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State/Territory Name: Massachusetts

State Plan Amendment (SPA) #: 17-006

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
JFK Federal Building, Government Center
Room 2275
Boston, Massachusetts 02203



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

February 27, 2018

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

Dear Secretary Sudders:

On February 20, 2018 our Central Office sent you a letter approving your proposed State Plan Amendment (SPA) No. 17-006. This letter conveys the Transmittal and Notice of Approval of State Plan Material (CMS-179) and the approved State plan pages. SPA No. 17-006 amends the State's approved Title XIX State plan payment methodologies for outpatient prescription drugs.

Please note that the initial approval letter sent on February 20, 2018 contained a typographical error in the date, incorrectly listing an approval date of February 20, 2017. Please discard that letter. A new approval letter will be issued from our Central Office correcting the approval date to February 20, 2018. This letter confirms that this SPA was approved on February 20, 2018, effective April 1, 2017.

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

- Attachment 4.19-B, pages 1e, 1e1, and 1e2.

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 (via e-mail): Daniel Tsai, Assistant Secretary for MassHealth, Medicaid Director
Kaela Konefal, Federal Authority Policy Analyst/State Plan Coordinator

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

February 20, 2018

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

Attention: Kaela Konefal

Dear Ms. Sudders:

We have reviewed Massachusetts' State Plan Amendment (SPA) 17-006 received in the Boston Regional Office on June 30, 2017. This SPA proposes changes to comply with requirements of the Covered Outpatient Drugs final rule with comment period (COD final rule) (CMS-2345-FC) (81 FR 5170) published on February 1, 2016.

SPA 17-006 establishes reimbursement for covered outpatient drugs using an actual acquisition cost methodology and implements a professional dispensing fee (PDF) reimbursement of \$10.02 for pharmacies for all drugs other than compounded drugs, or blood clotting factors obtained through the 340B program. This SPA also includes reimbursement methods for drugs purchased through the 340B program, physician-administered drugs, clotting factor, and drugs purchased at nominal price.

In considering the proposed PDF, the state was required to provide data and studies to demonstrate that the acquisition cost methodology and professional dispensing fees being paid are sufficient to ensure that MassHealth beneficiaries will have access to pharmacy services. In keeping with the requirements of section 1902 (a)(30)(A) of the Social Security Act, we believe the state has demonstrated that their reimbursement is consistent with efficiency, economy, and quality of care, and are sufficient to ensure that care and services are available at least to the extent they are available to the general population in the geographic area.

We believe that there is evidence regarding the sufficiency of Massachusetts' professional dispensing fee and reimbursement methodologies to approve SPA 17-006, at this time, with an effective date of April 1, 2017. Specifically, Massachusetts has reported to CMS that 1,248 pharmacies are enrolled in its network, a number comparable to 1,215 and 1,286 reported by the state's commercial plans.

With a 94 percent participation rate of in-state pharmacies reported by the state, we can infer that MassHealth beneficiaries will have access to pharmacy services at least to the extent available to the general population since Medicaid requires that beneficiaries be provided access to all covered outpatient drugs of participating drug manufacturers with a rebate agreement through a broad pharmacy network. In contrast, commercial insurers often have more limited drug formularies and a more limited pharmacy network.

As noted above, we believe there is evidence regarding the sufficiency of Massachusetts' professional dispensing fees and reimbursement methodologies from provided data and other credible sources to approve this SPA. Based on the information provided, and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that Massachusetts' SPA 17- 006 is approved with an effective date of April 1, 2017. A copy of the CMS-179 form, as well as pages approved for incorporation into Massachusetts' state plan will be forwarded by the Boston Regional Office. If you have any questions regarding this amendment, please contact Emeka Egwim, PharmD, R.Ph at (410) 786-1092.

Sincerely,

/s/

Meagan T. Khau
Deputy Director, Division of Pharmacy

cc: Richard McGreal, Associate Regional Administrator, Boston Regional Office
Julie McCarthy, Boston Regional Office
Daniel Tsai, Assistant Secretary, MassHealth
Paul Jeffrey, Director of Pharmacy, MassHealth

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES		1. TRANSMITTAL NUMBER <div style="text-align: center;">1 7 — 0 0 8</div>	2. STATE <div style="text-align: center; font-size: 1.5em;">MA</div>
TO: REGIONAL ADMINISTRATOR CENTERS FOR MEDICARE & MEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES		3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
5. TYPE OF PLAN MATERIAL (Check One) <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <input type="checkbox"/> NEW STATE PLAN <input type="checkbox"/> AMENDMENT TO BE CONSIDERED AS NEW PLAN <input checked="" type="checkbox"/> AMENDMENT </div>		4. PROPOSED EFFECTIVE DATE <div style="text-align: center; font-size: 1.2em;">04/01/17</div>	
COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate transmittal for each amendment)			
6. FEDERAL STATUTE/REGULATION CITATION <div style="font-size: 1.2em;">42 CFR Part 447</div>		7. FEDERAL BUDGET IMPACT <div style="font-size: 0.8em;"> a. FFY 2017 \$ 1,420,000 1,704,000 b. FFY 2018 \$ 1,420,000 3,408,000 </div>	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT Attachment 4.19-B page 1e-1e2		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) Attachment 4.19-B pages 1e	
10. SUBJECT OF AMENDMENT <div style="font-size: 1.1em;">Outpatient Prescription Drug Rates</div>			
11. GOVERNOR'S REVIEW (Check One) <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <div> <input type="checkbox"/> GOVERNOR'S OFFICE REPORTED NO COMMENT <input type="checkbox"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED <input type="checkbox"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL </div> <div> <input checked="" type="checkbox"/> OTHER, AS SPECIFIED <i>Not required under 42 CFR 430.12(b)(2)(i)</i> </div> </div>			
12. SIGNATURE OF STATE AGENCY OFFICIAL <div style="text-align: center;">/s/</div>		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	
13. TYPED NAME Marylou Sudders		14. TITLE Secretary	
15. DATE SUBMITTED 6/30/17		17. DATE RECEIVED 06/30/2017	
FOR REGIONAL OFFICE USE ONLY			
19. EFFECTIVE DATE OF APPROVED MATERIAL 04/01/2017		18. DATE APPROVED 02/20/2018	
PLAN APPROVED - ONE COPY ATTACHED			
21. TYPED NAME Richard R. McGreal		20. SIGNATURE OF REGIONAL OFFICIAL <div style="text-align: center;">/s/</div>	
23. REMARKS SPA MA 17-006		22. TITLE Associate Regional Administrator, Division of Medicaid & Children's Health Operations, Boston, MA	

State Plan under Title XIX of the Social Security Act

State: Massachusetts

Methods and Standards for Establishing Payment Rates – Other Types of Care

- I. Prescribed drugs, dentures, prosthetic devices, and eyeglasses** prescribed by a physician skilled in diseases of the eye or by an optometrist, whichever the individual may select — fee schedules established by EOHHS.

1. **Prescribed drugs:** The agency's rates were set by regulation as of April 1, 2017 and are effective for services on or after that date. All rates are published at <http://www.mass.gov/eohhs/gov/laws-regs/hhs/community-health-care-providers-ambulatory-care.html#101cmr331>. Except as otherwise noted in the plan, state developed fee schedule rates are the same for both governmental and private providers.

- A. For multiple source drugs that are neither brand name drugs designated as Brand Name Preferred nor brand name drugs that have been certified by the prescriber as medically necessary on the prescription form, requiring a prescription and dispensed by community retail pharmacies, other than blood clotting factor and drugs obtained through the 340B pricing program or through the Federal Supply Schedule, payment shall not exceed the lowest of:
- i. Federal Upper Limit (FUL), plus the professional dispensing fee;
 - ii. The lowest price for the drug available from one or more surveys of pharmacy costs designated by the agency, or, if no such surveys have been so designated, the drug's National Average Drug Acquisition Cost (NADAC), plus the professional dispensing fee;
 - iii. The drug's wholesale acquisition cost (WAC), if and only if no price determined in accordance with I(1)(A)(ii) above is available for the drug, plus the professional dispensing fee;
 - iv. The lowest price for a therapeutic equivalent of the drug available from one or more surveys of pharmacy costs designated by the agency, or, if no such surveys have been so designated, the lowest NADAC for a therapeutic equivalent of the drug, plus the professional dispensing fee; and
 - v. Usual and customary charge.
- B. For single source drugs, and multiple source drugs that have been designated as Brand Name Preferred, and multiple source drugs that are brand name drugs that have been certified by the prescriber as medically necessary on the prescription form, requiring a prescription and dispensed by community retail pharmacies, other than blood clotting factor and drugs obtained through the 340B pricing program or through the Federal Supply Schedule, payment shall not exceed the lower of:
- i. The lowest price for the drug available from one or more surveys of pharmacy costs designated by the agency, or, if no such surveys have been so designated, the drug's NADAC, plus the professional dispensing fee;
 - ii. The drug's WAC, if and only if no price determined in accordance with I(1)(B)(i) above is available for the drug, plus the professional dispensing fee; and
 - iii. Usual and customary charge.
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State Plan under Title XIX of the Social Security Act

State: Massachusetts

Methods and Standards for Establishing Payment Rates – Other Types of Care

- C. For drugs dispensed by institutional or long term care pharmacies, drugs dispensed by specialty pharmacies, and drugs primarily dispensed through the mail (other than through the 340B pricing program and the Federal Supply Schedule), payment shall be determined in accordance with paragraphs A and B above.
- D. For blood clotting factor not obtained through the 340B pricing program, payment shall not exceed the lowest of:
 - i. The lowest price for the drug available from one or more surveys of pharmacy costs designated by the agency, or, if no such surveys have been so designated, the drug's NADAC, plus the professional dispensing fee;
 - ii. The drug's WAC, if and only if no price determined in accordance with l(1)(D)(i) above is available for the drug, plus the professional dispensing fee;
 - iii. Average Sales Price (ASP) of the drug plus 6%, plus the professional dispensing fee; and
 - iv. Usual and customary charge.
- E. For drugs other than blood clotting factor obtained through the 340B pricing program, whether dispensed by a 340B covered entity or a contract pharmacy under contract with a 340B covered entity, payment shall be the 340B Actual Acquisition Cost (AAC) of the drug, plus the professional dispensing fee.
- F. For blood clotting factor obtained through the 340B pricing program, payment shall be the 340B Ceiling Price of the drug, plus the professional dispensing fee.
- G. For drugs obtained at nominal prices and not obtained through the 340B pricing program or the Federal Supply Schedule, payment shall be the actual acquisition cost of the drug, plus the professional dispensing fee.
- H. No Massachusetts providers obtain drugs for Medicaid members through the Federal Supply Schedule. Payment for such drugs will be defined in a state plan amendment if that circumstance changes.
- I. No Indian Health Service, tribal, and urban Indian pharmacies are enrolled in Massachusetts at this time. Payment to such entities will be defined in a state plan amendment if that circumstance changes.
- J. Investigational drugs are not covered.
- K. Physician administered drugs.
 - i. For drugs administered at a physician's office that appear on the Medicare B fee schedule, payment shall not exceed ASP of the drug plus 6%.

State Plan under Title XIX of the Social Security Act

State: Massachusetts

Methods and Standards for Establishing Payment Rates – Other Types of Care

- ii. For other drugs administered at a physician's office, payment shall not exceed the provider's actual acquisition cost as determined from the provider's invoice.

L. Professional dispensing fees for prescribed drugs.

- i. The professional dispensing fee for compounded drugs whose dispensing involves the mixing two or more commercially prepared products is \$17.52.
- ii. The professional dispensing fee for compounded drugs whose dispensing involves compounding lotions, shampoos, suspensions, or the mixing of powders or liquids into cream, ointment, or gel base is \$20.02.
- iii. The professional dispensing fee for compounded drugs whose dispensing involves compounding capsules, troches, suppositories, or pre-filled syringes \$25.02.
- iv. The professional dispensing fee for compounded drugs needing a sterile environment when mixing is \$40.02.
- v. The professional dispensing fee for blood clotting factor not obtained through the 340B program is \$10.02.
- vi. The professional dispensing fee for blood clotting factor obtained through the 340B program is 2.75 cents per unit.
- vii. The professional dispensing fee for all other prescribed drugs is \$10.02.