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**HEALTH AND SAFETY CODE - HSC**

**DIVISION 106. PERSONAL HEALTH CARE (INCLUDING MATERNAL, CHILD, AND ADOLESCENT) [123100 - 125850]** ( *Division 106 added by Stats. 1995, Ch. 415, Sec. 8.* )

**PART 5. HEREDITARY DISEASES/CONGENITAL DEFECTS [124975 - 125292.10]** ( *Part 5 added by Stats. 1995, Ch. 415, Sec. 8.* )

**CHAPTER 2. Genetic Disease Services [125125 - 125286.35]** ( *Chapter 2 added by Stats. 1995, Ch. 415, Sec. 8.* )

**ARTICLE 1. Genetically Handicapped Persons Program [125125 - 125191]** ( *Article 1 added by Stats. 1995, Ch. 415, Sec. 8.* )

[125125.](#) This article shall be known and may be cited as the Holden-Moscone-Garamendi Genetically Handicapped Persons Program.

(*Amended by Stats. 2015, Ch. 303, Sec. 353. (AB 731) Effective January 1, 2016.*)

[125130.](#) (a) The Director of Health Care Services shall establish and administer a program for the medical care of persons with genetically handicapping conditions, including cystic fibrosis, hemophilia, sickle cell disease, Huntington's disease, Friedreich's Ataxia, Joseph's disease, Von Hippel-Landau syndrome, and the following hereditary metabolic disorders: phenylketonuria, homocystinuria, branched chain amino acidurias, disorders of propionate and methylmalonate metabolism, urea cycle disorders, hereditary orotic aciduria, Wilson's Disease, galactosemia, disorders of lactate and pyruvate metabolism, tyrosinemia, hyperornithinemia, and other genetic organic acidemias that require specialized treatment or service available from only a limited number of program-approved sources.

(b) The program shall also provide access to social support services, that may help ameliorate the physical, psychological, and economic problems attendant to genetically handicapping conditions, in order that the genetically handicapped person may function at an optimal level commensurate with the degree of impairment.

(c) The medical and social support services may be obtained through physicians and surgeons Genetically Handicapped Persons Program specialized centers, and other providers that qualify pursuant to the regulations of the department to provide the services. "Medical care," as used in this section, is limited to noncustodial medical and support services.

(d) The director shall adopt regulations that are necessary for the implementation of this article.

(*Amended by Stats. 2015, Ch. 303, Sec. 354. (AB 731) Effective January 1, 2016.*)

[125135.](#) As used in this article, "genetically handicapping condition" shall mean a disease that is accepted as being genetic in origin by the American Society of Human Genetics.

(*Added by Stats. 1995, Ch. 415, Sec. 8. Effective January 1, 1996.*)

[125140.](#) The program established under this article shall include any or all of the following medical and social support services:

- (a) Initial intake and diagnostic evaluation.
- (b) The cost of blood transfusion and use of blood derivatives, or both.
- (c) Rehabilitation services, including reconstructive surgery.
- (d) Expert diagnosis.
- (e) Medical treatment.
- (f) Surgical treatment.
- (g) Hospital care.
- (h) Physical and speech therapy.
- (i) Occupational therapy.

- (j) Special treatment.
- (k) Materials.
- (l) Appliances and their upkeep, maintenance, and care.
- (m) Maintenance, transportation, or care incidental to any other form of services.
- (n) Respite care or other existing resources (e.g., sheltered workshops).
- (o) Genetic and long-term psychological counseling.
- (p) Appropriate administrative staff resources to carry out this article. The staff shall include, but not be limited to, at least one case manager per each 350 clients.

*(Added by Stats. 1995, Ch. 415, Sec. 8. Effective January 1, 1996.)*

**125150.** The director shall establish the rate structure for reimbursement of physicians and supportive services. The rates shall not be less than the amounts paid for provider services under the Medi-Cal Act (Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code).

*(Added by Stats. 1995, Ch. 415, Sec. 8. Effective January 1, 1996.)*

**125155.** Reimbursement under this article shall not be made for any services that are available to the recipient under any other private, state, or federal programs or under other contractual or legal entitlements, except for those instances where the department determines that prolonged use of employer health insurance would jeopardize the recipient's employment. However, no provision in this article shall be construed as limiting in any way state participation in any federal governmental program for medical care of persons with genetically handicapping conditions.

*(Added by Stats. 1995, Ch. 415, Sec. 8. Effective January 1, 1996.)*

**125155.1.** (a) Any person found eligible for services under this article whose employer-sponsored health coverage is later terminated or any person who applied for services provided under this article whose employer-sponsored health coverage was terminated during the six-month period prior to the date he or she applied for services pursuant to this article shall be determined ineligible for the services, unless the reason his or her employer-sponsored health coverage was terminated was because of one of the following:

(1) The individual for whom the employer-sponsored coverage had been available lost coverage because of one or more of the following reasons:

(A) A loss of employment or a change in employment status.

(B) A change of address to a ZIP Code that is not covered by the employer-sponsored health coverage.

(C) The individual's employer discontinued health benefits to all employees or dependents, or ceased to provide coverage or contributions for the category of employees or dependents applicable to the person or applicant.

(D) The death of, or a legal separation or divorce from, the individual through whom the applicant was covered.

(2) The applicant's employer-sponsored health coverage became unavailable because the services paid for under that coverage attained the lifetime coverage limit.

(3) Coverage was under a COBRA policy and the COBRA coverage period has ended.

(b) A person who applies for services provided pursuant to this article shall certify, at the time of application, under penalty of perjury, that he or she was not covered by employer-sponsored health coverage during the six-month period prior to the date of his or her application or, if he or she was covered by employer-sponsored health coverage, attest to why one of the reasons listed in subdivision (a) is applicable to him or her and provide documentation from the employer-sponsored health coverage that supports his or her attestation.

(c) A person who has been found eligible for services provided pursuant to this article who is covered by employer-sponsored health coverage that is terminated shall notify the Genetically Handicapped Persons Program within 45 days of the effective date of the termination and, when applicable, provide the program with the certification described in subdivision (b).

(d) An applicant or eligible person who fails to comply with subdivisions (b) and (c) shall be ineligible for services pursuant to this article for six months. The department shall provide written notice to all persons found to be ineligible pursuant to this section. The notice shall provide information on the ability of the person to appeal or seek a waiver of determinations of ineligibility.

(e) The department shall provide a process to appeal decisions of ineligibility based on this section in accordance with the procedures for resolution of complaints and appeals established for applicants and persons eligible for services pursuant to Article 5 (commencing with Section 123800) of Chapter 3 of Part 2.

(f) The director, on a case-by-case basis, may waive determinations of ineligibility pursuant to this section, or reduce the time periods set forth in subdivision (a) or subdivision (d), if the director determines that the determination or the time periods will result in undue hardship.

(g) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement this section by means of Genetically Handicapped Persons Program policy letters. Following consultation with a stakeholder workgroup consisting of, but not limited to, provider associations, provider representatives, and consumer groups to ensure stakeholder participation in the implementation of this section, including, but not limited to, any changes deemed necessary by the department and the stakeholder workgroup to update the application for enrollment form and the development of regulations, the department shall, within 18 months from the effective date of this section, adopt any necessary regulations in accordance with the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

*(Added by Stats. 2009, 4th Ex. Sess., Ch. 5, Sec. 14. Effective July 28, 2009.)*

**125157.** (a) The department may require a client under this article to apply to enroll or otherwise participate in any other state or federal program or other contractual or legal entitlement that would provide services to the client that would otherwise be reimbursed pursuant to this article.

(b) The department may, when it determines that it is cost effective, pay the premium for, or otherwise subsidize the subscriber cost-sharing obligation for, third-party health coverage for a person eligible for services under this article.

(c) The department may, for a person eligible for services under this article, when the person's third-party health coverage would lapse due to loss of employment, change in health status, lack of sufficient income or financial resources, or any other reason, continue the health coverage by paying the costs of continuation of group coverage pursuant to federal law or converting from a group to individual plan, when the department determines that it is cost effective.

(d) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement this section by means of Genetically Handicapped Persons Program policy letters. Following consultation with a stakeholder workgroup consisting of, but not limited to, provider associations, provider representatives, and consumer groups to ensure stakeholder participation in the implementation of this section, including, but not limited to, any changes deemed necessary by the department and the stakeholder workgroup to update the application for enrollment form and the development of regulations, the department shall, within 18 months from the effective date of this section, adopt any necessary regulations in accordance with the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

*(Added by Stats. 2009, 4th Ex. Sess., Ch. 5, Sec. 15. Effective July 28, 2009.)*

**125160.** The department shall receive and expend all funds made available to it by the federal government, the state, its political subdivisions or from other sources for the purposes of this article. Payment for the Genetically Handicapped Persons Program shall be made by the department.

*(Amended by Stats. 2015, Ch. 303, Sec. 355. (AB 731) Effective January 1, 2016.)*

**125166.** (a) Commencing July 1, 2009, except as provided in subdivision (d), each client determined or redetermined by the department to be eligible for services provided pursuant to this article shall pay an annual enrollment fee to the department as set forth in this section.

(b) (1) There shall be an annual enrollment fee based on the client's adjusted gross income or, if the client is a minor, the client's parents' or legal guardians' combined adjusted gross income, as reported on the relevant state or federal income tax forms for the previous tax year. In calculating the enrollment fee where both a state and a federal income tax form has been filed, the higher of the two adjusted gross income amounts shall be used.

(2) For adjusted gross income between 200 and 299 percent of the federal poverty level, the annual enrollment fee shall be 1.5 percent of adjusted gross income.

(3) For adjusted gross income equal to or greater than 300 percent of the federal poverty level, the annual enrollment fee shall be 3 percent of adjusted gross income.

(4) In the event the annual enrollment fee determined pursuant to paragraph (2) or (3) exceeds the cost of care incurred during the applicable year, the department shall reduce the enrollment fee by refund or credit to an amount equal to the cost of care.

(c) (1) Payment of the enrollment fee is a condition of program participation.

(2) The department may arrange for periodic payment of the fee during the year.

(3) The director, on a case-by-case basis, may waive or reduce the amount of an enrollment fee if the director determines payment of the fee will result in undue hardship for the family. Otherwise, failure to pay or arrange for payment of the enrollment fee within 60 days of the due date shall result in disenrollment and ineligibility for coverage of treatment services effective 60 days after the due date of the fee.

(d) The enrollment fee shall not be charged in the following cases:

(1) The client is eligible for the full scope of Medi-Cal benefits, without being required to pay a share of cost, at the time of enrollment fee determination.

(2) The client who is otherwise eligible to receive services has, or if the client is a minor, the client's parents or guardians have, an adjusted gross income of less than 200 percent of the federal poverty level.

(e) All enrollment fees shall be used in support of the program for services provided pursuant to this article.

(f) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement this section by means of Genetically Handicapped Persons Program policy letters. Following consultation with a stakeholder workgroup consisting of, but not limited to, provider associations, provider representatives, and consumers groups to ensure stakeholder participation in the implementation of this section, including, but not limited to, any changes to update the application for enrollment form and the development of regulations, the department shall, within 18 months from the effective date of this section, adopt regulations in accordance with the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

*(Added by Stats. 2009, 4th Ex. Sess., Ch. 5, Sec. 17. Effective July 28, 2009.)*

**125170.** The department shall maintain sufficient, appropriate staff to carry out this article.

*(Added by Stats. 1995, Ch. 415, Sec. 8. Effective January 1, 1996.)*

**125175.** The health care benefits and services specified in this article, to the extent that the benefits and services are neither provided under any other federal or state law nor provided nor available under other contractual or legal entitlements of the person, shall be provided to any patient who is a resident of this state and is made eligible by this article. After the patient has utilized the contractual or legal entitlements, the payment liability under Section 125166 shall then be applied to the remaining cost of genetically handicapped persons' services.

*(Amended by Stats. 2015, Ch. 303, Sec. 356. (AB 731) Effective January 1, 2016.)*

**125180.** The department shall require all applicants to the program who may be eligible for cash grant public assistance or for Medi-Cal to apply for Medi-Cal eligibility prior to becoming eligible for funded services.

*(Added by Stats. 1995, Ch. 415, Sec. 8. Effective January 1, 1996.)*

**125185.** (a) (1) By July 1, 2016, or a subsequent date determined by the department, Genetically Handicapped Persons Program (GHPP) requests for authorization of services, excluding requests for authorization of services submitted by dental providers enrolled in the Medi-Cal Dental program, shall be submitted in an electronic format determined by the department and shall be submitted via the department's Internet Web site or other electronic means designated by the department. The department may implement this requirement in phases.

(2) The department shall designate an alternate format for submitting requests for authorization of services when the department's Internet Web site or other electronic means designated in paragraph (1) are unavailable due to a system disruption.

(b) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may, without taking regulatory action, implement, interpret, or make specific this section and any applicable waivers and state plan amendments by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions. Thereafter, the department shall adopt regulations by July 1, 2017, in accordance with the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. The department shall consult with interested parties and appropriate stakeholders in implementing this section.

*(Added by Stats. 2014, Ch. 849, Sec. 2. (SB 1457) Effective January 1, 2015.)*

**125190.** Notwithstanding any other law, the department is considered to be the purchaser, but not the dispenser or distributor, of blood factor products under the Genetically Handicapped Persons Program. The department may receive manufacturers' discounts,

rebates, or refunds based on the quantities purchased under the Genetically Handicapped Persons Program. The discounts, rebates, or refunds received pursuant to this section shall be separate from any agreements for discounts, rebates, or refunds negotiated pursuant to Section 14105.3 of the Welfare and Institutions Code or any other program.

*(Amended by Stats. 2015, Ch. 303, Sec. 357. (AB 731) Effective January 1, 2016.)*

**125191.** (a) The department may enter into contracts with one or more manufacturers on a negotiated or bid basis as the purchaser, but not the dispenser or distributor, of factor replacement therapies under the Genetically Handicapped Persons Program for the purpose of enabling the department to obtain the full range of available therapies and services required for clients with hematological disorders at the most favorable price and to enable the department, notwithstanding any other state law, to obtain discounts, rebates, or refunds from the manufacturers based upon the large quantities purchased under the program. This subdivision does not interfere with the usual and customary distribution practices of factor replacement therapies. In order to achieve maximum cost savings, the Legislature hereby determines that an expedited contract process under this section is necessary. Therefore, a contract under this subdivision may be entered into on a negotiated basis and is exempt from Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code and Chapter 6 (commencing with Section 14825) of Part 5.5 of Division 3 of Title 2 of the Government Code. Contracts entered pursuant to this subdivision shall be confidential and shall be exempt from disclosure under the California Public Records Act (Division 10 (commencing with Section 7920.000) of Title 1 of the Government Code).

(b) (1) Factor replacement therapy manufacturers shall calculate and pay interest on late or unpaid rebates. The interest does not apply to any prior period adjustments of unit rebate amounts or department utilization adjustments. Manufacturers shall calculate and pay interest on late or unpaid rebates for quarters that begin on or after the effective date of the act that added this subdivision.

(2) Following the final resolution of any dispute regarding the amount of a rebate, any underpayment by a manufacturer shall be paid with interest calculated pursuant to paragraph (4), and any overpayment, together with interest at the rate calculated pursuant to paragraph (4), shall be credited by the department against future rebates due.

(3) Interest pursuant to paragraphs (1) and (2) shall begin accruing 38 calendar days from the date of mailing the invoice, including supporting utilization data sent to the manufacturer. Interest shall continue to accrue until the date of mailing of the manufacturer's payment.

(4) Interest rates and calculations pursuant to paragraphs (1) and (2) shall be identical to interest rates and calculations set forth in the federal Centers for Medicare and Medicaid Services' Medicaid Drug Rebate Program Releases or regulations.

(c) If the department has not received a rebate payment, including interest, within 180 days of the date of mailing of the invoice, including supporting utilization data, a factor replacement therapy manufacturer's contract with the department shall be deemed to be in default and the contract may be terminated in accordance with the terms of the contract. This subdivision does not limit the department's right to otherwise terminate a contract in accordance with the terms of that contract.

(d) The department may enter into contracts on a bid or negotiated basis with manufacturers, distributors, dispensers, or suppliers of pharmaceuticals, appliances, durable medical equipment, medical supplies, and other product-type health care services and laboratories for the purpose of obtaining the most favorable prices to the state and to assure adequate access and quality of the product or service. In order to achieve maximum cost savings, the Legislature hereby determines that an expedited contract process under this subdivision is necessary. Therefore, contracts under this subdivision may be entered into on a negotiated basis and shall be exempt from Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code and Chapter 6 (commencing with Section 14825) of Part 5.5 of Division 3 of Title 2 of the Government Code.

(e) The department may contract with one or more manufacturers of each multisource prescribed product or supplier of outpatient clinical laboratory services on a bid or negotiated basis. Contracts for outpatient clinical laboratory services shall require that the contractor be a clinical laboratory licensed or certified by the State of California or certified under Section 263a of Title 42 of the United States Code. This subdivision shall not be construed as prohibiting the department from contracting with less than all manufacturers or clinical laboratories, including just one manufacturer or clinical laboratory, on a bid or negotiated basis.

*(Amended by Stats. 2021, Ch. 615, Sec. 284. (AB 474) Effective January 1, 2022. Operative January 1, 2023, pursuant to Sec. 463 of Stats. 2021, Ch. 615.)*