Department of Health

Proposed Permanent Rules Relating to Cancer Surveillance

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 and outcomes of cancer in the state; and

B. investigating the occurrence of cancer.

4606.3302 DEFINITIONS.

Subpart 1. **Abstract.** "Abstract" means ~~a form~~ an electronic record, in a format specified by the commissioner ~~on~~, which contains 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:

(1) basal and squamous cell carcinomas of the skin;

(2) ~~squamous cell carcinoma~~ in situ neoplasms of the uterine cervix; and

(3) intraepithelial neoplasia of the uterine cervix;

B. basal and squamous cell carcinomas of the genitalia; and

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

Subp. 3a. **Cancer registry.** "Cancer 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.

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

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~~ made by a physician or dentist. 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. [See repealer.]

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 Practice 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~~ cancer 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 portions of a medical record, including pathology laboratory reports that contain the information required in part 4606.3304 for cases.

Subp. 18. [See repealer.]

4606.3303 COMPREHENSIVE REPORTS OF CANCER.

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

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

Subp. 3. **Hospitals and medical clinics.** Hospitals and medical clinics shall forward by first class mail, by messenger, or ~~via~~ by electronic ~~data submission~~ means, 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.**

A. Physicians and dentists ~~not~~ who diagnose cancer in humans shall forward by first class mail, by messenger, or by electronic means, case reports to the commissioner within 15 working days of the date of diagnosis.

B. A physician or dentist is exempted from item A if the physician or dentist (i) is 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.~~ (ii) knows the case was admitted to a hospital required to report by this part, or (iii) has received, from a medical laboratory required to report by this part, a written report indicating the presence of cancer in the case.

Subp. 5. **Designating a reporting entity.** Alternatively, ~~tumor~~ cancer 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. race;~~

~~J. ethnicity;~~

~~K. attending physician;~~

~~L. other attending physician;~~

~~M. diagnostic or treatment facility;~~

~~N. case's hospital or clinic medical record number;~~

~~O. hospital registry's accession number;~~

~~P. date of first admission to facility for diagnosis or treatment of the reportable tumor;~~

~~Q. date of discharge from the facility after diagnosis or treatment of the reportable tumor;~~

~~R. cancer diagnostic information:~~

~~(1) primary site;~~

~~(2) histologic type;~~

~~(3) grade;~~

~~(4) date of diagnosis or date specimen was obtained;~~

~~(5) pathologist's designation of whether the case is newly or previously diagnosed or not known;~~

~~(6) sequence number; and~~

~~(7) class of case;~~

~~S. stage and other prognostic factor information:~~

~~(1) general summary stage, in accordance with the guide listed in subpart 1a, item A;~~

~~(2) tumor size, in accordance with the standards listed in subpart 1a, item B;~~

~~(3) number of regional nodes examined and number positive, in accordance with the standards listed in subpart 1a, item B;~~

~~(4) pathologic T code, N code, and M code, in accordance with the manual listed in subpart 1a, item C;~~

~~(5) AJCC stage group (pathologic), in accordance with the manual listed in subpart 1a, item C;~~

~~(6) clinical T code, N code, and M code, in accordance with the manual listed in subpart 1a, item C;~~

~~(7) AJCC stage group (clinical), in accordance with the manual listed in subpart 1a, item C;~~

~~(8) the edition of the AJCC manual used; and~~

~~(9) distant metastasis, in accordance with the standards listed in subpart 1a, item B; and~~

~~T. treatment information:~~

~~(1) date and type of first course of any definitive treatment, including surgery, radiation, chemotherapy, hormone therapy, and immunotherapy and biological response modifiers (BRMs), in accordance with the standards listed in subpart 1a, item B; and~~

~~(2) if no treatment was performed, reason for no treatment, in accordance with the standards listed in subpart 1a, item B.~~

A. patient identifiers, including Social Security number, and demographics;

B. provider and facility information;

C. cancer diagnostic information;

D. extent of disease and other prognostic factor information;

E. first course of cancer-directed treatment;

F. follow-up information; and

G. other information as needed for system administration.

Subp. 1a. **Data items.** The commissioner shall, at least once per year and by publication in the State Register and electronic notice on the Minnesota Cancer Surveillance System Web site, provide a list of the data items to be reported under part 4606.3303, subpart 1, and specify the format to be used for electronic reports. The list will be revised according to national cancer reporting standards.

Subp. ~~1a.~~ 1b. **Reporting standards.** The following guides and standards for reporting ~~stage and other prognostic factor information and treatment~~ the information required in subparts 1 and 1a are incorporated by reference and are available through the Minitex interlibrary loan system~~:~~. They are also available electronically as specified in items A and D.

A. Standards for Cancer Registries: Volume II, Data Standards and Data Dictionary, Fourteenth Edition Record Layout Version 12 (2010), and subsequent editions; and Volume V, Electronic Pathology Reporting Standards, Version 3.0 (2009) and subsequent editions; North American Association of Central Cancer Registries (NAACCR), Springfield, Illinois. NAACCR reporting standards are updated frequently and are published electronically at www.naaccr.org.

~~A.~~ B. Summary Staging Guide, Cancer Surveillance Epidemiology and End Results Reporting, SEER Program (April 1977 ~~and subsequent editions) (reprint~~, reprinted July 1986), published by the National Institutes of Health (NIH), Public Health Service, U.S. Department of Health and Human Services, NIH publication number 86-2313 (cancers diagnosed before 2001). The ~~NIH~~ Summary Staging Guide is not subject to frequent change~~;~~.

~~B.~~ C. ~~For cancers diagnosed in or before 1995, the standards of the Commission on Cancer~~ SEER Summary Staging Manual - 2000 (July 2001), published by the NIH, Public Health Service, U.S. Department of Health and Human Services, NIH publication number 01-4969 (cancers diagnosed in 2001 through 2003). The SEER Summary Staging Manual is not subject to frequent change.

D. Collaborative Staging Manual and Coding Instructions version 1.0 and subsequent editions, published by the NIH, Public Health Service, U.S. Department of Health and Human Services, NIH publication number 04-5496 (cancers diagnosed in

2004 and later). The Collaborative Staging Manual is subject to frequent change and is published electronically at www.cancerstaging.org/cstage/index.html.

E. Data Acquisition Manual (revised edition September 1994), published by the Commission on Cancer, American College of Surgeons (cancers diagnosed in 1995). The manual is not subject to frequent change. ~~For cancers diagnosed in or after 1996, the~~

F. Standards of the Commission on Cancer, Volume II: Registry Operations and Data Standards (ROADS) (1996 and ~~subsequent editions~~ 1998), published by the Commission on Cancer, American College of Surgeons (cancers diagnosed in 1996 through 2002). The manual is not subject to frequent change.

G. Facility Oncology Registry Data Standards (FORDS) (2002 and subsequent editions), published by the Commission on Cancer, American College of Surgeons (cancers diagnosed in 2003 and later). The standards ~~are not subject to frequent change; and~~ of the Commission on Cancer are changed as often as every year.

~~C.~~ H. Manual for Staging of Cancer (4th edition 1992 and subsequent editions), American Joint Commission on Cancer (AJCC), published by J.B. Lippincott Company. The AJCC manual is not subject to frequent change.

I. SEER Program Coding and Staging Manual 2007; Johnson CH, Adamo M (eds.), National Cancer Institute, NIH publication number 07-5581, Bethesda, MD 2007. The SEER manual is not subject to frequent change.

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

Subp. 3. **Occupational data.** Hospitals, medical clinics, and physicians shall, upon request of the commissioner, report as much information as is known concerning the

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 occupational groups; and

B. there is a specific, planned mechanism for the surveillance and epidemiologic study of the cancer related to the 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. Electronic abstracts must be ~~legible and~~ submitted ~~on forms provided~~ in the format required 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 and treatment of cancer as are necessary to verify the accuracy and completeness of the cancer diagnostic and treatment 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, or is no longer caring for the case and is unable to identify the case's current attending physician.

REPEALER. Minnesota Rules, part 4606.3302, subparts 9 and 18, are repealed.