State of Minnesota

HOUSE OF REPRESENTATIVES

EIGHTY-NINTH SESSION

H. F. No. 3553

03/23/2016 Authored by Pugh and Whelan
The bill was read for the first time and referred to the Committee on Higher Education Policy and Finance

A bill for an act

relating to human services; requiring the ombudsman for mental health and developmental disabilities to monitor drug trials; amending Minnesota Statutes 2014, sections 245.92; 245.94; 245.945; 245.95, subdivision 1; 245.97, subdivision 5.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. Minnesota Statutes 2014, section 245.92, is amended to read:

245.92 OFFICE OF OMBUDSMAN; CREATION; QUALIFICATIONS; FUNCTION.

The ombudsman for persons receiving services or treatment for mental illness, developmental disabilities, chemical dependency, or emotional disturbance shall promote the highest attainable standards of treatment, competence, efficiency, and justice. The ombudsman may gather information and data about decisions, acts, and other matters of an agency, facility, or program, and shall monitor the treatment of individuals participating in a University of Minnesota Department of Psychiatry clinical drug trial. The ombudsman is appointed by the governor, serves in the unclassified service, and may be removed only for just cause. The ombudsman must be selected without regard to political affiliation and must be a person who has knowledge and experience concerning the treatment, needs, and rights of clients, and who is highly competent and qualified. No person may serve as ombudsman while holding another public office.

Sec. 2. Minnesota Statutes 2014, section 245.94, is amended to read:

245.94 POWERS OF OMBUDSMAN; REVIEWS AND EVALUATIONS; RECOMMENDATIONS.

Subdivision 1. **Powers.** (a) The ombudsman may prescribe the methods by which complaints to the office are to be made, reviewed, and acted upon. The ombudsman may not levy a complaint fee.

(b) The ombudsman may mediate or advocate on behalf of a client.

(c) The ombudsman may investigate the quality of services provided to clients and determine the extent to which quality assurance mechanisms within state and county government work to promote the health, safety, and welfare of clients, other than clients in acute care facilities who are receiving services not paid for by public funds. The ombudsman is a health oversight agency as defined in Code of Federal Regulations, title 45, section 164.501.

(d) At the request of a client, or upon receiving a complaint or other information affording reasonable grounds to believe that the rights of a client who is not capable of requesting assistance have been adversely affected, the ombudsman may gather information and data about and analyze, on behalf of the client, the actions of an agency, facility, or program.

(e) The ombudsman may gather, on behalf of a client, records of an agency, facility, or program, or records related to clinical drug trials from the University of Minnesota Department of Psychiatry, if the records relate to a matter that is within the scope of the ombudsman's authority. If the records are private and the client is capable of providing consent, the ombudsman shall first obtain the client's consent. The ombudsman is not required to obtain consent for access to private data on clients with developmental disabilities. The ombudsman is not required to obtain consent for access to private data on decedents who were receiving services for mental illness, developmental disabilities, or emotional disturbance. All data collected, created, received, or maintained by the ombudsman are governed by chapter 13 and other applicable law.

(f) Notwithstanding any law to the contrary, the ombudsman may subpoena a person to appear, give testimony, or produce documents or other evidence that the ombudsman considers relevant to a matter under inquiry. The ombudsman may petition the appropriate court in Ramsey County to enforce the subpoena. A witness who is at a hearing or is part of an investigation possesses the same privileges that a witness possesses in the courts or under the law of this state. Data obtained from a person under this paragraph are private data as defined in section 13.02, subdivision 12.

(g) The ombudsman may, at reasonable times in the course of conducting a review, enter and view premises within the control of an agency, facility, or program.

(h) The ombudsman may attend Department of Human Services Review Board and Special Review Board proceedings; proceedings regarding the transfer of patients

or residents, as defined in section 246.50, subdivisions 4 and 4a, between institutions operated by the Department of Human Services; and, subject to the consent of the affected client, other proceedings affecting the rights of clients. The ombudsman is not required to obtain consent to attend meetings or proceedings and have access to private data on clients with developmental disabilities.

(i) The ombudsman shall gather data of agencies, facilities, or programs classified as private or confidential as defined in section 13.02, subdivisions 3 and 12, regarding services provided to clients with developmental disabilities.

(j) To avoid duplication and preserve evidence, the ombudsman shall inform relevant licensing or regulatory officials before undertaking a review of an action of the facility or program.

(k) The ombudsman shall monitor the treatment of individuals participating in a University of Minnesota Department of Psychiatry clinical drug trial and ensure that all protections for human subjects required by federal law and the Institutional Review Board are provided.

(l) Sections 245.91 to 245.97 are in addition to other provisions of law under which any other remedy or right is provided.

Subd. 2. **Matters appropriate for review.** (a) In selecting matters for review by the office, the ombudsman shall give particular attention to unusual deaths or injuries of a client or reports of emergency use of manual restraint as identified in section 245D.061, served by an agency, facility, or program, or actions of an agency, facility, or program that:

(1) may be contrary to law or rule;

(2) may be unreasonable, unfair, oppressive, or inconsistent with a policy or order of an agency, facility, or program;

(3) may be mistaken in law or arbitrary in the ascertainment of facts;

(4) may be unclear or inadequately explained, when reasons should have been revealed;

(5) may result in abuse or neglect of a person receiving treatment;

(6) may disregard the rights of a client or other individual served by an agency or facility;

(7) may impede or promote independence, community integration, and productivity for clients; or

(8) may impede or improve the monitoring or evaluation of services provided to clients.

(b) The ombudsman shall, in selecting matters for review and in the course of the review, avoid duplicating other investigations or regulatory efforts.

(c) The ombudsman shall give particular attention to the death or unusual injury of any individual who is participating in a University of Minnesota Department of Psychiatry clinical drug trial.

Subd. 2a. **Mandatory reporting.** Within 24 hours after a client suffers death or serious injury, the agency, facility, ~~or~~ program director, or lead investigator of a clinical drug trial at the University of Minnesota Department of Psychiatry shall notify the ombudsman of the death or serious injury. The emergency use of manual restraint must be reported to the ombudsman as required under section 245D.061, subdivision 8. The ombudsman is authorized to receive identifying information about a deceased client according to Code of Federal Regulations, title 42, section 2.15, paragraph (b).

Subd. 3. **Complaints.** (a) The ombudsman may receive a complaint from any source concerning an action of an agency, facility, or program. After completing a review, the ombudsman shall inform the complainant and the agency, facility, or program. No client may be punished nor may the general condition of the client's treatment be unfavorably altered as a result of an investigation, a complaint by the client, or by another person on the client's behalf. An agency, facility, or program shall not retaliate or take adverse action against a client or other person, who in good faith makes a complaint or assists in an investigation. The ombudsman may classify as confidential, the identity of a complainant, upon request of the complainant.

(b) The ombudsman shall receive a complaint from any source concerning an action or inaction of the University of Minnesota Department of Psychiatry related to an individual who is enrolled in a department-approved clinical drug trial. No individual participating in the trial may be punished nor may the general condition of the individual's treatment be unfavorably altered as a result of an investigation or a complaint by the individual or the individual's advocate. The university shall not retaliate or take adverse action against any person who in good faith makes a complaint or assists in an investigation. The ombudsman may classify the identity of the complainant as confidential, upon request of the complainant.

Subd. 4. **Recommendations to agency.** (a) If, after reviewing a complaint or conducting an investigation and considering the response of an agency, facility, or program and any other pertinent material, the ombudsman determines that the complaint has merit or the investigation reveals a problem, the ombudsman may recommend that the agency, facility, or program:

(1) consider the matter further;

(2) modify or cancel its actions;

(3) alter a rule, order, or internal policy;

(4) explain more fully the action in question; or

(5) take other action.

(b) At the ombudsman's request, the agency, facility, or program shall, within a reasonable time, inform the ombudsman about the action taken on the recommendation or the reasons for not complying with it.

Subd. 5. **Recommendations to University of Minnesota.** If, after reviewing a complaint or conducting an investigation and considering the response of the clinical drug trial's primary investigator or the Department of Psychiatry, the ombudsman determines that the complaint has merit or the investigation reveals noncompliance with the federal protection of human subjects requirements or the requirements of the Institutional Review Board, the ombudsman shall recommend that the Board of Regents of the University of Minnesota take corrective action to remedy the violations.

Sec. 3. Minnesota Statutes 2014, section 245.945, is amended to read:

245.945 REIMBURSEMENT TO OMBUDSMAN FOR MENTAL HEALTH AND DEVELOPMENTAL DISABILITIES.

(a) The commissioner shall obtain federal financial participation for eligible activity by the ombudsman for mental health and developmental disabilities. The ombudsman shall maintain and transmit to the Department of Human Services documentation that is necessary in order to obtain federal funds.

(b) The Board of Regents of the University of Minnesota shall reimburse the Office of the Ombudsman for Mental Health and Developmental Disabilities for the oversight costs incurred in monitoring participants in Department of Psychiatry clinical drug trials. The ombudsman shall maintain and transmit documentation of costs incurred to the Board of Regents of the University of Minnesota.

Sec. 4. Minnesota Statutes 2014, section 245.95, subdivision 1, is amended to read:

Subdivision 1. **Specific reports.** The ombudsman may send conclusions and suggestions concerning any matter reviewed to the governor. Before making public a conclusion or recommendation that expressly or implicitly criticizes an agency, facility, program, or any person, the ombudsman shall consult with the governor and the agency, facility, program, or person concerning the conclusion or recommendation. When sending a conclusion or recommendation to the governor that is adverse to an agency, facility, program, or any person, the ombudsman shall include any statement of reasonable length made by that agency, facility, program, or person in defense or mitigation of the office's conclusion or recommendation. For purposes of this subdivision, "agency, facility,

program, or any person" includes the University of Minnesota Department of Psychiatry and its employees working in clinical drug trials.

Sec. 5. Minnesota Statutes 2014, section 245.97, subdivision 5, is amended to read:

Subd. 5. **Medical Review Subcommittee.** At least five members of the committee, including at least three physicians, one of whom is a psychiatrist, must be designated by the governor to serve as a Medical Review Subcommittee. Terms of service, vacancies, and compensation are governed by subdivision 2. The governor shall designate one of the members to serve as chair of the subcommittee. The Medical Review Subcommittee may have access to private and confidential data collected or created by the ombudsman that are necessary to fulfill the duties of the Medical Review Subcommittee under this section and may:

(1) make a preliminary determination of whether the death of a client that has been brought to its attention is unusual or reasonably appears to have resulted from causes other than natural causes and warrants investigation;

(2) review the causes of and circumstances surrounding the death;

(3) request the county coroner or medical examiner to conduct an autopsy;

(4) assist an agency in its investigations of unusual deaths and deaths from causes other than natural causes; ~~and~~

(5) make a preliminary determination of whether the death of a participant in a clinical drug trial conducted by the University of Minnesota Department of Psychiatry appears to have resulted from causes other than natural causes and warrants investigation and reporting as required by federal laws on the protection of human subjects; and

(6) submit a report regarding the death of a client to the committee, the ombudsman, the client's next-of-kin, and the facility where the death occurred and, where appropriate, make recommendations to prevent recurrence of similar deaths to the head of each affected agency or facility, or the Board of Regents of the University of Minnesota.