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State/Territory Name: California

State Plan Amendment (SPA) #: 19-0015

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

January 24, 2020

Mari Cantwell, State Medicaid Director
Department of Health Care Services
P.O. Box 997413, MS 0000
Sacramento, CA 95899-7413

Dear Ms. Cantwell:

The CMS Division of Pharmacy team has reviewed California State Plan Amendment (SPA) 19-0015, received in the San Francisco Regional Operations Group on November 15, 2019. This amendment proposes to revise the state's Medi-Cal Fee-For-Service (FFS) reimbursement methodology for blood factors in Hemophilia Treatment Centers, as described on Supplement 2 to Attachment 4.19-B, page 9, in the California Medicaid State Plan.

Based on the information provided, we are pleased to inform you that, consistent with the regulations at 42 CFR 430.20, SPA 19-0015 is approved with an effective date of July 1, 2020. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into the California state plan will be forwarded by the San Francisco Regional Operations Group.

If you have any questions regarding this amendment, please contact Mickey Morgan at (410) 786-4048 or mickey.morgan@cms.hhs.gov.

Sincerely,

A solid black rectangular box redacting the signature of John M. Coster.

John M. Coster, Ph.D., R.Ph
Director
Division of Pharmacy

cc: Harry Hendrix, Chief, Pharmacy Benefits Division
Trudi Balestreri, Project Manager, Pharmacy Benefits Division
Richard C. Allen, Director, Western Regional Operations Group
Cheryl Young, CMS San Francisco Regional Operations Group

**TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES**

1. TRANSMITTAL NUMBER <u>1 9</u> — <u>0 0</u> <u>15</u>	2. STATE California
3. PROGRAM IDENTIFICATION: Title XIX of the Social Security Act (Medicaid)	
4. PROPOSED EFFECTIVE DATE 07/01/2020	

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

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 CRF Part 447 Subpart I - Payment for Drugs	7. FEDERAL BUDGET IMPACT a. FFY 2020 \$ <u>(1.25 million)</u> b. FFY 2021 \$ <u>(5 million)</u>
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT Supplement 2 to Attachment 4.19-B, page 9	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (<i>If Applicable</i>) Supplement 2 to Attachment 4.19-B, page 9

10. SUBJECT OF AMENDMENT
Proposed Changes to Blood Factors Reimbursement

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


- GOVERNOR'S OFFICE REPORTED NO COMMENT OTHER, AS SPECIFIED
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

12. SENDING OFFICIAL 	16. RETURN TO Department of Health Care Services Attn: Director's Office P.O. Box 997413, MS 0000 Sacramento, CA 95899-7413
13. TYPED NAME Mari Cantwell	
14. TITLE State Medicaid Director	
15. DATE SUBMITTED November 15, 2019	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED November 15, 2019	18. DATE APPROVED January 24, 2020
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PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL July 1, 2020	20.  CIAL
21. TYPED NAME James G. Scott	22. TITLE Director, Division of Program Operations Medicaid & CHIP Operations Group

23. REMARKS
For Box 11 "Other, As Specified," Please note: The Governor's Office does not wish to review the State Plan Amendment.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT STATE: California
METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES - PRESCRIBED DRUGS

PAYMENT METHODOLOGY FOR CLOTTING FACTOR

1. Clotting factor is defined as coagulation factors and their recombinant analogs.
2. Payment for clotting factor purchased through and dispensed by a federally recognized hemophilia treatment center (HTC) or its contracted pharmacy will be the lower of:
 - a. The HTC's actual acquisition cost for the drug as defined in Welfare and Institutions Code section 14105.46, plus a professional dispensing fee of \$0.14 per unit, or
 - b. The Average Sales Price as reported to the federal Centers for Medicare and Medicaid Services by the manufacturer pursuant to Section 1847A of the federal Social Security Act (42 U.S.C. §1395w-3a), plus 20%.
3. Payment for clotting factor purchased outside of a federally recognized HTC and dispensed by specialty pharmacies, Centers of Excellence, or any other provider will be the lower of:
 - a. The provider's actual acquisition cost for the drug equal to invoice price minus any discounts (excluding a prompt pay discount of less than, or equal to 2%), rebates, or chargebacks, plus a professional dispensing fee of \$0.04 per unit, or
 - b. The Average Sales Price as reported to the federal Centers for Medicare and Medicaid Services by the manufacturer pursuant to Section 1847A of the federal Social Security Act (42 U.S.C. §1395w-3a) plus 20%.

This payment methodology is applicable to both pharmacy and non-pharmacy clotting factor claims.