

HOUSE RESEARCH

Bill Summary

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Overview

The Ombudsman for Mental Health and Developmental Disabilities acts on behalf of persons who receive services and treatment for mental illness, developmental disabilities, chemical dependency, or emotional disturbance. In this role, the ombudsman may, on behalf of a person receiving services, accept complaints, act as an advocate, or investigate the actions of an agency, facility, or program. This bill would expand the role of the ombudsman to include oversight of the treatment of individuals who are enrolled in clinical drug trials at the University of Minnesota Department of Psychiatry.

A special review of a clinical drug study at the University of Minnesota Department of Psychiatry was conducted by the Office of the Legislative Auditor. In the March 19, 2015, report, the auditor recommended that the legislature should enact legislation to authorize the Ombudsman for Mental Health and Developmental Disabilities to monitor individuals who are enrolled in Department of Psychiatry clinical drug trials.

Section

- 1 Office of Ombudsman; creation; qualifications; functions.** Amends § 245.92. Requires the Office of the Ombudsman for Mental Health and Developmental Disabilities to monitor treatment of individuals who are enrolled in clinical drug trials at the University of Minnesota Department of Psychiatry.

Section

2

Powers of ombudsman; reviews and evaluations; recommendations. Amends § 245.94.

Subd. 1. Powers. Allows the ombudsman to gather records related to clinical drug trials from the University of Minnesota Department of Psychiatry. Requires the ombudsman to ensure that the Department of Psychiatry complies with the protections for human subjects required by federal law and the Institutional Review Board.

Subd. 2. Matters appropriate for review. Instructs the ombudsman to give particular attention to the death or unusual injury of any individual who is enrolled in a Department of Psychiatry clinical drug trial.

Subd. 2a. Mandatory reporting. Requires the lead investigator of a clinical drug trial at the Department of Psychiatry to notify the ombudsman within 24 hours of a client death or serious injury.

Subd. 3. Complaints. Allows the ombudsman to accept 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 clinical drug trial. Provides that the university shall not punish or unfavorably alter a participant's treatment as a result of an investigation or complaint. Prohibits the university from taking adverse action against any person who makes a complaint or assists in an investigation. Allows the ombudsman, at the request of the complainant, to maintain the complainant's identity as confidential.

Subd. 4. Recommendations to agency. No changes.

Subd. 5. Recommendations to University of Minnesota. Requires the ombudsman to make recommendations to the Board of Regents for corrective action if, after investigation, the ombudsman determines a complaint has merit or an investigation reveals noncompliance with the protection of human subjects or the Institutional Review Board.

3

Reimbursement to Ombudsman for Mental Health and Developmental Disabilities.

Amends § 245.945. Requires the Board of Regents to reimburse the ombudsman for oversight costs incurred by the ombudsman. Instructs the ombudsman to maintain and transmit documentation of costs to the Board of Regents.

4

Specific reports. Amends § 245.95, subd. 1. Adds the University of Minnesota Department of Psychiatry and its clinical drug trial employees to the definition of "agency, facility, program, or person" for purposes of this subdivision.

5

Medical Review Subcommittee. Amends § 245.97, subd. 5. Allows the subcommittee to review the death of a participant in a clinical drug trial conducted by the Department of Psychiatry and make a preliminary determination whether the death warrants investigation and reporting as required by laws on the protection of human subjects.