

EXECUTIVE REORGANIZATION ORDER

E.R.O. No. 1995-20

333.26323 Transfer of the biologic products division of the department of public health and the pharmaceutical products fund to the Michigan biologic products institute by type III transfer.

WHEREAS, Article V, Section 2, of the Constitution of the State of Michigan of 1963 empowers the Governor to make changes in the organization of the Executive Branch or in the assignment of functions among its units which he considers necessary for efficient administration; and

WHEREAS, Article V, Section 4, of the Constitution of the State of Michigan of 1963 authorizes the establishment of temporary commissions or agencies for special purposes with a life of no more than two years and provides that such temporary commissions or agencies need not be allocated within a principal department; and

WHEREAS, Section 9111 of Act No. 368 of the Public Acts of 1978, being Section 333.9111 of the Michigan Compiled Laws, authorized establishment of the Biologic Products Division within the Michigan Department of Public Health; and

WHEREAS, Act No. 204 of the Public Acts of 1986, being Section 333.9112 of the Michigan Compiled Laws created the Pharmaceutical Products Fund in the state treasury and made the Michigan Department of Public Health responsible for administering it; and

WHEREAS, the functions, duties and responsibilities assigned to the Biologic Products Division can be more effectively administered and executed outside the Michigan Department of Public Health, due in part to the need of the Biologic Products Division to meet Federal regulatory and commercial requirements; and

WHEREAS, the long-term capability of the Biologic Products Division to meet Federal regulatory and other commercial requirements can best be achieved by removing the Division from state government as soon as is practicable; and

WHEREAS, the manufacture of products by the Biologic Products Division is not critical to the mission of the Michigan Department of Public Health.

NOW, THEREFORE, I, John Engler, Governor of the State of Michigan, pursuant to the powers vested in me by the Constitution of the State of Michigan of 1963 and the laws of the State of Michigan, do hereby order the following:

I. ESTABLISHMENT OF THE MICHIGAN BIOLOGIC PRODUCTS INSTITUTE AND THE MICHIGAN BIOLOGIC PRODUCTS COMMISSION

A. Definitions:

In this Executive Order the following definitions shall apply.

1. "Commission" means the Michigan Biologic Products Commission established as a temporary commission by this Executive Order.

2. "Director" means the person initially designated by the Governor as the Director of the Michigan Biologic Products Institute established as a temporary agency by this Executive Order.

3. "Institute" means the Michigan Biologic Products Institute established as a temporary agency by this Executive Order.

4. "Member" means a member appointed by the Governor to the Michigan Biologic Products Commission established as a temporary commission by this Executive Order.

B. Establishment of the Michigan Biologic Products Institute

1. The Michigan Biologic Products Institute is established by this Executive Order, pursuant to Article V, Section 4, of the Constitution of the State of Michigan of 1963, as a temporary agency with a life of no more than two years from the effective date of this Executive Order.

2. The Institute shall be an independent and autonomous entity with the intent that its authority, powers, duties and responsibilities and the authority, powers, duties and responsibilities of the Director, including personnel, budgeting, procurement and management-related functions, be exercised free from the direction and supervision of the principal departments in the Executive Branch.

3. The Director shall be the head of the Institute within the meaning of the Constitution of the State of Michigan of 1963, and of the Executive Organization Act of 1965, Act No. 380 of the Public Acts of 1965, being Section 16.101 et seq. of the Michigan Compiled Laws, and shall be the Appointing Authority as that term is used in the Constitution of the State of Michigan of 1963, and in the rules and procedures of the Civil Service Commission.

4. The Biologic Products Division of the Michigan Department of Public Health and the Pharmaceutical Products Fund, established under Sections 9111 and 9112 of Act No. 368 of the Public Acts of 1978, being Section 333.9111 and 333.9112 of the Michigan Compiled Laws are hereby transferred to the Michigan Biologic Products Institute by a Type III transfer, as defined by Section 3 of Public Act No. 380 of the Public Acts of 1965, being Section 16.103 of the Michigan Compiled Laws. The Michigan Biologic Products Institute shall assume all functions, duties, contractual obligations, responsibilities, inventory, tangible and intangible property and employees of the Biologic Products Division of the Michigan Department of Public Health, including administration of the Pharmaceutical Products Fund.

C. Establishment of the Michigan Biologic Products Commission

1. The Michigan Biologic Products Commission is established by this Executive Order, pursuant to Article V, Section 4, of the Constitution of the State of Michigan of 1963, to serve as a temporary entity with a life of no more than two years from the effective date of this Executive Order.

2. The Commission shall have three (3) voting members who shall be appointed by the Governor and such members shall serve as members at the pleasure of the Governor. None of these members shall be employees of the Institute. The Governor shall designate one (1) member of the Commission to serve as its chair and that member shall serve as chair at the pleasure of the Governor.

3. Members of the Commission shall serve without compensation for their membership on the Commission. Members of the Commission may receive reimbursement for necessary travel and expenses according to relevant procedures of the Civil Service Commission and the Department of Management and Budget.

4. The Commission may promulgate bylaws, not inconsistent with law and with this Executive Order, governing its organization and procedure. A majority of the serving voting members constitutes a quorum for the transaction of business at a meeting, notwithstanding the existence of one (1) or more vacancies. Voting upon actions taken by the Commission shall be conducted by a majority vote of the members present in person at a meeting of the Commission or present by use of amplified telephonic equipment.

5. The Commission shall meet at the call of the chair and as may be provided in the bylaws of the Commission. Meetings of the Commission may be held anywhere within the State of Michigan. The Commission shall be subject to the Open Meetings Act, Act No. 267 of the Public Acts of 1976, being Section 15.261 et seq. of the Michigan Compiled Laws. The Commission may, as appropriate, make inquiries, studies and investigations, hold hearings and receive comments from the public.

II. DUTIES AND RESPONSIBILITIES OF THE MICHIGAN BIOLOGIC PRODUCTS COMMISSION

The Commission shall provide supervision, policy control and direction to the Institute, and the Director. The Commission may, consistent with the provisions of this Executive Order, establish general goals and objectives relating to the operation and development of the Michigan Biologic Products Institute for the guidance of the Director.

The Michigan Biologic Products Commission shall:

1. Within eight (8) months of their initial organizational meeting, prepare, or cause to be prepared under contract, a detailed business plan with supporting documentation, including, but not limited to, any necessary legislation, describing the means by which the Michigan Biologic Products Institute will be transferred out of state government and into the private sector within the two year term of its temporary agency status under this Executive Order.

2. As part of the business plan, cause the fair market value of all state property, inventory, equipment and other assets associated with the manufacture of biologic products to be determined.

3. Contract with the initial Director; designate and contract with any future Directors.

4. Perform such other duties and responsibilities as may be assigned or transferred to the Commission by statute or by executive order.

III. OPERATIONS OF THE INSTITUTE

The current Responsible Head of biologic products manufacturing under licenses granted by the Food and Drug Administration is hereby designated to serve as the initial Director of the Institute. The Director shall report to and be directly responsible to the Commission. The Director shall, in addition to the other duties and responsibilities given to the Director herein or assigned or transferred to the Director as head of the Institute by statute or executive order, be responsible for the oversight and supervision of employees of the Institute, for administration of the Pharmaceutical Products Fund, for management of the Institute's facilities and for the operations of the Institute. The Director shall also perform such other duties and exercise other powers as the Commission may prescribe.

The Director may appoint or contract with such other deputies, assistants and employees as are necessary.

The Director shall receive reasonable compensation. Such compensation shall be established according to relevant procedures of the Civil Service Commission.

The Director shall:

1. Maintain the establishment license of the facilities for biologic product production and maintain existing product licenses, except for obsolete products, and obtain new licenses as appropriate.

2. Maintain existing contractual relationships and expand the value of the work being undertaken while

transferring responsibility for such work out of state government.

3. Fulfill the duties of a Responsible Head as delineated in 21 CFR 600.10(a), if applicable.

4. Report to the Commission on actions that affect the business of the Institute.

Notwithstanding Executive Directive 1995-2, the Director may hire or retain such contractors, subcontractors, advisors, consultants, and agents as the Director may deem advisable and necessary, in accordance with relevant statutes, and the rules and regulations of the Civil Service Commission, and may make and enter into contracts necessary or incidental to the exercise of the powers of and the performance of the duties of the Institute and the Director.

It is the intent of the Executive Order that the Director, the employees, and representatives of the Institute shall have the benefit of the provisions of Sections 2228(2) and 2465(2) of Act No. 368 of the Public Acts of 1978, being Sections 333.2228(2) and 333.2465(2) of the Michigan Compiled Laws.

IV. OPERATIONS OF BOTH THE INSTITUTE AND THE COMMISSION

Employees of the Institute are subject to Act No. 317 of the Public Acts of 1968, being Section 15.321 et seq. of the Michigan Compiled Laws, or Act No. 318 of the Public Act of 1968, being Section 15.301 et seq. of the Michigan Compiled Laws, as appropriate. Members of the Commission and employees of the Institute are subject to Act No. 196 of the Public Acts of 1973, being Section 15.341 et seq. of the Michigan Compiled Laws. Employees of the Institute are also subject to applicable Civil Service Commission rules and regulations concerning conflicts of interest.

A member of the Commission, the Director, employees and agents of the Institute shall discharge the duties of their positions in a nonpartisan manner, with good faith and with that degree of diligence, care and skill which an ordinarily prudent person would exercise under similar circumstances in a like position. In discharging their duties, a member of the commission, the Director, employees and agents of the Institute, when acting in good faith, may rely upon the opinion of counsel for the Institute, upon the report of an independent appraiser selected with reasonable care by the Institute and upon financial statements of the Institute represented to a member of the commission, the Director, employees or agents of the Institute to be correct by the person having charge of the Institute's books or accounts or represented to be correct in a written report by a certified public accountant or firm of certified public accountants.

V. MISCELLANEOUS PROVISIONS

All the licenses and contracts associated with the Biologic Products Division along with all property and equipment needed to support the licenses and to fulfill the contracts are hereby transferred to the Michigan Biologic Products Institute which shall continue to perform pursuant to those licenses and to fulfill those contracts.

The Director of the Michigan Biologic Products Institute shall provide executive direction and supervision for the implementation of the transfers. The Director of the Michigan Biologic Products Institute shall make internal organizational changes as may be administratively necessary to complete the realignment of responsibilities prescribed by this order.

The Director of the Michigan Biologic Products Institute shall immediately enter into negotiations with other state departments or individuals or groups outside of state government to obtain services such as personnel, budgeting, procurement, security, maintenance, and janitorial services.

All records, personnel, property and unexpended balances of appropriations, allocations and other funds used, held, employed, available or to be made available to the Biologic Products Division for the activities transferred are hereby transferred to the Michigan Biologic Products Institute.

The Michigan Department of Public Health shall make internal organizational changes as may be administratively necessary to complete the realignment of responsibilities prescribed by this order.

The Director of the Department of Public Health and Director of the Biologic Products Institute shall immediately initiate coordination to facilitate the transfer and develop a memorandum of record identifying any pending settlements, issues of compliance with applicable federal and state laws and regulations, or obligations to be resolved by the Michigan Biologic Products Institute.

All rules, orders, contracts and agreements relating to the assigned functions lawfully adopted prior to the effective date of this order shall continue to be effective until revised, amended or repealed.

Any suit, action or other proceeding lawfully commenced by, against or before any entity affected by this order shall not abate by reason of the taking effect of this order. Any suit, action or other proceeding may be maintained by, against or before the appropriate successor of any entity affected by this order.

The invalidity of any portion of this Executive Order shall not affect the validity of the remainder thereof.

All departments, boards, commissions or officers of the state or of any political subdivision thereof shall give to the Commission, or to any member or representative thereof, any necessary assistance required by the Commission, or any member or representative thereof, in the performance of the duties of the Commission so far as is compatible with its, his or her duties; free access shall also be given to any books, records or documents in its, his or her custody, relating to matters within the scope of the inquiry, study or investigation of the Commission.

The Institute may accept grants of funds and donations of funds, property, labor or other things of value from any department or agency of the State of Michigan and the United States and from any other public or private agency or person.

In fulfillment of the requirements of Article V, Section 2, of the Constitution of the State of Michigan, the provisions of this Executive Order shall become effective December 15, 1995.

History: 1995, E.R.O. No. 1995-20, Eff. Feb. 17, 1996