October 1983 Spec. Sess.
Senate Bill 3

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1983 Wisconsin Act 85

AN ACT *to create* 150.63 of the statutes, *relating to* authorizing hospitals and other health care providers to use innovative forms of medical technology without receiving formal approval from the department of health and social services.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 150.63 of the statutes is created to read:

150.63 Innovative medical technology exemption. (1) In this section:

(a) "Clinical trial" means clinical research conducted under approved protocols in compliance with federal requirements applicable to investigations involving human subjects, including the requirement for an informed consent advising the patient clearly of the risks associated with participating in the clinical development and evaluation project.

(b) "Innovative medical technology" means equipment or procedures that are potentially useful for diagnostic or therapeutic purposes and that introduce new technology in the diagnosis and treatment of illness.

(2) The department may grant an exemption from the requirements of approval under this subchapter for the research, development and evaluation of innovative medical technology, the development of the clinical applications of this technology or the research, development and evaluation of a major enhancement to existing medical technology if all of the following occur:

(a) The department receives an application for an exemption from a person intending to undertake a capital expenditure in excess of $600,000 or intending to undertake a substantial change in a health service.

(b) Prior to applying for an exemption, preliminary animal studies or preliminary clinical investigation establishes that the innovative medical technology or major enhancement to existing medical technology has a reasonable probability of advancing clinical diagnosis or therapy.

(c) In the development and evaluation of the clinical applications the applicant undertakes scientifically sound studies to determine clinical efficacy, safety, cost-effectiveness and appropriate utilization levels in a clinical setting.

(d) The clinical trials, evaluation or research are conducted according to scientifically sound protocols subject to peer review and approval in accord with the requirements applicable to investigations and clinical evaluation involving human subjects.

(e) The innovative medical technology is being installed to conduct necessary research, development and evaluation.

(f) The applicant does not include any recovery of capital expenses incurred as part of an exemption under this section in its expense and revenue budget for purposes of rate setting, until the applicant receives the approval of the federal food and drug administration and of the department under this subchapter for general medical use. The applicant may recover operating expenses only after all of the following occur:

1. Approval by the federal food and drug administration for safety and efficacy.

2. A 3rd party agrees to pay for these expenses.

(3) The department may not grant more than 2 exemptions for any particular type of innovative medical technology or for any particular major enhancement to existing medical technology. The department may not grant further exemptions after December 31, 1985.