Regulation 61-45

South Carolina Central Cancer Registry

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S.C. Department of Health and Environmental Control

2600 Bull Street | Columbia, SC 29201

Statutory Authority:	S.C. Code Section 44-35-10 et seq.

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A. PURPOSE. This regulation establishes rules implementing Sections 44-35-20 through -40, 1976 S.C. Code of Laws and Supplement, regarding the South Carolina Central Cancer Registry (SCCCR) requirements for reporting cancer cases, data elements to be collected, content and design of forms and reports, and the procedures for disclosure of confidential registry information.

B. DEFINITIONS.

1. "South Carolina Central Cancer Registry (SCCCR)" means the population-based cancer data system for the collection, storage, maintenance, analysis, and dissemination of all cancer cases occurring in South Carolina, diagnosed after December 31, 1995, under the administration of the South Carolina Department of Health and Environmental Control (DHEC).

2. "Reportable cases" means all malignant tumors, pathologically or clinically diagnosed, including in situ and invasive carcinomas, sarcomas, melanomas, leukemias, and lymphomas, excluding carcinoma in situ of the cervix, and all basal and squamous cell carcinomas of non-genital skin sites. Malignant tumors of the skin of genital sites as described in the current edition of the International Classification of Diseases for Oncology published by the World Health Organization, are reportable. Cases of reportable cancers with the following ambiguous terms in the final diagnosis shall also be reported: probable, suspect, suspicious, compatible with, consistent with, and most likely.

3. "Health care providers" means all South Carolina health care facilities and licensed practitioners that diagnose or treat patients with cancer. These include, but are not limited to, hospitals, independent pathology laboratories, freestanding surgical and treatment centers, physicians, nurse practitioners, and physician assistants.

4. "Resident of South Carolina" means a person who lives and sleeps most of the time in or considers their usual home to be in South Carolina as defined by the United States Census Bureau.

5. "Regional registry" means a population-based data system for the collection, storage, maintenance, analysis and interpretation of cancer data for a designated geographic region of the State.

6. "Pathologically diagnosed cancer cases" means cases determined by a licensed physician to have cancer present with histologic (tissue) confirmation.

7. "Clinically diagnosed cancer cases" means cases determined by a licensed physician to have cancer present without histologic (tissue) confirmation.

8. "North American Association of Central Cancer Registries (NAACCR)" means the body that establishes standards for central cancer registry operations.

9. "Department" or DHEC means the South Carolina Department of Health and Environmental Control.

10. "DHEC Cancer Control Advisory Committee (CCAC)" means the multidisciplinary committee that advises the Board of DHEC and the staff of the Division of Cancer Prevention and Control on professional issues pertaining to cancer prevention, detection, care, and surveillance. This includes all SCCCR activities.

11. "Surveillance Subcommittee" means the subcommittee of the DHEC Cancer Control Advisory Committee that is comprised of statewide representation of cancer researchers, the South Carolina Medical Association, the South Carolina Hospital Association, and the South Carolina Budget and Control Board Office of Research and Statistics. This subcommittee has the specific responsibility to determine the appropriateness of requests for confidential data release from the SCCCR.

C. REPORTING OF CANCER CASES.

1. Reportable cancer cases, as defined, which are initially diagnosed after December 31, 1995 shall be reported to DHEC within six months of initial diagnosis.

2. All health care providers that diagnose and/or treat cancer patients in the State are responsible for reporting cancer cases to DHEC, unless those health care providers are already reporting to a regional cancer registry.

3. Responsibility for Reporting:

a. Hospitals with existing cancer registries shall designate an appropriate person to be responsible for reporting all SCCCR reportable cases to DHEC.

b. Hospitals without a cancer registry shall designate the Director of Health Information Management or the functional equivalent employee to be responsible for reporting all SCCCR reportable cases to DHEC.

c. The Director or the functional equivalent of each independent pathology laboratory and private component of a hospital pathology laboratory shall be responsible for reporting the results of examination of tissue specimens and/or hematology examinations to DHEC. Pathologic and hematologic reports indicating the diagnosis of cancer, that have not been previously reported from that laboratory, shall be reported.

d. Physicians shall report to DHEC all new cancer cases diagnosed in their offices that are not referred to a hospital in the State for treatment.

e. The Director of functional equivalent of each freestanding surgical or treatment center shall be responsible for reporting all new cancer cases to DHEC.

f. Every health care provider shall allow representatives of DHEC upon demand to access, obtain, and copy information from all medical, pathological, and other pertinent records and logs related to cancer cases, as necessary for fulfilling the functions of the SCCCR. Adequate space shall be provided as needed to DHEC staff for record review at South Carolina health care facilities.

g. Regional registries shall abide by the same reporting requirements as for other health care providers in the State.

h. SCCCR staff shall be responsible for continuously monitoring compliance of reporting requirements from all health care providers.

i. SCCCR staff shall be responsible for monitoring timeliness, completeness, and quality of data. Statewide and national quality control audits shall be conducted to assess SCCCR data. The SCCCR shall participate in national quality control audits performed by NAACCR that include review of health care provider records.

j. Every health care provider shall participate in quality control studies developed by the SCCCR in order to access timeliness, completeness, and quality of data according to NAACCR standards.

k. SCCCR staff shall provide appropriate training to health care provider staff on data collection principles and practices as needed.

D. CANCER CASE IDENTIFICATION.

All health care providers shall provide case finding documents to permit identification of cancer cases to be reviewed and reported. These case finding documents shall include the following: disease and operation indices for cancer cases; pathology and cytology reports; new patient radiation or chemotherapy logs; and other alternative information deemed necessary to identify or verify reportable cancer cases.

E. DATA ITEMS TO BE REPORTED.

All health care providers shall provide to DHEC at least the following data items on all reportable cancer cases in accordance with standard definitions as listed in the current edition of the NAACCR Standards for Cancer Registries, Volume II, Data Standards and Data Dictionary obtained from the NAACCR. The current edition of NAACCR standards can be obtained from the SCCCR office at DHEC:

1. Last name, first name, middle initial

2. Address at initial diagnosis, including city, county, State, and zip code (zip + 4, where available)

3. Race

4. Spanish/Hispanic origin (if applicable)

5. Sex

6. Birth date

7. Social security number

8. Information on the industrial history of the individual with the cancers, to the extent such information is available from the same medical record

9. Information on the occupational history of the individual with the cancers, to the extent such information is available from the same record

10. Date of diagnosis

11. Date of admission

12. Source of information

13. Primary site of the cancer

14. Morphology type, behavior, and grade

15. Sequence number of the cancer

16. Laterality

17. Diagnostic confirmation

18. Stage of disease (pursuant to Summary Staging Guide)

19. Date and type of first course of definitive treatment when available in the medical record

20. Date of death

21. Underlying cause of death

F. CONTENT AND DESIGN OF FORMS AND REPORTS.

1. The information to be reported shall be provided on forms supplied by DHEC. The forms must be completed entirely. Supplemental information can be supplied for forms that cannot be completed entirely by submitting copies of pertinent medical information to include, at a minimum, pathology reports, history and physical, discharge summary, and radiographic reports.

2. Case reports from facilities with existing computerized cancer registries shall be submitted on appropriate electronic medium provided their data items are in accordance with national standards utilized by the SCCCR. The data must be submitted according to the NAACCR standard record layout as specified in the current edition of the Standards for Cancer Registries, Volume II, Data Standards and Data Dictionary.

3. Reportable cases from facilities served by the SCCCR field staff shall be collected in a manner determined by DHEC.

4. The SCCCR staff shall document on standard forms the reportability status and record review status of each health care provider that is contacted.

G. PROCEDURES FOR DISCLOSURE OF CONFIDENTIAL INFORMATION.

1. In accordance with Section 44-35-40, all data obtained from cancer reports submitted to the SCCCR are confidential. All data collected is confidential pursuant to Section 44-1-110. Information identifying individuals with cancer is exempt from Freedom of Information requests pursuant to Section 30-4-40, “Freedom of Information Act”, and may not be made available to the public. Identifying information regarding patients, physicians, or reporting facilities is not available by subpoena, and may only be released pursuant to a court order.

2. Data collected on patients whose legal residential address is outside the State of South Carolina may be shared with other State cancer registries provided a reciprocal data sharing agreement is in place with the respective State Health Departments. The SCCCR will insure that such agreements with other States provide data confidentiality provisions.

3. The DHEC CCAC shall advise and make recommendations to the Department about the issues related to cancer surveillance, including all Central Cancer Registry activities. A subcommittee of the CCAC called the Surveillance Subcommittee shall have specific responsibility to determine the appropriateness of requests for confidential data release. Membership of this subcommittee shall consist of statewide representation of cancer researchers, the South Carolina Medical Association, the South Carolina Hospital Association, and the South Carolina Budget and Control Board Office of Research and Statistics. Strict criteria set forth in the SCCCR Data Release Protocol written in coordination with the South Carolina Budget and Control Board Office of Research and Statistics Principles and Protocol for Release of Health Data shall be utilized to review each data release request. This Subcommittee also assures the DHEC Internal Review Board approval when appropriate in order to assure protection of human subjects.

4. Each applicant requesting access to confidential information will follow the procedure outlined in the SCCCR Data Release Protocol, completing the application and providing the required information, documentation, and assurances. The applicant shall provide, at no cost to the SCCCR, a reprint of each publication using Registry information. Any report or published papers must acknowledge DHEC and the SCCCR and data must only be published according to its intended purpose on the application for data release.

5. Requests for non-confidential data as specified in the SCCCR Data Release Protocol will be processed by SCCCR staff, subject to the confidentiality provisions set forth in DHEC regulations.

H. SEVERABILITY.

If any provision of these regulations or the application thereof to any facility, individual or circumstance shall be held invalid, such invalidity shall not affect the provisions or application of the regulations which can be given effect, and to this end the provisions of the regulations are declared to be severable.