115th MAINE LEGISLATURE

FIRST REGULAR SESSION-1991

Legislative Document **No. 1209**

H.P. 843 House of Representatives, March 20, 1991

Reference to the Committee on Human Resources suggested and ordered printed.

Ed Pert

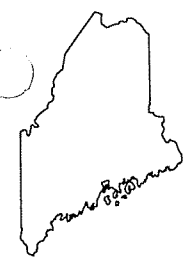
EDWIN H. PERT, Clerk

Presented by Representative CLARK of Brunswick.
Cosponsored by Representative BOUTILIER of Lewiston, Senator GILL of Cumberland and Representative MANNING of Portland.

STATE OF MAINE

IN THE YEAR OF OUR LORD
NINETEEN HUNDRED AND NINETY-ONE

An Act to Clarify the Authority of the Department of Human Services in Conducting Chronic Disease Investigation and Evaluating the Completeness or Data Quality in Disease Surveillance Programs.



Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA §387, sub-§3, ¶C, as enacted by PL 1989, c. 844, §1, is amended to read:

C. The commission shall adopt rules governing the conditions under which and purposes for which the department may use identifying information in a manner that is inconsistent with subsection 1. These rules must ensure that:

(1) Identifying information is used only to gain access to medical records and other medical information pertaining to an investigation designed to accomplish public health research of substantial public importance that the department is authorized by law to carry out;

(2) Medical information about any patient identified by name is not sought from any person without the prior written consent of that patient except when the information sought pertains solely to verification or comparison of health data that the department is otherwise authorized by law to collect and the commission finds that confidentiality can be adequately protected without patient consent and the department's activities do not involve contacts with any persons other than the patient's health care providers;

(3) Those persons conducting the investigation do not disclose medical information about any patient identified by name to any other person without that patient's consent;

(4) Those persons gaining access to medical information about an identified patient use that information to the minimum extent necessary to accomplish the purposes of the investigation for which approval was granted. Information regarding patients identified by name may not be transferred by the investigators;

(5) The protocol for any investigation is designed to preserve the confidentiality of all medical information that can be associated with identified patients, to specify the manner in which contact is made with patients, to require that inquiries seeking patient consent be channeled through the patient's attending physician and to maintain public confidence in the protection of confidential information; and

(6) An advisory body, independent of the department, is established and charged with responsibility for

approving the protocol of the investigation, overseeing the conduct of the investigation to assure consistency with the protocol and the commission's rules, and assessing both the scientific validity of the investigation and its effects upon patients. The advisory body must include a consumer representative, a practicing physician and a member of the Maine Medical Records Association.

Sec. 2. 22 MRSA §1692-B, as enacted by PL 1989, c. 844, §2, is amended to read:

§1692-B. Investigations

1. Access to reports and records. ~~The~~ Subject to the provisions of this section, the Department of Human Services must be given access to all confidential reports and records filed by physicians, hospitals or other private or public sector organizations, with all departments, agencies, commissions or boards of the State ~~for~~ that are reasonably the purpose of conducting investigations or evaluating the completeness or quality of data submitted to the department's disease surveillance programs. The department shall follow the data confidentiality requirements of the departments, agencies, commissions or boards of the State providing this information. All surveillance activities and follow-up investigations must be undertaken only as in the scope of the department's statutory and regulatory authority.

Upon notification by the Department of Human Services and following the obtaining of patient consent as provided in this section, physicians or hospitals shall provide to the department ~~any~~ further information requested ~~for~~, all as carried out consistent with approved protocols and statutory requirements that are reasonably related to the purpose of conducting investigations or evaluating the completeness or quality of data submitted to the department's disease surveillance programs.

When affected parties claim that the requested information goes beyond the scope of the department's authority or is otherwise objectionable, the affected parties may request an informal review of the matter with the director. If the affected party is not satisfied with the director's determination, the affected party may seek review of the matter under pertinent provisions of the Maine Administrative Procedure Act.

2. Limited immunity. A physician, hospital, or employee of a physician or hospital is not liable for any civil damages as a result of the department's use of information gathered under this section or otherwise as a result of that person's compliance

with the requirements of this section. This immunity is limited to legitimate activities pursued in good faith under this section.

3. Adoption of rules. The department shall adopt rules governing the conditions under which and purposes for which the department may use identifying information under this section. The rules must ensure that:

A. Identifying information is used only to gain access to medical records and other medical information pertaining to an investigation designed to accomplish public health research of substantial public importance that the department is authorized by law to carry out;

B. Medical information about an identified patient is not sought from any person without the prior written consent of that patient except when the information sought pertains solely to verification or comparison of health data that the department is otherwise authorized by law to collect and the department finds that confidentiality can be adequately protected without patient consent and the department's activities do not involve contacts with any persons other than the patient's health care providers;

C. Those persons conducting the investigation do not disclose medical information about an identified patient to any other person except a health care practitioner responsible for treating the patient;

D. Those persons gaining access to medical information about an identified patient use that information to the minimum extent necessary to accomplish the purposes of the investigation;

E. The protocol for any investigation is designed to preserve the confidentiality of all medical information that can be associated with identified patients, to specify the manner in which contact is made with patients, to require that inquiries seeking patient consent be channeled through the patient's attending physician and to maintain public confidence in the protection of confidential information;

F. An advisory body, independent from the department, is established and charged with responsibility for approving the protocol of the investigation, overseeing the conduct of the investigation to assure consistency with the protocol and the department's rules, and assessing both the scientific validity of the investigation and its effects upon patients;

G. The department does not seek information under this section if the proposed identification of or contact with

patients or health care practitioners would diminish the confidentiality of medical information or the public's confidence in the protection of that information in a manner that outweighs the expected benefit to the public of the proposed investigation; and

H. Whenever a physician or hospital furnishes patient information requested by the department in accordance with this section, the department reimburses the physician or hospital for the reasonable costs incurred in providing the information.

STATEMENT OF FACT

This bill makes clarifying amendments to the statutory authority permitting the Department of Human Services to carry out investigations of chronic diseases and evaluations of completeness of data that health care providers are required to file with the department. These mandatory reporting requirements are included in the cancer-incidence registry law, the Maine Revised Statutes, Title 22, chapter 255 and the occupational disease reporting law, Title 22, chapter 259-A.

The bill deals with provisions of law that govern a review of proposed public health studies on the part of the Maine Health Care Finance Commission. In cases where the Department of Human Services seeks access to data which directly identifies patients, it must seek approval from the Maine Health Care Finance Commission. The bill clarifies that public health studies must be those which the department is otherwise authorized to carry out. This section also clarifies that prior written consent of patients will be required except in cases where the department seeks to verify information already on file. In that case, the law is clarified to limit the department's contacts solely to the patient's health care providers for the purposes of verifying such information. This section also requires that inquiries seeking consent be channeled through the patient's attending physician.

The bill makes corresponding changes in the statutory authority extended to the Department of Human Services to carry out such studies. The bill clarifies that the department's access to information must be related to statutory authorities. It includes an appeals process where those for whom information is sought may object to the production of the information and specifies an appeal process. This section also clarifies the immunity provisions to parallel those set forth in the cancer-incidence laws and other related laws.