

**Department of State Health Services
Council Agenda Memo for State Health Services Council
July 9, 2008**

Agenda Item Title: Repeal of rules and new rules concerning the Hemophilia Assistance Program

Agenda Number: 3e

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background:

The Hemophilia Assistance Program (HAP) is located within the Family and Community Health Services Division, Specialized Health Services Section, Purchased Health Services Unit. The HAP provides services to adults 21 years of age and older with a diagnosis of hemophilia congenital factor VIII disorder (Hemophilia A), congenital factor IX disorder (Hemophilia B), or congenital factor XI disorder (Hemophilia C). The HAP benefits include payments for blood derivatives, blood concentrates, and manufactured pharmaceutical products. The HAP contracts with providers to deliver blood derivatives, blood concentrates, and manufactured pharmaceutical products to HAP clients. There are 12 HAP clients. The HAP budget for FY 08 is \$324,670 and is supported by legislative appropriations from General Revenue.

Summary:

The rules for HAP provide for the administration of the program by DSHS. The department proposes the repeal of the existing rules and the adoption of new rules at 25 TAC Chapter 37, Subchapter F, as a result of the mandatory four-year review of agency rules required by Section 2001.039 of the Government Code. The proposed rules reflect necessary substantive changes, including corrections of fact and updates relating to the consolidation of health and human services agencies. The proposed changes clarify and revise language, as well as make grammatical corrections to improve sentence flow and accuracy. Information was added to enhance understanding of authorizations, claims processing, filing deadlines, and rights and responsibilities for applicants, clients, and providers in reference to modifications, suspensions, denials, and terminations.

The rules affect HAP providers, applicants and clients.

The expected outcomes of the proposed rules are to: 1) accurately reflect updated information such as agency names; 2) enhance the understanding of HAP providers, applicants and clients regarding program policy; and 3) increase readability.

Summary of Input from Stakeholder Groups:

Recommendations were solicited via e-mail and regular mail from 50 HAP stakeholders on March 18, 2008, inclusive of:

- Six Hemophilia Treatment Centers in Texas;
- All members of the Texas Bleeding Disorders Advisory Council;
- Two Texas Chapters of the National Hemophilia Foundation;
- Five current DSHS HAP providers;
- Four current HAP clients;
- DSHS stakeholders – Advocacy Inc., Caremark Therapeutic Services, Choice Source Therapeutics, Galveston Hemophilia Program, Gulf States Hemophilia and Thrombophilia Center, North Texas Comprehensive Hemophilia Center, South Texas Comprehensive Hemophilia Center, and Texas Medical Association; and
- Eight DSHS managers for social work services for DSHS Health Services Regions.

The program received comments from the Gulf State Hemophilia and Thrombophilia Center on March 28, 2008. The Program also received comments via fax on March 31, 2008, from a member of the Texas Bleeding Disorders Advisory Council who serves in the Lone Star Chapter of the National Hemophilia Foundation.

Stakeholders provided the following feedback:

- A recommendation for the HAP to reimburse Medicare recipients 20% of their medical expenses;
- A recommendation that the HAP pay Medicare and private insurance premiums; and
- A recommendation to reimburse adult males insurance premiums of the Texas High Risk Insurance Pool or Medicaid Buy-in Program.

The above recommendations were not incorporated into the proposed rule text due to Health and Safety Code, Sections 41.002(a) and 41.004(a)(2), which prohibit implementation of the recommendations.

A stakeholder also recommended that the HAP continue to offer allowable products to those diagnosed with hemophilia. This recommendation currently aligns with program rules.

Proposed Motion: Motion to recommend HHSC approval for publication of rules contained in agenda item #3e

Approved by Assistant Commissioner/Director: Evelyn Delgado **Date:** 5/28/08

Presenter: Jann Melton-Kissel **Program:** Specialized Health Services **Phone No.:** 458-7111, ext. 2002
Section

Approved by CCEA: Rosamaria Murillo **Date:** May 28, 2008

Title 25. HEALTH SERVICES
Part 1. DEPARTMENT OF STATE HEALTH SERVICES
Chapter 37. Maternal and Infant Health Services
Subchapter F. Hemophilia Assistance Program
Repeal §§37.111-37.119
New §§37.111-37.119

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes the repeal of §§37.111 - 37.119, and new §§37.111 - 37.119 concerning the Hemophilia Assistance Program (HAP).

BACKGROUND AND PURPOSE

The proposed repeal and new rules will reorganize and update information, delete and revise language, and make grammatical corrections to improve flow, accuracy, and clarity.

Government Code, §2001.039, requires that each state agency review and consider for re-adoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Sections 37.111-37.119 have been reviewed, and the department has determined that reasons for adopting the sections continue to exist because rules on this subject are needed.

SECTION-BY-SECTION SUMMARY

The following changes to names and addresses have been made throughout §§37.111 - 37.119. References to legacy agencies, now part of the Health and Human Services Commission, have been amended to reflect the department's name change from "Texas Department of Health" to "Department of State Health Services," and references to the "Board of Health" have been deleted.

The proposed new §37.111 groups the terms "purpose," "confidentiality of information," and "forms" together.

The proposed new §37.112 includes new definitions for terms used with the rules.

The proposed new §37.113 clarifies the eligibility requirements, the application and eligibility dates, financial criteria, and residency requirements.

The proposed new §37.114 clarifies existing language, updates new language, and sets out conditions for benefits and limitations of the HAP.

The proposed new §37.115 clarifies provider enrollment criteria for the HAP, change of provider ownership requirements, the consequences for not continuing to meet the requirements, and provider limitations.

The proposed new §37.116 includes language for authorizations and claims processing, including filing deadlines.

The proposed new §37.117 includes language concerning rights and responsibilities for applicants, clients, providers, and participating providers.

The proposed new §37.118 includes language concerning modifications, suspensions, denials, and terminations for applicants, clients, providers, and participating providers.

The proposed new §37.119 clarifies the appeal process, describes the procedures for informal disposition of a complaint, and describes the procedures for an administrative review and fair hearing request.

FISCAL NOTE

Jann Melton-Kissel, RN, MBA, Director, Specialized Health Services Section, has determined that for each year of the first five-year period that the sections will be in effect, there will be no fiscal impact to state or local governments as a result of enforcing and administering the sections as proposed. The repeals and new sections are intended to clarify, update, and strengthen the subchapter, and are not anticipated to be controversial or have significant fiscal impact to the department or local government.

MICRO-BUSINESS AND SMALL BUSINESS IMPACT ANALYSIS

Ms. Melton-Kissel has also determined that there will be no effect on small businesses or micro-businesses required to comply with the sections as proposed, because neither small businesses nor micro-businesses that are providers of HAP will be required to alter their business practices in order to comply with the sections. There are no anticipated economic costs to persons who are required to comply with the sections as proposed. There is no anticipated negative impact on local employment.

ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS

Ms. Melton-Kissel has determined that the proposed changes have no adverse economic impact on small businesses. Therefore, an economic impact statement and regulatory flexibility analysis for small businesses are not required.

PUBLIC BENEFIT

Ms. Melton-Kissel has determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as a result of enforcing or administering the sections is improved accuracy and consistency in the rules, and more accurate interpretation of their intent. In addition, the new rules will allow the program to function more efficiently and effectively.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, do not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted by mail to Alesia Brown, Purchased Health Services Unit MC 1938, Department of State Health Services, P.O. Box 149347, Austin, Texas 78714-9347, by telephone at (512) 458-7111, extension 3664, or by email to alesia.brown@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The proposed repeal and new rules are authorized by Government Code, §531.0055(e), and the Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The proposed repeal and new rules affect Government Code, Chapter 531; and Health and Safety Code, Chapter 1001. Review of the sections implements Government Code, §2001.039.

Sections for repeal.

- §37.111. General.
- §37.112. Recipient Requirements.
- §37.113. Residency and Residency Documentation Requirements.

- §37.114. Applications and Eligibility Date.
- §37.115. Financial Criteria.
- §37.116. Limitations and Benefits Provided.
- §37.117. Participating Providers.
- §37.118. Forms.
- §37.119. Confidentiality of Information.

Legend: (Proposed New Rule)
Regular Print = Proposed new language

§37.111. General Information.

(a) Purpose. The purpose of this chapter is to establish rules for the Hemophilia Assistance Program (HAP). The authority for these rules is granted in the Health and Safety Code, Chapter 41.

(b) Confidentiality of Information.

(1) All information submitted, as required by this chapter, may be verified at the discretion of the Department of State Health Services (department) with or without notice to the applicant or client of benefits of the HAP, or to the providers of HAP services. Information required by this chapter and received by the department is kept confidential to the extent authorized by law.

(2) Information may be disclosed in summary, statistical, or other forms that do not identify particular individuals.

(c) Forms that have been developed by the department for use in the HAP will be provided to applicants, clients, and providers.

§37.112. Definitions. The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise.

(1) Administrative review--A process that allows applicants or clients the opportunity to request an informal review of any intended HAP action that would suspend, modify, deny, or terminate their eligibility for benefits participation in the HAP or reimbursement for allowable products.

(2) Allowable products--Blood derivatives, blood concentrates, and manufactured pharmaceutical products indicated for the treatment of hemophilia and approved for payment by the HAP.

(3) Applicant--An individual whose application has been submitted, but HAP has not made a final determination of eligibility. This includes an individual whose application is submitted by a representative or person with legal authority to act for the individual.

(4) Client--A person who has applied for program services and who meets all HAP eligibility requirements and is determined to be eligible for program services.

(5) Commission--The Health and Human Services Commission (HHSC).

(6) Date of service (DOS)--The date the allowable products are dispensed.

- (7) Department--Department of State Health Services.
- (8) Effective date--The initial date of eligibility for a HAP client.
- (9) Fair hearing--The informal hearing process the department follows under 25 Texas Administrative Code (TAC), §§1.51 - 1.55 (relating to Fair Hearing Procedures).
- (10) Federal Poverty Level guidelines (FPL)--The minimum income needed by a family for food, clothing, transportation, shelter, and other necessities in the United States, according to the United States Department of Health and Human Services, or its successor agency/agencies. FPL vary according to family size, and after adjustment for inflation, are published annually in the *Federal Register*.
- (11) Filing deadline--The last date that a claim may be received by the HAP and still be considered for benefits eligibility.
- (12) Hemophilia Assistance Program (HAP)--A program funded by the State of Texas that provides limited financial assistance to persons age 21 and older who have been diagnosed with hemophilia and meet other program eligibility requirements for blood derivatives, blood concentrates, and manufactured pharmaceutical products that are administered or dispensed by program-approved providers.
- (13) Hemophilia--A human physical condition characterized by bleeding, resulting from a genetically determined deficiency of a blood coagulation factor or an abnormal or deficient plasma procoagulant that prevents the blood from clotting properly. The diagnoses covered by the HAP include:
- (A) congenital factor VIII disorder (Hemophilia A);
 - (B) congenital factor IX disorder (Hemophilia B); and
 - (C) congenital factor XI disorder (Hemophilia C).
- (14) Inhibitor--A type of antibody that requires the use of higher doses of blood factor to contain a bleeding episode.
- (15) Provider--Any individual or entity approved by the HAP to provide allowable products to HAP clients.
- (16) Physician--An individual licensed by the Texas Medical Board to practice medicine in the State of Texas.
- (17) Reimbursement--Payment of a claim for allowable products administered or dispensed to a HAP client submitted by a provider.

(18) Reimbursement rate--The HAP payment rate for allowable products, determined annually for the following fiscal year based on the current year's Texas Medicaid Program reimbursement rate.

§37.113. Eligibility.

(a) Client Requirements.

(1) A person shall meet all of the following requirements to be eligible for benefits from the HAP:

- (A) have a diagnosis of hemophilia certified by a physician;
- (B) be 21 years of age or older;
- (C) be a resident of Texas as specified in subsection (d) of this section

and not be:

prison; or

- (i) incarcerated in a city, county, state, or federal jail, or
- (ii) a ward of the state.

(D) submit a complete application for benefits to the HAP;

(E) satisfy the financial criteria as specified in subsection (c) of this section, including any person or persons who have a legal obligation to support the client; and

(F) the applicant must not be eligible for Children with Special Needs Services Program, the Texas Medicaid Program, or Medicare.

(b) Applications and Eligibility Dates.

(1) Persons meeting the eligibility requirements set forth in subsection (a) of this section must submit a complete application in order to receive benefits through the HAP.

(2) An eligibility determination will be made upon receipt of a complete application, which shall consist of all of the following:

(A) a complete Application for Assistance Form, with the applicant's, or the applicant's representative's, and physician's original signatures or "mark";

(B) documentation of Texas residency as specified in subsection (d) of this section; and

(C) documentation of income as specified in subsection (c) of this section.

(3) Any application which does not meet all of the requirements of paragraph (2) of this subsection is incomplete and shall be returned to the submitting person for correction or completion if the missing information is not otherwise provided.

(4) The HAP eligibility date for HAP benefits will be either:

(A) the date the HAP receives a completed application; or

(B) the date of conditional authorization for allowable products, if all written information to establish eligibility is received within 30 calendar days following the date of conditional authorization.

(5) If HAP benefits are terminated, the eligibility date for any subsequent benefit period will be the date on which the HAP receives a subsequent completed application for HAP benefits or the date of conditional authorization for allowable products, if all written information to establish eligibility is received within 30 calendar days following the date of conditional authorization.

(6) All HAP clients are required to submit valid residency and income verification information as outlined in subsections (c) and (d) of this section upon request and at least annually, in order for the HAP to determine continuing program eligibility.

(7) The denial of any application submitted to the HAP shall be in writing and shall include the reason(s) for such denial. The applicant has the right of appeal as outlined in §37.119 of this title (relating to Right of Appeal).

(c) Financial Criteria.

(1) Income must be at or below 200% of the FPL.

(2) Acceptable income verification documentation as described in paragraph (3)(C) of this subsection shall be submitted with the application. Changes in income or financial qualifications that would affect the applicant's eligibility shall be reported to the HAP.

(3) Financial need is established on the basis of income available to the applicant and the person(s) who have a legal obligation to support the applicant. If the applicant and person(s) who have a legal obligation to support the applicant are unemployed, a statement(s) of termination from the employer(s), or other documentation acceptable to the HAP, is required.

(A) The income used to determine eligibility is the combined gross income of the applicant and of all persons who have a legal obligation to support the applicant.

- (B) Income includes, but is not limited to:
 - (i) earned wages;
 - (ii) pensions;
 - (iii) allotments;
 - (iv) alimony; and
 - (v) any other monies received on a regular basis for support

purposes.

- (C) Income verification documentation includes:
 - (i) employer's written verification of gross monthly income;
 - (ii) the most recent pay check stub/monthly employee earnings statement;
 - (iii) Internal Revenue Service Income Tax Return forms for the most recently completed year;
 - (iv) pension/allotment award letters; or
 - (v) any other documents considered valid by the HAP.

(d) Residency Requirements.

(1) The following conditions shall be met by an applicant and maintained by a client to satisfy the residency requirements in this section:

- (A) physically reside within the state; and
- (B) maintain a home or abode within the state.

(2) If the applicant is a legal dependent of, and residing with, a person establishing residency on behalf of the applicant (such as a parent, a sibling, an adult child, or spouse), or if the applicant is a person under legal guardianship, then the person providing support or the legal guardian of the applicant must meet the requirements of paragraph (1) of this subsection.

(3) If the applicant is a parent residing with an adult child who meets the requirements of paragraph (1) of this subsection, residency may be established through the adult child.

(4) If the applicant is a parent being supported by an adult child, whether or not the child meets the requirements of paragraph (1) of this subsection, the parent applicant's residency may be established by the adult child's providing the required documents that establish the Texas residency of the parent applicant.

(5) The provisions of paragraphs (3) and (4) of this subsection apply, even if no legal guardianship has been established.

(6) An applicant who is currently a Texas resident and currently approved to receive benefits from Temporary Assistance for Needy Families (TANF) or Food Stamps is not required to provide additional residency verification.

(7) A person establishing residency on behalf of the applicant, who is currently a Texas resident and currently approved to receive benefits from Temporary Assistance for Needy Families (TANF) or Food Stamps, is not required to provide additional residency verification.

(8) An applicant or person establishing residency on behalf of the applicant, may submit a copy of any one of the following documents as evidence of residency. All documents shall be in the applicant's name or in the name of the person establishing residency for the applicant, and provide verification of a Texas address or domicile:

(A) a valid Texas driver license, or an identification card issued by the Texas Department of Public Safety;

(B) a valid Texas voter's registration card, or a copy of a validated (by a Texas county clerk's office) application for a voter's registration card;

(C) a current Texas motor vehicle registration or automobile license plate registration renewal form;

(D) a statement reflecting that the applicant is currently receiving rent-free housing. The statement must be signed by an individual responsible for providing the rent-free housing and must include the address and phone number of the individual or the organization providing the rent-free housing;

(E) a Texas property tax receipt for the most recently completed tax year; or

(F) any of the following documents, which must not be older than three months immediately preceding the applicant's signature date on the HAP application not including the application month:

(i) a mortgage payment receipt;

(ii) a rent payment receipt;

- (iii) a utility payment receipt;
- (iv) a dated payroll or retirement check;
- (v) prepared employment/unemployment records;
- (vi) an account statement from a financial institution;
- (vii) Social Security supplemental income or disability income records, or Social Security retirement benefit records; or
- (viii) any other documents deemed appropriate by the HAP.

(e) Legal Relationship. If the applicant's residency is established through the residency of another person, the following conditions must be met.

(1) The applicant must include documentation of the legal relationship between the applicant and the resident or person providing financial support, such as:

(A) a marriage license or declaration of non-ceremonial marriage to document the marriage of the applicant and spouse;

(B) a birth certificate establishing the parent-child relationship between the applicant and the resident; or

(C) an income tax return showing the name and relationship of the applicant to the resident.

(2) Any difference between the name of the applicant and the name on any document must be explained by additional documentation (example: marriage license, divorce decree, or adoption decree).

§37.114. Benefits and Limitations.

(a) The HAP provides limited reimbursement to providers for blood derivatives, blood concentrates, and manufactured pharmaceutical products indicated for the treatment of hemophilia and prescribed to eligible clients for use in medical or dental facilities, or in the home.

(b) All HAP benefits are limited to those allowable products prescribed by a physician and received in Texas from a provider.

(c) The HAP will pay for allowable products based upon:

(1) available funds;

and (2) established limits for allowable products by type or category of product;

(3) the reimbursement rates established by the department.

(d) Eligible clients with a private or group health insurance must exhaust all benefits prior to receiving benefits from the HAP.

(e) The HAP is payer of last resort. Applicants and currently eligible HAP clients are no longer eligible when they become eligible for the Children with Special Health Care Needs (CSHCN) Services Program, the Texas Medicaid Program, or Medicare.

(f) To meet budgetary limitations, the department may:

(1) adjust the reimbursement rates established by the department;

(2) restrict the allowable products paid for under the HAP;

(3) adjust the established limits for allowable products;

(4) adjust the limits established based on the inhibitor status of the client or applicant;

(5) limit the number of providers approved to participate in the HAP; or

(6) establish a waiting list of persons eligible for the HAP. Appropriate information will be collected from each applicant who is placed on a waiting list. The information will be used to facilitate contacting the applicant and to allow efficient enrollment of the applicant when benefits become available. Eligibility must be maintained while on the waiting list.

§37.115. Providers.

(a) Applicable provider types for the HAP include, but are not limited to:

(1) pharmacies;

(2) hospitals; or

(3) blood banks.

(b) In order for a provider to qualify for participation and to enroll in the HAP, the provider shall meet the following criteria:

(1) enter into an agreement to participate in the HAP;

- (2) submit a completed HAP provider enrollment form to the HAP;
- (3) submit a completed department Child Support Certification form to the HAP;
- (4) be a current Texas Medicaid Program provider;
- (5) reimburse the HAP for any overpayments made to the provider by the HAP upon request;
- (6) not currently be on suspension as a HAP provider or as a Texas Medicaid Program provider;
- (7) accept the payment amount authorized by the HAP as payment in full; and
- (8) comply with provisions of the most current HAP Provider Manual.

(c) Changes in provider ownership require termination of the agreement to participate. A new agreement must be executed under the new ownership.

(d) The HAP may establish provider enrollment limitations in order to conserve funds, assure quality, and effectively administer the program.

(e) The HAP may modify, suspend, deny, or terminate a provider's approval to participate for the following reasons:

- (1) submission of false or fraudulent claims;
- (2) failure to provide and maintain quality services;
- (3) failure to adhere to medically acceptable standards;
- (4) breach of the provider agreement;
- (5) disenrollment as a Texas Medicaid Program provider; or
- (6) violation of the requirements of this chapter.

§37.116. Payment.

(a) Prior Authorization.

- (1) Prior authorization is required for all allowable products.
- (2) The HAP will grant conditional prior authorization for applicants who begin or are in the process of acquiring eligibility for the HAP. Providers must notify the HAP within five working days from the date of service.

(b) The HAP reimburses providers for allowable product(s) for eligible clients. Payment may be made only after the allowable product(s) has been dispensed and submission of a valid claim. Claims must meet the following criteria:

- (1) be submitted on the claim form accepted by the HAP;
- (2) be submitted by a HAP provider; and
- (3) be filed directly with the HAP.

(c) Filing Deadlines.

(1) Complete claims must be received by the HAP within 95 calendar days following the date of service.

(2) Incomplete and rejected claims will be denied.

(3) Denied claims may be considered for payment if the claim is corrected and resubmitted within 30 calendar days following the date of the HAP notice of denial or within the initial 95 calendar day filing deadline, whichever is later.

(d) Claims for products or services not allowed or covered by this chapter or for products provided to ineligible clients will not be reimbursed.

(e) The HAP is the payer of last resort. Applicants and currently eligible HAP clients are not eligible when they become eligible for CSHCN Services Program, Texas Medicaid Program or Medicare.

(f) The HAP reimbursement provides for only those products determined allowable by the HAP.

(g) Claims received by the HAP will be paid, rejected, or denied within 30 calendar days of receipt by the HAP.

§37.117. Rights and Responsibilities.

(a) Rights.

(1) The applicant and client shall have the right to:

- (A) apply for eligibility determination;
- (B) choose providers subject to the HAP limitations;

(C) be notified of the HAP decisions relating to modifications, suspensions, denials, or terminations;

(D) appeal the HAP decision and receive a response within the deadline as described in §37.119 of this title (relating to Right of Appeal); and

(E) have confidentiality of information in the manner and to the extent authorized by law.

(2) The provider shall have the right to:

(A) apply and enroll as a provider;

(B) be notified of the HAP decision relating to modifications, suspensions, denials, or terminations; and

(C) have confidentiality of information in the manner and to the extent authorized by law.

(b) Responsibilities.

(1) The applicant and client shall have the responsibility to:

(A) provide accurate medical information to providers and notify providers of HAP eligibility prior to delivery of services;

(B) provide the HAP with accurate information regarding any change of circumstance which might affect eligibility within 30 calendar days following such change; and

(C) notify the HAP of any lawsuit(s) contemplated or filed concerning the cause of the medical condition for which the HAP has made payment.

(2) The provider shall have the responsibility to:

(A) enroll as a HAP provider and submit a completed application to the HAP, including all documents requested;

(B) abide by the HAP rules and regulations;

(C) not discriminate against applicants or clients based on source of payment; and

(D) notify the HAP of any lawsuit(s) contemplated or filed concerning the cause of the medical condition for which the HAP has made payment.

§37.118. Modifications, Suspensions, Denials and Terminations.

(a) Any applicant or client shall be notified in writing of the action, the reason(s) for the action, and the right of appeal in accordance with §37.119 of this title (relating to Right of Appeal), if the HAP proposes to modify, suspend, deny, or terminate eligibility or benefits for reasons, which include but are not limited to the following:

- (1) the application or other requested information is erroneous or falsified;
- (2) financial eligibility requirements are not met;
- (3) failure to establish or maintain Texas residency;
- (4) financial and/or residency documentation is not provided as required or requested;
- (5) failure to provide information when requested;
- (6) client is or becomes incarcerated in a city, county, state, or federal jail, or prison;
- (7) client is or becomes a ward of the state;
- (8) failure to receive allowable products through a provider; or
- (9) failure to continue premium payments on individual or group insurance or prepaid medical plans, where such plans provide benefits for the care and treatment of persons who have hemophilia and eligibility for benefits under the plan(s) was effective prior to eligibility for the HAP, and failure to provide a statement on the application form outlining the reason(s) why such insurance cannot be maintained.

(b) When eligibility for HAP benefits is terminated, an applicant or client may reapply for the HAP benefit.

(c) Any provider shall be notified in writing, if the HAP modifies, suspends, denies, or terminates a client's benefits or provider's enrollment. The written notification shall include the reason(s) for the action. The reasons for modifying, suspending, denying, or terminating a provider's enrollment include but are not limited to:

- (1) failure to maintain required current licensures or certifications in the State of Texas;
- (2) failure to maintain status as a Texas Medicaid Program provider;
- (3) failure to have a current HAP provider agreement on file;

- on file;
- (4) failure to submit a completed department Child Support Certification form
 - (5) failure to notify the HAP of change of ownership;
 - (6) failure to comply with all the provisions of the HAP provider agreement and the Provider Manual; or
 - (7) reduction or curtailment in funds available for the HAP.

§37.119. Right of Appeal.

- (a) Appeal procedures for applicants, and clients.

- (1) Administrative Review.

- (A) If the HAP intends to modify, suspend, deny, or terminate benefits, the HAP shall give written notice of the reason and the right to request an administrative review of the denial within 30 calendar days following the date of the denial notice.

- (B) If a written request for administrative review is not received by the HAP within the 30 calendar days following the date of the denial notice, the HAP will presume the administrative review process has been waived, and the HAP proposed action shall be final.

- (C) If a written request for administrative review is received within 30 calendar days following the date of the denial notice, the HAP will conduct an administrative review of the circumstances on which the proposed modification, suspension, denial, or termination is based and give written notice of the HAP decision including the supporting reasons within 10 calendar days of receipt of the request for an administrative review.

- (2) The Commission establishes the Texas Medicaid Program reimbursement rate upon which the HAP bases its reimbursement rate(s). Clients may not request an administrative review and may not appeal prior authorization decisions and reimbursement amounts for claims that are paid in accordance with the reimbursement rate as defined in §37.112(18) of this title (relating to Definitions).

- (b) Fair Hearing.

- (1) Applicants, and clients who are dissatisfied with a HAP administrative review decision and/or supporting reasons may request a fair hearing in writing addressed to the Hemophilia Assistance Program, Purchased Health Services Unit MC 1938, Department of State Health Services, P.O. Box 149347, Austin, Texas 78714-9347, within 20 calendar days following the date of receipt of the administrative review decision notice.

(2) If the request for a fair hearing is not received within 20 calendar days following the date of the receipt of the administrative review decision notice, the HAP will presume the fair hearing process has been waived, and the HAP may take final action.

(3) A fair hearing shall be conducted in accordance with §§1.51 - 1.55 of this title (relating to Fair Hearing Procedures).

§37.111. General.

(a) — Purpose. The purpose of this chapter is to establish rules for the Hemophilia Assistance Program (HAP). The authority for these rules is granted in the Texas Health and Safety Code, Chapter 41.

(b) — Definitions. The following words and terms, when used in this chapter, shall have the following meaning unless the context clearly indicates otherwise.

(1) — Allowable product — Blood derivatives, blood concentrates, and manufactured pharmaceutical products indicated for the treatment of hemophilia and approved for payment by the Hemophilia Assistance Program.

(2) — Applicant — An individual whose application has been submitted and has not received a final determination of eligibility. This includes an individual whose application is submitted by a representative or person with legal authority to act for the individual.

(3) — Department — The Texas Department of Health.

(4) — HAP — The Hemophilia Assistance Program.

(5) — Hemophilia — A human physical condition, characterized by bleeding, resulting from a genetically determined deficiency of a blood coagulation factor or hereditarily resulting in an abnormal or deficient plasma procoagulant.

(6) — Inhibitor — A type of antibody, more common in severe hemophilia A than hemophilia B, which requires the use of higher doses of blood factor to contain a bleeding episode. This is usually confirmed by the Bethesda inhibitor assay and reported as the Bethesda titer. The development of an inhibitor rarely occurs in those with mild hemophilia.

(7) — Participating provider — Any individual or entity with HAP approval to provide allowable products to HAP recipients.

(8) — Recipient — An individual who is eligible to receive HAP benefits.

§37.112. Recipient Requirements.

(a) — A person shall meet all of the following requirements to be eligible for benefits from the Hemophilia Assistance Program (HAP):

(1) — have a diagnosis of hemophilia certified by a licensed physician;

(2) — be 21 years of age or older;

(3) — be a resident of Texas as determined in §37.113 of this title (relating to Residency and Residency Documentation Requirements) and not be:

~~(A) — incarcerated in a city, county, state, or federal jail, or prison; or~~

~~(B) — a ward of the state.~~

~~(4) — submit an application for benefits to the HAP;~~

~~(5) — meet, or the person(s) who have a legal obligation to support the applicant meet, the financial guidelines as outlined in §37.115 of this title (relating to Financial Criteria). The person or persons who have a legal obligation to support the recipient will be determined by the applicable state law; and~~

~~(6) — not be eligible for Medicare or Medicaid.~~

~~(b) — A recipient may have all HAP benefits modified, suspended, or terminated for any of the following reasons:~~

~~(1) — failure to maintain Texas residency or, upon demand, furnish evidence of such using the criteria in §37.113 of this title;~~

~~(2) — failure to provide income data as requested to determine continued HAP eligibility;~~

~~(3) — recipient is incarcerated in a city, county, state, or federal jail, or prison;~~

~~(4) — recipient becomes a ward of the state;~~

~~(5) — recipient makes a material misstatement or misrepresentation on their application or any document required to support their application;~~

~~(6) — failure to continue premium payments on individual or group insurance or prepaid medical plans, where such plans provide benefits for the care and treatment of persons who have hemophilia and the person's eligibility for benefits under the plan(s) was effective prior to eligibility for HAP, or provide a statement on the application form outlining the reason(s) why such insurance cannot be maintained; or~~

~~(7) — failure to receive services through a participating provider.~~

~~(c) — When eligibility for HAP benefits is terminated for any of the reasons outlined in subsection (b) of this section, an applicant shall reapply for HAP benefits.~~

~~(d) — A recipient whose benefits are modified, suspended, or terminated may appeal the HAP decision under the procedure contained in §§1.51—1.55 ([http://info.sos.state.tx.us/pls/pub/readtac\\$ext.ViewTAC?tac_view=5&ti=25&pt=1&ch=1&sch=C&rl=Y](http://info.sos.state.tx.us/pls/pub/readtac$ext.ViewTAC?tac_view=5&ti=25&pt=1&ch=1&sch=C&rl=Y)) of this title (relating to Fair Hearing Procedures).~~

§37.113. Residency and Residency Documentation Requirements.

~~(a) — The following conditions shall be met by an applicant and maintained by a recipient to satisfy the residency requirements in this section:~~

~~(1) — physically reside within the state; and~~

~~(2) — maintain a home or abode within the state.~~

~~(b) — If the applicant is a legal dependent of, and residing with, a resident (such as an adult child or spouse); or is a person under legal guardianship, then the resident providing support or the legal guardian of the applicant shall meet the requirements of subsection (a) of this section.~~

~~(c) — If the applicant is a parent residing with their adult child who is a resident of Texas, residency may be determined through the adult child. If the applicant is a parent being supported by their adult child, whether or not the child is a resident of Texas, the residency may be determined by the adult child providing the required documents supporting the Texas residency of the parent. These provisions apply even if no legal guardianship has been established.~~

~~(d) — All documents submitted to establish the residency of an applicant shall be in English or accompanied by an accurate English translation, if required by the Hemophilia Assistance Program (HAP).~~

~~(e) — An applicant who is currently a Texas resident and has been currently approved to receive benefits from Temporary Assistance for Needy Families (TANF) or Food Stamps, is not required to provide additional residency verification.~~

~~(f) — A person establishing residency for the applicant under subsections (b) and (c) of this section, who is currently a Texas resident and has been currently approved to receive benefits from Texas Medicaid, Temporary Assistance for Needy Families (TANF), or Food Stamps, is not required to provide additional residency verification.~~

~~(g) — An applicant, or person establishing residency for the applicant under subsections (b) and (c) of this section, may submit a copy of any one of the following documents as evidence of residency. All documents shall be in the applicant's name, or in the name of the person establishing residency for the applicant, and provide some verification of a Texas address or domicile:~~

~~(1) — a valid Texas driver's license, or an identification card issued by the Texas Department of Public Safety;~~

~~(2) — a valid Texas voter's registration card, or a copy of a validated (at the county clerk's office) application for a voter's registration card;~~

~~(3) — a current Texas motor vehicle registration or automobile license plate registration renewal form;~~

~~(4) — a mortgage payment receipt from any of the three months immediately preceding the date of the application;~~

~~(5) — a rent payment receipt from any of the three months immediately preceding the date of the application;~~

~~(6) — a statement reflecting that the applicant is currently receiving rent free housing. The statement must be signed by the individual providing the rent free housing and must include the address and phone number of the individual providing the rent free housing;~~

~~(7) — a utility payment receipt from any of the three months immediately preceding the date of the application;~~

~~(8) — a Texas property tax receipt for the most recently completed tax year;~~

~~(9) — a payroll or retirement check dated within the three months immediately preceding the date of the application;~~

~~(10) — employment/unemployment records prepared within the three months immediately preceding the date of the application;~~

~~(11) — a statement from a financial institution issued within the three months preceding the date of the application; or~~

~~(12) — social security supplemental income or disability income records, or social security retirement benefit records issued within the three months immediately preceding the date of the application.~~

~~(h) — Applications submitted under subsections (b) and (c) of this section shall also include evidence of the legal relationship between the applicant and the resident, such as:~~

~~(1) — a marriage license or declaration of non-ceremonial marriage to document the marriage of the applicant and spouse;~~

~~(2) — a birth certificate establishing the parent/child relationship between the applicant and the resident; or~~

~~(3) — an income tax return showing name and relationship of the applicant to the resident.~~

(i) — Any difference between the name of the applicant and the name on any document must be explained by additional documentation (Example: marriage license, divorce decree, or adoption decree).

~~§37.114. Applications and Eligibility Date. Persons meeting the eligibility requirements set forth in §37.112(a)(1), (2), (3), (5) and (6) of this title (relating to Recipient Requirements) must make an application for benefits through the Hemophilia Assistance Program (HAP).~~

(1) — Complete application. A complete application is required before any eligibility determination will be made. A complete application shall consist of all of the following:

~~(A) a complete Application for Benefits, with the applicant's, or the applicant's representative's, original signature or "mark";~~

~~(B) a diagnosis of hemophilia certified by a licensed physician;~~

~~(C) documentation of Texas residency as required by §37.113 of this title (relating to Residency and Residency Documentation Requirements);~~

~~(D) applicant financial data. Acceptable data to establish the applicant's financial qualifications shall be submitted with the application. Changes in income or financial qualifications that would affect the applicant's eligibility shall be reported to the HAP.~~

~~(i) The applicant, or the person(s) who has a legal obligation to support the applicant, may submit any of the following documents to verify income:~~

~~(I) copy of the most recent paycheck;~~

~~(II) copy of the most recent paycheck stub or monthly employee earnings statement;~~

~~(III) employee's written verification of gross monthly income;~~

~~(IV) pension/allotment award letters;~~

~~(V) a copy of the IRS individual income tax return form and supporting schedules for the most recently completed tax year; or~~

~~(VI) any other documents considered valid by HAP.~~

~~(ii) If the applicant, or person(s) who has a legal obligation to support the applicant, is unemployed, a statement of termination from the employer, or other documentation acceptable to HAP, is required.~~

~~(2) — Incomplete applications. Any application which does not meet all of the requirements of paragraph (1) of this subsection is incomplete. Incomplete applications may be returned to the submitting person for correction or completion.~~

~~(3) — Eligibility date for HAP benefits. The HAP eligibility date will be either:~~

~~(A) — the date HAP receives a completed application; or~~

~~(B) — the date of conditional authorization for allowable products, if all written information to establish eligibility is received within 30 days of the date of conditional authorization.~~

~~(4) — Eligibility date for reinstatement of HAP benefits. If HAP benefits are terminated, the eligibility date for any subsequent benefit period will be the date on which HAP receives a subsequent completed application for HAP benefits.~~

~~(5) An applicant whose eligibility for benefits is denied may appeal HAP's decision under the procedure contained in §§1.51—1.55 ([http://info.sos.state.tx.us/pls/pub/readtac\\$ext.ViewTAC?tac_view=5&ti=25&pt=1&ch=1&sch=C&rl=Y](http://info.sos.state.tx.us/pls/pub/readtac$ext.ViewTAC?tac_view=5&ti=25&pt=1&ch=1&sch=C&rl=Y)) of this title (relating to Fair Hearing Procedures).~~

~~§37.115. Financial Criteria. Financial need is established on the basis of income legally available to the applicant or the person(s) who have a legal obligation to support the applicant.~~

~~(1) — The income used to determine eligibility is the combined gross income of the applicant and of all persons who have a legal obligation to support the applicant.~~

~~(2) — Income includes earned wages, pensions or allotments, alimony, or any monies received on a regular basis for support purposes. Verification of income data will be required as set out in §37.114(1)(D) of this title (relating to Applications and Eligibility Date).~~

~~(3) — The income level for eligibility is based on a percentage of the Federal Poverty Level Guidelines currently published by the U.S. Health and Human Services and adopted by the Texas Department of Health (department). Priority levels are based on available funds and may be adjusted by the department in order to meet budgetary limitations. Priority levels are as follows.~~

~~(A) Priority 1 — 100% or below;~~

~~(B) Priority 2 — 101% — 115%;~~

~~(C) Priority 3 — 116% — 130%;~~

~~(D) Priority 4 — 131% — 145%;~~

~~(E) Priority 5 — 146% — 160%;~~

~~(F) Priority 6 — 161% — 185%; or~~

~~(G) Priority 7 — 186% — 200%.~~

~~§37.116. Limitations and Benefits Provided.~~

~~(a) — The Hemophilia Assistance Program (HAP) provides limited reimbursement to participating providers for blood derivatives, blood concentrates, and manufactured pharmaceutical products indicated for the treatment of hemophilia and prescribed to eligible recipients for use in medical or dental facilities or in the home.~~

~~(b) — All HAP benefits are limited to those allowable products prescribed by a licensed physician and received in Texas from a participating provider.~~

~~(c) — Depending on the recipient's eligibility status, HAP will pay for allowable products per recipient based upon:~~

~~(1) — available funds;~~

~~(2) — established limits for allowable products by type or category of product;~~

~~and~~

~~(3) — the reimbursement rates established by the Texas Department of Health (department).~~

~~(d) — Recipients eligible for coverage of allowable products under a private/group health insurance plan are not eligible to receive HAP benefits. A recipient that has exhausted this coverage may be eligible to receive benefits from HAP.~~

~~(e) — To meet budgetary limitations, the department may:~~

~~(1) — adjust the priority level for receipt of benefits, as outlined in §37.115(3) of this title (relating to Financial Criteria);~~

~~(2) adjust the reimbursement rates established by the department;~~

~~(3) restrict the allowable products paid for under the HAP;~~

~~(4) adjust the established limits for allowable products;~~

~~(5) adjust the limits established based on the inhibitor status of the recipient or applicant;~~

~~(6) limit the number of providers approved to participate in the HAP; or~~

~~(7) establish a waiting list of persons eligible for HAP. Appropriate information will be collected from each applicant who is placed on a waiting list. The information will be used to facilitate contacting the applicant when benefits become available and to allow efficient enrollment of the applicant for those benefits.~~

~~§37.117. Participating Providers. In order for a provider to qualify for participation in the Hemophilia Assistance Program (HAP), the provider shall meet the following criteria:~~

- ~~(1) — enter into an agreement to participate in HAP;~~
- ~~(2) — submit a completed HAP provider enrollment form to HAP;~~
- ~~(3) — be a current Texas Medicaid provider;~~
- ~~(4) — reimburse HAP for any overpayments made to the provider by HAP upon request; and~~
- ~~(5) — not currently be on suspension as a HAP provider or a Texas Medicaid provider.~~

~~§37.118. Forms. Forms which have been developed by the Texas Department of Health (department) for use in the Hemophilia Assistance Program (HAP) will be provided to applicants, recipients and providers, as necessary.~~

~~§37.119. Confidentiality of Information.~~

~~(a) — All information required by this chapter to be submitted may be verified at the discretion of the Texas Department of Health (department) and without notice to the applicant or recipient of benefits of the Hemophilia Assistance Program (HAP), or to the providers of HAP services. This information is confidential to the extent authorized by law.~~

~~(b) Information may be disclosed in summary, statistical, or other forms which do not identify particular individuals.~~