

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Department for Medicaid Services

3 Office of the Commissioner

4 (New Administrative Regulation)

5 907 KAR 3:205. Hemophilia Treatment Reimbursement and Coverage Via the 340B  
6 Drug Pricing Program.

7 RELATES TO: 42 USC Chapter 6A, Subchapter II, Part D, subpart vii, 256b; 42 USC  
8 701(a)(2)

9 STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3), 205.560(2),  
10 42 USC Chapter 6A, Subchapter II, Part D, subpart vii, 256b

11 NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family  
12 Services, Department for Medicaid Services has responsibility to administer the  
13 Medicaid Program. KRS 205.520(3) authorizes the cabinet, by administrative regulation,  
14 to comply with a requirement that may be imposed, or opportunity presented by federal  
15 law for the provision of medical assistance to Kentucky's indigent citizenry. This  
16 administrative regulation establishes the department's reimbursement, coverage, and  
17 other provisions related to hemophilia treatment reimbursed via the 340B drug pricing  
18 program.

19 Section 1. Definitions. (1) "340B drug pricing program" means a federally-established  
20 drug discount program available for designated entities.

21 (2) "340B drug pricing program ceiling price" means the highest price allowed, by

1 federal law, for a drug, factor product, or related item available via the 340B drug pricing  
2 program.

3 (2) “Comprehensive hemophilia diagnostic treatment center” or “CHDTC” means a  
4 center pursuant to 42 USC Chapter 6A, Subchapter II, Part D, subpart vii, 256b(4)(g).

5 (3) “Department” means the Department for Medicaid Services or its designee.

6 (4) “Factor product” means a blood clotting agent used to treat hemophilia.

7 (5) “Recipient” is defined in KRS 205.8451(9).

8 Section 2. Participation Requirements. (1) To qualify for reimbursement via the  
9 department’s 340B drug pricing program, a comprehensive hemophilia diagnostic  
10 treatment center shall:

11 (a) Be currently receiving a grant via 42 USC 701(a)(2);

12 (b) Submit the following to the United States Department of Health and Human  
13 Services (USDHHS), Health Resources and Services Administration (HRSA), Office of  
14 Pharmacy Affairs (OPA):

15 1. A request to participate in the 340B drug pricing program to the United States  
16 Department of Health and Human Services, Health Resources and Services  
17 Administration, Office of Pharmacy Affairs:

18 2. The entity’s Medicaid billing information; and

19 3. A completed 340B registration form; and

20 (c) Be approved by the department and the USDHHS HRSA OPA for participation in  
21 the 340B drug pricing program.

22 (2) A CHDTC participating in the department’s 340B drug pricing program shall:

23 (a) Ensure that current information, including business name and address, are

1 always provided to the United States Department of Health and Human Services,  
2 Health Resources and Services Administration, Office of Pharmacy Affairs; and

3 (b) Comply with 42 USC Chapter 6A, Subchapter II, Part D, subpart vii, 256b(a)(5)  
4 and (7).

5 (3) A CHDTC qualifying for reimbursement via the department's 340B drug pricing  
6 program pursuant to subsection (1) of this section shall be eligible for the  
7 reimbursement established in Section 4 of this administrative regulation on the first day  
8 of the calendar quarter following approval for participation. For example, a CHDTC  
9 approved for the department's 340B drug pricing program participation on January 10,  
10 2009, shall be eligible to receive reimbursement via the program effective April 1, 2009.

11 Section 3. General Provisions. (1) For the department to reimburse for hemophilia  
12 treatment, including a factor product or related item, for a recipient:

13 (a) The recipient shall be a current recipient; and

14 (b) The factor product shall be:

15 1. Medically necessary for the recipient;

16 2. Approved by the Food and Drug Administration; and

17 3. Prescribed for an indication that has been approved by the Food and Drug  
18 Administration or for which there is documentation in official compendia or peer-  
19 reviewed medical literature supporting its medical use.

20 Section 4. Hemophilia Treatment Reimbursement Via the 340B Drug Pricing  
21 Program.

22 (1) The department shall reimburse for hemophilia treatment, including a factor  
23 product or related item, provided by a participating CHDTC:

- 1 (1) Exclusively via the department's 340B drug pricing program;
- 2 (2) Not via the department's pharmacy reimbursement provisions established in 907
- 3 KAR 1:018; and
- 4 (3) At the 340B drug pricing program ceiling price for the factor product pursuant to
- 5 42 USC Chapter 6A, Subchapter II, Part D, subpart vii, 256b plus a dispensing fee of
- 6 twelve (12) and one-half (1/2) cents per unit dose.

7 Section 5. Appeal Rights. A CHDTC may appeal a department decision associated  
8 with this administrative regulation in accordance with 907 KAR 1:671.

907 KAR 3:205

REVIEWED:

\_\_\_\_\_  
Date

\_\_\_\_\_  
Elizabeth A. Johnson, Commissioner  
Department for Medicaid Services

APPROVED:

\_\_\_\_\_  
Date

\_\_\_\_\_  
Janie Miller, Secretary  
Cabinet for Health and Family Services

907 KAR 3:205

A public hearing on this administrative regulation shall, if requested, be held on August 21, 2008 at 9:00 a.m. in the Cabinet for Health and Family Services, Health Services Board Room, 275 East Main Street; Frankfort, Kentucky; 40621. Individuals interested in attending this hearing shall notify this agency in writing by August 14, 2008, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business September 2, 2008. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

**CONTACT PERSON:** Jill Brown, Office of Legal Services, 275 East Main Street 5W-B, Frankfort, KY 40601, (502) 564-7905, Fax: (502) 564-7573.

REGULATORY IMPACT ANALYSIS  
AND TIERING STATEMENT

Administrative Regulation #: 907 KAR 3:205  
Cabinet for Health and Family Services  
Department for Medicaid Services  
Agency Contact Person: Dr. Thomas Badgett (502) 564-4321 or Stuart Owen (502)  
564-6204

- (1) Provide a brief summary of:
  - (a) What this administrative regulation does: This administrative regulation establishes the Department for Medicaid Services (DMS) coverage and reimbursement provisions for hemophilia treatment via a federal program known as a 340B drug pricing program.
  - (b) The necessity of this administrative regulation: This administrative regulation is necessary to establish DMS coverage and reimbursement provisions for hemophilia treatment via a federal program known as a 340B drug pricing program.
  - (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by establishing DMS coverage and reimbursement provisions for hemophilia treatment via a federal program known as a 340B drug pricing program.
  - (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the statutes by establishing DMS coverage and reimbursement provisions for hemophilia treatment via a federal program known as a 340B drug pricing program.
  
- (2) If this is an amendment to an existing administrative regulation, provide a brief summary of:
  - (a) How the amendment will change this existing administrative regulation: This is a new administrative regulation.
  - (b) The necessity of the amendment to this administrative regulation: This is a new administrative regulation.
  - (c) How the amendment conforms to the content of the authorizing statutes: This is a new administrative regulation.
  - (d) How the amendment will assist in the effective administration of the statutes: This is a new administrative regulation.
  
- (3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: DMS projects that approximately thirty-seven (37) individuals will receive hemophilia treatment via the 340B drug pricing program rather than via regular Medicaid pharmacy coverage. Currently the University of Kentucky's hemophilia treatment center is the only center known to qualify as a comprehensive hemophilia diagnostic

treatment center (CHDTC); however, others may be interested in pursuing this option in the future depending upon the result of this initiative.

- (4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:
  - (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: An entity who desires to participate as a CHDTC in the 340B drug pricing program must comply with and meet the corresponding federally-established requirements.
  - (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3). No cost is imposed on a qualifying entity.
  - (c) As a result of compliance, what benefits will accrue to the entities identified in question (3). A qualifying entity will receive enhanced reimbursement for hemophilia treatment provided via the associated dispensing fee.
- (5) Provide an estimate of how much it will cost to implement this administrative regulation:
  - (a) Initially: The Department for Medicaid Services (DMS) anticipates that the amendment could save DMS approximately \$200,000 (\$139,000 federal funds/\$61,000 state funds) annually.
  - (b) On a continuing basis: DMS anticipates that the amendment could save DMS approximately \$200,000 (\$139,000 federal funds/\$61,000 state funds) annually.
- (6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The sources of revenue to be used for implementation and enforcement of this administrative regulation are federal funds authorized under the Social Security Act, Title XIX and matching funds of general fund appropriations.
- (7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: Neither an increase in fees nor funding will be necessary to implement this administrative regulation.
- (8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish or increase any fees.
- (9) Tiering: Is tiering applied? (Explain why tiering was or was not used) Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it.

## FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Reg NO: 907 KAR 3:205

Contact Person: Dr. Thomas Badgett (502) 564-4321 or Stuart Owen (502) 564-6204

1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments or school districts)?

Yes X No \_\_\_\_\_

If yes, complete 2-4.

2. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? Only entities who qualify as comprehensive hemophilia diagnostic treatment centers in accordance with federal regulation shall be able to be reimbursed via the Department for Medicaid Services (DMS) 340B drug pricing program.
3. Identify each state or federal regulation that requires or authorizes the action taken by the administrative regulation. This amendment is required by KRS 205.5605 and 205.5606.
4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.
  - (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? The Department for Medicaid Services (DMS) anticipates that the amendment could save DMS approximately \$200,000 (\$139,000 federal funds/\$61,000 state funds) annually.
  - (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? The Department for Medicaid Services (DMS) anticipates that the amendment could save DMS approximately \$200,000 (\$139,000 federal funds/\$61,000 state funds) annually.
  - (c) How much will it cost to administer this program for the first year? DMS anticipates this administrative regulation saving rather than costing additional monies.
  - (d) How much will it cost to administer this program for subsequent years? DMS anticipates this administrative regulation saving rather than costing additional

monies.