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FLORIDA CANCER DATA SYSTEM

PREFACE

In 1978, the Department of Health and Rehabilitative Services, now known as the Florida Department of Health, contracted with the Sylvester Comprehensive Cancer Center/University of Miami School of Medicine to implement and maintain the Florida Cancer Data System (FCDS). FCDS has been operational and collecting incidence data on cancer cases seen in Florida hospitals on or after January 1, 1981. Ambulatory diagnostic/treatment centers and pathology laboratories began cancer case reporting with patients seen on or after July 1, 1997. Dermatologists began actively reporting cases January 1, 2011. Urologists, Medical Oncologists, and Hematology/Oncologists began reporting patients seen on or after January 1, 2013. Additional specialty physician reporting is expected in the future.

Cancer reporting to FCDS is mandated by Florida statutes. All cancer cases seen in any health facility licensed under Florida Statute Section 395 or Section 408.07 must be reported to FCDS according to Florida Statutes Section 385.202. This includes all hospitals, ambulatory diagnostic and treatment centers, clinical laboratories and physicians' offices.

Currently, FCDS processes over 280,000 cancer case abstracts each year. When these cases are unduplicated, there are approximately 130,000 newly diagnosed incidence cancer cases per year. Currently, the FCDS database contains approximately 3,500,000 cases.

The 2024 edition of the FCDS Data Acquisition Manual (DAM) is compatible with 2024 national consensus standards as disseminated by the North American Association of Cancer Registries and the CDC National Program of Cancer Registries. These standards are created and endorsed by the Center for Disease Control and Prevention/National Program of Cancer Registries (CDC/NPCR), the North American Association of Central Cancer Registries (NAACCR), the National Cancer Institute/Surveillance Epidemiology & End Results Program (NCI/SEER), and the Commission on Cancer/American College of Surgeons (COC/ACoS).

CONFIDENTIALITY

According to Florida Statute 381, Public Health: General Provisions, "Information submitted in reports required by this section is confidential, exempt from the provisions of s.119.07 (1), and is to be made public only when necessary to public health. A report so submitted is not a violation of the confidential relationship between practitioner and patient."

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) became law April 14, 2001. While most organizations had two full years until April 14, 2003 to comply, questions regarding how this new law impacts cancer reporting continues to arise. The North American Association of Central Cancer Registries (NAACCR) has provided materials that address these questions. As you will see, HIPAA regulations only impact current state cancer reporting procedures. Specifically,

HIPAA allows for the reporting of identifiable cancer data to public health entities. Because the Florida Cancer Data System falls under the definition of a public health entity, HIPAA allows your facility to continue to report data to us in compliance with state law. Written informed consent from each cancer patient reported to public health entities is not required under HIPAA; rather hospitals must simply document that reporting has occurred.

FCDS continues to adhere to all Florida Statutes and Department of Health guidelines, and follow strict security measures to assure patient and institutional confidentiality.

IMMUNITY FROM LIABILITY

No institution or individual complying with Florida statutes 385.202, 405.01, 381.0031, and Florida State Administrative Code(may not have latest update) Rules 64D-3.004 and 64D3.034 shall be civilly or criminally liable for divulging information or providing materials to the statewide registry as required by the law.

Please see supporting Federal and State Laws and Administrative Rules.

- Florida State Law: Title XXIX, Chapters - 381.0031, 385.202, 405.01, 405.02, 405.03, 408.07 – Establishment of and Governance of FCDS
- Florida Public Health Rule 64D-3.003, 64D-3.031, 64D-3.034, 64D-3.006 – Specifics and Clarifications of Cancer Reporting in Florida
- Federal Public Law 107-260 – Oct 29, 2002 116 Stat.1743 of the Public Health Service Act – Establishment of CDC NPCR
- HIPAA Privacy Rule 45 CFR 164.512(b) - FCDS is HIPAA-EXEMPT under the HIPAA Privacy Rule 45 CFR 164.512(b) as a Public Health Authority – FCDS under DOH conducts Public Health Activities.

Title XXIX - Chapter 381 - Public Health: General Provisions

381.0031 Report of diseases of public health significance to department.

Title XXIX - Chapter 385 - Chronic Diseases

385.202 Statewide cancer registry

Title XXIX - Chapter 405 - Medical Information Available for Research

405.01 Release of medical information to certain study groups; exemption from liability

405.02 Limitation on publication of released information

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Title XXIX - Chapter 408 - Health Care Administration

408.07 Definitions

Rule 64D-3.003 Notification by Laboratories

Rule 64D-3.006 Reports, Medical Facilities and Freestanding Radiation Therapy Centers

Rule 64D-3.031 Notification by Laboratories

Rule 64D-3.034 Cancer Reporting

PUBLIC LAW 107-260-Oct 29, 2002 116 STAT.1743 - National Program of Cancer Registries

HIPAA Privacy Rule [45 CFR 164.512(b)] - DISCLOSURES FOR PUBLIC HEALTH ACTIVITIES

FLORIDA STATE LAW

Title XXIX

**PUBLIC
HEALTH**

Chapter 381

Public Health: General Provisions

381.0031 Report of diseases of public health significance to department.--

(1) Any practitioner licensed in this state to practice medicine, osteopathic medicine, chiropractic medicine, naturopathy, or veterinary medicine; any hospital licensed under part I of chapter 395; or any laboratory licensed under chapter 483 that diagnoses or suspects the existence of a disease of public health significance shall immediately report the fact to the Department of Health.

(2) Periodically the department shall issue a list of infectious or noninfectious diseases determined by it to be a threat to public health and therefore of significance to public health and shall furnish a copy of the list to the practitioners listed in subsection (1).

(3) Reports required by this section must be in accordance with methods specified by rule of the department.

(4) Information submitted in reports required by this section is confidential, exempt from the provisions of s. [119.07\(1\)](#), and is to be made public only when necessary to public health. A report so submitted is not a violation of the confidential relationship between practitioner and patient.

(5) The department may obtain and inspect copies of medical records, records of laboratory tests, and other medical-related information for reported cases of diseases of public health significance described in subsection (2). The department shall examine the records of a person who has a disease of public health significance only for purposes of preventing and eliminating outbreaks of disease and making epidemiological investigations of reported cases of diseases of public health significance, notwithstanding any other law to the contrary. Health care practitioners, licensed health care facilities, and laboratories shall allow the department to inspect and obtain copies of such medical records and medical-related information, notwithstanding any other law to the contrary. Release of medical records and medical-related information to the department by a health care practitioner, licensed health care facility, or laboratory, or by an authorized employee or agent thereof, does not constitute a violation of the confidentiality of patient records. A health care practitioner, health care facility, or laboratory, or any employee or agent thereof, may not be held liable in any manner for damages and is not subject to criminal penalties for providing patient records to the department as authorized by this section.

(6) The department may adopt rules related to reporting diseases of significance to public health, which must specify the information to be included in the report, who is required to report, the method and time period for reporting, requirements for enforcement, and required follow-up activities by the department which are necessary to protect public health.

This section does not affect s. [384.25](#).

History.--s. 2, ch. 29834, 1955; ss. 19, 35, ch. 69-106; s. 67, ch. 77-147; s. 4, ch. 89-311; s. 2, ch. 90-347; s. 15, ch. 91-297; s. 2, ch. 95-188; s. 184, ch. 96-406; s. 175, ch. 97-101; s. 4, ch. 98-151; s. 252, ch. 98-166; s. 8, ch. 2000-367.

Note.--Former s. 381.231.

385.202 Statewide cancer registry.--

(1) Each facility licensed under chapter 395 and each freestanding radiation therapy center as defined in s. [408.07](#) shall report to the Department of Health such information, specified by the department, by rule, which indicates diagnosis, stage of disease, medical history, laboratory data, tissue diagnosis, and radiation, surgical, or other methods of diagnosis or treatment for each cancer diagnosed or treated by the facility or center. Failure to comply with this requirement may be cause for registration or licensure suspension or revocation.

(2) The department shall establish, or cause to have established, by contract with a recognized medical organization in this state and its affiliated institutions, a statewide cancer registry program to ensure that cancer reports required under this section shall be maintained and available for use in the course of any study for the purpose of reducing morbidity or mortality; and no liability of any kind or character for damages or other relief shall arise or be enforced against any hospital by reason of having provided such information or material to the department.

(3) The department or a contractual designee operating the statewide cancer registry program required by this section shall use or publish said material only for the purpose of advancing medical research or medical education in the interest of reducing morbidity or mortality, except that a summary of such studies may be released for general publication. Information which discloses or could lead to the disclosure of the identity of any person whose condition or treatment has been reported and studied shall be confidential and exempt from the provisions of s. [119.07](#)(1), except that:

(a) Release may be made with the written consent of all persons to whom the information applies;

(b) The department or a contractual designee may contact individuals for the purpose of epidemiologic investigation and monitoring, provided information that is confidential under this section is not further disclosed; or

(c) The department may exchange personal data with any other governmental agency or a contractual designee for the purpose of medical or scientific research, provided such governmental agency or contractual designee shall not further disclose information that is confidential under this section.

(4) Funds appropriated for this section shall be used for establishing, administering, compiling, processing, and providing biometric and statistical analyses to the reporting facilities. Funds may also be used to ensure the quality and accuracy of the information reported and to provide management information to the reporting facilities.

(5) The department may, by rule, classify facilities for purposes of reports made to the cancer registry and specify the content and frequency of the reports. In classifying facilities, the department shall exempt certain facilities from reporting cancer information that was previously reported to the department or retrieved from existing state reports made to the department or the Agency for Health Care Administration. The provisions of this section shall not apply to any facility whose primary function is to provide psychiatric care to its patients.

History.--ss. 2, 3, 4, 9, ch. 78-171; s. 5, ch. 82-213; s. 2, ch. 83-234; s. 96, ch. 86-220; s. 1, ch. 90-6; s. 3, ch. 95-188; s. 201, ch. 96-406; s. 190, ch. 97-101; s. 31, ch. 97-237; s. 24, ch. 99-397.

Note.--Former s. 381.3812.

CONFIDENTIALITY

Title XXIX

Chapter 405

PUBLIC HEALTH Medical Information Available For Research

405.01 Release of medical information to certain study groups; exemption from liability.—

Any person, hospital, assisted living facility, hospice, sanatorium, nursing or rest home or other organization may provide information, interviews, reports, statements, memoranda, or other data relating to the condition and treatment of any person to research groups, governmental health agencies, medical associations and societies, and in-hospital medical staff committees, to be used in the course of any study for the purpose of reducing morbidity or mortality. No liability of any kind or character for damages or other relief shall arise or be enforced against any person or organization by reason of having provided such information or material, or by reason of having released or published the findings and conclusions of such groups to advance medical research and medical education, or by reason of having released or published generally a summary of such studies.

History.--s. 1, ch. 65-533; s. 19, ch. 90-344; s. 27, ch. 95-210.

Title XXIX

Chapter 405

PUBLIC HEALTH Medical Information Available For Research

405.02 Limitation on publication of released information.—

Research groups, governmental health agencies, organized medical associations and societies, and in-hospital medical staff committees shall use or publish said material only for the purpose of advancing medical research or medical education in the interest of reducing morbidity or mortality, except that a summary of such studies may be released by any such group for general publication.

History.--s. 2, ch. 65-533; s. 20, ch. 90-344; s. 244, ch. 96-406.

Title XXIX

Chapter 405

PUBLIC HEALTH Medical Information Available For Research

405.03 Confidentiality.—

In all events, the identity of any person whose condition or treatment has been studied shall be confidential and exempt from the provisions of s. [119.07\(1\)](#).

History.--s. 3, ch. 65-533; s. 21, ch. 90-344; s. 245, ch. 96-406.

408.07 Definitions.—As used in this chapter, with exception of ss. 408.031-408.045, the term:

- (1) "Accepted" means that the agency has found that a report or data submitted by a health care facility or a health care provider contains all schedules and data required by the agency and has been prepared in the format specified by the agency, and otherwise conforms to applicable rule or Florida Hospital Uniform Reporting System manual requirements regarding reports in effect at the time such report was submitted, and the data are mathematical reasonable and accurate.
- (2) "Adjusted admission" means the sum of acute and intensive care admissions divided by the ratio of inpatient revenues generated from acute, intensive, ambulatory, and ancillary patient services to gross revenues. If a hospital reports only subacute admissions, then "adjusted admission" means the sum of subacute admissions divided by the ratio of total inpatient revenues to gross revenues.
- (3) "Agency" means the Agency for Health Care Administration.
- (4) "Alcohol or chemical dependency treatment center" means an organization licensed under chapter 397.
- (5) "Ambulatory care center" means an organization which employs or contracts with licensed health care professionals to provide diagnosis or treatment services predominantly on a walk-in basis and the organization holds itself out as providing care on a walk-in basis. Such an organization is not an ambulatory care center if it is wholly owned and operated by five or fewer health care providers.
- (6) "Ambulatory surgical center" means a facility licensed as an ambulatory surgical center under chapter 395.
- (7) "Audited actual data" means information contained within financial statements examined by an independent, Florida-licensed, certified public accountant in accordance with generally accepted auditing standards, but does not include data within a financial statement about which the certified public accountant does not express an opinion or issues a disclaimer.
- (8) "Birth center" means an organization licensed under s. 383.305.
- (9) "Cardiac catheterization laboratory" means a freestanding facility that employs or contracts with licensed health care professionals to provide diagnostic or therapeutic services for cardiac conditions such as cardiac catheterization or balloon angioplasty.
- (10) "Case mix" means a calculated index for each health care facility or health care provider, based on patient data, reflecting the relative costliness of the mix of cases to that facility or provider compared to a state or national mix of cases.
- (11) "Clinical laboratory" means a facility licensed under s. 483.091, excluding: any hospital laboratory defined under s. 483.041(6); any clinical laboratory operated by the state or a political subdivision of the state; any blood or tissue bank where the majority of revenues are received from the sale of blood or tissue and where blood, plasma, or tissue is procured from volunteer donors and donated, processed, stored, or distributed on a nonprofit basis; and any clinical laboratory which is wholly owned and operated by physicians who are licensed pursuant to chapter 458 or chapter 459 and who practice in the same group practice, and at which no clinical laboratory work is performed for patients referred by any health care provider who is not a member of that same group practice.
- (12) "Comprehensive rehabilitative hospital" or "rehabilitative hospital" means a hospital licensed by the agency as a specialty hospital as defined in s. 395.002; provided that the hospital provides a program of comprehensive medical rehabilitative services and is designed, equipped, organized, and operated solely to deliver comprehensive medical rehabilitative services, and further provided that all licensed beds in the hospital are classified as "comprehensive rehabilitative beds" pursuant to s. 395.003(4), and are not classified as "general beds."

- (13) "Consumer" means any person other than a person who administers health activities, is a member of the governing body of a health care facility, provides health services, has a fiduciary interest in a health facility or other health agency or its affiliated entities, or has a material financial interest in the rendering of health services.
- (14) "Continuing care facility" means a facility licensed under chapter 651.
- (15) "Critical access hospital" means a hospital that meets the definition of "critical access hospital" in s. 1861(mm)(1) of the Social Security Act and that is certified by the Secretary of Health and Human Services as a critical access hospital.
- (16) "Cross-subsidization" means that the revenues from one type of hospital service are sufficiently higher than the costs of providing such service as to offset some of the costs of providing another type of service in the hospital. Cross-subsidization results from the lack of a direct relationship between charges and the costs of providing a particular hospital service or type of service.
- (17) "Deductions from gross revenue" or "deductions from revenue" means reductions from gross revenue resulting from inability to collect payment of charges. For hospitals, such reductions include contractual adjustments; uncompensated care; administrative, courtesy, and policy discounts and adjustments; and other such revenue deductions, but also includes the offset of restricted donations and grants for indigent care.
- (18) "Diagnostic-imaging center" means a freestanding outpatient facility that provides specialized services for the diagnosis of a disease by examination and also provides radiological services. Such a facility is not a diagnostic-imaging center if it is wholly owned and operated by physicians who are licensed pursuant to chapter 458 or chapter 459 and who practice in the same group practice and no diagnostic-imaging work is performed at such facility for patients referred by any health care provider who is not a member of that same group practice.
- (19) "FHURS" means the Florida Hospital Uniform Reporting System developed by the agency.
- (20) "Freestanding" means that a health facility bills and receives revenue, which is not directly subject to the hospital assessment for the Public Medical Assistance Trust Fund as described in s. 395.701.
- (21) "Freestanding radiation therapy center" means a facility where treatment is provided through the use of radiation therapy machines that are registered under s. 404.22 and the provisions of the Florida Administrative Code implementing s. 404.22. Such a facility is not a freestanding radiation therapy center if it is wholly owned and operated by physicians licensed pursuant to chapter 458 or chapter 459 who practice within the specialty of diagnostic or therapeutic radiology.
- (22) "GRAA" means gross revenue per adjusted admission.
- (23) "Gross revenue" means the sum of daily hospital service charges, ambulatory service charges, ancillary service charges, and other operating revenue. Gross revenues do not include contributions, donations, legacies, or bequests made to a hospital without restriction by the donors.
- (24) "Health care facility" means an ambulatory surgical center, a hospice, a nursing home, a hospital, a diagnostic-imaging center, a freestanding or hospital-based therapy center, a clinical laboratory, a home health agency, a cardiac catheterization laboratory, a medical equipment supplier, an alcohol or chemical dependency treatment center, a physical rehabilitation center, a lithotripsy center, an ambulatory care center, a birth center, or a nursing home component licensed under chapter 400 within a continuing care facility licensed under chapter 651.
- (25) "Health care provider" means a health care professional licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 463, chapter 464, chapter 465, chapter 466, part I, part III, part IV, part V, or part X of chapter 468, chapter 483, chapter 484, chapter 486, chapter 490, or chapter 491.
- (26) "Health care purchaser" means an employer in the state, other than a health care facility, health insurer, or health care provider, who provides health care coverage for her or his employees.

Title XXIX
PUBLIC HEALTH

Chapter 408
Health Care Administration

- (27) "Health insurer" means any insurance company authorized to transact health insurance in the state, any insurance company authorized to transact health insurance or casualty insurance in the state that is offering a minimum premium plan or stop-loss coverage for any person or entity providing health care benefits, any self-insurance plan as defined in s. 624.031, any health maintenance organization authorized to transact business in the state pursuant to part I of chapter 641, any prepaid health clinic authorized to transact business in the state pursuant to part II of chapter 641, any multiple-employer welfare arrangement authorized to transact business in the state pursuant to ss. 624.436-624.45, or any fraternal benefit society providing health benefits to its members as authorized pursuant to chapter 632.
- (28) "Home health agency" means an organization licensed under part IV of chapter 400.
- (29) "Hospice" means an organization licensed under part VI of chapter 400.
- (30) "Hospital" means a health care institution licensed by the Agency for Health Care Administration as a hospital under chapter 395.
- (31) "Lithotripsy center" means a freestanding facility that employs or contracts with licensed health care professionals to provide diagnosis or treatment services using electro-hydraulic shock waves.
- (32) "Local health council" means the agency defined in s. 408.033.
- (33) "Market basket index" means the Florida hospital input price index (FHIPI), which is a statewide market basket index used to measure inflation in hospital input prices weighted for the Florida-specific experience which uses multistate regional and state-specific price measures, when available. The index shall be constructed in the same manner as the index employed by the Secretary of the United States Department of Health and Human Services for determining the inflation in hospital input prices for purposes of Medicare reimbursement.
- (34) "Medical equipment supplier" means an organization that provides medical equipment and supplies used by health care providers and health care facilities in the diagnosis or treatment of disease.
- (35) "Net revenue" means gross revenue minus deductions from revenue.
- (36) "New hospital" means a hospital in its initial year of operation as a licensed hospital and does not include any facility, which has been in existence as a licensed hospital, regardless of changes in ownership, for over 1 calendar year.
- (37) "Nursing home" means a facility licensed under s. 400.062 or, for resident level and financial data collection purposes only, any institution licensed under chapter 395 and which has a Medicare or Medicaid certified distinct part used for skilled nursing home care, but does not include a facility licensed under chapter 651.
- (38) "Operating expenses" means total expenses excluding income taxes.
- (39) "Other operating revenue" means all revenue generated from hospital operations other than revenue directly associated with patient care.
- (40) "Physical rehabilitation center" means an organization that employs or contracts with health care professionals licensed under part I or part III of chapter 468 or chapter 486 to provide speech, occupational, or physical therapy services on an outpatient or ambulatory basis.
- (41) "Prospective payment arrangement" means a financial agreement negotiated between a hospital and an insurer, health maintenance organization, preferred provider organization, or other third-party payor which contains, at a minimum, the elements provided for in s. 408.50.

(42) "Rate of return" means the financial indicators used to determine or demonstrate reasonableness of the financial requirements of a hospital. Such indicators shall include, but not be limited to: return on assets, return on equity, total margin, and debt service coverage.

(43) "Rural hospital" means an acute care hospital licensed under chapter 395, having 100 or fewer licensed beds and an emergency room, and which is:

- (a) The sole provider within a county with a population density of no greater than 100 persons per square mile;
- (b) An acute care hospital, in a county with a population density of no greater than 100 persons per square mile, which is at least 30 minutes of travel time, on normally traveled roads under normal traffic conditions, from another acute care hospital within the same county;
- (c) A hospital supported by a tax district or subdistrict whose boundaries encompass a population of 100 persons or fewer per square mile;
- (d) A hospital with a service area that has a population of 100 persons or fewer per square mile. As used in this paragraph, the term "service area" means the fewest number of zip codes that account for 75 percent of the hospital's discharges for the most recent 5-year period, based on information available from the hospital inpatient discharge database in the State Center for Health Statistics at the Agency for Health Care Administration; or
- (e) A hospital designated as a Critical Access Hospital by the Department of Health in accordance with federal regulations and state requirements.

Population densities used in this subsection must be based upon the most recently completed United States census.

(44) "Special study" means a nonrecurring data-gathering and analysis effort designed to aid the agency in meeting its responsibilities pursuant to this chapter.

(45) "Teaching hospital" means any Florida hospital officially affiliated with an accredited Florida medical school which exhibits activity in the area of graduate medical education as reflected by at least seven different graduate medical education programs accredited by the Accreditation Council for Graduate Medical Education or the Council on Postdoctoral Training of the American Osteopathic Association and the presence of 100 or more full-time equivalent resident physicians. The Director of the Agency for Health Care Administration shall be responsible for determining which hospitals meet this definition.

History.--s. 71, ch. 92-33; s. 75, ch. 92-289; s. 13, ch. 93-129; s. 39, ch. 93-217; s. 17, ch. 95-144; s. 38, ch. 97-103; s. 2, ch. 98-14; s. 2, ch. 98-21; s. 14, ch. 98-89; s. 44, ch. 2000-153; s. 28, ch. 2000-163; s. 2, ch. 2000-227. ch. 2003-258; s. 5, ch. 2005-81; s. 77, ch. 2006-197; s. 10, ch. 2006-261.

Rule 64D-3.003

64D-3.003 Notification by Laboratories.

(1) Each laboratory director or designee in charge of a laboratory shall report, or cause to be reported evidence suggestive of or diagnostic of diseases or conditions listed in subsection 64D-3.002(1), F.A.C., from any specimen derived from a human body, or from an animal in the case of rabies or plague testing, to the county health department director or administrator or the State Health Officer or to either of their designated representatives. Such reports shall be made within 72 hours of recognition by telephone, or other electronic means, or in writing, except for certain specified diseases as indicated by a (T), which shall be reported immediately by telephone and followed by a written report. Exceptions to laboratory reporting as defined by this rule are provided for sexually transmitted diseases including AIDS, as indicated in Rule 64D-3.017, F.A.C.

(2) All reports of cancer identified by laboratories licensed under Chapter 483, F.S., shall be submitted to the Florida Cancer Data System within six (6) months of diagnosis.

(3) The State Health Officer shall periodically, but no less than annually, issue a listing of laboratory test results that are to be reported. The July 1999 "Reportable Laboratory Findings," incorporated by reference in this rule, shall be updated to reflect changes in technology and practice and may be obtained from the Department of Health, Bureau of Epidemiology, 4052 Bald Cypress Way, Bin A-12, Tallahassee, Florida 32399-1720.

(4) To allow follow-up of laboratory findings by the local county health department director/administrator or their designee, all specimens submitted for laboratory tests or examinations related to a disease or condition listed in subsection 64D-3.002(1), F.A.C., shall be accompanied by certain identifying information. In addition to the name and date of birth of the person from whom the specimen was obtained; the name, address and telephone number of the processing clinical laboratory; and the diagnostic test(s) performed, specimen type and result, the following information shall be provided:

(a) Address, telephone number, race, sex, and ethnicity of the person from whom the specimen was obtained or, if this is not available,

(b) Name, address and telephone number of the submitting physician, health care provider or other authorized person who submitted the specimen.

(5) The practitioner who first authorizes, orders, requests or submits a specimen shall be responsible for obtaining and providing the information required in (4) above at the time the specimen is sent to or received by the laboratory.

(6) Notification of test results shall be submitted by telephone, or other electronic means, or in writing on a form furnished by the laboratory. Reports shall be made within 72 hours of a test result. Any preliminary telephone communication must be followed up by a written report.

(7) If the laboratory that makes the positive finding received the specimen from another laboratory, the laboratory making the positive finding shall be responsible for reporting such results as defined in subsection 64D-3.003(1), F.A.C.

(8) In addition to the reporting requirements pursuant to subsection 64D-3.003(1), F.A.C., each laboratory that obtains

a human isolate of *Escherichia coli* O157:H7, or *Neisseria meningitidis* or *Haemophilus influenzae* from a sterile site

or *Staphylococcus aureus* with a vancomycin minimum inhibitory concentration (MIC) = or > 8 micrograms per milliliter from any site shall retain a subculture of the isolate on suitable media for at least six months after receipt of the specimen in the laboratory. In lieu of retaining this subculture, the laboratory is permitted to send the subculture to the Florida Department of Health State Central Laboratory, which will maintain a record indicating the date that these subcultures were submitted to the Central Laboratory.

(9) In addition to the reporting requirements pursuant to subsection 64D-3.003(1), F.A.C., each laboratory that makes a finding, or suggestive finding, of malaria or cyclospora parasites in a specimen of a patient shall retain a stained permanent slide for at least six months after receipt of the specimen in the laboratory. In lieu of retaining the slide(s), the laboratory may send such slide(s) to the State of Florida Department of Health Central Laboratory, which will maintain a record indicating the date that these specimens were submitted to the Central Laboratory.

(10) Each laboratory licensed to perform tests for any reportable disease or condition shall make its records for such diseases or conditions available for on-site inspection by the department or its authorized representatives.

(11) Persons submitting specimens for reportable laboratory tests to the Florida Department of Health, pursuant to subsection 64D-3.003(4), F.A.C., are required to supply the laboratories with sufficient information to comply with the provisions of this section.

Specific Authority 381.0011(13), 381.003(2), 381.0031(6), 384.33 FS. Law Implemented 381.0011, 381.003, 381.0031, 384.25 FS. History—New 12-29-77, Amended 6-7-82, Formerly 10D-3.66, Amended 2-26-92, 7-21-96, Formerly 10D-3.066, Amended 11-2-98, 7-5-99, 6-4-00, 6-9-03. *Repealed* 11-20-06...

Editorial Note: See 64D-3.031

Rule 64D-3.031

64D-3.031 Notification by Laboratories.

(1) Each person or designee who is in charge of a public, federal, private, military or hospital laboratory responsible for receiving the initial order to perform serologic, immunologic, microscopic, biochemical, molecular or cultural tests on specimens derived from a human body or an animal or for collecting the specimen shall report or cause to be reported any laboratory test suggestive of or diagnostic of diseases or conditions listed in the Table of Notifiable Diseases or Conditions, Rule 64D-3.029, F.A.C. per this rule.

(2) Receipt of a laboratory test order requesting the identification of reportable agents shall be considered by the laboratory as an indication of suspected diagnosis. However, laboratories need only to report suspected cases if indicated in the “suspect immediately” column under laboratories in the Table of Notifiable Diseases or Conditions, Rule 64D-3.029, F.A.C.

(3) To allow follow-up of laboratory findings suggestive of or diagnostic of diseases or conditions in the Table of Notifiable Diseases or Conditions, the form upon which the information will be reported shall be furnished by the laboratory that includes the following information:

(a) The Patient’s:

1. First and last name, including middle initial;
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2. Address including street city, state and zip code;
3. Phone number, including area code;
4. Date of birth;
5. Sex;
6. Race;
7. Ethnicity (specify if of Hispanic descent or not of Hispanic descent);
8. Pregnancy status if applicable;
9. Social Security number;

(b) The Laboratory

1. Name, address and telephone number of laboratory performing test;
2. Type of specimen (for example stool, urine, blood, mucus, etc.);
3. Date of specimen collection;
4. Site (for example cervix, eye, etc., if applicable);
5. Date of report;
6. Type of tests performed and results, including reference range, titer when quantitative procedures are performed, and including all available results on speciating, grouping or typing of organisms;
7. Submitting provider’s name, address including street, city, zip code and telephone number, including area code.

(4) Laboratories located out of state, licensed under Part 1, Chapter 483, F.S., who collect specimens in Florida or who receive the initial order for testing from a practitioner, blood bank, plasmapheresis center or other health care provider located in Florida, shall report in the same way as if the findings had been made by a laboratory located in Florida.

(5) Upon the Department’s implementation of its Electronic Laboratory Reporting System (ELR) for laboratory findings suggestive of or diagnostic of diseases or conditions, reports will be submitted electronically to the Department using Health Level Seven (HL7)

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version 2.3.1 format. The CDC Implementation Guide for Transmission of Laboratory-Based Reporting of Public Health Information using version 2.3.1 of the Health Level Seven (HL7) Standard Protocol, incorporated by reference, is available at the Department of Health, ELR Project, 4052 Bald Cypress Way, Bin A-12, Tallahassee, Florida 32399-1715.

(a) The Department’s ELR System shall include:

1. The initial contact with the reporting laboratory;
2. A content review and testing of the laboratories’ HL7 transmissions; and

Rule 64D-3.031

64D-3.031 Notification by Laboratories.

3. The transition from testing to production for the HL7 laboratory transmissions.

(b) The Department and laboratory will agree on a date of implementation

(c) Laboratories reporting electronically through ELR and the Department shall agree to a date that the transmission of findings suggestive of or diagnostic of diseases or conditions listed in the Table of Notifiable Disease or Conditions, Rule 64D-3.029 F.A.C., electronically in HL7 version 2.3.1 format to the Department is acceptable and considered good faith reporting and the laboratory will no longer be required to submit paper forms pursuant to 64D-3.031(3) F.A.C.

(d) The Department shall ensure access to the laboratory findings suggestive of or diagnostic of disease or conditions listed in the Table of Notifiable Diseases or Conditions to authorized representatives of the department.

(6) This section does not prohibit a laboratory from making a report by telephone, in writing, or facsimile to the county health department having jurisdiction for the area in which the office of the submitting practitioner or the patient's residence is located.

(7) In order to study disease incidence, each laboratory licensed to perform tests for any notifiable disease or condition shall report the test volume for each related diagnostic test performed for the notifiable diseases listed in 64D-3.029, F.A.C.

(a) Reports are to be filed annually on or before April 1 of each year to the Department electronically in a format agreed upon by the department and the laboratory with the following information:

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(1) Type of diagnostic test;

(2) Patient's date of birth;

(3) Patient's sex;

(4) Race;

(5) Ethnicity (specify if of Hispanic descent or not of Hispanic descent).

(8) Each laboratory licensed to perform tests for any reportable disease or condition shall make its records for such diseases or conditions available for on-site inspection by the Department or its authorized representatives.

Specific Authority 381.0011(7), 381.0011(13), 381.003(2), 381.0031(5), 381.0031(6), 384.33, 392.66 FS. Law Implemented 381.0011, 381.003, 381.0031, 384.25(1), 392.53(1) FS. History—New _____.

Editorial Note: History—New 12-29-77, Amended 6-7-82, Formerly 10D-3.66, Amended 2-26-92, 7-21-96, Formerly 10D-3.066, Amended 11-2-98, 7-5-99, 6-4-00, 6-9-03, 9-1-05, Formerly 64D3.003, 64D-3.017 & 64D-3.023

64D-3.034 Cancer Reporting.

64D-3.034 Cancer Reporting

(1) Reporting Requirements:

- a. Each facility and laboratory licensed under Chapters 395 and 483, and Section 408.07(20), F.S., respectively and practitioners licensed under Chapter 458, 459, 464, F.S., are required to report to the Florida Cancer Data System as required by Section 385.202, F.S., within six (6) months of each diagnosis and within six (6) months of the date of each treatment.
- b. Each facility shall submit each cancer case report electronically. Those facilities with fewer than 35 cancers annually requiring abstracting may submit paper copies or portions of the medical record, provided the copies contain all of the required information as per (1)(c).
- c. The data items, coding schemes, definitions, record layouts, and reporting procedures are to follow the guidance provided in the Florida Cancer Data System Data Acquisition Manual (2005, or current edition), incorporated by reference, available at <http://www.fcds.med.miami.edu/inc/downloads.shtml>.

(2) Notwithstanding (1), each facility, center, and laboratory that reports cancer cases to the Florida Cancer Data System shall make its records available for on-site review by the department or its authorized representatives.

Specific Authority 381.0011(13), 381.003(2), 381.0031(6), 384.33, 385.202(5), 392.66 FS. Law Implemented 381.0011, 381.003, 381.0031, 384.25, 385.202, 392.53 FS. History—New

Editorial Note: History—Formerly 10D-3.77, 10D-3.077, and 64D-3.006 (3) (5)...

64D-3.006

64D-3.006 Reports, Medical Facilities and Freestanding Radiation Therapy Centers.

(1) The chief administrative officer of each civilian facility licensed under Chapter 395, F.S., and freestanding radiation therapy centers, as defined in Section 408.07, F.S., shall (and the United States military and Veterans Administration hospitals are requested to) appoint an individual from the staff, hereinafter referred to as “reporting officer,” who shall be responsible for reporting cases or suspect cases of diseases on the notifiable disease list in persons admitted to, attended to, or residing in the facility (cf. Notification by Laboratories, Rule 64D-3.003, F.A.C.).

(2) Reporting of a case or suspected case of notifiable disease or condition by a facility or center fulfills the requirements of the licensed practitioner to report; however, it is the responsibility of the practitioner to ensure that the report is made as stipulated in Rule 64D-3.002, F.A.C. Reports shall be made within 72 hours of diagnosis. Special provisions for reporting sexually transmissible diseases, including HIV infection, are found in Rule 64D-3.016, F.A.C., and for cancer, in subsection 64D-3.006(3), F.A.C.

(3) Reporting of cancer cases by a licensed practitioner, a hospital facility licensed under Chapter 395, F.S., and freestanding radiation therapy centers, as defined in Section 408.07, F.S., to the Florida Cancer Data System as required by Section 385.202, F.S., shall be accomplished within six (6) months of the date of each diagnosis and within six (6) months of the date of each treatment.

(4) Florida Cancer Data System staff will provide each freestanding ambulatory surgical center with an annual list of cancer cases for which reports are required and allow three (3) months from the date of notification for submission of reports to the Florida Cancer Data System for each case on the list. This annual list will be generated by comparing the ambulatory patient data maintained by the Agency for Health Care Administration with the Florida Data System file for each calendar year. This comparison will be made each year after the Florida Cancer Data System file for each year is complete, including all hospital and pathology laboratory data expected for that year. The list sent to each freestanding ambulatory surgical center will contain only those records from the Agency for Health Care Administration ambulatory patient dataset or from cancer case data received from ambulatory centers that cannot be matched with any previously reported case.

(5) For reportable cancer cases, each family licensed under chapter 395, F.S., and each freestanding radiation therapy center as defined in Section 408.07, F.S., shall electronically submit to the Florida Cancer Data System all available data items as specified in the Data Acquisition Manual and Confidential Abstract Report. Those facilities and centers with fewer than thirty-five (35) cancer cases annually requiring abstracting may submit to FCDS paper copies of portions of the case record that include all available information that is needed for abstracting by FCDS staff. The coding schemes, record layouts, and definitions for these items are those issued by the Florida Cancer Data System in its Data Acquisition Manual and Confidential Abstract Report, DOH Form 2029, dated July 1997, incorporated herein by reference. These documents are available from the Florida Department of Health, Bureau of Epidemiology, 4052 Bald Cypress Way, Bin A-12, Tallahassee, Florida 32399-1720.

Specific Authority 381.0011(13), 381.003(2), 381.0031(6), 384.33, 385.202(5), 392.66 FS. Law Implemented 381.0011, 381.003, 381.0031, 384.25, 385.202, 392.53 FS. History—New 12-29-77, Amended 6-7-82, Formerly 10D-3.77, Amended 2-26-92, 7-21-96, Formerly 10D-3.077, Amended 11-2-98, 7-5-99, 6-4-00.

PUBLIC LAW 107-260—OCT. 29, 2002 116 STAT. 1743

Public Law 107-260

107th Congress

An Act to amend the Public Health Service Act to provide for the collection of data on benign brain-related tumor through the national program of cancer registries.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Benign Brain Tumor Cancer Registries Amendment Act”.

SEC. 2. NATIONAL PROGRAM OF CANCER REGISTRIES; BENIGN BRAIN-RELATED TUMORS AS ADDITIONAL CATEGORY OF DATA COLLECTED.

- (a) In GENERAL—Section 399B of the Public Health Service Act (42 U.S.C. 280e), as redesignated by section 502 (2) (A) of Public Law

106-310 (114 Stat. 1115), is amended in subsection (a)—

- (1) by redesignating paragraphs (1) through (5) as subparagraphs (A) through (3), respectively, and indenting appropriately;

- (2) by striking “(a) IN GENERAL—The Secretary” and inserting the following:

- (a) IN GENERAL—

“(1) STATEWIDE CANCER REGISTRIES—The Secretary”;

- (3) in the matter preceding subparagraph (A) (as so redesignated). By striking “population-based” and all that follows through “data” and inserting the following: “population-based, statewide registries to collect, for each condition specified in paragraph (2)(A), data”; and

- (4) by adding at the end the following:

“(2) CANCER; BENIGN BRAIN-RELATED TUMORS—

“(A) IN GENERAL—For purposes of paragraph (1), the conditions referred to in this paragraph are the following:

“(i) Each form of in-situ and invasive cancer with the exception of basal cell and squamous cell carcinoma of the skin), including malignant brain-related tumors.

“(ii) Benign brain-related tumors

“(B) BRAIN-RELATED TUMOR—For purposes of subparagraph (A):

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“(i) The term ‘brain-related tumor’ means a listed primary tumor (whether malignant or benign) occurring in any of the following sites:’

“(I) The brain, meninges, spinal cord, cauda equina, a cranial nerve or nerves or any other part of the central nervous system.

“(II) The pituitary gland, pineal gland, or craniopharyngeal duct.

“(ii) The term ‘listed’, with respect to a primary tumor, means a primary tumor that is listed in the International Classification of Diseases for Oncology (commonly referred to as the ICD-O).

“(iii) The term ‘International Classification of Diseases for Oncology’ means a classification system that includes topography (site) information and histology (cell type information) developed by the World Health Organization, in collaboration with international centers, to promote international comparability in the collection, classification, processing and presentation of cancer statistics. The ICDO system is a supplement to the International Statistical Classification of Diseases and Related Health Problems (commonly known as the ICD) and is the standard coding system used by cancer registries worldwide. Such term includes any modification made to such system for purposes of the United States. Such term further includes any published classification system that is internationally recognized as a successor to the classification system referred to in the first sentence of this clause.

“(C) STATEWIDE CANCER REGISTRY—References in this section to cancer registries shall be considered to be references to registries described in this subsection.”

- (b) APPLICABILITY—The amendments made by subsection (a) apply to grants under section 399B of the Public Health Service Act for fiscal year 2002 and subsequent fiscal years, except that, in the case of a State that received such a grant for fiscal year 2000, the Secretary of Health and Human Services may delay the applicability of such amendments to the State for not more than 12 months if the Secretary determines that compliance with such amendments requires the enactment of a statute by the State or the issuance of State regulations.

Approved October 29, 2002.

LEGISLATIVE HISTORY—s. 2558:
Congressional record, Vol. 148 (2002):
Aug. 1. considered and passed Senate.
Oct 10. considered and passed House.

DISCLOSURES FOR PUBLIC HEALTH ACTIVITIES
[45 CFR 164.512(b)]

Background

The HIPAA Privacy Rule recognizes the legitimate need for public health authorities and others responsible for ensuring public health and safety to have access to protected health information to carry out their public health mission. The Rule also recognizes that public health reports made by covered entities are an important means of identifying threats to the health and safety of the public at large, as well as individuals. Accordingly, the Rule permits covered entities to disclose protected health information without authorization for specified public health purposes.

How the Rule Works

General Public Health Activities. The Privacy Rule permits covered entities to disclose protected health information, without authorization, to public health authorities who are legally authorized to receive such reports for the purpose of preventing or controlling disease, injury, or disability. This would include, for example, the reporting of a disease or injury; reporting vital events, such as births or deaths; and conducting public health surveillance, investigations, or interventions. See 45 CFR 164.512(b)(1)(i). Also, covered entities may, at the direction of a public health authority, disclose protected health information to a foreign government agency that is acting in collaboration with a public health authority. See 45 CFR 164.512(b)(1)(i). Covered entities who are also a public health authority may use, as well as disclose, protected health information for these public health purposes. See 45 CFR 164.512(b)(2).

A “public health authority” is an agency or authority of the United States government, a State, a territory, a political subdivision of a State or territory, or Indian tribe that is responsible for public health matters as part of its official mandate, as well as a person or entity acting under a grant of authority from, or under a contract with, a public health agency. See 45 CFR 164.501. Examples of a public health authority include State and local health departments, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention, and the Occupational Safety and Health Administration (OSHA).

Generally, covered entities are required reasonably to limit the protected health information disclosed for public health purposes to the minimum amount necessary to accomplish the public health purpose. However, covered entities are not required to make a minimum necessary determination for public health disclosures that are made pursuant to an individual’s authorization, or for disclosures that are required by other law. See 45 CFR 164.502(b). For disclosures to a public health authority, covered entities may reasonably rely on a minimum necessary determination made by the public health authority in requesting the protected health information. See 45 CFR 164.514(d)(3)(iii)(A). For routine and recurring public health disclosures, covered entities may develop standard protocols, as part of their minimum necessary policies and procedures, that address the types and amount of protected health information that may be disclosed for such purposes. See 45 CFR 164.514(d)(3)(i).

Other Public Health Activities. The Privacy Rule recognizes the important role that persons or entities other than public health authorities play in certain essential public health activities. Accordingly, the Rule permits covered entities to disclose protected health information, without authorization, to such persons or entities for the public health activities discussed below.

- **Child abuse or neglect.** Covered entities may disclose protected health information to report known or suspected child abuse or neglect, if the report is made to a public health authority or other

appropriate government authority that is authorized by law to receive such reports. For instance, the social services department of a local government might have legal authority to receive reports of child abuse or neglect, in which case, the Privacy Rule would permit a covered entity to report such cases to that authority without obtaining individual authorization. Likewise, a covered entity could report such cases to the police department when the police department is authorized by law to receive such reports. See 45 CFR 164.512(b)(1)(ii). See also 45 CFR 512(c) for information regarding disclosures about adult victims of abuse, neglect, or domestic violence.

- Quality, safety or effectiveness of a product or activity regulated by the FDA. Covered entities may disclose protected health information to a person subject to FDA jurisdiction, for public health purposes related to the quality, safety or effectiveness of an FDA-regulated product or activity for which that person has responsibility. Examples of purposes or activities for which such disclosures may be made include, but are not limited to:
 - Collecting or reporting adverse events (including similar reports regarding food and dietary supplements), product defects or problems (including problems regarding use or labeling), or biological product deviations;
 - Tracking FDA-regulated products;
 - Enabling product recalls, repairs, replacement or lookback (which includes locating and notifying individuals who received recalled or withdrawn products or products that are the subject of lookback); and
 - Conducting post-marketing surveillance.

See 45 CFR 164.512(b)(1)(iii). The “person” subject to the jurisdiction of the FDA does not have to be a specific individual. Rather, it can be an individual or an entity, such as a partnership, corporation, or association. Covered entities may identify the party or parties responsible for an FDA-regulated product from the product label, from written material that accompanies the product (known as labeling), or from sources of labeling, such as the Physician’s Desk Reference.

- Persons at risk of contracting or spreading a disease. A covered entity may disclose protected health information to a person who is at risk of contracting or spreading a disease or condition if other law authorizes the covered entity to notify such individuals as necessary to carry out public health interventions or investigations. For example, a covered health care provider may disclose protected health information as needed to notify a person that (s)he has been exposed to a communicable disease if the covered entity is legally authorized to do so to prevent or control the spread of the disease. See 45 CFR 164.512(b)(1)(iv).
- Workplace medical surveillance. A covered health care provider who provides a health care service to an individual at the request of the individual’s employer, or provides the service in the capacity of a member of the employer’s workforce, may disclose the individual’s protected health information to the employer for the purposes of workplace medical surveillance or the evaluation of work-related illness and injuries to the extent the employer needs that information to comply with OSHA, the Mine Safety and Health Administration (MSHA), or the requirements of State laws having a similar purpose. The information disclosed must be limited to the provider’s findings regarding such medical surveillance or work-related illness or injury. The covered health care provider must provide the individual with written notice that the information will be disclosed to his or her employer (or the notice may be posted at the worksite if that is where the service is provided). See 45 CFR 164.512(b)(1)(v).