

**Department of State Health Services  
Council Agenda Memo for State Health Services Council  
November 18-19, 2015**

**Agenda Item Title:** Amendments to rules concerning the Hemophilia Assistance Program

**Agenda Number:** 4.c

**Recommended Council Action:**

For Discussion Only

For Discussion and Action by the Council

**Background:**

The Hemophilia Assistance Program, in the Family and Community Health Services Division, Specialized Health Services Section, Purchased Health Services Unit, provides blood factor replacement products that have been approved for payment by the program and are indicated for the treatment of hemophilia.

The program contracts with pharmacies, hospitals, and blood banks throughout the state. Program clients are adults who have been diagnosed with hemophilia and who have met all program eligibility requirements.

The program's budget for fiscal year 2016 is \$323,477 in General Revenue.

**Summary:**

The purpose of the amendments is to implement House Bill 1038, 84th Legislature, Regular Session, 2015, which allows the program to offer insurance premium payment assistance to Texas residents with hemophilia. The amendments add and revise definitions, update benefits and limitations, and establish the reimbursement criteria for premium payments.

Historically, funds have paid for costly blood factor replacement products. The amendments allow the program to help individuals pay for insurance premiums with existing funds. By providing assistance in obtaining comprehensive insurance coverage, the client will have access to primary and specialty care in treatment plans that reduce the risk of poor outcomes and permanent disability.

The rules affect program clients by enhancing understanding of program policy and reflecting program information accurately for better interpretation of the rules by the public. The amendments will benefit program clients by allowing the program to assist eligible clients to obtain health insurance by providing insurance premium payment assistance.

**Key Health Measures:**

The program reports the number of Hemophilia Assistance Program clients as part of a state performance measure. The program can serve up to 12 clients with a maximum benefit of \$25,000 for blood factor replacement products. As of July 30, 2015, there are four clients eligible to receive benefits. Once the rules are adopted and fully implemented, the program projects 46 clients may be eligible for insurance premium payment assistance, in addition to the clients who receive only the blood factor benefit.

The program will continue to monitor and report the number of clients served. DSHS will routinely review program data to ensure that the rule changes do not have any unintended consequences on service delivery. DSHS will also review and consider all feedback received from clients, stakeholders, and providers.

**Summary of Input from Stakeholder Groups:**

The program solicited stakeholder input of the rules on the program website and sent electronic mail to 4,428 subscribers of the website. Notified stakeholders include, but are not limited to, the Texas Bleeding Disorders Advisory Council; Lonestar Chapter of the National Hemophilia Foundation; Hemophilia Outreach of El Paso; Central Texas Hemophilia Association; Gulf States Hemophilia and Thrombophilia Center; North Texas Comprehensive Hemophilia Center; Texas Children's Hospital; Hemostasis and Thrombosis Center; South Texas Hemophilia and Thrombosis Treatment Center; Fort Worth Comprehensive Hemophilia Center; Galveston Hemophilia Program; Texas Medical Association; Texas Nurses Association; Texas Hospital Association; National Association of Social Workers –Texas; Disability Rights Texas; and DSHS managers for social work services in health services regions.

The program received one recommendation from the Texas Bleeding Disorders Coalition. The stakeholder suggested that DSHS develop a framework by which eligible patients may have assistance from DSHS staff, their Hemophilia Treatment Center Social Worker, or another specified resource to select the best insurance for their needs. This recommendation was not incorporated into the proposed rules because the program has limited staff resources and the Hemophilia Treatment Centers have qualified staff who are prepared to assist clients in identifying appropriate and affordable health plans.

**Proposed Motion:**

Motion to recommend HHSC approval for publication of rules contained in agenda item #4.c.

**Approved by Assistant Commissioner/Director:** Evelyn Delgado **Date:** 10/7/2015

**Presenter:** Carol Labaj **Program:** Purchased Health Services Unit **Phone No.:** 512-776-3104

**Approved by CPEA:** Carolyn Bivens **Date:** 10/13/2015

Title 25. Health Services  
Part 1. Department of State Health Services  
Chapter 37. Maternal and Infant Health Services  
Subchapter F. Hemophilia Assistance Program  
Amendments §§37.112 - 37.114 and 37.116 - 37.118

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes amendments to §§37.112 - 37.114 and 37.116 - 37.118, concerning the Hemophilia Assistance Program (program).

BACKGROUND AND PURPOSE

As authorized by Health and Safety Code, Chapter 41, the program contracts with pharmacies, hospitals, and blood banks throughout the state to provide blood factor replacement products that have been approved for payment by the program and are indicated for the treatment of hemophilia. House Bill 1038, 84th Legislature, Regular Session, 2015, amended Health and Safety Code, §41.002, and allows the program to provide insurance premium payment assistance to Texas residents with hemophilia. All program clients are adults who have been diagnosed with hemophilia and have met all program eligibility requirements.

The proposed amendments establish guidelines by which the program may reimburse eligible clients for insurance premium payments.

SECTION-BY-SECTION SUMMARY

Proposed amendments to §37.112 revise existing definitions and add new definitions. New terms used in this subchapter include "approved health plan" and "insurance premium payment."

Proposed amendment to §37.113 updates eligibility requirements to allow program clients to be dually eligible for Medicare and the program.

Proposed amendments to §37.114 revise benefits and limitations by adding language regarding the payment of insurance premiums.

Proposed amendments to §37.116 add new language for the payment of insurance premiums and establish filing deadlines for premium reimbursements.

Proposed amendment to §37.117 updates clients' rights to include choosing a health plan, subject to program limitations.

Proposed amendment to §37.118 adds new language allowing the department to modify, suspend, deny, or terminate a client's eligibility for failure to reimburse the department for overpayments.

## FISCAL NOTE

Sam Cooper, LMSW-IPR, Director, Specialized Health Services Section, has determined that for each year of the first five years that the sections will be in effect, there will be no fiscal implications to state or local governments as a result of enforcing and administering the sections as proposed.

## SMALL AND MICRO-BUSINESSES IMPACT ANALYSIS

Mr. Cooper has also determined that there will be no adverse effect on small businesses or micro-businesses required to comply with the sections as proposed because small businesses and micro-businesses will not be required to alter their business practices in order to comply with the sections.

## ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

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.

## PUBLIC BENEFIT

Mr. Cooper 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 anticipated benefit is the ability to help individuals by paying for insurance premiums with the existing funds allotted to the program. Historically, the funds were only used to pay for costly blood factor replacement products. The new benefit is a cost-effective use of program funding and will help provide comprehensive health care to people seeking treatment for hemophilia.

## 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 proposed amendments do 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 Laura Ethridge, Purchased Health Services Unit, Mail Code 1938, Department of State Health Services, P.O. Box 149347, Austin, Texas 78714-9347; by telephone at (512) 776-3664; or by email to [laura.ethridge@dshs.state.tx.us](mailto:laura.ethridge@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 amendments are authorized by Government Code, §531.0055, and 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 amendments affect Government Code, Chapter 531; and Health and Safety Code, Chapters 41 and 1001.

Legend: (Proposed Amendment(s))

Single Underline = Proposed new language

**[Bold, Print, and Brackets]** = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

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

(1) - (3) (No change.)

(4) Approved health plan--An insurance plan that provides coverage for hemophilia medical treatment.

(5) [(4)] Attestation--A statement by a person or the person's legally authorized representative attesting that:

(A) the person does not have access to private health care insurance that provides coverage for the benefit, service, or assistance; or

(B) the person has access to private health care insurance that provides coverage for the benefit, service, or assistance.

(6) [(5)] CHIP--The Children's Health Insurance Program administered by the Commission under Title XXI of the Social Security Act.

(7) [(6)] Claim--A request for payment or reimbursement of services or insurance premiums.

(8) [(7)] Client--A person who has applied for program services and who meets all program eligibility requirements and is determined to be eligible for program services, and may include:

(A) a person who has applied to the program for the first time and is determined to be eligible for program services;

(B) a person who has re-applied to the program (after a lapse in eligibility) and is determined to be eligible for program services; or

(C) a person who has applied to the program and is determined to be eligible for program services and is currently on the program's waiting list.

(9) [(8)] Commission--The Health and Human Services Commission.

(10) [(9)] CSHCN Services Program--Children with Special Health Care Needs Services Program.

(11) [(10)] Date of service--The date the allowable products are dispensed.

(12) [(11)] Denial--An action by the program that disallows program eligibility, benefits, or administrative review requests.

(13) [(12)] Department--Department of State Health Services.

(14) [(13)] Eligibility date for program benefits--The effective date of client eligibility for program benefits is the date of receipt of a complete, approved application.

(15) [(14)] Exclusion--The federal and state offices of Inspector General maintain lists that exclude certain people or businesses from participating as service providers for federal and state health care programs.

(16) [(15)] Factor--A substance that is injected into the vein of a person with hemophilia to replace the missing blood clotting factor and allow the blood to clot properly.

(17) [(16)] Fair hearing--The informal hearing process the department follows in accordance with §§ 1.51 - 1.55 of this title (relating to Fair Hearing Procedures).

(18) [(17)] Family--In order to determine family size for the calculation of the applicant's percentage of the Federal Poverty Level for program eligibility, the family includes the following persons who live in the same residence:

(A) the applicant;

(B) any persons who have a legal responsibility to support the applicant;

(C) children under age 18 or wards of the applicant; and

(D) children under age 18 or wards of any persons who have a legal responsibility to support the applicant.

(19) [(18)] 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 or agencies. FPL varies according to family size, and after adjustment for inflation, is published annually in the *Federal Register*.

(20) [(19)] Filing deadline--The last date that a claim may be received by the program and still be considered eligible for payment of benefits.

(21) [(20)] Hemophilia Assistance Program (program)--A state funded program that provides limited financial assistance to persons age 18 and older who have been diagnosed with

hemophilia and meet other program eligibility requirements for blood factor replacement products that are administered or dispensed by program-approved providers or insurance premium payment assistance.

(22) [(21)] 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 program include:

- (A) congenital factor VIII disorder (Hemophilia A);
- (B) congenital factor IX disorder (Hemophilia B); and
- (C) congenital factor XI disorder (Hemophilia C).

(23) [(22)] Income--The gross income, either earned or unearned, before deductions over a given period of time for each family member.

(24) [(23)] Incomplete claim--A request for payment or reimbursement of services or insurance premiums that is missing required information.

(25) Insurance premium payment-- A payment made to an approved health plan.

(26) [(24)] Medicaid--A program of medical care authorized by Title XIX of the Social Security Act and the Human Resources Code.

(27) [(25)] Medicare--A federal program that provides medical care for people age 65 or older and the disabled as authorized by Title XVIII of the Social Security Act.

(28) [(26)] Other Coverage--Coverage, in addition to benefit coverage as referenced in §37.114 of this title (related to Benefits and Limitations), to which a person is entitled for payment of the costs of services or insurance premiums included in the scope of coverage of the program, but not limited to, benefits available from:

(A) an insurance policy, group health plan, health maintenance organization, or prepaid medical plan;

(B) Title XVIII, Title XIX, or Title XXI of the Social Security Act (42 U.S.C. §§1395 et seq., 1396 et seq., and 1397aa et seq.), as amended;

(C) the United States Department of Veterans Affairs;

(D) the TRICARE program of the United States Department of Defense;

(E) workers' compensation or any other compulsory employers' insurance program;

(F) a public program created by federal or state law or under the authority of a municipality or other political subdivision of the state, excluding benefits created by the establishment of a municipal or county hospital, a joint municipal-county hospital, a county hospital authority, a hospital district, a county indigent health care program, or the facilities of a publicly supported medical school; or

(G) a cause of action for the cost of care, including medical care, dental care, facility care, and medical supplies, required for a person applying for or receiving services from the department or a settlement or judgment based on the cause of action if the expenses are related to the need for services provided under this chapter.

(29) [(27)] Physician--An individual licensed by the Texas Medical Board to practice medicine in the state.

(30) [(28)] Prior Authorization--The process of getting approval from the program, before a product is dispensed, to determine if it can be considered for reimbursement.

(31) [(29)] Program--The Hemophilia Assistance Program.

(32) [(30)] Provider--Any individual or entity, as defined in §37.115, of this title (relating to Providers) approved by the program to provide allowable products to clients.

(33) [(31)] Recertification of Program Eligibility--Upon request of the program, clients must submit the information required in order to determine their continuing eligibility for program services.

(34) [(32)] Reimbursement--Payment of a claim for insurance premiums submitted by a client or allowable products administered or dispensed to a client submitted by a program provider.

(35) [(33)] Reimbursement rate--The program payment rate for allowable products, determined annually for the following fiscal year.

(36) [(34)] Social Security Administration (SSA)--A United States government agency that administers the social insurance programs in the United States. The agency covers a wide range of social security services, such as disability, retirement and survivors' benefits.

(37) [(35)] Social Security Disability Insurance (SSDI)--A payroll tax-funded, federal insurance program managed by the SSA, that provides income to people who are unable to work because of a disability.

(38) [(36)] State--The State of Texas.

(39) [(37)] Texas resident--A person who:

(A) is physically present within the geographic boundaries of the state:

(i) intends to remain within the state;

(ii) maintains an abode within the state (i.e., house or apartment, not merely a post office box);

(iii) has not come to the state from another country for the purpose of obtaining medical care with the intent to return to the person's native country; and

(B) does not claim residency in any other state or country; or

(C) is a person residing in the state who is the legally dependent spouse of a Texas resident; or

(D) is an adult residing in the state, and plans to continue to reside, with a parent(s), managing conservator, guardian of the adult's person, or caretaker who is a Texas resident.

#### §37.113. Program Eligibility.

(a) Client Requirements. In order to be determined eligible for program benefits, applicants must meet the medical, age, residency, financial, and other criteria in this section, and submit a complete application for program benefits.

(1) - (4) (No change.)

(5) Other criteria. The applicant must not be eligible for Medicaid or[, **Medicare,**] the Children's Health Insurance Program (CHIP). The program may require an applicant currently not enrolled in Medicaid, Medicare, CHIP, SSDI, or the CSHCN Services Program to apply for any of these applicable programs when the applicant's age, income, or medical disability determination meets the eligibility criteria for any of these programs and, if eligible, to participate in those programs.

(6) (No change.) This is a suggestion. Opened up (7)(A) to add this word highlighted.

(7) Application.

(A) To be considered by the program, a complete application must be made on forms required by the department. The application must have the signature or mark of the applicant, or the applicant's legally authorized representative, and the physician's signature.

(B) - (D) (No change.)

(8) - (9) (No change.)

(b) (No change.)

§37.114. Benefits and Limitations.

An eligible client may receive either blood factor replacement products or insurance premium payment assistance in the same fiscal year, but not at the same time.

(1) [(a)] Blood Factor Replacement Products. The program provides limited reimbursement to program providers for blood factor replacement products indicated for the treatment of hemophilia and prescribed to eligible clients for use in medical or dental facilities, or in the home.

(2) [(b)] Program [All program] benefits for allowable products are limited to those [allowable products] prescribed by a physician and dispensed by a program provider.

(3) [(c)] The program will pay for allowable products based upon:

(A) [(1)] available funds;

(B) [(2)] established limits for allowable products by type or category; and

(C) [(3)] the reimbursement rates established by the department.

(4) [(d)] Eligible clients with [a] private or group health insurance for which the program does not provide insurance premium payment assistance must exhaust all benefits prior to receiving program benefits for allowable products [from the program].

(5) Insurance Premium Payment Assistance. The program may assist eligible clients in obtaining public or private health insurance by providing insurance premium payment assistance if paying for such health insurance can reasonably be expected to be cost effective for the program.

(6) [(e)] The program is payer of last resort. Applicants and currently eligible clients are no longer eligible when they become eligible for the CHIP, SSDI, or Medicaid **[or Medicare]**.

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

(A) [(1)] adjust the reimbursement rates established by the department;

(B) [(2)] restrict **[the]** allowable products and insurance premium payments paid for under the program;

(C) [(3)] adjust the annual benefit limits; or

(D) [(4)] establish a waiting list of persons eligible for the program. 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.

§37.116. Claims Payment.

(a) - (b) (No change.)

(c) The program reimburses eligible clients for insurance premium payments made to program approved health plans. Reimbursements may be made after the program's receipt of a valid proof of insurance premium payment.

(d) [(c)] Filing Deadlines.

(1) Complete claims must be received by the program within 95 calendar days from the end of the month of the date of service or 95 calendar days from the end of the month for which the premium was paid.

(2) Incomplete and ineligible claims will be denied.

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

§37.117. Rights and Responsibilities.

(a) Client Rights. The applicant, client, or legally authorized representative have the right to:

(1) - (2) (No change.)

(3) choose a health plan, if applicable, subject to program limitations;

(4) [(3)] be notified of program decisions relating to modifications, suspensions, denials, or terminations;

(5) [(4)] have all client files and other information maintained in a confidential manner to the extent authorized by law;

(6) [(5)] appeal program decisions and receive a response within the deadline as described in §37.119 of this title (relating to Right of Appeal); and

(7) [(6)] reapply for the program when eligibility for the program is denied or terminated.

(b) - (d) (No change.)

§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 program proposes to modify, suspend, deny, or terminate program eligibility or benefits for reasons, which include but are not limited to the following:

(1) - (7) (No change.)

(8) failure to receive allowable products through a program provider; **[or]**

(9) failure to reimburse the department, as requested, for overpayments made to the client; or

(10) [(9)] failure to continue insurance 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 program, and failure to provide a statement on the application form outlining the reason(s) why such insurance cannot be maintained.

(b) (No change.)