Department of Health

Adopted Permanent Rules Relating to Cancer Surveillance System

Rules as Adopted

4606.3300 PURPOSE.

The purpose of parts 4606.3300 to 4606.3309 is to establish a process and assign responsibility for:

A. collecting data from pathology laboratory reports and other demographic data on the occurrence of cancer in the state; and

B. investigating the occurrence of cancer.

4606.3301 SCOPE.

Parts 4606.3300 to 4606.3309 apply generally to the diagnosis of, reporting of, and epidemiologic studies of cancer; and scientific research on the treatment and prevention of cancer.

4606.3302 DEFINITIONS.

Subpart 1. **Abstract.** "Abstract" means a form specified by the commissioner on which the information required in part 4606.3304 has been copied.

Subp. 2. **Attending physician.** "Attending physician" means the physician who provides primary clinical care for the cancer case.

Subp. 3. **Cancer.** "Cancer" means:

A. malignant and in situ neoplasms of all sites, except basal and squamous cell carcinomas of the skin;

B. basal and squamous cell carcinomas of the lip, eyelid, or genitalia; and

C. all brain and central nervous system neoplasms regardless of malignancy.

Subp. 4. Case. "Case" means any Minnesota resident, living or deceased, having a cancer diagnosed by a physician or dentist.

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Subp. 5. **Case report.** "Case report" means a complete report of a diagnosis of cancer, which has been generated as a result of examination of demographic information and a pathology, cytology, hematology, biopsy, surgical, or autopsy specimen. At a minimum, this shall consist of source documents that contain all or as much as is known of the information required in part 4606.3304.

Subp. 6. **Commissioner.** "Commissioner" means the state commissioner of health, or the commissioner's authorized officers, or employees.

Subp. 7. **Demographic form.** "Demographic form" means the front page of a hospital medical record, the hospital business office form, or the pathology specimen submission slip that contains the demographic information required in part 4606.3304 for cases.

Subp. 8. **Dentist.** "Dentist" means any person who is licensed by the Minnesota Board of Dentistry to practice dentistry.

Subp. 9. **Electronic data submission.** "Electronic data submission" means transferring data from a computer used by a reporting entity to a computer specified by the commissioner through the use of a modem, magnetic tape, or magnetic disk.

Subp. 10. **Epidemiologic studies.** "Epidemiologic studies" means the compilation of data on health and disease, its scientific analysis to determine the distribution and causes of health problems in populations, and the application of this study to the control of health problems.

Subp. 11. **Hospital.** "Hospital" means any institution licensed as such by the commissioner under Minnesota Statutes, section 144.50.

Subp. 12. **Medical clinic.** "Medical clinic" means any institution staffed by one or more physicians where diseases of human beings are diagnosed.

Subp. 13. **Medical laboratory or pathology laboratory.** "Medical laboratory" or "pathology laboratory" means any facility that reports the results of examinations of organ

tissue, cells, or blood specimens from the human body for cancer to physicians who use the reports for purposes of diagnosis or patient care.

Subp. 14. **Minnesota resident.** "Minnesota resident" means a person who provides a permanent address within the borders of the state at the time of cancer diagnosis. In the case of minors, residency shall be determined as that of the parent or legal guardian. This does not mean that Minnesota is the person's legal residence or voting residence.

Subp. 15. **Physician.** "Physician" means a person who is licensed by the Minnesota Board of Medical Examiners to practice medicine.

Subp. 16. **Reporting entity.** "Reporting entity" means the individual or operational unit within an institution such as a medical laboratory, hospital, clinic, or tumor registry, designated by the institution to submit case reports required by parts 4606.3300 to 4606.3309.

Subp. 17. **Source documents.** "Source documents" means copies of the demographic forms and the pathology laboratory reports that contain the information required in part 4606.3304 for cases.

Subp. 18. **Tumor registry.** "Tumor registry" means a collection of cancer data on patients that is maintained as an identified repository of such data for, or within any hospital, medical clinic, or centralized institution.

4606.3303 COMPREHENSIVE REPORTS OF CANCER.

Subpart 1. **Tumor registries.** Tumor registries shall forward by first class mail, by messenger, or via electronic data submission, case reports to the commissioner within 15 working days of the date the patient's tumor registry was completed.

Subp. 2. **Medical laboratories.** Medical laboratories shall forward by first class mail, by messenger, or via electronic data submission, case reports to the commissioner for all cases of cancer within 15 working days of the date of diagnosis.

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Subp. 3. **Hospitals and medical clinics.** Hospitals and medical clinics shall forward by first class mail, by messenger, or via electronic data submission, case reports to the commissioner for all cases of cancer diagnosed in the institution within 15 working days of the date of diagnosis.

Subp. 4. **Physicians and dentists.** Physicians and dentists not working within a hospital, medical clinic, or medical laboratory required to report by this part, who examine specimens of human organ tissue, cells, or blood with findings indicative of the presence of cancer, shall forward by first class mail, by messenger, or via electronic data submission, case reports to the commissioner within 15 working days of the date of diagnosis.

Subp. 5. **Designating a reporting entity.** Alternatively, tumor registries, medical laboratories, hospitals, medical clinics, or any combination of these within or as part of an institution, may notify the commissioner of the identity of a reporting entity to report on behalf of the institution and as such shall meet the requirements of cancer reporting under subparts 1 to 4.

4606.3304 REPORTS.

Subpart 1. **Case information.** Reports of case information that are required in part 4606.3303 must consist of source documents and contain as much of the following information as is known:

A. last name;

B. first name;

C. middle name or initial;

D. address, including house number, street, rural route number, city, state, and zip code;

E. county of residence;

F. date of birth;

G. sex;

H. social security number;

I. attending physician;

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J. other attending physician;

K. diagnostic or treatment facility;

L. case's hospital or clinic medical record number; and

M. cancer diagnostic information:

(1) primary site;

(2) histologic type;

(3) date of diagnosis or date specimen was obtained; and

(4) pathologist's designation of whether the case is newly or previously diagnosed or not known.

Subp. 2. **Abstracts or electronic data submission.** Alternatively, reports of case information that are required in part 4606.3303 may consist of completed abstracts or electronic data submission and must contain the information required in subpart 1.

Subp. 3. **Race, ethnicity, and occupational data.** Hospitals, medical clinics, and physicians shall, upon request of the commissioner, report as much information as is known concerning the race, ethnicity, and occupational history of cancer cases. The commissioner shall by publication in the State Register request reports of such information when the following conditions exist:

A. epidemiologic surveillance and studies based on this information will assist in identifying cancer risks in certain racial, ethnic, or occupational groups; and

B. there is a specific, planned mechanism for the surveillance and epidemiologic study of the cancer related to the racial, ethnic, or occupational group.

4606.3305 DATA SUBMISSION.

Subpart 1. **Completeness.** Every case report shall include, at a minimum, legible source documents, or completed abstracts, or electronic data submission that must contain the data required in part 4606.3304. Abstracts must be legible and submitted on forms provided by the commissioner. Electronic

data must be submitted in a manner and format that conforms to the state cancer surveillance system computer system.

Subp. 2. **Missing information.** The reporting entity or individual shall, within five working days of notification by the commissioner, supply all missing information, if known, or clarify information submitted in any report required in parts 4606.3303 and 4606.3304.

Subp. 3. **Inspection.** For the purpose of assuring the quality and completeness of individual cancer case reports, each reporting entity or individual shall allow the commissioner to inspect the demographic portions of a patient's medical record or medical records related to the diagnosis of cancer as are necessary to verify the accuracy and completeness of the cancer diagnostic information and demographic data.

4606.3306 PHYSICIAN CONSENT.

Subpart 1. **Attempt to obtain consent.** When undertaking epidemiologic studies, the commissioner shall attempt to locate and obtain the consent of the attending physician as identified in the case report before approaching any case named in a report or a personal representative of a deceased case as defined in Minnesota Statutes, section 13.10, subdivision 1, paragraph (c).

Subp. 2. **Approach without consent.** The commissioner may approach a case named in a report or a personal representative of a deceased case as defined in Minnesota Statutes, section 13.10, subdivision 1, paragraph (c), without the consent of the attending physician as identified in the case report in order to conduct epidemiologic investigations if the attending physician is deceased, is no longer licensed in the state, is no longer practicing, or cannot otherwise be located.

4606.3307 AUTHORIZED RESEARCH.

Subpart 1. **Criteria.** The commissioner of health may enter into contracts to conduct research, using data collected pursuant to parts 4606.3300 to 4606.3309, with public and private research agencies or with individuals who satisfy all of the following criteria:

A. the research proposed to be conducted will assist in improving the diagnosis, treatment, or prevention of cancer and the public health;

B. there is documented evidence that the principal investigator for the research proposed is qualified:

(1) by having attained the degree of medical doctor, doctor of dental surgery, doctor of science, doctor of philosophy, or equivalent degree from an accredited college or university; and

(2) by specific academic graduate level training in epidemiology, biomedical research or biometry, or documented evidence of biomedical or related medical research experience; and

C. there is a written protocol which includes but is not limited to a complete description of:

(1) the proposed scientific research hypotheses;

(2) the purpose of the proposed research;

(3) the specific methodologies, including data required from the commissioner, to be used in conducting the research and testing of scientific hypotheses;

(4) the projected or anticipated result of the research;

(5) the period of time during which the proposed research will be conducted and when a final report will be completed;

(6) the physical facilities to be employed in conducting the research; and

(7) the methods to be used to assure that privacy of data is maintained in accordance with state law, and that access to private, nonpublic data is limited to those authorized by the commissioner to have access.

Subp. 2. **Release of information.** Under no circumstances will researchers be provided access to personal identifiers that would allow contact of a patient without attempting to obtain physician consent as described in part 4606.3306. The following personal identifiers will not be released:

A. last name;

B. first name;

C. middle name or initial;

D. address;

E. county of residence; or

F. social security number.

No researcher operating under contractual agreement with the commissioner as described in subpart 1 shall release any personal identifier, mark, or description obtained during an investigation that could be used for identification of an institution, a physician, or an individual who is or was the subject of a case report required in part 4606.3303.

Subp. 3. **Evaluation of proposals.** The commissioner shall evaluate proposals based upon the criteria in items A to E.

A. The proposed research has social and scientific merit that is directed primarily toward improving the diagnosis, treatment, defining of risks, or prevention of cancer.

B. All co-investigators are qualified to undertake the proposed research by means of specific academic training or demonstrable, related experience in epidemiology, medical, biomedical, or statistical research.

C. The hypotheses to be tested are explicit, and are determined to be researchable and feasible by the scientific peer review committee described in subpart 4.

D. The methods proposed for testing the hypothesis clearly define:

(1) the population or cancers to be studied;

(2) the type and amount of data to be collected;

(3) the source of the data;

(4) the procedures for collecting and maintaining the data; and

(5) the specific measurement techniques to be employed in analysis of data, including discussion of: major variables, statistical methods, methods of testing data reliability and validity, and required levels of accuracy, precision, or completeness of the data to be collected.

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E. The results of this study will be interpreted so that the findings can be used or generalized to other populations and provide a timely, substantive, and important contribution to the understanding of cancer diagnosis, treatment, or prevention in Minnesota.

Subp. 4. **Scientific peer review committee.** To assist in evaluating the scientific merits of proposals for research, the commissioner may appoint up to seven scientists to conduct scientific peer review who are qualified by having:

A. attained the degree of medical doctor, doctor of science, doctor of philosophy, or equivalent degree from an accredited college or university;

B. specific training in medicine, epidemiology, cancer research, or biometry from an accredited college or university; and

C. two or more years of applied experience in epidemiology, medical research, biomedical research, or biometry.

4606.3308 CONTRACTS FOR DEVELOPMENT, EXTENSION OF SERVICES, AND QUALITY ASSURANCE.

Subpart 1. **Contracts.** The commissioner may, upon receipt of an application described in this section, contract with any institution or reporting entity in compliance with part 4606.3304 for the following purposes:

A. providing more efficient, expedient, and complete cancer registry and reporting systems for those required to report under part 4606.3303;

B. extending the capability and efficiency of the commissioner to meet the mandate established under Minnesota Statutes, sections 144.671 to 144.69; and

C. maintaining and validating the quality, accuracy, and completeness of cancer case data.

Subp. 2. **Notice of availability of funds.** The commissioner shall publish and distribute a notice of availability of funds and request for contract proposals to all hospitals, medical laboratories, tumor registries, and medical

clinics required to report under part 4606.3303.

Subp. 3. **Content of application.** Applications made under this section shall address all of the following information requirements, including:

A. Full corporate or company name, address, and tax identification number of applicant institution, or in the case of multiple institutions, the full corporate or company name, address, and tax identification number of the principal applicant institution, and the full corporate or company names and addresses of other institutions participating in the application.

B. A description of the individual components of the reporting systems to be provided by the applicant. The quality assurance standards in part 4606.3305 shall be incorporated into all applications. For each component to be provided, the application must describe, but not be limited to:

(1) the specific objectives to be achieved during the funding period;

(2) the methods by which each objective will be achieved;

(3) the institutions to be involved in the registry or reporting system;

(4) criteria to be used to evaluate achievement of objectives;

(5) budget and budget justification; and

(6) a summary of the training and experience relevant to the components to be provided by the key personnel.

C. Assurance that services will be provided in accordance with state and federal laws and rules.

D. Assurance that the privacy of all data will be maintained in accordance with law and acceptable medical practice.

Subp. 4. **Priority.** Priority will be given to applications proposing to provide cancer reporting systems addressing one or more of the following criteria:

A. the highest quality and completeness of data;

B. services to the greatest number of persons;

C. services to the largest geographic area; and

D. demonstrated capacity to perform on the proposal.

4606.3309 CHARGES FOR DATA.

The commissioner may charge fees for out-of-pocket expenses including hourly employee wages, employee expenses, electronic data processing costs, duplicating, and clerical charges incurred as a result of requests by agencies for summary data compilation or analyses under the following conditions:

A. the agency requesting the summary data is not a community health services agency as defined in Minnesota Statutes, chapter 145;

B. the request requires more than one person hour of time to complete for an employee of the commissioner who is classified as either a programmer/analyst or higher, or an epidemiologist I or higher; and

C. the estimated total out-of-pocket expenses, regardless of person hours needed to satisfy the request, are greater than $50.

REPEALER. Minnesota Rules, part 4605.8000 is repealed.

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