marylou Sudders**	**Daniel Cohen** **Interim State Plan Coordinator** **Executive Office of Health and Human Services** **Office of Medicaid** **One Ashburton Place, 11th Floor** **Boston, MA 02108**
14. TITLE: **Secretary**	
15. DATE SUBMITTED: **March 31, 2016**	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 03/31/2016	18. DATE APPROVED: 05/12/2016
PLAN APPROVED - ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL: 04/25/2016	20. SIGNATURE OF REGIONAL OFFICIAL: /s/
21. TYPED NAME: Richard R. McGreal	22. TITLE: Associate Regional Administrator, Division of Medicaid & Children's Health Operations, Boston, MA

23. REMARKS:

06/07/2016 MA authorized pen&ink change to correct Box #8.
08/02/2016 MA authorized pen&ink change to correct Box #8 to eliminate duplication with existing page 3a2 already in State plan

FORM CMS-179 (07-92)

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.
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.
8. Only drugs supplied to MassHealth members will be covered under this agreement. 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 MCO(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 new CMS-approved form 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.

☑ **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 cosmetic purposes or hair growth
☑ (d) agents when used for the symptomatic relief cough and colds (covered only when dispensed to members residing in a nursing facility).
☑ (e) prescription vitamins and mineral products, except prenatal vitamins and fluoride-containing products

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☐ (c) agents when used for cosmetic purposes or hair growth
☑ (d) agents when used for the symptomatic relief cough and colds (covered only when dispensed to members residing in a nursing facility)
☑ (e) prescription vitamins and mineral products, except prenatal vitamins and fluoride-containing products

STATE OF MASSACHUSETTS
SUPPLEMENTAL REBATE AGREEMENT
Between
THE MASSACHUSETTS EXECUTIVE OFFICE OF HEALTH AND HUMAN SERVICES
And
[DRUG MANUFACTURER]

This State Supplemental Rebate Agreement ("Agreement") is dated as of this [XXX] day of [MONTH], [YEAR], by and between the Massachusetts Executive Office of Health and Human Services (EOHHS), the single state agency for the administration of MassHealth, the medical assistance and benefit program pursuant to Title XIX of the Social Security Act (42 U.S.C. 1396 *et. seq.*), Title XXI of the Social Security Act (42 U.S.C. 1397aa *et. seq.*), M.G.L. c. 118E, and other applicable laws and waivers; and [DRUG MANUFACTURER] ("_____" or "Drug Manufacturer").

RECITALS

WHEREAS, EOHHS has the authority to enter into agreements with pharmaceutical manufacturers to collect supplemental rebates for the benefit of MassHealth Members, provided such agreements are authorized by the Centers for Medicare & Medicaid Services of the U.S. Department of Health and Human Services (CMS); and

WHEREAS, [DRUG MANUFACTURER] is willing to provide supplemental rebates to EOHHS based on the actual dispensing of [DRUG MANUFACTURER] Covered Drugs for MassHealth Members.

NOW THEREFORE, in consideration of the foregoing and of the representations, warranties and covenants set forth below, the parties agree as follows:

SECTION 1. DEFINITIONS

As used herein, the following terms shall have the meanings set forth below:

Agreement - this State Supplemental Rebate Agreement, including all documents attached or incorporated herein by reference.

Average Manufacturer Price (AMP) - as defined in section 1927(k)(1) of the Social Security Act (42 U.S.C. 1396r-8(k)(1)) and corresponding federal regulations promulgated and in effect from time to time (as amended, modified or superseded from time to time).

Best Price – as defined in section 1927 of the Social Security Act (42 U.S.C. 1396r-8) and corresponding federal regulations promulgated and in effect from time to time (as amended, modified or superseded from time to time).

CMS - the Centers for Medicare & Medicaid Services of the U.S. Department of Health and Human Services, or any successor or renamed agency carrying out the functions and duties heretofore carried out by such office.

[Competitive Drug or Competing Drug – Insert description of applicable Competing Drugs].[1]

Covered Drug(s) – [DRUG MANUFACTURER]'s formulation(s) of those certain drug(s) in the dosage form(s), strength(s) and 11-digit NDC codes identified in **Attachment A** of this Agreement, as Attachment A may be updated from time to time during the term of the Agreement pursuant to an amendment signed by EOHHS and [DRUG MANUFACTURER].

Federal Rebate - with respect to each Covered Drug, the quarterly payment by [DRUG MANUFACTURER] to EOHHS pursuant to the National Drug Rebate Agreement between [DRUG MANUFACTURER] and the Secretary of the U.S. Department of Health and Human Services for such Covered Drug.

Guaranteed Net Price – with respect to each Covered Drug, the final fixed price per Unit of such Covered Drug, which is the applicable per Unit price set forth on **Attachment A,** calculated as the (i) WAC minus (ii) the Federal Rebate minus (iii) the State Supplemental Rebate. This per Unit price is assured by [DRUG MANUFACTURER] to EOHHS for each calendar quarter, or portion thereof, during which EOHHS submits invoices to [DRUG MANUFACTURER] for State Supplemental Rebates for the Covered Drug(s) throughout the term of this Agreement. [For this Agreement, the Guaranteed Net Price(s) listed on [[Table 1] *or* [Table 3]] of **Attachment A** apply].[2]

MassHealth – the medical assistance and benefit programs administered by EOHHS pursuant to Title XIX of the Social Security Act (42 U.S.C. 1396 *et. seq.*), Title XXI of the Social Security Act (42 U.S.C. 1397aa *et. seq.*), M.G.L. C. 118E, and other applicable laws and waivers.

MassHealth Drug List (or MHDL) - a list of commonly prescribed drugs and therapeutic class tables published by EOHHS that identifies many of the drugs payable under MassHealth on a fee-for-service basis, as described by 130 CMR 406.412, and specifies which drugs on the list require Prior Authorization. Except for certain drugs and drug therapies described in 130 CMR 406.413(B), any drug that does not appear on the MassHealth Drug List requires Prior Authorization. See also 130 CMR 450.303. The MassHealth Drug List and related rules apply to MassHealth Members for whom claims for covered outpatient drugs are submitted to MassHealth on a fee-for-service basis.

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[1] Bracketed language is included for purposes of the template only. EOHHS will insert the appropriate description in the specific agreement.

[2] Bracketed language is included for purposes of the template only. EOHHS may specify which Table(s) apply in the final agreement, as necessary.

[MassHealth MCO- A MassHealth managed care organization (MCO) that is responsible for coverage of covered outpatient drugs for MassHealth Members who are enrolled in that MCO.][3]

MassHealth Member- any person enrolled in Massachusetts Medicaid and eligible to receive prescription drug benefits. [[This includes both MassHealth members for whom claims are submitted to MassHealth for covered outpatient drugs on a fee-for-service basis, as well as Medicaid members enrolled in a Participating MassHealth MCO] *or* [This refers solely to MassHealth members for whom claims are submitted for covered outpatient drugs on a fee-for-service basis]].

[MCO Drug List (or **MCO-DL)**- A MassHealth MCO's published list or formulary of covered prescription drugs and associated drug coverage requirements applicable to MassHealth Members enrolled in that MCO (or an equivalent list).]

National Drug Rebate Agreement - the national drug rebate agreement in place between [DRUG MANUFACTURER] and the Secretary of the U.S. Department of Health and Human Services, pursuant to Section 4401 of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508) [See, Section 1927(c)(1) and Section 1927(c)(3) of the Social Security Act (42 U.S.C. 1396r-8(c)(1) and 42 U.S.C. 1396r-8(c)(3)).].

[Participating MassHealth MCO –[Insert applicable definition of Participating MassHealth MCO].][4]

Pharmacy - a facility that is properly licensed to dispense legend drugs, and enrolled as a MassHealth provider [for purposes of MassHealth Member utilization on a fee-for-service basis, or that qualifies as a participating in-network provider for purposes of dispensing drugs for MassHealth Member utilization through a Participating MassHealth MCO].

[Preferred Status -[Insert applicable definition of Preferred Status].][5]

Prior Authorization (or PA) – approval from EOHHS [or a Participating MassHealth MCO] or [its] [their] agent(s), that is required in certain instances before a provider may supply medical services and/or drugs. Prior Authorization determines only the medical necessity of an authorized service.

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[3] Brackets are included for purposes of this template only. Under this template, EOHHS has the option of also including, under an agreement, supplemental drug rebates based on MassHealth Member utilization through Participating MassHealth MCOs (in addition to fee-for-service claims). EOHHS will include MCO-related definitions, and the appropriate bracketed language within the definition of "MassHealth Member" and other definitions, depending on whether, for that specific agreement, MassHealth Member utilization through Participating MassHealth MCOs will also be subject to supplemental rebate, or if supplemental rebates are solely based on fee-for-service claims. The same applies to language referencing MCO-related terms in brackets throughout the later sections, and in Attachment A. If the agreement only covers fee-for-service claims, MCO-related bracketed language will be deleted, as appropriate.

[4] Bracketed language is included for purposes of the template only. EOHHS will insert the appropriate description in the specific agreement.

[5] Bracketed language is included for purposes of the template only. EOHHS will insert the appropriate description in the specific agreement.

State Supplemental Rebate – for each Covered Drug, an amount paid on a calendar quarter basis by [DRUG MANUFACTURER] to EOHHS pursuant to this Agreement, and in accordance with Section 1927(c)(1) of the Social Security Act (42 U.S.C. 1396r-8(c)(1)), for each Unit of such Covered Drug dispensed for use by MassHealth Members and included on claims paid by EOHHS [or a Participating MassHealth MCO] during the quarter. The State Supplemental Rebate shall be an amount paid to EOHHS by [DRUG MANUFACTURER] that is in addition to the [DRUG MANUFACTURER]'s Federal Rebate for the Covered Drug, consistent with Section 1927 (a)(4) of the Social Security Act (42 U.S.C. 1396r-8(a)(4)), and that results in the applicable Guaranteed Net Price per Unit of such Covered Drug set forth on **Attachment A**; *provided that*, if for any calendar quarter this calculation results in a negative State Supplemental Rebate for a Covered Drug, the State Supplemental Rebate for such Covered Drug for that calendar quarter shall be zero.

Step Edit or Step Therapy - a potentially defined order of therapeutic choices that will be reflected in the Prior Authorization requirements in the MassHealth Drug List [or Participating MassHealth MCO's MCO-DL] for Covered Drugs and their Competitive Drugs.

Unit – the lowest identifiable amount of a Covered Drug (e.g., tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams), which shall be the same unit specified by the Drug Manufacturer for such Covered Drug under the National Drug Rebate Agreement.

Wholesale Acquisition Cost (WAC)- that price which constitutes the State-defined Wholesale Acquisition Cost (WAC) for the Covered Drug as determined on the last day of the calendar quarter that corresponds to the calendar quarter for which the State utilization is reported to the manufacturer.

SECTION 2. EOHHS OBLIGATIONS

Section 2.1 MassHealth Drug List[/ MCO Drug List]

To be eligible for the State Supplemental Rebate for claims for Drug Manufacturer's Covered Drug(s) listed on **Attachment A** paid by MassHealth on a fee-for-service basis, EOHHS shall list the Covered Drug(s) on the MassHealth Drug List. [To be eligible for the State Supplemental Rebate for MassHealth Member utilization of Drug Manufacturer's Covered Drug(s) listed on **Attachment A** paid through a Participating MassHealth MCO, the Participating MassHealth MCO must list the Covered Drug(s) on its MCO Drug List (MCO-DL)].

Nothing in this Agreement shall prohibit EOHHS from requiring Prior Authorization for any Covered Drug or from modifying or eliminating the Preferred Status, if applicable, of any Covered Drug, or from imposing Step Therapy relating to the Covered Drug(s) during the term of this Agreement. The parties agree that the corresponding Guaranteed Net Price pertaining to such Covered Drug(s) as set forth on **Attachment A** shall apply, and the resulting State Supplemental Rebate shall be payable by Drug Manufacturer in such circumstance.

Section 2.2 State Supplemental Rebate Invoicing

EOHHS shall submit to [DRUG MANUFACTURER] invoices for State Supplemental Rebates that are due based on the formula set forth in **Section 3.1**, below, that are separate from the invoices EOHHS submits for the Federal Rebate. EOHHS shall submit the State Supplemental Rebate invoice to [DRUG MANUFACTURER] within sixty (60) days after the end of each calendar quarter, or portion thereof, during which EOHHS [or a Participating MassHealth MCO] paid for the Covered Drug(s). Any amended invoice shall be submitted by EOHHS within fifteen (15) months after the end of the calendar quarter in which EOHHS [or a Participating MassHealth MCO] paid for the Covered Drug(s).[6]

Section 2.3 Patient Information

EOHHS, its agents, employees and contractors shall not provide [DRUG MANUFACTURER] with any patient identifiable information or protected health information ("PHI") or any other information prohibited or regulated by laws or regulations governing confidentiality of medical or other information.

Section 2.4 Discretion to Secure Additional Savings

Nothing in this Agreement shall prohibit EOHHS from entering into a supplemental rebate agreement with any other drug manufacturer for any drugs, including Competitive Drugs.

SECTION 3. [DRUG MANUFACTURER] OBLIGATIONS

Section 3.1 State Supplemental Rebate Payment

[DRUG MANUFACTURER] agrees to provide a State Supplemental Rebate to EOHHS for each Unit of each Covered Drug listed on **Attachment A** that is submitted to MassHealth [or a Participating MassHealth MCO] for payment on behalf of MassHealth Members and paid during each calendar quarter (or portion thereof) throughout the term of this Agreement. The State Supplemental Rebate amount that must be paid for each such Unit shall be an amount that results in the Covered Drug's applicable Guaranteed Net Price per Unit, as set forth on **Attachment A**. The State Supplemental Rebate shall be paid on a calendar quarter basis.

The State Supplemental Rebate is an amount that is in addition to the [DRUG MANUFACTURER]'s Federal Rebate for the Covered Drug, consistent with Section 1927 (a)(4) of the Social Security Act (42 U.S.C. 1396r-8(a)(4)). Nothing in this Agreement shall be construed to relieve [DRUG MANUFACTURER] from its obligation to pay Federal Rebates to EOHHS pursuant to its National Drug Rebate Agreement with CMS.

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[6] EOHHS may modify to clarify additional detail pertaining to invoicing for MassHealth Member utilization through MCOs, if necessary.

Section 3.2 Payment Timeframe

[DRUG MANUFACTURER] shall pay to EOHHS, the State Supplemental Rebate in accordance with this Agreement, within thirty-eight (38) days after receipt of an invoice from EOHHS under **Section 2.2**.

Section 3.3 Incomplete Submission

[DRUG MANUFACTURER] shall have no obligation to pay State Supplemental Rebates for MassHealth Member utilization that is not included as part of an invoice submitted to the Drug Manufacturer in accordance with this Agreement. [DRUG MANUFACTURER] shall notify EOHHS or its designee of any incomplete submission within thirty (30) days of [DRUG MANUFACTURER]'s receipt of any incomplete submission.

Section 3.4 Over/Underpayment

If either party discovers an error in the payment of State Supplemental Rebates, it shall notify the other of such error. The parties shall attempt to reconcile all differences through discussion and negotiation. In the event that EOHHS and [DRUG MANUFACTURER] are not able to resolve a discrepancy through informal discussion and negotiation, within sixty (60) days of a party's written notice of error, the party identifying the error shall notify the Medicaid Drug Rebate Dispute Resolution Program Coordinator in CMS Region 1, and initiate resolution through the Medicaid Drug Rebate Dispute Resolution Program. Any amount determined to be an overpayment, either through agreement of the parties or through the dispute resolution process, shall be deducted from subsequent State Supplemental Rebates payable under this Agreement. If no subsequent State Supplemental Rebates are payable, EOHHS will refund any such overpayment to [DRUG MANUFACTURER] within thirty (30) days of the determination of the overpayment. In the event that any amount is determined to be an underpayment, either through agreement of the parties or through the dispute resolution process, [DRUG MANUFACTURER] shall remit any underpayment to EOHHS within thirty (30) days of the determination of such underpayment.

Section 3.5 Discretion to Market

Nothing in this Agreement shall be construed to prohibit [DRUG MANUFACTURER] from discontinuing production, marketing or distribution of a Covered Drug or from transferring or licensing a Covered Drug to a third party. It is understood that [DRUG MANUFACTURER] is liable for the payment of State Supplemental Rebates only for Covered Drug(s) (as identified by the 11-digit NDC codes in **Attachment A**) distributed directly or through the wholesale channel to Pharmacies or other qualified MassHealth providers and dispensed to MassHealth Members on a fee-for-service basis [or distributed directly or through the wholesale channel to Participating MassHealth MCOs' in-network Pharmacies or other qualified in-network providers and dispensed to MassHealth Members enrolled in the Participating MassHealth MCO]. If [DRUG MANUFACTURER] elects to discontinue production, marketing or distribution of a Covered Drug or to transfer or license a Covered Drug to a third party, [DRUG MANUFACTURER] shall make every reasonable effort to notify EOHHS prior to such action.

Section 3.6 Reporting of WAC

Drug Manufacturer agrees to publish a wholesale acquisition cost for each Covered Drug by NDC with First Data Bank, or other national price compendium designated by EOHHS, throughout the term of this Agreement.

SECTION 4. TERM AND TERMINATION

Section 4.1 Effective Date; Termination

A. Effective Date and Term of Agreement

This Agreement shall be effective **[DATE]** [7], and shall continue in force through **[DATE]**, unless it is terminated sooner pursuant to **Section 4.1.B**, below, or extended by an amendment in writing signed by both parties in accordance with **Section 4.3**, below. This Agreement may be extended in any increments for up to _____ additional [years] at EOHHS' option, upon terms agreed to by the parties.

B. Termination

1. Termination for Breach

If either party commits a material breach of this Agreement, the non-breaching party shall deliver written notice by certified mail, return receipt requested, of the alleged breach to the breaching party, with an opportunity for the breaching party to cure the breach during the thirty (30) day period following delivery. Failure to cure shall give the non-breaching party the right to cancel this Agreement at the end of the thirty (30) day period. The non-breaching party shall give the breaching party final written notice of the cancellation of this Agreement.

2. Termination Without Cause

EOHHS may terminate this Agreement without cause as of the end of any calendar quarter by giving [DRUG MANUFACTURER] thirty (30) days prior written notice.

Section 4.2 Accrued Obligations/Remedies

The expiration or termination of this Agreement shall not affect any rights or obligations of the parties that have accrued prior to the effective date of such termination. The fact that either party exercises any right of termination it may have under this Agreement shall not prevent such party from pursuing any other remedy it may be entitled to in law or equity. Any remedy provided herein shall not be deemed an exclusive remedy unless expressly provided for as such.

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[7] For purposes of the template only. EOHHS will insert the appropriate length that is applicable for the specific agreement.

Section 4.3 Execution, Amendment and Waiver

This Agreement shall be binding only upon signature by both parties, and is subject to approval by CMS. CMS authorizes supplemental drug rebate agreements via the State Plan Amendment approval process. A separate approval letter from CMS for each agreement is not required.

The parties may agree to modify, increase or reduce the list of Covered Drug(s) during the term of the Agreement, or to modify the scope in accordance with Section 5.7, below, by an amendment signed by both parties. In addition, the following provisions of this Agreement may be altered or amended, and nonmaterial changes made to the other provisions of this Agreement, by an amendment in writing signed by both parties:

- Section 1 (Definitions);
- Section 5.3 (Notices);
- Section 4.1. (Effective Date; Termination);
- Attachment A.

Other amendments or alterations to this Agreement may be made by an amendment in writing signed by both parties, as authorized by CMS. Drug Manufacturer agrees to amend the Agreement as may be required by CMS.

SECTION 5. MISCELLANEOUS

Section 5.1 Record Keeping and Audit

The parties agree that federal and Commonwealth record retention and freedom of information laws, regulations and policies govern this Agreement. As such, the parties agree that they shall retain all records relating to this Agreement for seven (7) years after the execution of this Agreement or the creation of the record, whichever is later, or for such longer period as is required by State or federal law or necessary for resolution of any litigation, claim, negotiation, audit or inquiry involving the Agreement.

Section 5.2 Confidentiality

The [DRUG MANUFACTURER] shall comply with all state and federal laws and regulations relating to confidentiality, privacy, and security.

Section 5.3 Notices

Unless the method of delivery is otherwise specified in another section of this Agreement, any notice required or permitted to be given by either party to the other under this Agreement shall be given in person or sent by first class mail or express delivery, addressed to the other party at the address set forth below.

To [DRUG MANUFACTURER]:
[DRUG MANUFACTURER]
[ADDRESS]

To EOHHS:
Massachusetts Executive Office of Health and Human Services
100 Hancock Street, Room 7021
Quincy, MA 02171
Attn: Paul L. Jeffrey, Director of MassHealth Pharmacy

Unless otherwise specified in another section of this Agreement, notice will be deemed received three days after it is postmarked, if delivery is by first class or express mail, or one day after the date delivered as specified on the delivery slip if delivery is given in person.

Section 5.4 Force Majeure

Noncompliance with any obligations hereunder due to force majeure, such as acts of God, laws or regulations of any government, war, civil commotion, destruction of production facilities and materials, fire, earthquake or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers, and any other causes beyond the reasonable control of the parties, shall not constitute breach of contract.

Section 5.5 Assignment

Neither party shall have the right to assign this Agreement to a third party without the prior written consent of the other party, which consent shall not be unreasonably withheld. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve any party of responsibility for the performance of any obligations that have accrued prior to such assignment.

Section 5.6 No Waiver of Rights

The failure of either party to insist upon the strict observation or performance of any provision of this Agreement or to exercise any right or remedy shall not impair or waive any such right or remedy in the future. Every right and remedy given by this Agreement to the parties may be exercised from time to time as often as appropriate.

Section 5.7 Option to Modify Scope

EOHHS reserves the right, at its discretion and at any time during the term of the Agreement, to modify any provision in the Agreement when EOHHS deems necessary or reasonable to reflect any change in policy or program goals, including, without limitation, to modify the scope of the Agreement and supplemental rebate amounts[, and to provide for collection of supplemental drug rebates on MassHealth Member utilization covered through Participating MassHealth MCOs, as well as fee-for-service claims, to the extent MassHealth Member utilization through Participating MassHealth MCOs is not included in the original executed Agreement]. EOHHS additionally reserves the right, at its discretion and at any time during the term of the Agreement, to amend the Agreement to implement state or federal statutory or regulatory requirements, judicial orders, settlement agreements, or any state or federal requirements, initiatives or changes affecting the MassHealth program. In the event that

EOHHS seeks to implement such changes in the Agreement (except for any change required by CMS as part of the State Plan Amendment approval process), EOHHS will provide written notice to the Drug Manufacturer and will initiate negotiations with the Drug Manufacturer.

Section 5.8 Entire Agreement

This Agreement contains the entire agreement and understanding of the parties. This Agreement (including Attachments) may not be amended or modified except in accordance with **Section 4.3** of this Agreement.

Section 5.9 Governing Law

The laws of the Commonwealth of Massachusetts shall govern this Agreement. In the event of a lawsuit involving this Agreement, venue shall be proper only in Suffolk County, Massachusetts.

Section 5.10 Effect of Future Laws

In the event of the enactment, promulgation, rescission, modification or interpretation of any law or regulation after the date hereof which would (a) materially and/or adversely affect the manner in which either party is obligated to perform under this Agreement, (b) adversely affect for either party the net prices or State Supplemental Rebates or other terms applicable under this Agreement, or (c) have the effect of requiring the net prices or State Supplemental Rebates or other terms applicable under this Agreement to be extended or offered to any third party, each party shall have the right to enter into good faith negotiations with the other in order to seek to agree on reasonable terms for maintaining the intent of this Agreement affected by such enactment, promulgation, etc. Agreement on any such terms shall be in the sole discretion of each party. If the parties do not agree within sixty (60) days of a party's written request for negotiations, either party may terminate this Agreement with respect to the affected Covered Drugs upon expiration of the sixty (60) day period, with immediate effect.

Section 5.11 Compliance with Law

In connection with its respective obligations under this Agreement, each party shall comply with all applicable federal, state and local laws and regulations, including without limitation any disclosure or consent requirements.

Section 5.12 Authority

EOHHS and [DRUG MANUFACTURER] each represent and warrant to the other that the person signing below has all requisite legal power and authority to execute this Agreement on behalf of each party and each party shall thereby be bound.

Section 5.13 Best Price Contingency

The effectiveness of this Agreement shall be contingent on [DRUG MANUFACTURER]'s Best Price and AMP not being affected by the State Supplemental Rebate.

Section 5.14 CMS Approval Contingency

The effectiveness of the State Supplemental Rebate Agreement shall be contingent on CMS authorizing the agreement via the State Plan Amendment approval process. A separate approval letter from CMS for each agreement is not required.

IN WITNESS THEREOF, the parties set forth below execute this Agreement:

[DRUG MANUFACTURER]	**MASSACHUSETTS EXECUTIVE OFFICE OF HEALTH AND HUMAN SERVICES**
_____	_____
[Authorized Signatory]	[Authorized Signatory]
_____	_____
Date	Date

ATTACHMENT A[8]

Covered Drugs

The provisions of the following paragraphs [1 – 6] apply to this Attachment A and this Agreement.

[Part I: State Supplemental Rebates Apply to Fee-For-Service Claims Only:]

1. The Agreement shall apply to each Covered Drug listed in the "Covered Drugs" column below and identified by the corresponding NDC Number(s) for claims paid by MassHealth on a fee-for-service basis. Under this paragraph 1, MassHealth Member utilization through Participating MassHealth MCOs is *not* included under the Agreement.

Table 1: Fee-for-service claims only

NDC Number	**Covered Drugs** **(i) Drug name** **(ii) Strength** **(iii) Dosage form** **(iv) Package description / size**	***Exclusive Basis (1 of 1)*** **Guaranteed Net Price** **(per Unit)**	***Dual Basis (1 of 2)*** **Guaranteed Net Price** **(per Unit)**	***1 of Many (1 of 3 or more)*** **Guaranteed Net Price** **(per Unit)**	***Non-Preferred*** **Guaranteed Net Price** **(per Unit)**
	(i) (ii) (iii) (iv)	$ _____	$ _____	$ _____	$ _____
	(i) (ii) (iii) (iv)	$ _____	$ _____	$ _____	$ _____

2. The terms that apply to paragraph 1 of this **Attachment A** are as follows:

- The designation **"Exclusive Basis (1 of 1)"** from the chart above and associated Guaranteed Net Price(s) apply if the Drug Manufacturer's Covered Drug(s) (and no Competing Drugs) are listed with Preferred Status on the MassHealth Drug List (MHDL).

- The designation **"Dual Basis (1 of 2)"** from the chart above and associated Guaranteed Net Price(s) apply if the Drug Manufacturer's Covered Drug(s) and Competing Drugs of one other manufacturer are listed with Preferred Status on the MHDL.

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[8] This version of Attachment A may generally be used when the Guaranteed Net Price differs based on whether Competing Drugs of other manufacturers also have Preferred Status. EOHHS may modify Attachment A to reflect the particular terms of the specific supplemental rebate agreement. For instance, EOHHS may remove Part II (paragraphs 3 & 4) if MassHealth Member utilization through Participating MassHealth MCOs is not also included under the agreement, or adjust paragraphs 2, 4 and 6, to further explain the conditions to the various designations ("Exclusive Basis (1 of 1)", "Dual Basis (1 of 2)", etc., and what "Preferred Status" or other defined terms mean for that particular agreement. This footnote, and any bracketed language, is included for purposes of this template only.

- The designation **"1 of Many (1 of 3 or more)"** from the chart above and associated Guaranteed Net Price(s) apply if the Drug Manufacturer's Covered Drug(s) and Competing Drugs of two or more other manufacturers are listed with Preferred Status on the MHDL.

- The designation **"Non-Preferred"** from the chart above and associated Guaranteed Net Price(s) apply if the Drug Manufacturer's Covered Drug(s) are not listed with Preferred Status on the MHDL.

[Part II: State Supplemental Rebates Apply to Fee-For-Service Claims *and* MassHealth Member utilization through Participating MassHealth MCOs:]

3. The Agreement shall apply to each Covered Drug listed in the "Covered Drugs" column below and identified by the corresponding NDC Number(s) for claims paid by MassHealth on a fee-for-service basis **and** for claims paid through a Participating MassHealth MCO. Under this paragraph 3, both MassHealth fee-for-service claims and MassHealth Member utilization through Participating MassHealth MCOs are included under the Agreement.

Table 3: Fee-for-service and MCO claims

NDC Number	**Covered Drugs** **(i) Drug name** **(ii) Strength** **(iii) Dosage form** **(iv) Package description / size**	***Exclusive Basis (1 of 1)*** **Guaranteed Net Price** **(per Unit)**	***Dual Basis (1 of 2)*** **Guaranteed Net Price** **(per Unit)**	***1 of Many (1 of 3 or more)*** **Guaranteed Net Price** **(per Unit)**	***Non-Preferred*** **Guaranteed Net Price** **(per Unit)**
	(i) (ii) (iii) (iv)	$ _____	$ _____	$ _____	$ _____
	(i) (ii) (iii) (iv)	$ _____	$ _____	$ _____	$ _____

4. The terms that apply to paragraph 3 of this **Attachment A** are as follows:

- The designation **"Exclusive Basis (1 of 1)"** from the chart above and associated Guaranteed Net Price(s) apply (i) to MassHealth fee-for-service claims if the Drug Manufacturer's Covered Drug(s) (and no Competing Drugs) are listed with Preferred Status on the MassHealth Drug List (MHDL), and (ii) to MassHealth Member utilization of the Covered Drug(s) through Participating MassHealth MCO(s) if the MCO Drug List(s) (MCO-DL(s)) of Participating MassHealth MCO(s) have been aligned to the MHDL with respect to the Drug Manufacturer's Covered Drug(s) and the Competing Drugs of other manufacturers.

- The designation **"Dual Basis (1 of 2)"** from the chart above and associated Guaranteed Net Price(s) apply (i) to MassHealth fee-for-service claims if the Drug Manufacturer's Covered Drug(s) and Competing Drugs of one other manufacturer are listed with Preferred Status on the

MHDL, and (ii) to MassHealth Member utilization of the Covered Drug(s) through Participating MassHealth MCO(s) if the MCO-DL(s) of Participating MassHealth MCO(s) have been aligned to the MHDL with respect to the Drug Manufacturer's Covered Drug(s) and the Competing Drugs of other manufacturers.

- The designation **"1 of Many (1 of 3 or more)"** from the chart above and associated Guaranteed Net Price(s) apply (i) to MassHealth fee-for-service claims if the Drug Manufacturer's Covered Drug(s) and Competing Drugs of two or more other manufacturers are listed with Preferred Status on the MHDL, and (ii) to MassHealth Member utilization of the Covered Drug(s) through Participating MassHealth MCO(s) if the MCO-DL(s) of Participating MassHealth MCO(s) have been aligned to the MHDL with respect to the Drug Manufacturer's Covered Drug(s) and the Competing Drugs of other manufacturers.

- The designation **"Non-Preferred"** from the chart above and associated Guaranteed Net Price(s) apply (i) to MassHealth fee-for-service claims if the Drug Manufacturer's Covered Drug(s) are not listed with Preferred Status on the MHDL, and (ii) to MassHealth Member utilization of the Covered Drug(s) through Participating MassHealth MCO(s) if the MCO-DL(s) of Participating MassHealth MCO(s) have been aligned to the MHDL with respect to the Drug Manufacturer's Covered Drug(s) and the Competing Drugs of other manufacturers.

[Part III: Additional Terms Applicable to both Parts I and II:]

5. All Guaranteed Net Price amounts set forth in the table in paragraphs 1 and 3 of this **Attachment A** are expressed on a per Unit basis. The State Supplemental Rebate will automatically be recalculated in accordance with the formula specified in Section 1 of the Agreement, should the WAC or Federal Rebate change. If for any calendar quarter this calculation results in a negative State Supplemental Rebate for a Covered Drug, the State Supplemental Rebate for such Covered Drug for that calendar quarter shall be zero.

6. For purposes of determining the designations in paragraphs 2 and 4 of this **Attachment A**, the following apply:

- All capitalized terms not otherwise defined below have the meaning set forth in Section 1 of the Agreement.
- [Insert additional terms further explaining or clarifying the terms and conditions applicable to the designations in paragraphs 2 and 4, above, and the defined terms used therein (including, as applicable, Preferred Status, Prior Authorization, and Step Therapy).][9]
- [Covered Drugs shall be considered to have Preferred Status even if the Preferred Status does not apply to (a) outstanding refills of Covered Drugs or Competing Drugs as of the effective date of this Agreement; (b) claims for which MassHealth is secondary payer; and (c) fee-for-service claims that are not submitted through the Pharmacy Online Processing System (POPS).]

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[9] For instance, EOHHS may modify or include additional terms in this and the next bullet (and add additional bullets), to reflect what "Preferred Status" means for the particular agreement, or to include additional terms negotiated with the manufacturer. For some agreements, Covered Drugs with Preferred Status may not require Prior Authorization, and the specific GNP from the chart that applies will depend on how many other drug manufacturers with Competing Drugs also do not require Prior Authorization. Or, it may depend on how many other drug manufacturers with Competing Drugs are also not subject to a particular Step Therapy requirement, or a Prior Authorization requirement of prescriber attestation of contraindication to a Competing Drug of another drug manufacturer in situations where use of both the Covered Drug (or Competing Drug) and the Competing Drug of the other drug manufacturer is clinically appropriate.

ATTACHMENT A[10]

Covered Drugs

The provisions of the following paragraphs [1 – 4] apply to this Attachment A and this Agreement.

[Part I: State Supplemental Rebates Apply to Fee-For-Service Claims Only:]

1. The Agreement shall apply to each Covered Drug listed in the "Covered Drugs" column below and identified by the corresponding NDC Number(s) for claims paid by MassHealth on a fee-for-service basis. Under this paragraph 1, MassHealth Member utilization through Participating MassHealth MCOs is *not* included under the Agreement.

Table 1: Fee-for-service claims only

NDC Number	Covered Drugs (i) Drug name (ii) Strength (iii) Dosage form (iv) Package description / size	Guaranteed Net Price (per Unit)
	(i) (ii) (iii) (iv)	$ _____
	(i) (ii) (iii) (iv)	$ _____

[Part II: State Supplemental Rebates Apply to Fee-For-Service Claims *and* MassHealth Member utilization through Participating MassHealth MCOs:]

2. The Agreement shall apply to each Covered Drug listed in the "Covered Drugs" column below and identified by the corresponding NDC Number(s) for claims paid by MassHealth on a fee-for-service basis **and** for claims paid through a Participating MassHealth MCO. Under this

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[10] This version of Attachment A may generally be used when the Guaranteed Net Price does not change based on whether other manufacturers also have Competing Drugs with Preferred Status (although could be used in those situations on a case-by-case basis), or for certain agreements when Prior Authorization may be required for all Covered Drugs and Competing Drugs outside of a Step Therapy scenario. EOHHS may modify Attachment A to reflect the particular terms of the specific supplemental rebate agreement. For instance, EOHHS may remove Part II (paragraph 2) if MassHealth Member utilization through Participating MassHealth MCOs is not also included under the agreement, or adjust paragraph 4 to further explain what "Preferred Status" or other defined terms mean for that particular agreement. This footnote, and any bracketed language, is included for purposes of this template only.

paragraph 2, both MassHealth fee-for-service claims and MassHealth Member utilization through Participating MassHealth MCOs are included under the Agreement.

Table 3: Fee-for-service and MCO claims

NDC Number	Covered Drugs (i) Drug name (ii) Strength (iii) Dosage form (iv) Package description / size	Guaranteed Net Price (per Unit)
	(i) (ii) (iii) (iv)	$ _____
	(i) (ii) (iii) (iv)	$ _____

[Part III: Additional Terms Applicable to both Parts I and II:]

3. All Guaranteed Net Price amounts set forth in the table in paragraphs 1 and 2 of this **Attachment A** are expressed on a per Unit basis. The State Supplemental Rebate will automatically be recalculated in accordance with the formula specified in Section 1 of the Agreement, should the WAC or Federal Rebate change. If for any calendar quarter this calculation results in a negative State Supplemental Rebate for a Covered Drug, the State Supplemental Rebate for such Covered Drug for that calendar quarter shall be zero.

4. For purposes of the Agreement, the terms that apply to paragraphs 1 and 2 of this **Attachment A**, are as follows:

- All capitalized terms not otherwise defined below have the meaning set forth in Section 1 of the Agreement.
- [Insert additional terms further explaining or clarifying the terms and conditions applicable to paragraphs 1 and 2, above.][11]
- [The Guaranteed Net Price(s) set forth above shall apply even if the terms and conditions set forth in Attachment A do not apply to (a) outstanding refills of Covered Drugs or Competing Drugs as of the effective date of this Agreement; (b) claims for which MassHealth is secondary payer; and (c) fee-for-service claims that are not submitted through the Pharmacy Online Processing System (POPS).]

[11] For instance, EOHHS may insert additional terms or modify this and the next bullet (and add additional bullets) to reflect what "Preferred Status" means for the particular agreement, or to specify whether all Covered Drugs will continue to require Prior Authorization or to include additional terms negotiated with the manufacturer.