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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 2. MATERNAL, CHILD, AND ADOLESCENT HEALTH [123225 - 124250] (*Part 2 added by Stats. 1995, Ch. 415, Sec. 8.)*

CHAPTER 3. Child Health [123650 - 124174.6] (*Chapter 3 added by Stats. 1995, Ch. 415, Sec. 8.)*

ARTICLE 2.5. Infant Botulism Treatment and Prevention Program [123700 - 123709] (*Heading of Article 2.5 renumbered from Article 3.55 (and relocated from Chapter 2 of Part 1 of Division 1) by Stats. 1996, Ch. 1023, Sec. 116.)*

123700. (a) Infant botulism is an acute, life-threatening paralytic disease of babies caused by a potent bacterial neurotoxin.

(b) Half of all cases of infant botulism in the United States occur in California, where the causative bacterial spores are known to be highly endemic. In any given year between 30 and 50 infants with botulism are hospitalized in California, thus qualifying infant botulism as an "orphan disease" as defined by the federal Orphan Drug Act of 1983 (P.L. 97-414, as amended).

(c) The cost of hospitalization of these afflicted babies for the five years 1988–92 were approximately fourteen million dollars (\$14,000,000). Over two million seven hundred thousand dollars (\$2,700,000) of these costs were paid by the State Department of Health Services through its Medi-Cal and California Children's Services programs, while over one million four hundred thousand (\$1,400,000) of these costs were absorbed as operating losses by California hospitals.

(d) Hospital stay for these critically-ill infants averages five weeks and costs approximately seventy thousand dollars (\$70,000) per case. In 1992 a single case was hospitalized over six months at a cost in excess of five hundred five thousand dollars (\$505,000). In 1988 a single infant was hospitalized for 10 months at a cost of over six hundred thirty-five thousand dollars (\$635,000).

(e) In an effort to reduce these costs, the State Department of Health Services began in early 1992 a four-year clinical trial of a potential new medicine, human Botulism Immune Globulin (BIG), specifically designed for the treatment of infant botulism. The funding for this clinical trial is being provided by the United States Food and Drug Administration.

(f) As defined in the federal Orphan Drug Act, the State Department of Health Services is the official sponsor of BIG. As such, the department is responsible for providing and distributing an ongoing supply of BIG to infant botulism patients nationwide if the clinical trial shows that BIG is safe and effective treatment for infant botulism. The clinical trial is expected to end in 1996.

(g) If human-derived BIG proves to be effective, then physicians can choose to use it to treat foodborne botulism and wound botulism, rather than using the existing horse-serum-derived botulism antitoxin, which has serious side effects. Foodborne botulism and wound botulism also qualify as "orphan diseases" under the federal Orphan Drug Act.

(h) Other scientific evidence indicates that infant botulism and related illnesses may be responsible for one of every 20 sudden infant death cases in California. More sudden infant deaths occur in California each year than in any other state.

(i) The Legislature finds and declares that the enactment of this article is necessary for the protection of the public's health, investigations and further research into the optimal medical treatment of infant botulism, including product improvement of BIG, and into the causes and prevention of infant botulism and related sudden infant death cases, and providing expert medical consultation for the care of infants with this disease.

(*Added by renumbering Section 330.10 (as added by Stats. 1995, Ch. 674) by Stats. 1996, Ch. 1023, Sec. 117. Effective September 29, 1996.*)

123702. (a) The State Department of Health Services shall establish an Infant Botulism Treatment and Prevention Unit. This unit shall have responsibility for ensuring the production and distribution of BIG to patients in California and nationwide suspected of having infant botulism or other forms of human botulism in accord with applicable federal law.

(b) As permitted by federal law, the state department shall charge a fee for BIG, and the fees shall be deposited in the special Infant Botulism Treatment and Prevention Fund established by Section 123709.

(c) Notwithstanding any other provision of law, the funds generated by the sale of BIG are to be expended only for the purposes authorized by this article.

(d) The amount of the fee shall be established by regulation and periodically adjusted by the State Director of Health Services in order to meet but not exceed the total costs of this article. This adjustment of fees shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, except that upon adoption of the adjusted fee by the director, the provision revising the fee shall be filed with the Secretary of State and shall be printed in the California Code of Regulations.

(e) It is the intent of the Legislature that the state department consider providing BIG to low-income families at no charge.

(Added by renumbering Section 330.15 (as added by Stats. 1995, Ch. 674) by Stats. 1996, Ch. 1023, Sec. 118. Effective September 29, 1996.)

123704. The Infant Botulism Treatment and Prevention Unit shall provide all the following services:

(a) Produce, or cause to have produced, and maintain, a supply of BIG sufficient to treat the expected number of annual cases of infant botulism in the United States, and to store, or arrange storage for, same.

(b) Distribute BIG to patients suspected of having infant botulism or other forms of botulism in California and in the rest of the United States on appropriate medical indications.

(c) Investigate ways to improve the treatment of infant botulism and related illness, including technical improvement of BIG, and implement them as appropriate.

(d) Provide diagnostic laboratory services and medical and public health expertise about infant botulism and related illnesses to all physicians, hospitals, laboratories, and parents statewide.

(e) Investigate all cases or suspected cases of infant botulism with both field and laboratory techniques as appropriate, in order to acquire the broadest data base for prevention and optimal treatment.

(f) Develop and implement control measures for the prevention of infant botulism and related illnesses.

(g) Share with other public health agencies the expertise gained in the development of BIG as it relates to other toxin-mediated infectious diseases of public health importance, and apply that expertise as appropriate.

(h) Establish scientific collaborations with university, forensic, hospital, public health, pharmaceutical, and biotechnology institutions, as appropriate as determined by the unit, that have resources and expertise to contribute to the study, prevention, or treatment of infant botulism and related illnesses.

(Added by renumbering Section 330.20 (as added by Stats. 1995, Ch. 674) by Stats. 1996, Ch. 1023, Sec. 119. Effective September 29, 1996.)

123705. It is the intent of the Legislature that the program carried out pursuant to this article shall be fully supported from the fees collected for providing BIG to patients with suspected infant botulism or other forms of botulism and that these fees be made available for expenditure by the state department as appropriated by the Legislature in the annual Budget Act. However, it is the intent of the Legislature that until June 30, 1999, the Legislature may appropriate in the annual Budget Act the funds necessary for the support of programs authorized in this article in excess of fee revenues collected. It is, further, the intent of the Legislature that these appropriations be provided as a loan from the General Fund to be repaid with interest to the General Fund over the subsequent five years with interest at the rate earned by moneys invested in the Pooled Money Investment Account.

(Added by renumbering Section 330.25 (as added by Stats. 1995, Ch. 674) by Stats. 1996, Ch. 1023, Sec. 120. Effective September 29, 1996.)

123707. (a) The State Department of Health Services may manufacture, test, distribute, and maintain licensure of the product Botulism Immune Globulin Intravenous (Human) if all necessary federal licenses are obtained. The department was issued United States License No. 1622 on October 23, 2003, by the United States Food and Drug Administration under the authority of Section 351(a) of the Public Health Service Act controlling the manufacture and sale of biological products. The product may be labeled with the proprietary name BabyBIG®.

(b) The United States Food and Drug Administration license agreement stipulated the contracts and commodity purchases required to manufacture, test, distribute, and maintain licensure of Botulism Immune Globulin Intravenous (Human). Therefore, contracts and commodity purchases for any manufacture, testing, distribution, packaging, development, and licensure of Botulism Immune Globulin Intravenous (Human) by the department shall be exempt from competitive bidding and shall be exempt from the requirements of Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code.

(c) Since the incidence of infant botulism in California can vary by as much as 60 percent from year to year, and since continuity of program operations is critical to the health and well-being of these infants, any funds not expended at the end of the fiscal year shall be carried forward into the next fiscal year, notwithstanding any other provision of law.

(d) In carrying out this article, the Infant Botulism Treatment and Prevention Unit may adopt regulations, make and receive grants, and enter into contracts and interagency agreements.

(Amended by Stats. 2004, Ch. 228, Sec. 6. Effective August 16, 2004.)

123709. The Infant Botulism Treatment and Prevention Fund is hereby established as a special fund in the State Treasury. All moneys collected by the state department pursuant to this article shall be deposited in the Infant Botulism Treatment and Prevention Fund, and shall be made available to the state department for expenditure for the purposes of this article as appropriated by the Legislature in the annual Budget Act.

(Added by renumbering Section 330.35 (as added by Stats. 1995, Ch. 674) by Stats. 1996, Ch. 1023, Sec. 122. Effective September 29, 1996.)