

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Department for Medicaid Services

3 Office of the Commissioner

4 (Amended after Comments)

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. **The department's coverage and reimbursement for hemophilia treatment**
19 **is not restricted to hemophilia treatment provided by an entity participating in the**
20 **340B drug pricing program. Hemophilia treatment coverage, of hemophilia**
21 **treatment provided by an entity not participating in the 340B drug pricing**

1 **program, shall be in accordance with the department’s pharmacy coverage**
2 **provisions established in 907 KAR 1:019. Hemophilia treatment reimbursement,**
3 **for hemophilia treatment provided by an entity not participating in the 340B drug**
4 **pricing program, shall be in accordance with the department’s pharmacy**
5 **reimbursement provisions established in 907 KAR 1:018.**

6 Section 1. Definitions. (1) “340B drug pricing program” means a federally-established
7 drug discount program available for designated entities.

8 (2) “340B drug pricing program ceiling price” means the highest price allowed, by
9 federal law, for a drug, factor product, or related item available via the 340B drug pricing
10 program.

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

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

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

15 (5) **“Federal financial participation” is defined in 42 CFR 400.203.**

16 **(6) “Recipient” is defined in KRS 205.8451(9).**

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

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

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

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

4 2. The entity's Medicaid billing information; and

5 3. A completed 340B registration form; and

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

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

9 (a) Ensure that current information, including business name and address, are
10 always provided to the United States Department of Health and Human Services,
11 Health Resources and Services Administration, Office of Pharmacy Affairs; and

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

14 (3) A CHDTC qualifying for reimbursement via the department's 340B drug pricing
15 program pursuant to subsection (1) of this section shall be eligible for the
16 reimbursement established in Section 4 of this administrative regulation on the first day
17 of the calendar quarter following approval for participation. For example, a CHDTC
18 approved for the department's 340B drug pricing program participation on January 10,
19 2009, shall be eligible to receive reimbursement via the program effective April 1, 2009.

20 Section 3. General Provisions **for Hemophilia Treatment Coverage and**
21 **Reimbursement for Treatment Provided by a 340B Drug Pricing Program Entity.**

22 (1) For the department to reimburse for hemophilia treatment **provided by a CHDTC**
23 **participating as a 340B drug pricing program entity**, including a factor product or

1 related item, for a recipient:

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

3 (b) The factor product shall be:

4 1. Medically necessary for the recipient;

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

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

9 Section 4. Hemophilia Treatment Reimbursement Via the 340B Drug Pricing
10 Program.

11 ~~[(4)]~~The department shall reimburse for hemophilia treatment, including a factor
12 product or related item, provided by a ~~[participating]~~ CHDTC participating as a 340B
13 drug pricing program entity:

14 (1) Exclusively via the department's 340B drug pricing program;

15 (2) Not via the department's pharmacy reimbursement provisions established in 907
16 KAR 1:018; and

17 (3) At the 340B drug pricing program ceiling price for the factor product pursuant to
18 42 USC Chapter 6A, Subchapter II, Part D, subpart vii, 256b plus a dispensing fee of
19 twelve (12) and one-half (1/2) cents per unit ~~[dose]~~.

20 Section 5. Hemophilia Treatment Coverage and Reimbursement if Provided by a
21 Non-340B Drug Pricing Program Entity. (1) The department's coverage and
22 reimbursement for hemophilia treatment is not restricted to hemophilia treatment
23 provided by an entity participating in the 340B drug pricing program.

1 **(2) A recipient shall:**

2 **(a) Not be restricted to only receive hemophilia treatment via a 340B drug**
3 **pricing program entity; and**

4 **(b) Shall have freedom of choice of provider.**

5 **(3) Hemophilia treatment coverage, of hemophilia treatment provided by an**
6 **entity not participating in the 340B drug pricing program, shall be in accordance**
7 **with the department's pharmacy coverage provisions established in 907 KAR**
8 **1:019.**

9 **(4) Hemophilia treatment reimbursement, for hemophilia treatment provided by**
10 **an entity not participating in the 340B drug pricing program, shall be in**
11 **accordance with the department's pharmacy reimbursement provisions**
12 **established in 907 KAR 1:018.**

13 **Section 6. Federal Financial Participation. A provision established in this**
14 **administrative regulation shall be effective contingent upon the department's**
15 **receipt of federal financial participation for the respective provision.**

16 **Section 7.**Appeal Rights. **(1)** A CHDTC may appeal a department decision
17 associated with this administrative regulation in accordance with 907 KAR 1:671.

18 **(2) A recipient may appeal the department's denial, suspension, reduction, or**
19 **termination of a covered drug or decision regarding the amount of a drug**
20 **dispensed based upon an application of this administrative regulation in**
21 **accordance with 907 KAR 1:563.**

907 KAR 3:205
(Amended after Comments)

REVIEWED:

Date	Elizabeth A. Johnson, Commissioner Department for Medicaid Services
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APPROVED:

Date	Janie Miller, Secretary Cabinet for Health and Family Services
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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: The amendment after comments clarifies that the provisions of this administrative regulation only apply to hemophilia treatment coverage and reimbursement for hemophilia treatment provided by a 340B drug pricing program entity; that the dispensing fee is per unit rather than per unit dose; that recipients are not restricted to only receiving hemophilia treatment via a 340B participating entity and have freedom of choice of provider; and establishes that the policies in the administrative regulation are contingent upon the receipt of federal financial participation by the department.
 - (b) The necessity of the amendment to this administrative regulation: The amendment after comments is necessary to clarify that recipients have freedom of choice of provider and to maintain the viability of the Medicaid program by clarifying that policies are contingent upon the provision of federal financial participation by the Centers for Medicare and Medicaid Services (CMS) to the department. CMS provides approximately seventy (70) of program funding to

the department - compared to fifty (50) percent of administrative funding. The department, as part of its mission to serve the citizens of the Commonwealth of Kentucky in a fiscally responsible manner, must strive to ensure that program policies are contingent upon receipt of federal funding. Failure to maintain this safe guard could jeopardize the health, safety and welfare of recipients of Medicaid program services as well as impose an injurious and unsound financial burden on the citizens of Kentucky.

- (c) How the amendment conforms to the content of the authorizing statutes: The amendment after comments conforms to the content of the authorizing statutes by clarifying that recipients have freedom of choice of provider and by rendering policies contingent upon federal financial participation consistent with KRS 205.520(3).
 - (d) How the amendment will assist in the effective administration of the statutes: The amendment after comments will assist in the effective administration of the authorizing statutes by clarifying that recipients have freedom of choice of provider and by rendering policies contingent upon federal financial participation consistent with KRS 205.520(3).
- (3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: DMS projects that approximately sixty-five (65) individuals will receive hemophilia treatment via the 340B drug pricing program rather than via regular Medicaid pharmacy coverage. Each of these individuals possesses the freedom to choose their provider. Each may choose to receive hemophilia treatment via the only center expected to qualify as a comprehensive hemophilia diagnostic treatment center (CHDTC) or via an entity reimbursed via the Medicaid pharmacy program for hemophilia treatment rather than via the 340B drug pricing program.
- (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. Individuals receiving hemophilia treatment will continue to have the freedom to choose their provider. Each may choose to receive hemophilia treatment via the only center currently known to qualify as a CHDTC or via an entity reimbursed via the Medicaid pharmacy program for hemophilia treatment rather than via the 340B drug pricing program.
 - (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 expected to be 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) initially anticipated that the amendment could save DMS approximately \$200,000 (\$139,000 federal funds/\$61,000 state funds) annually. That expectation was based on prior utilization of individuals – approximately thirty-seven (37) - who received hemophilia treatment via the only known CHDTC pursuing participation in the 340B drug pricing program. Subsequent to the initial filing of the administrative regulation, DMS learned that the number of Medicaid individuals served by the entity is approximately sixty-five (65). Therefore, DMS anticipates that savings could also increase proportionately to the increased number of individuals served. DMS emphasizes, though, that even though more individuals are currently being served by the entity, utilization could always change as individuals receiving hemophilia treatment via the Medicaid program have and will continue to have freedom of choice regarding provider. No individual will be required to only receive hemophilia treatment via a 340B drug pricing program entity.

DMS understands that the majority of individuals treated via the particular hemophilia treatment center have been patients of the center since their initial diagnosis which, in some cases, is since birth with very few seeking treatment elsewhere despite having a choice. Presumably, though not certainly, these individuals would continue receiving hemophilia treatment at the entity.

DMS also notes that the savings accounts for the loss of rebate dollars as drugs provided by 340B entities are ineligible for rebates.

(b) On a continuing basis: DMS initially anticipated that the amendment could save DMS approximately \$200,000 (\$139,000 federal funds/\$61,000 state funds) annually. That expectation was based on prior utilization of individuals – approximately thirty-seven (37) - who received hemophilia treatment via the only known CHDTC pursuing participation in the 340B drug pricing program. Subsequent to the initial filing of the administrative regulation, DMS learned that the number of Medicaid individuals served by the entity is approximately sixty-five (65). Therefore, DMS anticipates that savings could also increase proportionately to the increased number of individuals served. DMS emphasizes, though, that even though more individuals are currently being served by the entity, utilization could always change as individuals receiving hemophilia treatment via the Medicaid program have and will continue to have freedom of choice regarding provider. No individual will be required to only receive hemophilia treatment via a 340B drug pricing program entity.

DMS understands that the majority of individuals treated via the particular hemophilia treatment center have been patients of the center since their initial diagnosis which, in some cases, is since birth with very few seeking treatment

elsewhere despite having a choice. Presumably, though not certainly, these individuals would continue receiving hemophilia treatment at the entity.

DMS also notes that the savings accounts for the loss of rebate dollars as drugs provided by 340B entities are ineligible for rebates.

- (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? DMS initially anticipated that the amendment could save DMS approximately \$200,000 (\$139,000 federal funds/\$61,000 state funds) annually. That expectation was based on prior utilization of individuals – approximately thirty-seven (37) - who received hemophilia treatment via the only known CHDTC pursuing participation in the 340B drug pricing program. Subsequent to the initial filing of the administrative regulation, DMS learned that the number of Medicaid individuals served by the entity is approximately sixty-five (65). Therefore, DMS anticipates that savings could also increase proportionately to the increased number of individuals served. DMS emphasizes, though, that even though more individuals are currently being served by the entity, utilization could always change as individuals receiving hemophilia treatment via the Medicaid program have and will continue to have freedom of choice regarding provider. No individual will be required to only receive hemophilia treatment via a 340B drug pricing program entity.

DMS understands that the majority of individuals treated via the particular

hemophilia treatment center have been patients of the center since their initial diagnosis which, in some cases, is since birth with very few seeking treatment elsewhere despite having a choice. Presumably, though not certainly, these individuals would continue receiving hemophilia treatment at the entity.

DMS also notes that the savings accounts for the loss of rebate dollars as drugs provided by 340B entities are ineligible for rebates.

- (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? DMS initially anticipated that the amendment could save DMS approximately \$200,000 (\$139,000 federal funds/\$61,000 state funds) annually. That expectation was based on prior utilization of individuals – approximately thirty-seven (37) - who received hemophilia treatment via the only known CHDTC pursuing participation in the 340B drug pricing program. Subsequent to the initial filing of the administrative regulation, DMS learned that the number of Medicaid individuals served by the entity is approximately sixty-five (65). Therefore, DMS anticipates that savings could also increase proportionately to the increased number of individuals served. DMS emphasizes, though, that even though more individuals are currently being served by the entity, utilization could always change as individuals receiving hemophilia treatment via the Medicaid program have and will continue to have freedom of choice regarding provider. No individual will be required to only receive hemophilia treatment via a 340B drug pricing program entity.

DMS understands that the majority of individuals treated via the particular hemophilia treatment center have been patients of the center since their initial diagnosis which, in some cases, is since birth with very few seeking treatment elsewhere despite having a choice. Presumably, though not certainly, these individuals would continue receiving hemophilia treatment at the entity.

DMS also notes that the savings accounts for the loss of rebate dollars as drugs provided by 340B entities are ineligible for rebates.

- (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.