MISSISSIPPI DIVISION OF MEDICAID

PHARMACY STAKEHOLDER MEETING

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HEMOPHILIA REIMBURSEMENT





CMS FINAL RULE (CMS-2345-F) STATE PLAN

- States must submit an amendment to its State Plan to the Centers for Medicare and Medicaid Services (CMS)
- Effective date of no later than April 1, 2017
- Required for compliance with the new reimbursement requirements in the CMS Covered Outpatient Drug final rule

- State Plan pages must include the following reimbursement information:
 - A. Ingredient Cost methodology in accordance with the Actual Acquisition Cost (AAC) definition – COMPLETE

CMS FINAL RULE (CMS-2345-F) STATE PLAN

- State Plan pages must include the following reimbursement information:
- B. Payment for the following drugs do not need to meet the AAC definition, however, states must define INGREDIENT COST/PROFESSIONAL DISPENSING FEE:
 - Specialty drugs not typically dispensed by a retail community pharmacy
 - Clotting Factor from Specialty Pharmacies, Hemophilia Treatment Centers and Centers of Excellence

HEMOPHILIA INGREDIENT COST REIMBURSEMENT OPTIONS

- WAC-based Discount by Product
 - Discounts off WAC variable by product
 - Based on market experience
- WAC-based Discount for All Products
 - Discount off WAC not variable by product
 - Aggregate discount most likely does not represent true ingredient cost by individual product (not required by CMS rule)
- Average Sales Price (ASP) Based rates
 - Maintained by CMS (e.g., Medicare Part B HCPCS code reimbursement)
 - Hemophilia drugs reimbursed under medical services typically reimbursed under this method
 - Rate includes the CMS blood clotting factor furnishing fee (\$0.202 per unit for CY 2016)
- Hemophilia Provider Survey
 - WAC-based equivalent rates to the provider invoice ingredient cost

WAC — 10%, DISPENSING FEE \$0.01 PER UNIT

| | | | Difference | | | | | | | | |
|----------------------------------|--------------|--------------|------------|------|--------------|--------------|----------|---------|-----|--------------|--------------|
| | Brand | Brand Generi | | eric | Total | Brand | | Generic | | Total | Total |
| | FFS | МСО | FFS | МСО | | FFS | МСО | FFS | МСО | | |
| Ingredient Reimbursement | \$31,677,000 | \$33,000 | \$0 | \$0 | \$31,710,000 | \$27,117,000 | \$28,000 | \$0 | \$0 | \$27,145,000 | -\$4,565,000 |
| Dispensing Fee Reimbursement | \$3,000 | \$10 | \$0 | \$0 | \$3,000 | \$163,000 | \$150 | \$0 | \$0 | \$163,000 | \$160,000 |
| Estimated Total Reimbursement | \$31,680,000 | \$33,000 | \$0 | \$0 | \$31,713,000 | \$27,280,000 | \$28,000 | \$0 | \$0 | \$27,308,000 | -\$4,405,000 |

^{*}Benefix® and Stimate® ingredient cost reimbursements are WAC + 0%.

^{*}Approximately 694 claims; approximately 16,355,183 units.

^{*}Approximately 15 unique providers.

^{*}WAC – 10% reimbursement based on Wisconsin Medicaid pharmacy program (https://www.forwardhealth.wi.gov/WIPortal/content/Provider/medicaid/pharmacy/resources.htm.spage#)

^{*}All reimbursement analyses are based on FFS and MCO claims from June 1, 2015 through May 31, 2016 with paid dates June 30, 2016.

WAC — 10%, DISPENSING FEE \$0.02 PER UNIT

| Current Reimbursement | | | | | | | | Difference | | | |
|----------------------------------|--------------|----------|-------|-----|--------------|--------------|----------|------------|-----|--------------|--------------|
| | Brand Gen | | neric | | Brand | | Generic | | | | |
| | FFS | МСО | FFS | МСО | Total | FFS | мсо | FFS | МСО | Total | Total |
| Ingredient Reimbursement | \$31,677,000 | \$33,000 | \$0 | \$0 | \$31,710,000 | \$27,117,000 | \$28,000 | \$0 | \$0 | \$27,145,000 | -\$4,565,000 |
| Dispensing Fee Reimbursement | \$3,000 | \$10 | \$0 | \$0 | \$3,000 | \$327,000 | \$300 | \$0 | \$0 | \$327,000 | \$324,000 |
| Estimated Total Reimbursement | \$31,680,000 | \$33,000 | \$0 | \$0 | \$31,713,000 | \$27,444,000 | \$28,000 | \$0 | \$0 | \$27,472,000 | -\$4,241,000 |

^{*}Benefix® and Stimate® ingredient cost reimbursements are WAC + 0%.

^{*}Approximately 694 claims; approximately 16,355,183 units.

^{*}Approximately 15 unique providers.

^{*}All reimbursement analyses are based on FFS and MCO claims from June 1, 2015 through May 31, 2016 with paid dates June 30, 2016.

WAC — 10%, DISPENSING FEE \$0.03 PER UNIT

| | Current Reimbursement | | | | | | | \$0.03 Dispensing Fee per unit | | | | |
|----------------------------------|-----------------------|----------|---------|--------------|--------------|--------------|----------|--------------------------------|-------|--------------|--------------|--|
| | Brand | I | Generic | | Total | Brand | | Generic | | Total | Total | |
| | FFS | МСО | FFS | Total MCO | FFS | мсо | FFS | MCO | Total | Total | | |
| Ingredient Reimbursement | \$31,677,000 | \$33,000 | \$0 | \$0 | \$31,710,000 | \$27,117,000 | \$28,000 | \$0 | \$0 | \$27,145,000 | -\$4,565,000 | |
| Dispensing Fee Reimbursement | \$3,000 | \$10 | \$0 | \$0 | \$3,000 | \$490,000 | \$450 | \$0 | \$0 | \$490,000 | \$487,000 | |
| Estimated Total Reimbursement | \$31,680,000 | \$33,000 | \$0 | \$0 | \$31,713,000 | \$27,607,000 | \$28,000 | \$0 | \$0 | \$27,635,000 | -\$4,078,000 | |

^{*}Benefix® and Stimate® ingredient cost reimbursements are WAC + 0%.

^{*}Approximately 694 claims; approximately 16,355,183 units.

^{*}Approximately 15 unique providers.

^{*}All reimbursement analyses are based on FFS and MCO claims from June 1, 2015 through May 31, 2016 with paid dates June 30, 2016.

ASP, DISPENSING FEE \$0.01 PER UNIT

| Current Reimbursement | | | | | | | | Difference | | | |
|----------------------------------|--------------|---------------|-----|-----|--------------|--------------|----------|------------|------|--------------|--------------|
| | Branc | Brand Generic | | ric | | | Brand | | eric | Total | Total |
| | FFS | МСО | FFS | МСО | Total | FFS | МСО | FFS | мсо | Total | Total |
| Ingredient Reimbursement | \$31,677,000 | \$33,000 | \$0 | \$0 | \$31,710,000 | \$26,529,000 | \$29,000 | \$0 | \$0 | \$26,558,000 | -\$5,152,000 |
| Dispensing Fee Reimbursement | \$3,000 | \$10 | \$0 | \$0 | \$3,000 | \$163,000 | \$150 | \$0 | \$0 | \$163,000 | \$160,000 |
| Estimated Total Reimbursement | \$31,680,000 | \$33,000 | \$0 | \$0 | \$31,713,000 | \$26,692,000 | \$29,000 | \$0 | \$0 | \$26,721,000 | -\$4,992,000 |

^{*}Ingredient cost is based on ASP + 6% and \$0.202 Furnishing Fee from the CMS October 2016 file.

^{*}If no ASP, ingredient cost reimbursement is WAC + 0%.

^{*}Approximately 694 claims; approximately 16,355,183 units.

^{*}Approximately 15 unique providers.

^{*}All reimbursement analyses are based on FFS and MCO claims from June 1, 2015 through May 31, 2016 with paid dates June 30, 2016.

ASP, DISPENSING FEE \$0.02 PER UNIT

| | | \$0.02 Dispensing Fee per unit | | | | | Difference | | | | |
|----------------------------------|--------------|--------------------------------|------|------------------|--------------|--------------|------------|------|------|--------------|--------------|
| | Brand | | Gene | Generic Total | | Brand | | Gene | eric | Total | Total |
| | FFS | MCO | FFS | МСО | Total | FFS | мсо | FFS | МСО | Total | Total |
| Ingredient Reimbursement | \$31,677,000 | \$33,000 | \$0 | \$0 | \$31,710,000 | \$26,529,000 | \$29,000 | \$0 | \$0 | \$26,558,000 | -\$5,152,000 |
| Dispensing Fee Reimbursement | \$3,000 | \$10 | \$0 | \$0 | \$3,000 | \$327,000 | \$300 | \$0 | \$0 | \$327,000 | \$324,000 |
| Estimated Total Reimbursement | \$31,680,000 | \$33,000 | \$0 | \$0 | \$31,713,000 | \$26,856,000 | \$29,000 | \$0 | \$0 | \$26,885,000 | -\$4,828,000 |

^{*}Ingredient cost is based on ASP + 6% and \$0.202 Furnishing Fee from the CMS October 2016 file.

^{*}If no ASP, ingredient cost reimbursement is WAC + 0%.

^{*}Approximately 694 claims; approximately 16,355,183 units.

^{*}Approximately 15 unique providers.

^{*}All reimbursement analyses are based on FFS and MCO claims from June 1, 2015 through May 31, 2016 with paid dates June 30, 2016.

ASP, DISPENSING FEE \$0.03 PER UNIT

| Current Reimbursement | | | | | | \$0.03 Dispensing Fee per unit | | | | | Difference |
|----------------------------------|--------------|----------|---------|-----|--------------|--------------------------------|----------|---------|-----|--------------|--------------|
| | Brand | l | Generic | | Total | Brand | | Generic | | Total | Total |
| | FFS | мсо | FFS | МСО | Total | FFS | МСО | FFS | МСО | Total | Total |
| Ingredient Reimbursement | \$31,677,000 | \$33,000 | \$0 | \$0 | \$31,710,000 | \$26,529,000 | \$29,000 | \$0 | \$0 | \$26,558,000 | -\$5,152,000 |
| Dispensing Fee Reimbursement | \$3,000 | \$10 | \$0 | \$0 | \$3,000 | \$490,000 | \$450 | \$0 | \$0 | \$490,000 | \$487,000 |
| Estimated Total Reimbursement | \$31,680,000 | \$33,000 | \$0 | \$0 | \$31,713,000 | \$27,019,000 | \$29,000 | \$0 | \$0 | \$27,048,000 | -\$4,665,000 |

^{*}Ingredient cost is based on ASP + 6% and \$0.202 Furnishing Fee from the CMS October 2016 file.

^{*}If no ASP, ingredient cost reimbursement is WAC + 0%.

^{*}Approximately 694 claims; approximately 16,355,183 units.

^{*}Approximately 15 unique providers.

^{*}All reimbursement analyses are based on FFS and MCO claims from June 1, 2015 through May 31, 2016 with paid dates June 30, 2016.

HEMOPHILIA DRUGS DISCOUNT RANGES IN COMMERCIAL AND MEDICAID PLANS

| | Rang | e | Range |) |
|-----------------|--------------|--------------|--------------|--------------|
| Hemophilia Drug | AWP Discount | AWP Discount | WAC Discount | WAC Discount |
| ADVATE | -23.8% | -36.8% | -8.6% | -24.2% |
| ADYNOVATE | -26.0% | -27.0% | -11.2% | -12.4% |
| ALPHANATE | -26.7% | -36.8% | -12.1% | -24.2% |
| ALPHANINE | -27.6% | -42.7% | -13.1% | -31.0% |
| ALPROLIX | -18.0% | -19.0% | -1.6% | -2.8% |
| BEBULIN | -10.63% | -15.0% | 2.0% | 7.25% |
| BENEFIX | -12.5% | -14.2% | 2.8% | 5.0% |
| CORIFACT | -20.2% | -25.0% | -4.2% | -10.0% |
| ELOCTATE | -23.5% | -28.0% | -8.2% | -13.6% |
| FEIBA NF | -23.25% | -26.7% | -7.9% | -11.5% |
| HELIXATE | -28.0% | -36.8% | -13.6% | -24.2% |
| HEMOFIL | -29.6% | -40.3% | -15.5% | -27.9% |
| HUMATE-P | -25.2% | -30.3% | -10.3% | -16.4% |
| KOATE-DVI | -25.7% | -33.5% | -10.8% | -20.2% |
| KOGENATE FS | -24.2% | -36.8% | -9.1% | -24.2% |
| MONOCLATE | -25.4% | -33.9% | -10.5% | -20.0% |
| MONONINE | -20.0% | -26.0% | -6.8% | -11.2% |
| NOVOEIGHT | -32.4% | | -18.9% | |
| NOVOSEVEN RT | -22.0% | | -6.4% | |
| NUWIQ | -26.0% | | -11.2% | |
| OBIZUR | -17.5% | -24.4% | -1.0% | -9.3% |
| PROFILNINE | -9.63% | -20.0% | -4.1% | 8.45% |
| RECOMBINATE | -28.7% | -36.8% | -14.4% | -24.2% |
| RIXUBIS | -24.7% | -32.0% | -9.6% | -18.21% |
| WILATE | -22.1% | -42.0% | -6.6% | -29.7% |
| XYNTHA | -26.7% | -37.7% | -12.0% | -25.2% |
| XYNTHA SOLOFUSE | -24.8% | -34.5% | -9.7% | -21.4% |

HEMOPHILIA DRUG REIMBURSEMENT OPTIONS

| | Ingredient Cost Per Average Units per Claim | | | |
|--------------------------------|--|---|-----------|-----------|
| Hemophilia Drug | Average Units Per Claim | Current Ingredient Cost Per Average Units Per Claim | WAC-10% | ASP |
| FEIBA NF 2,500 UNIT (NOMINAL) | 83,420 | \$190,132 | \$162,169 | \$160,251 |
| NOVOSEVEN RT 5 MG VIAL | 68,571 | \$144,823 | \$123,429 | \$130,491 |
| FEIBA NF 651-1,200 UNIT VIAL | 56,753 | \$126,854 | \$108,285 | \$109,023 |
| ADYNOVATE 1,251-2,500 UNITS VL | 53,280 | \$111,590 | \$94,945 | \$105,494 |
| ELOCTATE 3,000 UNIT NOMINAL | 36,845 | \$80,086 | \$68,310 | \$69,710 |
| BENEFIX 3,000 UNIT KIT | 55,264 | \$79,757 | \$75,712 | \$83,835 |
| ELOCTATE 2,000 UNIT NOMINAL | 35,657 | \$77,503 | \$66,108 | \$67,463 |
| ALPROLIX 3,000 UNIT NOMINAL | 22,514 | \$70,532 | \$60,180 | \$63,377 |
| FEIBA NF 1,000 UNIT (NOMINAL) | 27,795 | \$63,350 | \$54,033 | \$53,394 |
| ELOCTATE 1,000 UNIT NOMINAL | 27,972 | \$60,800 | \$51,860 | \$52,923 |
| KOGENATE FS 2,000 UNIT VIAL | 24,765 | \$37,485 | \$32,542 | \$29,644 |
| ADVATE 801-1,200 UNITS VIAL | 12,668 | \$20,289 | \$17,330 | \$15,164 |
| RECOMBINATE 220-400 UNIT VIAL | 10,526 | \$16,859 | \$14,400 | \$12,600 |

COMPARISON OF INGREDIENT COST REIMBURSEMENT OPTIONS

| | WAC-10%, Dispensing Fee \$0.01 per unit | WAC-10%, Dispensing Fee \$0.02 per unit | WAC-10%, Dispensing Fee \$0.03 per unit | ASP, Dispensing Fee \$0.01 per unit | ASP, Dispensing Fee \$0.02 per unit | ASP, Dispensing Fee \$0.03 per unit |
|----------------------------------|---|---|---|---|---|---|
| INGREDIENT REIMBURSEMENT | \$27,145,000 | \$27,145,000 | \$27,145,000 | \$26,558,000 | \$26,558,000 | \$26,558,000 |
| DISPENSING FEE REIMBURSEMENT | \$163,000 | \$327,000 | \$490,000 | \$163,000 | \$327,000 | \$490,000 |
| ESTIMATED TOTAL REIMBURSEMENT | \$27,308,000 | \$27,472,000 | \$27,635,000 | \$26,721,000 | \$26,885,000 | \$27,048,000 |

All reimbursement analyses are based on FFS and MCO claims from June 1, 2015 through May 31, 2016 with paid dates June 30, 2016.

STAKEHOLDER DISCUSSION

