PUBLIC HEALTH CODE (EXCERPT)
Act 368 of 1978

333.22243 Acquisition of new technology before approval of federal food and drug administration; notice; requirements; deactivation and removal of new technology from service; conditions to utilizing new technology beyond specified period.

Sec. 22243. (1) Unless the commission provides otherwise in a standard approved under section 22215(1)(h), a person may acquire new technology before the new technology is approved by the federal food and drug administration if the person notifies the department before acquiring the new technology, and the acquisition of the new technology continuously meets all of the following requirements:

(a) Has been authorized by the federal food and drug administration under an investigational device exemption and approved research project pursuant to 21 C.F.R. part 812.

(b) Is operated consistently with the research protocols established and approved by the federal food and drug administration for the investigational device exemption.

(c) Is solely related to research and testing for purposes of determining the safety and effectiveness of the new technology for use on human subjects.

(d) Is funded so that there will be no recovery of either capital or operating expenses for the use of the new technology either from patients or from third party payers. However, usual and customary charges or other payment arrangements for related services rendered to patients that are consistent with standard nonexperimental treatment, including, but not limited to, room, board, ancillary services, and outpatient services may be charged to patients or third party payers, or both, in accordance with normal billing practices. Each patient upon whom the new technology is used shall be informed of the requirements of this subdivision.

(e) Is maintained under a separate cost center that includes overhead costs, for expenditure reporting related to the research project.

(f) Is developed so that capital funding for the research project will be obtained from sources other than the Michigan state hospital finance authority or any other governmentally supported financing source. This subdivision does not prohibit a person from using grants for research activities.

(g) Is operated so as to provide, upon request of the department, data obtained from the research project that the department may use in developing certificate of need review standards relative to the new technology. Aggregate data obtained as part of a federally approved data set shall meet the requirements of this part, except that supplemental data may be requested by the department.

(h) Is not marketed or advertised to other health care providers or the public.

(2) A person acquiring new technology under this section shall deactivate and remove the new technology from service on the date of notice that federal approval under the investigational device exemption for the new technology acquired under 21 C.F.R. part 812 has expired or been withdrawn, or the date of receipt of a department compliance order alleging a violation of this section.

(3) A person may continue to utilize new technology acquired under this section beyond the period specified in subsection (2) if any 1 of the following applies:

(a) The continued use is in compliance with section 22243(1)(d) to (h).

(b) The department issues a notice that the new technology will not be added to the list of covered medical equipment pursuant to section 22241(2)(a).

(c) The commission adds the new technology to the list of covered medical equipment, and the continued use is consistent with applicable certificate of need review standards, if any.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988.

Popular name: Act 368