

The Florida Cancer Data System (FCDS) is charged with maintaining a high-quality database of useable, timely, complete, and accurate clinical data for every reportable case of cancer diagnosed or treated in Florida. The FCDS Data Acquisition Manual (FCDS DAM) includes guidelines and instructions for case identification, case eligibility (which cases must be reported to FCDS), abstracting and coding, and multiple appendices referenced throughout the manual. The manual only addresses data items that are required by FCDS, the Florida Department of Health (DOH), and the Centers for Disease Control and Prevention (CDC) National Program of Cancer Registries (NPCR) to support Florida's statewide, population-based cancer registry. These guidelines have been established to achieve and maintain this objective.

All reporting facilities, regardless of affiliation, must adhere to the following guidelines for cancer data reporting. The instructions and codes in this manual take precedence over all previous instructions and manuals.

It is the responsibility of the reporting facility and the facility abstractor to be familiar with and understand the content of the most current version of the FCDS Data Acquisition Manual and to update it upon receipt of any changes from FCDS. This responsibility exists regardless of whether case abstraction and reporting are being performed by an employee of the reporting facility or through some contractual arrangement with an independent abstracting agency or individual within or outside the state of Florida.

CONFIDENTIALITY - Patient information, personal health information, medical records, and healthcare facility data are all confidential and continue to be a concern about cancer and other disease reporting. Please do not fax or email patient information to FCDS. Also, please be careful when discussing cases over the phone with FCDS staff.

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 1070260 – 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.

A. CASE ELIGIBILITY

Florida facilities are legislatively mandated to report any case of cancer meeting the Florida “cancer” definition, regardless of facility or network affiliation or Class of Case. FCDS requires complete abstracting of additional select neoplasms that the Commission on Cancer/American College of Surgeons does not require, such as benign and borderline brain and central nervous system tumors and certain reproductive site cancers.

If your facility participates in the diagnosis, staging, treatment, or continuing care of a patient during the first course of treatment, progression of disease, or disease recurrence, the case must be reported to FCDS.

If any diagnostic, staging, or other evaluative studies are conducted at your facility (diagnostic imaging, re-biopsy, sentinel node biopsy, surgical resection, other staging or treatment, etc.), then your facility must report the case regardless of the Class of Case. Please review all standard cancer diagnosis codes and procedure codes.

Patients whose First Course of Therapy is “Active Surveillance” or “Watchful Waiting” must be reported as their cancer has been diagnosed but will not be treated until or unless the patient has clinical symptoms, imaging, or laboratory evidence of disease progression. This treatment decision is usually for non-aggressive neoplasms and very early-stage cancers that do not meet the standard threshold for active treatment.

Please be cautious when distinguishing the two very different types of cases of Active Surveillance/Watchful Waiting versus No Treatment. No-treatment cases are usually patients with advanced or untreatable diseases or when the patient has other comorbid factors that prohibit cancer treatment. Active Surveillance cases are often low-grade, slow-growing, early-stage neoplasms that may not require intervention at this time.

“No Treatment” is a different treatment decision than “Watchful Waiting” or “Active Surveillance” and should not be coded as ‘treatment given’ using Treatment Status = 2 (Active Surveillance/Watchful Wait).

“Consult-Only” and “Second Opinion” cases may be an exception to reporting depending upon what took place at the facility to confirm a diagnosis or establish or confirm the validity of a proposed treatment plan. Some second opinions/consultations include ordering new laboratory and/or imaging tests. Anytime your facility orders a new test – the case is no longer a consult only...even if that is the only test done. Other second opinions/consults include only a review of tests already performed elsewhere.

A proper “consult only” or “second opinion” case is any case where the facility provides a second opinion or expert panel review of earlier performed diagnostic or workup studies without additional testing at your facility. A second opinion may include re-reading pathology slides or re-reading diagnostic imaging studies.

If your facility does not perform additional testing, the case is not reportable to FCDS. However, if your facility performs any additional testing for this or any other cancer and the patient has evidence of active disease or is undergoing treatment for cancer at any facility, **the case is reportable to FCDS.**

Exception 1: Patients undergoing planned first course or later course long-term hormonal treatment for breast or prostate cancer that continues to demonstrate no active neoplasm *should not be reported*. Any other type of cancer or patient with active malignancy (any evidence of disease) must be reported.

Patients seen in an ambulatory care setting for port-a-cath placement only where no chemotherapeutic or anti-neoplastic agent(s) is injected into the port *do not need to be reported UNLESS they have active disease*. Patients with active disease whether being treated or not are reportable to FCDS.

Please note that many types of drugs may be administered through a port-a-cath delivery system. The medical record and medication flow sheets **MUST** be reviewed. For the case to meet this criterion, they cannot include administering any anti-neoplastic agent(s) through the port-a-cath. The case must be reported if any anti-neoplastic agent is administered at the reporting facility, either as an outpatient or inpatient.

PI Rads, BI Rads, LI Rads alone are not reportable to FCDS. PI Rads, BI Rads, LI Rads confirmed with biopsy or physician statement are reportable to FCDS. The Date of Diagnosis is the date of the positive biopsy or definitive statement from physician. This FCDS rule was updated to align with CoC.

1. Reportable Patients

All patients first seen at the reporting facility on or after January 1, 1981 (July 1, 1997, for free-standing/ambulatory surgery centers and freestanding radiation therapy centers), whether as an inpatient, outpatient, or in an ambulatory care setting, who meet one or more of the below criteria must be reported to FCDS. Any patient with a coded diagnosis of cancer but not reported may be included in Casefinding Audits for review to ensure the case is truly not reportable. This may require a second complete review of the chart.

IMPORTANT NOTE: The start date for your registry for the state of Florida is 1/1/1981, or the day your facility opened. It is not the exact start date that the Commission on Cancer assigns your facility. All reporting began in 1981. FCDS has cancer cases from your facility going back to 1981. If you submit a new cancer for a person already registered by your facility with FCDS, you must use the same Accession Number assigned to that person before your CoC Start Date. The older Accession Numbers are in the Alphabetical Listing Report of ALL Cases

Reported to FCDS by your Facility. This ‘alpha list’ runs interactively and is the most up-to-date listing of all cases ever reported by your facility. It can be run in Accession Number Order or Alphabetical Order in IDEA.

Reportable Patients

- a) all patients with an active, malignant neoplasm (in-situ or invasive), whether being treated or not (includes “active surveillance” cases) – with limited exceptions such as CIN III and PIN III (see Reportable Tumors)
- b) all patients with an active, benign, or borderline brain or central nervous system (CNS) tumor, diagnosed on or after 01/01/2004, whether being treated or not (includes active surveillance and never treated)
- c) all patients undergoing prophylactic, neoadjuvant, or adjuvant therapy for malignancy,
- d) all patients undergoing ‘active surveillance’ or ‘watch and wait’ approach to therapy,
- e) patients seen as in-patient, out-patient, or in-clinic are reportable,
- f) all patients diagnosed at autopsy,
- g) all historical cases that meet FCDS reportable guidelines.

2. Not Reportable Patients

- a) patients in complete remission with no evidence of cancer (NED). See revised Note below regarding chronic neoplasms,
- b) patients with no evidence of cancer and not receiving prophylactic or adjuvant therapy,
- c) patients seen only in consultation to provide a second opinion to confirm a diagnosis or a treatment plan (no additional testing can be performed at your facility or the case is reportable),
- d) patients first seen at the reporting facility before January 1, 1981 (July 1, 1997, for free-standing centers) and returning after that date for treatment of the same primary malignant neoplasm,
- e) patients who receive transient care to avoid interrupting a course of therapy started elsewhere.

Revised Note: Patients with neoplastic conditions such as chronic leukemia, myelodysplastic syndromes, and myeloproliferative diseases, or other lymphoid/myeloid neoplasms designated as ‘chronic’ may achieve a state of clinical remission. These patients in remission, with no active cancer, are not reportable to FCDS.

3. Reportable Neoplasms

Determination of whether a given primary neoplasm is reportable is made by reference to the histology and behavior codes of the *International Classification of Diseases for Oncology, 3rd ed.*, including approved updates and errata published by WHO and supported by NAACCR for ICD-O-3.

FCDS requires that all neoplasms with behavior of /2 (in-situ) or /3 (malignant) be reported to FCDS with minor exclusions, including CIN III and PIN III or carcinoma in situ of the cervix or prostate.

Additionally, FCDS requires reporting all benign, borderline, and malignant tumors of the Brain, Central Nervous System, Cranial Nerves, Intracranial Glands, Meninges, and Peripheral Nerve Tumors.

- a) **In Situ and Invasive Cancers** - FCDS includes all primary malignancies - in situ and/or invasive. Therefore, any cancer with an ICD-O behavior code of /2 (in situ) or /3 (malignant) is reportable to FCDS (**except** carcinoma in situ of the cervix, carcinoma in situ of the prostate, CIN III, and PIN III). Cancers with benign or borderline behavior are discussed elsewhere in this section. If a tumor with an ICD-O behavior code of /0 or /1 is determined to be in situ or invasive by how it behaves (in a malignant fashion) or by a pathologist, the case is reportable.
 - i. **Anal Intraepithelial Neoplasia (AIN III)** is reportable to FCDS and should be included in casefinding activities. This non-invasive neoplasm of the anus or anal canal (C21.0-C21.1) is not the same as the SCC of perianal skin (C44.5). It is important to distinguish between true anal cancers and skin of anus neoplasms. Neoplasms of the skin of anus (perianal skin) are not reportable, even if they extend into the anal canal. **AIN III** of the perianal skin is not reportable to FCDS.

- ii. **Penile Intraepithelial Neoplasia Grade III (PeIN III)** is reportable to FCDS and should be included in casefinding activities.
- iii. **Vulvar Intraepithelial Neoplasia Grade III (VIN III)** is reportable to FCDS and should be included in casefinding activities.
- iv. **Vaginal Intraepithelial Neoplasia Grade III (VAIN III)** is reportable to FCDS and should be included in casefinding activities.
- v. **Lobular Intraepithelial Neoplasia Grade III (LIN III) breast C500-C509**
- vi. The CoC does not require Lobular Carcinoma In-Situ (LCIS) to be abstracted or reported to NCDB. **However, LCIS is reportable to FCDS and all central cancer registries nationwide.**
- vii. **(Pancreatic Intraepithelial Neoplasia (PanIN III)** is reportable to FCDS (histology 8148/2) and should be included in casefinding activities.
- viii. ***Glandular Intraepithelial Neoplasia, Grade III/High Grade Glandular Dysplasia** is reportable as adenocarcinoma in situ of the esophagus with histology code 8148/2.
- ix. **Glandular Intraepithelial Neoplasia, Grade III/High Grade Glandular Dysplasia of other colorectal sites are not reportable unless the pathologist specifically states the tumor is ‘in-situ’ or ‘non-invasive’ or your Cancer Committee has agreed on this.**
- x. **Specific Neoplasms with High Grade Dysplasia in Some Gastrointestinal Sites (C160-C166, C168-C169, C170-C173, C178-C179, C181)** are reportable as of 1/1/2022 (2022 List Below)
- xi. **Non-invasive follicular thyroid neoplasm with papillary like nuclear features (NIFTP) is a low-grade tumor of the thyroid gland and is no longer reportable.**
- xii. **Post Transplant Lymphoproliferative Disorder (PTLD) 9971/1 is reportable as 9971/3 as of 01/01/2025**

***Note 1:** AJCC TNM Manual, 8th edition states for Esophageal Cancers: “High grade dysplasia includes all non-invasive neoplastic epithelia that was formerly called carcinoma in situ, a diagnosis that is no longer used for columnar mucosae anywhere in the gastrointestinal tract.” Therefore, all high grade/severe dysplasia of esophagus are reportable as carcinoma in situ.

***Note 2:** AJCC TNM Manual, 8th edition states for Colon Cancers: “The terms ‘high grade dysplasia’ and ‘severe dysplasia’ may be used as synonymous for in situ adenocarcinoma and in situ carcinoma. These cases should be assigned a pTis.” It is necessary to contact your pathologist and/or cancer committee to determine if s/he applies this definition to all colon cancers. If so, high grade/severe dysplasia of any colon site is reportable as adenocarcinoma in situ (8140/2).

- b) **Specified malignant neoplasms of the skin are reportable conditions:** Kaposi sarcoma, malignant melanoma, in-situ melanoma, early melanoma, evolving melanoma, Merkel cell carcinoma, sebaceous adenocarcinoma, sweat gland adenocarcinoma, mycosis fungoides and T-cell or B-cell lymphoma of skin.
- c) **Dermatofibrosarcoma protuberans is no longer reportable to FCDS as of 1/1/2021.**

- d) **Carcinoid Tumor of Appendix Diagnosis Date 1/1/2015 forward is a Reportable Malignancy.**
- e) **8323/3 – clear cell papillary renal cell carcinoma of the kidney has been reclassified as an ISUP Grade 1 (low-grade neoplasm), which is not malignant. However, this cancer is still reportable in the United States using the 8323/3 malignant clear cell papillary renal cell carcinoma of kidney code.**
- f) **In Utero Diagnosis and Treatment – beginning in 2009, diagnosis and treatment dates for a fetus before birth are to be assigned the actual date of the event. In the past, those dates were set by rule to the date the baby was born. The exact date may be used for cases diagnosed before 2009 and must be used for cases diagnosed on 1/1/2009 and later.**
- g) **Basal and squamous skin cancers in genital sites (histology codes 8000-8110) are reportable.**

Genital Sites include the following anatomic locations:

- | | | |
|--------------------------|---------------------|--------------------------|
| h) C51.0 - C51.1 – Labia | i) C51.2 - Clitoris | j) C51.8 - C51.9 - Vulva |
| k) C52.9 - Vagina | l) C60.0 - Prepuce | m) C60.9 - Penis |
| n) C63.2 - Scrotum | | |

- i) **Clarification for Reporting /2 and /3 Pancreatic Neoplasms** - The classification and reporting of tumors of the pancreas and the pancreato-biliary system can be confusing in part due to the terminology associated with tumors arising within this body system and complicated by the mixed nature of benign, borderline, in-situ and invasive neoplasms and various histologic subtypes associated with pancreato-biliary neoplasms. ALL in-situ and invasive (malignant) neoplasms of the pancreas are reportable to FCDS. However, some reportable neoplasms are associated with terminology that registrars do not recognize as reportable malignancy. FCDS is making every effort to capture these pancreato-biliary primary tumors early in the disease process as endoscopic ultrasound (EUS) and new imaging are improving diagnosis.

Further Clarification has indicated that any reportable tumor must reference one or more of the following terms; neoplasm with high grade dysplasia, noninvasive neoplasm, invasive neoplasm. Tumors, lesions, or abnormalities identified on endoscopic ultrasound associated only with adenoma, low grade dysplasia, moderate grade dysplasia, intermediate grade dysplasia or ‘not otherwise specified’ are classified by WHO as ‘benign’ and are not reportable. Pancreatic tumor (IPMN/IOPN/ITPN/CPEN) seen on endoscopic ultrasound without biopsy is not reportable unless clinically malignant due to metastasis. *Note: some of these patients still get a Whipple Procedure as if they had malignancy. So, treatment is not the defining characteristic of a malignancy in this case.* Please take care when reviewing these cases.

The IPMN Path Description must include at least one of the clarifying descriptive terms below;

- **IPMN, with high grade dysplasia**
- **IPMN, non-invasive**
- **IPMN, in situ**
- **IPMN, associated with invasive carcinoma**
- **IPMN, invasive**

| Reportable | ICD-O-3 | Description |
|------------|---------|--|
| Yes | 8150/3 | Cystic Pancreatic Endocrine Neoplasm, invasive (CPEN) |
| Yes | 8163/2 | Papillary neoplasm, pancreaticobiliary-type, with high grade intraepithelial neoplasia |
| Yes | 8163/3 | Pancreatobiliary-type carcinoma |

SECTION I: GUIDELINES FOR CANCER DATA REPORTING

6

| Reportable | ICD-O-3 | Description |
|------------|---------|--|
| Yes | 8240/3 | Neuroendocrine Tumor, Grade 1 (NET GR1) of the pancreas |
| Yes | 8246/3 | Neuroendocrine Carcinoma of the pancreas |
| Yes | 8249/3 | Neuroendocrine Tumor, Grade 2 (NET GR2) of the pancreas |
| Yes | 8440/3 | Cystadenocarcinoma of the pancreas |
| Yes | 8452/3 | Solid Pseudo-Papillary Neoplasm (SPN) of the pancreas |
| Yes | 8453/2 | Intraductal Papillary Mucinous Neoplasms (IPMN) of the pancreas with high grade dysplasia |
| Yes | 8453/2 | Intraductal Papillary Mucinous Neoplasm (IPMN) of the pancreas, non-invasive |
| Yes | 8453/3 | Intraductal Papillary Mucinous Neoplasm (IPMN) with an associated invasive carcinoma |
| Yes | 8453/3 | Intraductal Papillary Mucinous Carcinoma, invasive |
| Yes | 8470/2 | Mucinous Cystic Neoplasm (MCN) of the pancreas with high-grade dysplasia |
| Yes | 8470/2 | Non-invasive Mucinous Cystic Neoplasm (MCN) of the pancreas with high-grade dysplasia |
| Yes | 8470/2 | Mucinous Cystadenocarcinoma, non-invasive (MCN) |
| Yes | 8470/3 | Mucinous Cystadenocarcinoma of the pancreas |
| Yes | 8470/3 | Mucinous Cystic Neoplasm (MCN) of the pancreas with invasive carcinoma |
| Yes | 8471/3 | Papillary Mucinous Cystadenocarcinoma of the pancreas |
| Yes | 8500/3 | Infiltrating Duct Carcinoma of the pancreas |
| Yes | 8503/2 | Intraductal Oncocytic Papillary Neoplasm (IOPN) of the pancreas with high grade dysplasia |
| Yes | 8503/2 | Intraductal Oncocytic Papillary Neoplasm (IOPN) of the pancreas, noninvasive |
| Yes | 8503/2 | Intraductal Tubule-Papillary Neoplasm (ITPN) of the pancreas with high grade dysplasia |
| Yes | 8503/2 | Intraductal Tubule-Papillary Neoplasm (ITPN) of the pancreas, noninvasive |
| Yes | 8503/3 | Intraductal Tubule-Papillary Neoplasm (ITPN) with invasive carcinoma |
| Yes | 8552/3 | Mixed acinar-ductal carcinoma |
| No | n/a | Histologies with Behavior Code of /0 (benign) |
| No | n/a | Histologies with Behavior Code of /1 (borderline) |
| No | n/a | Serous cystadenomas, solid and cystic papillary (Hamoudi) tumors, lympho-epithelial cysts and simple cysts are all benign and not reportable |

- j) **Benign and Borderline Cancers** - Benign and borderline primary intracranial and central nervous system (CNS) tumors with a behavior code of /0 or /1 in ICD-O-3 are reportable as of 01/01/2004.

Benign/Borderline Cancers diagnosed and/or treated before 1/1/2004 are not reportable to FCDS.

FCDS requires reporting of all benign, borderline, and malignant tumors of the Brain, Central Nervous System, Cranial Nerves, Intracranial Glands, Meninges and Peripheral Nerve Tumors.

CDC published a reference manual in 2004 entitled, “Data Collection of Primary Central Nervous System Tumors.” The manual is free of charge in PDF format on the CDC NPCR Website at <http://www.cdc.gov/npcr/pdf/btr/braintumorguide.pdf>. This document and ICD-O-3 are the primary references when determining case reportability for primary brain and CNS tumors.

- Sphenoid Wing Meningioma is a Reportable Neoplasm beginning with 1/1/2004 diagnoses.
- Glomus Jugulare Tumors, Paraganglioma and Carotid Body Tumors are Reportable beginning with 1/1/2019 diagnoses for primary sites C75.4 and C75.5. Malignant Paraganglioma of Other Sites (C47.9) are reportable for pre-2019 diagnoses. See Solid Tumor Rules for clarification.
- Report pilocytic astrocytoma/juvenile pilocytic astrocytoma as 9421/1 for all CNS sites as of 01/01/2023

SECTION I: GUIDELINES FOR CANCER DATA REPORTING

7

- Report diffuse astrocytoma, MYB- or MYBL1-altered and diffuse low-grade glioma, MAPK pathway-altered (9421/1) as of 01/01/2023
- Report multinodular and vacuolating neuronal tumor (9509/0) as of 01/01/2023
- Report juvenile xanthogranuloma (9749/1) as of 01/01/2023 (C715 is the most common site)
- Neoplasm and tumor are reportable terms for intracranial and CNS because they are listed in ICD-O-3.2 with behavior codes of /0 and /1

Table of Anatomic (Primary) Sites for Reportable Benign and Borderline Tumors of Intra-cranial and Other Central Nervous System Tumors.

| Anatomic Intracranial and CNS Sites for Reportable Benign / Borderline Tumors | | |
|--|--|---------------------|
| General Term | Anatomic Site | ICD-O-3 Code |
| Meninges | Cerebral meninges | C700 |
| | Spinal meninges | C701 |
| | Meninges, NOS | C709 |
| Brain | Cerebrum | C710 |
| | Frontal lobe | C711 |
| | Temporal lobe | C712 |
| | Parietal lobe | C713 |
| | Occipital lobe | C714 |
| | Ventricle, NOS | C715 |
| | Cerebellum, NOS | C716 |
| | Brain stem | C717 |
| | Overlapping lesion of brain | C718 |
| | Brain, NOS | C719 |
| Spinal cord, cranial nerves, and other parts of the central nervous system | Spinal cord | C720 |
| | Cauda equine | C721 |
| | Olfactory nerve | C722 |
| | Optic nerve | C723 |
| | Acoustic nerve | C724 |
| | Cranial nerve, NOS | C725 |
| | Overlapping lesion of brain and central nervous system | C728 |
| | Nervous system, NOS | C729 |
| Pituitary gland, craniopharyngeal duct and pineal gland | Pituitary gland | C751 |
| | Craniopharyngeal duct | C752 |
| | Pineal gland | C753 |

REPORTABLE NEOPLASMS OR RECLASSIFIED TUMORS**Please check individual year ICD-O-3 Update Guidelines for How to Use New Codes****2021 New Reportable Neoplasms/Reclassified Tumors**

- a. Early or evolving melanoma, in situ and invasive – now reportable neoplasms
- b. ALL Gastro-Intestinal Stromal Tumors (GIST) – now classified ‘malignant’
- c. Thymoma Neoplasms – most now classified ‘malignant’ – see Histology/Behavior Codes
- d. Pheochromocytoma and Medullary Paraganglioma of Adrenal Gland

2022 New Reportable Neoplasms/Reclassified Tumors

- a. LAMN – low grade appendiceal mucinous neoplasm (C18.1)
- b. HAMN – high grade appendiceal mucinous neoplasm (C18.1)
- c. Serrated dysplasia, high grade (C160-C166, C168-C169, C170-C173, C178-C179)
- d. Adenomatous polyp, high grade dysplasia (C160-C166, C168-C169, C170-C173, C178-C179)
- e. Intestinal-type adenoma, high grade (C160-C166, C168-C169, C170-C173, C178-C179)
- f. Chondrosarcoma, grade 1
- g. 9 New Histology Codes with Associated New Histology Terms
 - o 8455/3 - Intraductal oncocytic papillary neoplasm with associated invasive carcinoma (C250-C254, C257-C259)
 - o 8483/3 - Adenocarcinoma, HPV-associated C530-C531, C538-C539)
 - o 8484/3 - Adenocarcinoma, HPV-independent, NOS C530-C531, C538-C539)
 - o 8859/3 - Myxoid pleomorphic liposarcoma
 - o 8976/3 - Gastroblastoma (C16.0 – C16.9)
 - o 9111/3 - Mesonephric-like adenocarcinoma
 - o 9366/3 - Round cell sarcoma with EWSR1-non-ETS fusions
 - o 9367/3 - CIC-rearranged sarcoma
 - o 9368/3 - Sarcoma with BCOR genetic alterations

2022 New Codes & New Terms – Do not Use for Cases Diagnosed Prior to 1/1/2022

| ICD-O | Term |
|--------|---|
| 8033/3 | Carcinoma with sarcomatoid component |
| 8044/3 | Small cell carcinoma, large cell variant (C56.9) |
| 8085/3 | Squamous cell carcinoma, HPV-associated |
| 8086/3 | Squamous cell carcinoma, HPV-independent |
| 8086/3 | Squamous cell carcinoma, HPV-independent |
| 8144/2 | Intestinal-type adenoma, high grade (C160 – C166, C168-C169, C170-C173, C178-C179) |
| 8150/3 | Oncocytic neuroendocrine tumor, non-functioning pancreatic |
| 8150/3 | Pleomorphic neuroendocrine tumor, non-functioning pancreatic |
| 8150/3 | Clear cell neuroendocrine tumor, non-functioning pancreatic |
| 8163/2 | Papillary neoplasm, pancreatobiliary type, with high grade intraepithelial neoplasia C241 |
| 8150/3 | Cystic neuroendocrine tumor, non-functioning pancreatic |
| 8174/3 | Hepatocellular carcinoma, steatohepatic |
| 8174/3 | Hepatocellular carcinoma, macrotrabecular massive |
| 8174/3 | Hepatocellular carcinoma, chromophobe |
| 8174/3 | Hepatocellular carcinoma, neutrophil-rich |
| 8174/3 | Hepatocellular carcinoma, lymphocyte-rich |
| 8200/3 | Solid-basaloid adenoid cystic carcinoma |

SECTION I: GUIDELINES FOR CANCER DATA REPORTING

9

| | |
|--------|--|
| 8200/3 | Adenoid cystic carcinoma with high-grade transformation |
| 8210/2 | Adenomatous polyp, high grade dysplasia (C160 – C166, C168-C169, C170-C173, C178-C179) |
| 8211/2 | Tubular adenoma, high grade |
| 8213/2 | Serrated dysplasia, high grade (C160 – C166, C168-C169, C170-C173, C178-C179) |
| 8243/3 | Goblet cell adenocarcinoma |
| 8261/2 | Villous adenoma, high grade |
| 8262/3 | Adenoma-like adenocarcinoma |
| 8263/2 | Tubulovillous adenoma, high grade |
| 8310/3 | Adenocarcinoma, HPV-independent, clear cell type |
| 8455/2 | Intraductal oncocytic papillary neoplasm, NOS (C250-C254, C257-C259) |
| 8455/3 | Intraductal oncocytic papillary neoplasm w/associated invasive carcinoma (C250-C259) |
| 8480/2 | Low grade appendiceal mucinous neoplasm (LAMN) (C181) |
| 8480/2 | High grade appendiceal mucinous neoplasm (HAMN) (C181) |
| 8482/3 | Adenocarcinoma, HPV-independent, gastric type (C530-C531, C538-C539) |
| 8483/2 | Adenocarcinoma in situ, HPV-associated (C530-C531, C538-C539) |
| 8483/3 | Adenocarcinoma, HPV-associated C530-C531, C538-C539) |
| 8484/2 | Adenocarcinoma in situ, HPV-independent, NOS C530-C531, C538-C539) |
| 8484/3 | Adenocarcinoma, HPV-independent, NOS C530-C531, C538-C539) |
| 8500/2 | DCIS of low nuclear grade |
| 8500/2 | DCIS of intermediate nuclear grade |
| 8500/2 | DCIS of high nuclear grade |
| 8503/2 | Ductal carcinoma in situ, papillary |
| 8509/3 | Tall cell carcinoma with reversed polarity |
| 8520/2 | Florid lobular carcinoma in situ |
| 8576/3 | Paneth cell carcinoma |
| 8590/1 | Uterine tumor resembling ovarian sex cord tumor |
| 8804/3 | Proximal or large cell epithelioid sarcoma |
| 8804/3 | Classic epithelioid sarcoma |
| 8811/3 | Epithelioid myxofibrosarcoma |
| 8832/3 | Myxoid dermatofibrosarcoma protuberans |
| 8832/3 | Dermatofibrosarcoma protuberans with myoid differentiation |
| 8832/3 | Plaque-like dermatofibrosarcoma protuberans |
| 8859/3 | Myxoid pleomorphic liposarcoma |
| 8912/3 | Congenital spindle cell rhabdomyosarcoma with VGLL2/NCOA2/CITED2 rearrangements |
| 8912/3 | MYOD1-mutant spindle cell/sclerosing rhabdomyosarcoma |
| 8912/3 | Intraosseous spindle cell rhabdomyosarcoma with TFCP2/NCOA2 rearrangements |
| 8976/3 | Gastroblastoma (C16.0 – C16.9) |
| 8990/3 | NTRK-rearranged spindle cell neoplasm (emerging) |

| | |
|--------|---|
| 9110/3 | Adenocarcinoma, HPV-independent, mesonephric type |
| 9111/3 | Mesonephric-like adenocarcinoma |
| 9120/3 | Post radiation angiosarcoma of the breast |
| 9120/3 | Epithelioid angiosarcoma |
| 9133/3 | Epithelioid hemangioendothelioma with WWTR1-CAMTA1 fusion |
| 9133/3 | Epithelioid hemangioendothelioma with YAP1-TFE3 fusion |
| 9140/3 | Classic indolent Kaposi sarcoma |
| 9140/3 | Endemic African Kaposi sarcoma |
| 9140/3 | AIDS-associated Kaposi sarcoma |
| 9140/3 | Iatrogenic Kaposi sarcoma |
| 9200/1 | Osteoblastoma |
| 9222/3 | Chondrosarcoma, grade 1 |
| 9261/1 | Osteofibrous dysplasia-like adamantinoma |
| 9366/3 | Round cell sarcoma with EWSR1-non-ETS fusions |
| 9367/3 | CIC-rearranged sarcoma |
| 9368/3 | Sarcoma with BCOR genetic alterations |
| 9687/3 | Endemic Burkitt lymphoma |
| 9687/3 | Sporadic Burkitt lymphoma |
| 9687/3 | Immunodeficiency-associated Burkitt lymphoma |

2023 New Reportable Neoplasms/Reclassified Tumors

The 2023 ICD-O-3.2 Update Guidelines include comprehensive tables listing all changes to ICD-O-3.2, including new ICD-O codes, terminology, and reportability changes effective for cases diagnosed 1/1/2023 forward. The 2023 update represents changes identified in recently published 5th Ed WHO Classification of Tumors books. Included in these guidelines are instructions for using the tables together with ICD-O-3.2.

The update includes important information on reportable versus non-reportable high-grade dysplasia in specified gastrointestinal sites. The 2023-specific ICD-O-3.2 Coding Guidelines and Implementation Documents, including Histology & Behavior Codes changes, are available in Appendix R of this manual. Complete 2023 ICD-O-3.2 Coding Guidelines and Implementation Documents are also available from NAACCR at <https://www.naaccr.org/icdo3/>.

- **Important for cases diagnosed 2023 forward:** Beginning 1/1/2023, all cases diagnosed with pilocytic astrocytoma/juvenile pilocytic astrocytoma and related terminology are to be reported with behavior /1. They will no longer be collected with malignant behavior (/3).
- Code 9421/3 will be valid for diagnoses of high-grade astrocytoma with piloid features (HFAP).
- Coding instructions are in the remarks section for 9421/1 and 9421/3 in the 2023 ICD-O Update
- 2023 ICD-O Updates include:
 - 5 new ICD-O histology codes/terms
 - 1 histology changed behavior and is reportable
 - 41 new preferred or related terms

| ICD-O | New Codes and Terms |
|--------|--|
| 8272/3 | Pituitary adenoma/pituitary neuroendocrine tumor (PitNET) (C75.1) |
| 8693/3 | Cauda equina neuroendocrine tumor (cranial and paraspinal nerves) |
| 9385/3 | Diffuse hemispheric glioma, H3 G34-mutant |
| 9385/3 | Diffuse midline glioma, H3 K27-altered |
| 9385/3 | Diffuse pediatric-type glioma, H3-wildtype and IDH-wildtype |
| 9385/3 | Infant-type hemispheric glioma |
| 9391/3 | Posterior fossa ependymoma, NOS |
| 9391/3 | Spinal ependymoma, NOS (C72.0) |
| 9391/3 | Supratentorial ependymoma, NOS |
| 9396/3 | Posterior fossa group A (PFA) ependymoma |
| 9396/3 | Posterior fossa group B (PFB) ependymoma |
| 9396/3 | Spinal ependymoma, MYCN-amplified (C72.0) |
| 9396/3 | Supratentorial ependymoma, YAP1 fusion-positive |
| 9396/3 | Supratentorial ependymoma, ZFTA fusion-positive |
| 9400/3 | Astrocytoma, IDH-mutant, grade 2 |
| 9401/3 | Astrocytoma, IDH-mutant, grade 3 |
| 9413/0 | Polymorphous low-grade neuroepithelial tumor of the young |
| 9421/1 | Diffuse astrocytoma, <i>MYB</i>- or <i>MYBL1</i>-altered |
| 9421/1 | Diffuse low-grade glioma, MAPK pathway–altered† |
| 9421/3 | High-grade astrocytoma with piloid features (HGAP) |
| 9430/3 | Astroblastoma, MN1-altered |
| 9445/3 | Astrocytoma, IDH-mutant, grade 4 |
| 9450/3 | Oligodendroglioma, IDH-mutant and 1p/19q-codeleted, grade 2 |
| 9451/3 | Oligodendroglioma, IDH-mutant and 1p/19q-codeleted, grade 3 |
| 9470/3 | Medulloblastoma, histologically defined (C71.6) |
| 9473/3 | CNS embryonal tumor, NEC/NOS |
| 9480/3 | Primary intracranial sarcoma, DICER1-mutant |
| 9500/3 | CNS tumor with BCCR internal tandem duplication |
| 9500/3 | CNS neuroblastoma, FOXR2-activated |
| 9509/0 | Multinodular and vacuolating neuronal tumor |
| 9509/1 | Myxoid glioneuronal tumor |
| 9509/3 | Diffuse leptomeningeal glioneuronal tumor |
| 9540/3 | Malignant melanotic nerve sheath tumor |
| 9699/3 | MALT lymphoma of the dura |
| 9749/1 | Juvenile xanthogranuloma (C71.5) |
| 9749/3 | Rosai-Dorfman disease |

2024 New Reportable Neoplasms/Reclassified Tumors

The 2024 ICD-O-3.2 update includes changes identified during review of recently published World Health Organization's *International Histological Classification of Tumors* 5th Edition books (WHO "Blue Books"). For 2024, no major changes have been identified during review of the 5th Editions WHO Urinary and Male Genital Tumors.

The majority of changes for 2024 are new related terms for existing codes, five new ICD-O codes, four reportable and one non-reportable, and one histology that has changed behaviors and is now reportable.

Complete 2024 ICD-O-3.2 Coding Guidelines and Implementation Documents are available from NAACCR at <https://www.naacr.org/icdo3/>.

See Appendix R for a complete set of instructions.

| ICD-O Code | Term | Required NPCR/FCDS | Remarks |
|------------|--|--------------------|---|
| 8147/3 | Adenoid cystic (basal cell) carcinoma (C61.9) | Y | Related term |
| 8120/3 | Conventional urothelial carcinoma | Y | New term |
| 9085/3 | Diffuse embryoma | Y | Related term |
| 8311/3 | ELOC (formerly TCEB1)mutated RCC (C64.9) | Y | New term |
| 8311/3 | Eosinophilic solid and cystic RCC (C64.9) | Y | New term |
| 8311/3 | Fumarate hydratase-deficient RCC ALK-rearranged RCC (C64.9) | Y | New term |
| 9070/2 | Intratubular embryonal carcinoma | Y | New term and behavior |
| 9061/2 | Intratubular seminoma | Y | New term and behavior |
| 9080/2 | Intratubular teratoma | Y | New term and behavior |
| 9061/2 | Intratubular trophoblast | Y | New term and behavior |
| 9071/2 | Intratubular yolk-sac tumor | Y | New term and behavior |
| 8120/3 | Large nested urothelial carcinoma | Y | New term |
| 8130/2 | Low-grade papillary urothelial carcinoma with an inverted growth pattern | Y | New term |
| 8960/1 | Mixed congenital mesoblastic nephroma | Y | New term. Not reportable |
| 9085/3 | Mixed teratoma and yolk-sac tumor | Y | Related term |
| 8130/2 | Non-invasive high-grade papillary urothelial carcinoma with an inverted growth pattern | Y | New term |
| 8130/2 | Non-invasive papillary urothelial carcinoma, high-grade | Y | New term |
| 8130/2 | Non-invasive papillary urothelial carcinoma, low-grade | Y | New term |
| 8860/0 | Oncocytic angiomyolipoma | Y | New term. Not reportable |
| 9104/3 | Placental site trophoblastic tumor of testis | Y | Behavior change from /1 to /3. Reportable for cases DX 1/1/2024 forward-Testis ONLY |
| 8122/3 | Plasmacytoid urothelial carcinoma | Y | Related term |
| 8020/3 | Poorly differentiated urothelial carcinoma | Y | Related term |
| 8140/3 | Prostatic intraepithelial-like carcinoma (C61.9) | Y | Related term |
| 8070/3 | Pure squamous carcinoma of urothelial tract | Y | New term |
| 8510/3 | Renal medullary carcinoma (C64.9) | Y | New term |
| 9061/3 | Seminoma with syncytiotrophoblastic cells | Y | Related term |
| 8510/3 | SMARCB1-deficient dedifferentiated RCC of other specific subtypes (C64.9) | Y | New term |
| 8510/3 | SMARCB1-deficient medullary-like RCC (C64.9) | Y | New term |

SECTION I: GUIDELINES FOR CANCER DATA REPORTING

13

| | | | |
|--------|--|---|---|
| 8510/3 | SMARCB1-deficient undifferentiated RCC, NOS (C64.9) | Y | New term |
| 9063/3 | Spermatocytic tumor with sarcomatous differentiation | Y | Related term |
| 8085/3 | Squamous cell carcinoma, HPV-associated | Y | Valid for C60._; C63.2 beginning 1/1/2024 p16 is a valid test to determine HPV status and can be used to code HPV associated and HPV independent histologies |
| 8086/3 | Squamous cell carcinoma, HPV-independent | Y | Valid for C60._; C63.2 beginning 1/1/2024 p16 is a valid test to determine HPV status and can be used to code HPV associated and HPV independent histologies |
| 8311/3 | T(6;11)RCC (C64.9) | Y | New term |
| 9080/3 | Teratoma, postpubertal-type | Y | New preferred term |
| 8311/3 | TFEB-altered RCC (C64.9) | Y | New term |
| 8311/3 | TFEB-rearranged RCC (C64.9) | Y | New term |
| 8120/3 | Tubular and microcystic urothelial carcinoma | Y | New term |
| 8311/3 | Xp11 translocation RCC (C64.9) | Y | New term |

2025 New Reportable Neoplasms/Reclassified Tumors

No ICD-O-3.2 update for 2025 was released. Please continue to use the Solid Tumor Rules, ICD-O3.2, ICD-O-3.2 Annotated list, and previous ICD-O guidelines.

9971/3- PTLD

As of January 1, 2025, Post Transplant Lymphoproliferative Disorder (PTLD) 9971/1 is reportable as 9971/3.

Note: Post Transplant Lymphoproliferative Disorder (PTLD) was previously reportable as 9971/3 for 2010-2020 when it was the only diagnosis. In 2021, based on the 4th edition of WHO Hematopoietic Blue Book, NAACCR 2025 Implementation Guidelines 17 PTLT became 9971/1, where it was only reportable if it occurred in the brain. Starting in 2025, PTLT (9971) as the only diagnosis will become a /3 (malignant) again and will be reportable for all cases.

4. Not Reportable Neoplasms

a. Primary skin tumors (C44._) with histology codes 8000-8110

Skin Cancers - Basal cell carcinoma and squamous cell carcinoma of non-genital skin sites are common malignancies. These tumors are not to be reported to FCDS, regardless of stage. All other malignant tumors of the skin must be reported including but not limited to malignant melanoma, Merkel cell carcinoma, lymphoma of skin, and other non-squamous and non-basal cell skin cancers. Only the following malignant neoplasms of the skin (C44.0-C44.9) are not reportable:

| | |
|-----------------|--|
| M 8000 – M 8005 | Neoplasm, malignant, NOS of the skin |
| M 8010 – M 8046 | Epithelial carcinoma, NOS of the skin |
| M 8050 – M 8084 | Papillary and squamous cell neoplasm of the skin |
| M 8090 – M 8110 | Basal cell carcinoma of the skin |

- b. AIN III (8077/2) of Perianal Skin (C44.5) is not reportable.
- c. AIN III of anus or anal canal (C21.0- C21.1) is reportable to FCDS.

5. Reporting Multiple Primary Tumors - Single versus Multiple Primaries

Solid Tumor Rules

The *Solid Tumor Rules* contains site-specific rules for breast, colon, head and neck, kidney, lung, malignant and non-malignant CNS, renal pelvis/ureter/bladder, cutaneous melanoma for cases diagnosed 1/1/21 and forward, and for other sites for cases diagnosed 1/1/23 and forward. A special set of rules was developed for hematopoietic and lymphoid neoplasms. The multiple primary rules guide and standardize the determination of the number of primary tumors or abstracts to be created. The histology rules contain detailed histology coding instructions. More information on these rules can be found on the NCI SEER website at <https://seer.cancer.gov/tools/solidtumor/>

Hematopoietic and Lymphoid Neoplasm Case Reportability and Coding Rules and Heme DB

The *Hematopoietic and Lymphoid Neoplasm Case Reportability and Coding Manual* and the accompanying Hematopoietic Database replaced the ICD-O-3 Book as the primary coding reference for Myeloid and Lymphoid Neoplasms. At the same time, the 2022 rules and DB have replaced earlier versions of the DB and the historical February 2001 Single Versus Subsequent Primaries of Lymphatic and Hematopoietic Disease rules and foldout table. An online version of the new rules and database is available at <https://seer.cancer.gov/tools/heme/>.

6. Clarification of Reporting Requirements

a) Malignant Neoplasms/Benign tumors

A patient is considered to have a benign, borderline, or malignant neoplasm when so indicated by a recognized medical practitioner. In determining a diagnosis of cancer, a positive pathology report takes precedence over all other reports or statements. Many benign and borderline neoplasms of the brain and central nervous system are diagnosed based on diagnostic imaging (CT, PET, MRI, etc.). Other cancers may be diagnosed by alternate means, such as direct visualization (without biopsy), or a diagnosis may be based upon clinical evidence alone. The data item “Diagnostic Confirmation” is used to identify the method of diagnosis for each case. The codes are to be used in a hierarchical order in most cases. In the absence of a positive pathology report, all information in the record must be assessed to determine whether or not the case is reportable and to identify the method used to establish (confirm) the diagnosis.

b) Clinically Diagnosed Cases Are Reportable

In the absence of a histologic or cytological confirmation of a reportable cancer, accession a case based on the clinical diagnosis (when a recognized medical practitioner says the patient has a cancer or carcinoma or when the patient is undergoing cancer treatment that may not have been histologically or otherwise confirmed). A clinical diagnosis may be recorded as part of the final diagnosis on the face sheet or other parts of the medical record. See Note and Exceptions below.

Note: A pathology report usually takes precedence over a clinical diagnosis. The case would not be reported if the patient had a negative biopsy.

Exception 1: If the physician treats a patient for cancer despite the negative biopsy, abstract and report the case.

Exception 2: If enough time has passed that it is reasonable to assume that the physician has seen the negative pathology, but the clinician continues to call this a reportable disease, accession the case. A reasonable amount of time would equal or greater than 6 months.

c) Ambiguous Terminology

The Following Guidelines should be used to differentiate between ‘Definitive Terminology’ and ‘Ambiguous Terminology’, and which terminology has priority over the other to establish the presence or absence of cancer or to delineate more clearly what a primary site, histology, or other term should mean.

- When ‘definitive terminology’ is used on a report, the radiologist/pathologist is already confident that a cancer is present, the diagnosis is not in question or ambiguous. It is cancer until or unless it is later proven not to be cancer. The physician has high confidence that a stated ‘definitive term’ is what they say it is. They do not have to repeat themselves and say that they are ‘suspicious’ about the presence or absence of disease – they are already confident it is what they say it is in the report.
- Apply ‘definitive terminology’ over ‘ambiguous terminology.’ Reports do not have to restate ‘suspicious for cancer’ or ‘likely mucinous adenocarcinoma’ when a definitive assessment or terminology is used in the first confirmation of cancer, or to use the date of that report as the initial date of diagnosis or confirmed histology when a ‘definitive term’ is present.
- When a physician uses definitive terminology, they are stating that a mass, tumor, neoplasm or a specified histology is what they say it is unless or until it is otherwise proven not to be what they say it is based on some other test or if a subsequent test clarifies a more specific diagnosis.

For example; when an imaging report states, ‘mass in left lung,’ or they state measurements for a tumor or nodes or metastasis – the physician is telling you that they already think the abnormality is cancer until or unless it is later proven not to be a cancer or some other more definitive testing method rules out cancer. A ‘definitive term’ is a statement made with confidence that it is what they say it is. Again, there is no need to restate ‘suspicious for cancer’ because the physician already thinks it is cancer.

- The report does not have to restate that the mass is suspicious for cancer. The definitive terminology has already made that statement, and a cancer diagnosis is established at that time. Biopsy or resection may clarify the type of cancer, but the radiologist already believes with high confidence that the mass is cancer. This report is used for the initial cancer diagnosis date, not the biopsy or other test date.
- When ‘definitive terminology’ is used to describe a primary tumor, the presence or absence of regional or distant lymph node(s), or the presence or absence of metastatic disease – the physician is stating with confidence that tumor, nodes or metastasis is present and is cancer unless otherwise proven not to be cancer by some other more definitive method or test.
- The ‘ambiguous terminology’ list of words and phrases for the presence or absence of disease is applied only when ‘definitive terminology’ is NOT used to describe the presence or absence of a tumor or a specific histologic type/subtype.
- Some abnormalities cannot be further described using a definitive term because they are too small or cannot be further characterized sufficiently to state it is cancer, such as ‘lung nodule.’ Lung nodules are just too small to know if they are tumor nodules or reactive ones, such as reactions to an infectious process in the lungs. They cannot be characterized as tumor or mass.
- You use the ‘ambiguous terminology’ lists of words and phrases when only ‘ambiguous terminology’ is used and there is no ‘definitive terminology’ in the report. Not the other way around...

Another example would be a pathology report that states, ‘mucinous adenocarcinoma.’ This is a definitive diagnosis of ‘mucinous adenocarcinoma’ and you code the histology as ‘mucinous adenocarcinoma.’

- When a report states ‘suspicious for mucinous adenocarcinoma’ or ‘suggests mucinous adenocarcinoma,’ only then do you apply the ‘ambiguous terminology’ guidelines to determine whether you code the histology as ‘mucinous adenocarcinoma’ or ‘adenocarcinoma, NOS.’
- You only use the ‘ambiguous terminology’ guidelines when ‘definitive terminology’ is not present.
- ‘Ambiguous terminology’ does not have to be used on imaging to confirm the presence or absence of neoplasm, and is never used instead of or in place of ‘definitive terminology’.

As part of the registry case-finding activities, all diagnostic reports should be reviewed to confirm whether a case is reportable. This includes pathology reports, genetic testing reports, immunophenotype reports, bone marrow biopsy reports, autopsy reports, diagnostic imaging reports, and medical testing results.

Definitive Diagnostic Terminology always supersedes the use of Ambiguous Terminology in any report.

If the diagnostic assessment terminology is ambiguous, use the following guidelines to determine whether a case should be abstracted and reported to FCDS. Words or phrases that are synonyms of these terms do not constitute a diagnosis. For example, “likely” alone does not constitute a diagnosis.

In the absence of definitive evidence, the following terms should be interpreted as diagnostic of cancer:

| | | | |
|-----------------|---------------------|-------------|------------------|
| Apparent(ly) | consistent with | neoplasm* | suspicious (for) |
| Appears | favor(s) | presumed | tumor * |
| comparable with | malignant appearing | probable | typical of |
| compatible with | most likely | suspect(ed) | |

* use of the terms “neoplasm” and “tumor” begin with cases diagnosed 1/1/2004 and later and are to be used in conjunction with nonmalignant (benign or borderline ICD-O-3 behavior codes /0 or /1) primary intracranial and central nervous systems, only (C70.0-C72.9, C75.1-C75.3).

Exception: If cytology is reported as "suspicious," abstract the case only if a positive biopsy or a physician's clinical impression of cancer supports the cytology findings.

Example of Diagnostic Terms:

Example 1: The inpatient discharge summary documents a chest x-ray *consistent with carcinoma* of the right upper lobe. The patient refused further work-up or treatment. *Consistent with carcinoma* is indicative of cancer.

Ambiguous Terms That Do Not Constitute a Diagnosis without additional information

When applied to a malignancy, the following modifying terms should NOT be considered diagnostic of cancer without additional information such as treatment for cancer.

| | | | |
|------------------------------|-----------------------|---------------------------------|--------------------|
| Cannot be ruled out possible | questionable suggests | equivocal potentially malignant | rule out worrisome |
|------------------------------|-----------------------|---------------------------------|--------------------|

Positive molecular marker or cytogenetic testing without pathologic or clinical evidence of reportable disease are indicative of risk only and do not constitute a diagnosis.

Ambiguous Terms - In Situ and Invasive (Behavior codes /2 and /3)

- If an **ambiguous term(s)** precedes a word synonymous with an **in situ or invasive tumor (e.g., cancer, carcinoma, malignant neoplasm, non-invasive cancer, etc.)**, the case is reportable. Abstract and report the case

Example: The pathology report says: Prostate biopsy with markedly abnormal cells that are typical of adenocarcinoma.” Abstract and report the case.

Negative Example: The final diagnosis on the outpatient report reads: Rule out leukemia. Do not abstract or report the case. Do track that you reviewed the record and deemed the case not reportable. Be sure to include why the case is not reportable to FCDS so you do not have to re-review the case during the annual AHCA (Agency for Healthcare Administration) casefinding audit.

- **Discrepancies:** If one section of the medical record(s) uses a reportable term such as “apparently” and another section of the medical record(s) uses a term that is not on the reportable list, accept the reportable term and abstract the case.

Exception: Do not abstract a case based on *suspicious* cytology alone. The case is to be abstracted only if proven by *positive* cytology or *other diagnostic method* including a physician’s clinical diagnosis. See the data item Diagnostic Confirmation for methods of diagnosis.

Note: If the **word or an equivalent term does not appear** on the reportable list or is not a form of a word on the reportable list, the term is not diagnostic of cancer. Do not report the case. Forms of the word are such as: “Favored” rather than Favor(s); “appeared to be” rather than appears. Do not substitute synonyms such as “supposed” for presumed or “equal” for comparable.

- Use these terms when **screening** diagnoses on pathology reports, operative reports, imaging/scans, and other diagnostic testing other than tumor markers.

Note: If the ambiguous diagnosis is **proven to be not reportable** by biopsy, cytology, or physician’s statement (cancer was ruled out as diagnosis), **do not report** the case.

Example: Mammogram shows calcifications suspicious for intraductal carcinoma. The biopsy of the area around the calcifications is negative for malignancy. Do not report the case.

Ambiguous Terms - Benign and borderline primary intracranial and CNS tumors

- Use the “Ambiguous Terms that are Reportable” list to identify benign and borderline primary intracranial and CNS tumors that are reportable.
- If any of the reportable **ambiguous terms precede** either the word “**tumor**” or the word “**neoplasm**,” the case is reportable. Abstract and report the case.

Example: The mass on the CT scan is consistent with pituitary tumor. Abstract and report the case.

- **Discrepancies:** If one section of the medical record(s) uses a reportable term such as “apparently” and another section of the medical record(s) uses a term that is not on the reportable list, accept the reportable term, abstract and report the case.

Exception: Do not abstract a case based only on suspicious cytology without additional confirmation of the presence of disease. The case is abstracted and reported if proven by positive cytology or other diagnostic methods including a physician’s clinical diagnosis. See the data item Diagnostic Confirmation for methods of diagnosis.

Note: If the **word or an equivalent term does not appear** on the reportable list or is not a form of a word on the reportable list, the term is not diagnostic of cancer. Do not abstract the case. Forms of the word are “Favored” rather than Favor(s); “appeared to be” rather than appears. Do not substitute synonyms such as “supposed” for presumed or “equal” for comparable.

- Use these terms when **screening** diagnoses on pathology reports, scans, ultrasounds, and other diagnostic testing other than tumor markers.

Note: If the **ambiguous** diagnosis is **not reportable** by biopsy, cytology, or physician’s statement, **do not abstract or report** the case.

Table 3. Primary Site Codes for Non-Malignant Primary Intracranial and Central Nervous System Tumors (non-malignant primary intracranial and central nervous system tumors with a behavior code of 0 or 1 [benign/borderline] are reportable regardless of histologic type for these topography codes).

| Topography | |
|--|--|
| Codes | Description |
| C70.0 C70.1 C70.9 | Meninges Cerebral Meninges Spinal meninges Meninges, NOS |
| C71.0 C71.1 C71.2 C71.3 C71.4 C71.5 C71.6 C71.7 C71.8 C71.9 | BrainCerebrum Frontal lobe Temporal lobe Parietal lobe Occipital lobe Ventricle, NOS Cerebellum, NOS Brain stem Overlapping lesion of brain Brain, NOS |
| C72.0 C72.1 C72.2 C72.3 C72.4 C72.5 C72.8 C72.9 | Spinal Cord, Cranial Nerves, and Other Parts of the Central Nervous System Spinal cord Cauda equina Olfactory nerve Optic nerve Acoustic nerve Cranial nerve, NOS Overlapping lesion of brain and central nervous system Nervous system, NOS |
| C75.1 C75.2 C75.3 | Other Endocrine Glands and Related Structures Pituitary gland Craniopharyngeal duct Pineal gland |

d) Outpatient/Ambulatory Care Only Cases

There must be sufficient documentation in the medical chart (positive radiology report, positive pathology report, physician statement, etc.) that definitively establishes that the patient either has active malignancy and/or is currently undergoing therapy for malignancy. Do not abstract the case if insufficient documentation exists in the medical chart.

e) Non-Analytic Cases

The American College of Surgeons/Commission on Cancer does not require accredited facilities to abstract non-analytic cases. However, FCDS requires collecting and reporting all cases that meet the FCDS reporting requirements, regardless of Class of Case. These are cases that were diagnosed months or years before the time they come to your facility with evidence of recurrent or progressive cancer. FCDS requires that these active cancers be reported even when your facility was not involved in the initial care of the patient's cancer. Many CoC Non-Analytic Cases are both Reportable and Analytic to FCDS and NPCR. Please report a complete case history for these.

Non-Analytic Case Reporting - The Importance of These Cases to Your Registry and FCDS

- Analytic Cases (Class of Case 00-22) are the crux of the NCDB, a clinical research database with **voluntary** reporting that includes about 70-80% of hospitals in the United States.
- Analytic Cases are used in research and are important to understand how your facility performs on newly diagnosed cancers and adherence to new treatment regimens, 5-year survival, etc.
- State Cancer Reporting Laws in ALL States plus the CDC NPCR and NCI SEER require that ALL cases within a defined geographic region (Florida) be identified and reported for 100% of the United States.
- This is the definition of 'population-based reporting' and the crux of cancer incidence rates and cancer mortality rates.
- While Hospital Analytic Cases are the crux of the NCDB and form a foundation for central registry data, they are not the only part of the central registry foundation. Non-analytic cases are equally important, particularly when the patient has evidence of cancer, recurrence of cancer, or progression of cancer.
- Furthermore, non-analytic cases of recurrent/progressive cancers generate more revenue from workup/treatment than your analytic cases. It is more expensive to treat metastatic cancers.
- These non-analytic reportable cancers have evidence of metastatic disease, recurrent disease, progressive disease, when they enter your facility. Their disease is active and needing treatment.
- Advanced, Recurrent and Progressive cancers require greater care, advanced diagnostic and treatment resources, clinical trials capabilities to offer multiple options for advanced disease, and repeat visits for continuity of care and end of life care. These patients are more expensive to treat than patients with a new diagnosis, workup and initial course of therapy.

f) Historical Cases

The American College of Surgeons/Commission on Cancer does not require accredited facilities to abstract historical cases. However, FCDS requires collecting and reporting certain historical cancers even when the patient has no evidence the historical cancer is "active" (Patient is without evidence of cancer).

Patients diagnosed with any cancer during their lifetime are many times more likely to develop new cancers. Researchers need to know the number and types of any cancers each patient has had during his/her lifetime to research and evaluate cancer incidence effectively.

Suppose a patient has had at least one primary reportable neoplasm that is currently active or under treatment. In that case, all other primary reportable neoplasms the patient has ever had (active or inactive), regardless of the date of diagnosis, must be reported. Each case of cancer must be abstracted and reported separately.

Information about the previous (historical) primary(s) may be sketchy. The abstractor should attempt to complete an abstract with as much information as is available in the medical record.

If the patient has no reportable neoplasms, active or under treatment, or no other primary neoplasms, the patient has never needed to be reported.

Do not use obsolete histology codes when reporting historical cases, regardless of the method for reporting these cases (Minimal Historical Grid or Full Abstract). The case will fail edits. This includes obsolete histology

codes, obsolete treatment codes, obsolete staging systems or stage code(s).

g) Multi-Facility Reporting (shared cases)

FCDS requires that any cancer case that meets FCDS case reporting requirements must be submitted by every facility providing services to the patient. Therefore, facilities that are members of shared, combined, or joint cancer registries and/or cancer programs must report each cancer case seen in each facility separately unless approved to do so by the Florida Department of Health and FCDS. When you send FCDS changes to one of the abstracts in your multi-facility shared cases, FCDS only changes the one abstract. It is up to the registry to identify every case affected by the change to a single case within a multi-facility reporting system.

FCDS does provide one option for multi-facility networked facilities. Some facilities may qualify to be classified as “**Umbrella Facilities**” using one umbrella facility number to report all cases within their network. There are pros and cons to setting up a set of umbrella facilities in case any change of ownership occurs within the network. It is reasonably easy to set up an ‘umbrella’ group. However, it is much more difficult to take apart a set of ‘umbrella facilities’ and reassign each separate facility the cases seen only at that facility. Please contact the FCDS with any inquiries regarding these options.

h) Each Facility is Responsible for Reporting to FCDS/Use of Contract Abstracting Service Providers

It is the responsibility of the medical record custodian or the facility administering care to report the case to FCDS. Suppose your facility employs a contracted abstracting service provider to meet Florida Cancer Reporting Requirements. In that case, the facility is still fully responsible for all cancer reporting activities, data quality activities, corrections, documentation, FCDS Audits, and special requests. FCDS does not contract directly with any individual, organization, company or service to perform abstracting services. These contracts are strictly between the reporting facility and the service provider. It is up to the facility to ensure that all data quality expectations are met, all deadlines are met, all requirements are met, and all activities are carried out to meet the facility's responsibilities to the Florida Department of Health through the Florida Cancer Data System. FCDS is a state-mandated population-based statewide cancer surveillance system. Participation in FCDS is mandated under Florida Statute. FCDS is not a voluntary cancer reporting system like the CoC NCDB. Further, FCDS annually reviews the Agency for Health Care Administration (AHCA) cancer patient data as a retrospective quality control completeness audit. The AHCA database provides an after-the-fact case finding mechanism; ensuring cancer cases that have been reported to AHCA are also included in the FCDS database.

i) Annual Reporting Deadline – June 30th

The June 30th Deadline is an annual milestone for cancer reporting in Florida. Florida law requires that all cancer cases diagnosed/treated for cancer, having a cancer-related health visit while undergoing cancer treatment, or having any evidence of disease at the time of encounter must be abstracted and transmitted to FCDS within 6 months of the date of first encounter for cancer.

FCDS reinforces the 6-month reporting standard with a June 30th Deadline each year.

Reporting Compliance and Data Quality Reports are run following the June 30th Deadline.

FCDS will notify facilities not in compliance with the 6-month reporting rule of the delinquency. Each facility will be asked to develop a remedial plan to bring the facility back into compliance with state statutes. The plan must also include a statement indicating how the facility plans to stay compliant once the current reporting year has been completed and compliance has been reached for the year in question.

If no action is taken or delinquency continues, FCDS will notify the Florida Department of Health that the facility is non-compliant and further action will be taken. The Florida Department of Health and FCDS must approve any remediation or other action plan. FCDS will monitor the plan.

B. CASEFINDING

Casefinding is used to identify new cancer cases, inpatient or outpatient. All facilities are responsible for complete casefinding for all patients seen at your facility, regardless of the type of service. The following multiple sources in the hospital must be searched to keep missed reportable cases to a minimum. The procedure outlined below should be adapted to each facility:

1. **Pathology Reports** (biopsy specimen, surgical specimen, bone marrow biopsy, FNA, core biopsy, molecular genetic testing, immunophenotyping, cytology, autopsy, addenda, consultation reports, etc.)
2. **HIM/Medical Record Disease Indices or Unified Billing System Report – All Services**
(All Patient Services - Inpatient and Outpatient, Clinics, Hospice, etc.)
3. **Radiation Therapy** Department (patient logs and/or billing reports)
4. **Infusion or Treatment Center** (patient logs and/or billing reports)
5. **Outpatient Departments** (including cancer specialty clinics, chemotherapy clinics, infusion centers, day surgery, emergency room, medical oncology logs, etc.)
6. **Diagnostic Imaging** (Radiology) Department (MRI, CT, PET, x-ray, mammogram, etc.)

1) **Pathology Reports**

ALL ANATOMIC (SURGICAL) PATHOLOGY REPORTS (including reports from biopsy specimen, surgical resection specimen, bone marrow biopsy, needle biopsy and fine needle aspiration biopsy, diagnostic hematology, cytology, immune-histo-cytochemistry, immunophenotype, genetic studies, and autopsy reports and all addenda) for inpatients, outpatients and ambulatory care patients MUST be reviewed to determine whether or not a cancer is reportable.

Pathology reports must also be reviewed at least annually to ensure that no cases have been missed.

Pathology may be included in Casefinding Audits and the Annual ReCasefinding Audit.

Most cancer patients have a biopsy or operative resection performed, and nearly all the reportable cases can be identified by pathology reports alone. Check with your pathology department to see if the department information system can facilitate the review of these reports.

Electronic Copies of All Cancer-Related Pathology Reports MUST be submitted electronically to FCDS under the FCDS E-Pathology Reporting Program. Please Contact Meg Herna at FCDS.

2) **HIM/Medical Record Disease Index/Unified Billing System Report – All Services**

Every patient record with a reportable ICD-10-CM code (see Current Casefinding List) must be reviewed to determine whether or not the case meets FCDS criteria for case reporting. All patient service areas must be included in these reports. The FCDS Casefinding Lists have been pared down to only include diagnoses of active disease. Therefore, most cases on your list must be abstracted and reported.

Upon review, if a patient is found not to have a malignancy as coded by the HIM/Medical Record or Billing Department or does not meet FCDS criteria for case reporting, the name should be added to the facility's "Not Reportable List." The list may be substituted with the facility "suspense" file based on available vendor tools.

The "Not Reportable List" is useful when FCDS is conducts casefinding audits based on AHCA ((Agency for Healthcare Administration) data. Some facilities will save a "Not Reportable List" as an electronic file embedded within their software such as a "suspense" case and should include comments that the registrar reviewed the medical record and determined that the case does not meet reportable criteria. The "suspense" case should include documentation as to why the facility will not report the case either in text and/or using the FCDS AHCA Disposition Codes below.

|  AHCA Disposition Code List 4/4/2022 12:09:25 PM Page: 1 of 1 | | |
|--|---|--------------|
| Code | Description | Match Status |
| 1 | Reportable-Missed Case-Case to be Abstracted & Reported by Facility | M |
| 2 | N/R - Tumor was Not Malignant - Behavior = 0 or 1 | N |
| 3 | N/R - NonReportable Skin Cancer - Site=C44.* and Morph = 8000 to 8110 | N |
| 4 | N/R - No Evidence of Cancer at This Time - NED | N |
| 5 | N/R - Consultation Only | N |
| 6 | N/R - Cancer Not Proven - Equivocal | N |
| 7 | Case Previously Reported to FCDS by this Facility | M |
| 8 | N/R - Outpatient Record with No Active Cancer Documented in Record | N |
| 9 | N/R - Insitu Cancer of Cervix or CIN III | N |
| 10 | N/R - Other | N |
| 11 | Reportable-Case Abstracted BUT Not found in FCDS files - Abst Requested | R |
| 12 | N/R - No Cancer Mentioned in Medical Record | N |
| 13 | Skins we elected not to FB since most of them turn out N/R | N |
| 14 | N/R - Hematopoietic Diseases Dx Prior to 2001 | N |
| 15 | N/R - Case DX Prior to FCDS Reference Date - Same Cancer/Same Facility | N |
| 16 | N/R - Benign or Borderline Brain/CNS Tumor Dx Prior to 2004 | N |
| 20 | Unknown if Reportable - No Record of this Patient at this Facility | N |
| 21 | Unknown if Reportable - Lost Medical Record | N |
| 30 | Unknown if Reportable - No Follow-Back Ever Returned by this Facility | R |
| 40 | N/R - Special Case - Other | N |
| 50 | Hospice Case - Not A Hospital | U |
| 51 | Transitional Care Center - Not A Hospital | U |
| 52 | Not A Valid Facility Number | U |
| 60 | This AHCA Record Matches a Vital Statistics Record (DCN-Identified) | U |
| 70 | Closed Facility | U |
| 90 | Not Cancer Related Cases | U |
| 998 | Matching Algorithm Has Been Run | R |
| 999 | Pending Match | R |

3) Radiation Therapy Department

New patient registration rosters and radiation therapy summaries are excellent casefinding sources for patients treated with radiation. Unified Billing System Reports also can be used to identify these cases.

4) Outpatient Departments

New patient registration rosters for single-day surgery departments, oncology-related service areas (specialty clinics, chemotherapy clinics, infusion centers, day surgery, and other ambulatory care), outpatient departments (including outpatient diagnostic radiology and laboratory service areas) and emergency rooms are additional casefinding sources for patients seen only in an ambulatory care setting. Unified Billing System Reports also can be used to identify these cases.

5) Diagnostic Imaging (Radiology) Department

New patient registration rosters for patients receiving diagnostic imaging services (x-ray, CT scan, PET scan, MRI, or other imaging) are an excellent source for identifying new cancer cases.

ICD-10-CM CASE FINDING LIST FOR REPORTABLE TUMORS – Oct 1, 2024 and later encounters

- 6) The following ICD-10-CM list will be used to identify potentially reportable tumors. Some ICD-10-CM codes contain conditions that are not reportable. These records should be reviewed and assessed individually to verify whether they are reportable to FCDS. ICD-10-CM implementation is expected nationwide for all hospitals nationwide on October 1, 2024.

| ICD-10-CM Code | ICD-10-CM Code Definition |
|----------------|---|
| C00 – C43 | Malignant neoplasms |
| C44.13- | Sebaceous Cell Carcinoma of Skin of Eyelid, Including Canthus |
| C45 – C96 | Malignant neoplasms including Hematopoietic neoplasms |
| C4A- | Merkel cell carcinoma |
| C49.A- | GI stromal tumor |
| C7A.0 – C7A.8 | Malignant carcinoid tumors |
| D00. – D09. | Carcinoma in situ (Excludes carcinoma in situ tumors of the cervix (D06.), prostatic intraepithelial neoplasia (PIN III) (8148/2) of the prostate. Other prostate in situ histologies are reportable). |
| D18.02 | Hemangioma of intracranial structures |
| D32.- | Benign neoplasm of meninges (cerebral, spinal and unspecified) |
| D33.- | Benign neoplasm of brain and other parts of central nervous system |
| D35.00-D35.02 | Benign neoplasm of adrenal gland - pheochromocytoma, medullary paraganglioma, chromaffin paraganglioma, chromaffin tumor, |
| D35.2 - D35.4 | Benign neoplasm of pituitary gland, craniopharyngeal duct and pineal gland |
| D42.-, D43.- | Neoplasm of uncertain or unknown behavior of meninges, brain, CNS |
| D44.3 – D44.5 | Neoplasm of uncertain behavior of pituitary gland, craniopharyngeal duct and pineal gland |
| D45 | Polycythemia vera (9950/3); Polycythemia vera (9950/3) ICD-10-CM Coding instruction note: Excludes familial polycythemia (C75.0), secondary polycythemia (D75.1) |
| D46.- | Myelodysplastic syndromes (9980,9982,9983,9985,9986,9989,9991,9992, 9993) |
| D46.A – D46.Z | Other myelodysplastic syndromes |
| D47.02 | Systemic mastocytosis |
| D47.1-D47.9 | Myeloproliferative diseases (9963, 9975) Essential (hemorrhagic) thrombocythemia (9962/3); Includes: Essential thrombocytosis, idiopathic hemorrhagic thrombocythemia Osteomyelofibrosis (9961/3); Includes: Chronic idiopathic myelofibrosis Neoplasm of uncertain behavior of lymphoid, hematopoietic and related tissue, unspecified (9970/1, 9931/3) |
| D47.Z – D47.Z9 | Neoplasm of uncertain behavior of lymphoid, hematopoietic and related tissue, unspecified (9960/3, 9970/1, 9971/3, 9931/3) Note: As of January 1, 2025, Post Transplant Lymphoproliferative Disorder (PTLD) 9971/1 is reportable as 9971/3 for all cases. |
| D49.6, D49.7 | Neoplasm of unspecified behavior of brain, endocrine glands and other CNS |
| D72.11- | Hypereosonophilic syndrome [HES] (9964/3) |
| N85.02 | Endometrial intraepithelial neoplasia [EIN] |
| R90.0 | Intracranial space-occupying lesion found on diagnostic imaging of CNS |

C. ABSTRACTING

1. Personnel Requirements – Abstractor Training and FCDS Abstractor Code

Abstractor Training: Trained personnel must perform abstracting. FCDS provides references in Appendix P for numerous online training programs from basic programs to certificate and degree programs to obtain an ODS Certification.

Other training is available through SEER*Training, SEER*Educate, the Commission on Cancer, the American Joint Committee on Cancer, the National Cancer Registrars Association (NCRA), the Florida Cancer Registrars Association (FCRA), and the North American Association of Central Cancer Registries (NAACCR). Please see the annually updated document “2024 References and Resources for Cancer Registrars” on our website and included as Appendix P in this manual.

FCDS Fundamental Learning Collaborative for the Cancer Surveillance Community (FLccSC)

The FCDS Fundamental Learning Collaborative for the Cancer Surveillance Community (FLccSC) learning management system (LMS) was developed to provide a web-based educational platform for cancer surveillance professionals in Florida. Courses are designed for students of all experience/skill levels. There are courses and modules for those new to the cancer surveillance field and continuing education courses for the seasoned professional. The FCDS Abstractor Code Test is one of the modules in FLccSC.

FLccSC is a cancer surveillance community educational collaboration. FLccSC is a web-based portal allowing Central Cancer Registries (CCR) to customize a fully functioning state-specific Learning Management System (LMS). The Florida Cancer Data System and the South Carolina Central Cancer Registry developed FLccSC collaboratively. State Departments of Health and the CDC/NPCR funded the initial development.

- Students access FLccSC from a link on each state’s CCR website. Once registered, they will only see the LMS pages and content from their respective CCR. Once they successfully complete an educational module, they will receive a Certificate of Completion, including CEUs where applicable.
- FLccSC is a web-based educational collaborative LMS that is available 24/7. It is cost-efficient because students do not have to travel to a central training site or purchase training materials.
- FLccSC support includes access to a Help Desk for technical support and tutorials as a menu item on both the student site (frontend) and the Administration site (backend).
- Step by step tutorials detail how to develop and maintain the CCR FLccSC site and educational content.
- FLccSC allows educational material to be shared between CCRs at the e-Administrator's discretion.
- There are many e-administrator tutorials and tutorials for students available on the FLccSC Site.

FCDS Abstractor Code: Every registrar or abstractor planning to work in the State of Florida is required to obtain an individual FCDS Abstractor Code. FCDS assigns this code to persons who successfully pass the FCDS Abstractor Code Online Test, regardless of certification by NCRA as an ODS, experience in the registry industry, or other factors. As of January 1, 2013, any individual planning to acquire a New FCDS Abstractor Code or renew an Existing FCDS Abstractor Code must take and pass the FCDS Abstractor Code Test. Annual re-testing is also required to ensure all abstractors retain a current level of understanding of cancer registry reporting requirements, abstracting, and coding standards and procedures.

The FCDS Abstractor Code Requirement has been an FCDS Policy for many years. It applies to every cancer registrar working in Florida (ODS or non-ODS, Florida resident, local or out-of-state contractor, interim service provider, or other registry staff, regardless of years’ experience or certification).

FCDS will not accept cases from individuals without a current FCDS Abstractor Code. When IDEA users log in, their account and Abstractor Code status are displayed. In addition, FCDS sends weekly email reminders to abstractors whose codes are about to expire 30 days before the expiration date.

Exams are short (20 multiple-choice or T/F questions) with a variable mix of content questions.

Questions are updated annually to ensure current standards are familiar to the tester. Questions are randomly selected from a pool of more than 350 questions covering 7 major topic areas. No two exams will be alike.

The 7 topic areas include:

- Florida Reporting Requirements
- General Abstracting Knowledge
- Anatomy and Physiology
- Primary Site/Histology/Grade
- Stage at Diagnosis (SS2018, SSDI, Grade Coding Instructions)
- Latest Rule Changes
- Treatment and Survival

Standard References Used for Testing:

- FCDS DAM (current version)
- ICD-O-3.2 and all Updates
- Solid Tumor Rules
- Hematopoietic/Lymphoid Neoplasms and Database
- SEER Summary Staging Manual 2018
- Site-Specific Data Items
- Grade Coding Manual
- SEER*Rx (<https://seer.cancer.gov/seertools/seerrx/>)
- Self-Instruction <http://training.seer.cancer.gov/> and <https://seer.cancer.gov/archive/training/manuals/>
- Basic anatomy/physiology/medical terminology related to cancer – SEER Archived Instruction Manuals
- Cancer Characteristics, Medical Terminology, Human Anatomy as Related to Tumor Formation

2. Case Abstracting Requirements – Timeliness

Florida Statute requires that cases be completely abstracted (all information must be included regarding the diagnosis, staging, first course of treatment, cancer progression or recurrence) within 6 months of the first patient encounter for cancer at your facility. Individual cases must be abstracted no later than six months after the date of first contact with the reporting facility. The only exceptions to this reporting timeline are the free-standing ambulatory surgical centers reporting under the Ambulatory Centers Cancer Reporting Program. Cases may be abstracted earlier than six months after the date of first contact, but only if the required information regarding the first course of therapy is available and complete.

All cases meeting the reporting requirements outlined in Section I.A must be abstracted following the guidelines outlined in Section II of this document. Questions regarding interpreting individual data items should be referred to the FCDS office.

Each reporting facility must certify that they have completed the full year cycle of reporting each year. This Certification of Completeness is found in the FAA/HOSPADMIN Menu in FCDS IDEA Software.

FCDS monitors the number and percentage of total cases submitted after the FCDS Annual Reporting Deadline and the number and percentage of total cases submitted after the Facility has Certified Completeness in reporting their annual cycle of cases. This is part of monitoring Timeliness at FCDS.

FCDS continues to monitor patients with cancer to ensure that first-course therapy is consistent with the stage of disease and specific biomolecular and genetic tumor markers for targeted therapies. Do not send cases too early. For cases not yet completed by the June 30th deadline, you may code the treatment as recommended, unknown if administered. All cases are required to be reported to FCDS by June 30th.

All abstracts are required to pass the FCDS EDITS metafile.

3. Maintain a ‘Medical Record Reviewed but Deemed Not Reportable to FCDS’ List of Cases

A list of cases reviewed but not reported to FCDS (**not reportable list**) should be maintained by each reporting facility either in electronic or other format. This can be as part of your abstracting software maintained in your “suspense” file or a separate document with easy access. A sample form is included at the end of this Section. Any patient encounter on a facility casefinding list that does not meet the reporting requirements outlined in Section I should be recorded on the “Not Reportable List” explaining why the case will not be reported. FCDS suggests you include the FCDS Disposition Code associated with the reason not reported to help annual AHCA Follow-Back activities.

The list should include the patient’s name, social security number, medical record number, date of birth, ICD-10-CM Cancer Diagnosis Code, admission date, and disposition code or reason they were not reported. The list may be kept in a paper notebook, spreadsheet, vendor software suspense file, or any other easily accessible format. You may use the FCDS form or you may create your own.

Casefinding audits are performed annually at every reporting facility through annual case matching with the Florida Agency for Health Care Administration (AHCA) data files to assure completeness of reporting. The not reportable list will expedite resolution of cases that appear as ‘missed cases’ during these casefinding audits. Missed Cases Are Late Reported Cases – always.

Failure to keep the list will result in FCDS requesting that the reporting facility pull each ‘missed case’ record again and review whether or not it should have been reported to FCDS. An explanation must then be submitted to FCDS detailing any reason any case will not be reported to FCDS or the case must be abstracted and reported to FCDS.

FCDS Disposition Codes may be included in the file as reference because the case is not reportable.

| <div>  <div> AHCA Disposition Code List <div>4/4/2022 12:09:25 PM Page: 1 of 1</div> </div> </div> | | |
|--|---|--------------|
| Code | Description | Match Status |
| 1 | Reportable-Missed Case-Case to be Abstracted & Reported by Facility | M |
| 2 | N/R - Tumor was Not Malignant - Behavior = 0 or 1 | N |
| 3 | N/R - NonReportable Skin Cancer - Site=C44.* and Morph = 8000 to 8110 | N |
| 4 | N/R - No Evidence of Cancer at This Time - NED | N |
| 5 | N/R - Consultation Only | N |
| 6 | N/R - Cancer Not Proven - Equivocal | N |
| 7 | Case Previously Reported to FCDS by this Facility | M |
| 8 | N/R - Outpatient Record with No Active Cancer Documented in Record | N |
| 9 | N/R - Insitu Cancer of Cervix or CIN III | N |
| 10 | N/R - Other | N |
| 11 | Reportable-Case Abstracted BUT Not found in FCDS files - Abst Requested | R |
| 12 | N/R - No Cancer Mentioned in Medical Record | N |
| 13 | Skins we elected not to FB since most of them turn out N/R | N |
| 14 | N/R - Hematopoietic Diseases Dx Prior to 2001 | N |
| 15 | N/R - Case DX Prior to FCDS Reference Date - Same Cancer/Same Facility | N |
| 16 | N/R - Benign or Borderline Brain/CNS Tumor Dx Prior to 2004 | N |
| 20 | Unknown if Reportable - No Record of this Patient at this Facility | N |
| 21 | Unknown if Reportable - Lost Medical Record | N |
| 30 | Unknown if Reportable - No Follow-Back Ever Returned by this Facility | R |
| 40 | N/R - Special Case - Other | N |
| 50 | Hospice Case - Not A Hospital | U |
| 51 | Transitional Care Center - Not A Hospital | U |
| 52 | Not A Valid Facility Number | U |
| 60 | This AHCA Record Matches a Vital Statistics Record (DCN-Identified) | U |
| 70 | Closed Facility | U |
| 90 | Not Cancer Related Cases | U |
| 998 | Matching Algorithm Has Been Run | R |
| 999 | Pending Match | R |

4. Abstracting Non-Analytic and Historical Cases

Although the Commission on Cancer/American College of Surgeons (COC/AcoS) does not require accredited
FCDS Data Acquisition Manual 2025
Revised 2025

facilities to abstract non-analytic or historical cases, a population-based cancer registry such as FCDS must record all cancers meeting the FCDS reporting requirements, regardless of class of case, place of diagnosis or date of diagnosis. These cases require the same attention to detail and text as any CoC “analytic” type case. These cases must be abstracted, and quality reviewed with the same rigorous data quality and documentation expectation. Include chronologic information about the cancer as available.

FCDS realizes that much of the information about the original diagnosis, staging, and treatment of non-analytic and historical cancers may be unavailable or incomplete. The abstractor should attempt to complete each abstract with as much information as is available in the medical record. Historical Cancers that currently exhibit active disease (recurrence or progression of cancer) must be reported as a complete FCDS Abstract. Enter as much information as is available in your medical record.

Duplicate Case Submissions (cases previously reported to FCDS) can be problematic when resent to FCDS as a new submission after having already been reported. Always reference and use the Facility Alpha Listing found in the FCDS Reports Menu with your facility reference date of 1/1/1981, regardless of CoC Changes to Your State of Florida Reference Date. This report is updated every time you submit cases to FCDS. It is a complete reference of all cases ever reported to FCDS from your facility since 1981. New cancers for cases with old Accession Numbers must include the old Accession Number. FCDS recognizes many registrars do not utilize this listing properly to determine which cancers need which sequences reported and which cancers have been reported prior to your CoC Reference Date. Always remember your FCDS Reference Date is 1981 or the day your facility opened.

5. Abstracting Historical Cases Optional Minimal Dataset

The historical case refers to a primary reportable neoplasm (malignant or benign/borderline brain/CNS tumors) that is not active (no evidence of disease) and currently not receiving any treatment and the patient is seen at the reporting facility for another cancer/benign reportable neoplasm that is active and/or undergoing treatment.

There are two methods for reporting a Historical Case: FCDS will accept historical cases reported as full abstracts or reported using the minimal dataset.

- a. For every abstract submitted, the record layout will allow for the entry of up to five (5) historical cases. The fields required for each of the five cases include:
 1. Sequence Number
 2. Diagnosis Date
 3. Primary Site (ICD-O-3)
 4. Histology (ICD-O-3)
 5. Behavior (ICD-O-3)
 6. Laterality
 7. State of Residence at Diagnosis (State Abbreviation)
 8. County of Residence at Diagnosis (FIPS County Code)
 9. Schema Discriminator 1
 10. Schema Discriminator 2
- b. These fields will be edited at transmission time and include Sequence Number and Diagnosis Date and State and County edit checks.
- c. These fields should ONLY be used when abstracting a historical case with insufficient information.
- d. A complete abstract MUST be reported to FCDS for cases with sufficient information in the patient’s medical record or when the patient has evidence of the historical cancer at the time of patient encounter (persistent disease, progression of disease or disease recurrence – patient with evidence of this cancer at the time of patient encounter).

- e. REMEMBER, the minimal dataset only applies to Class of Case 33 Historical Cases with insufficient information. All other Non-Analytical cases, including Class of Case 33 historical cases with enough information, REQUIRE a full abstract to be reported to FCDS.
- f. Historical Cases should not include Unknown Primary Cancers (C80.9 or C76.*).
- g. Quality Control for these cases will be increased, and documentation supporting the minimal dataset may need to be provided.

6. Reporting Historical Cases in the State Specific fields

- a. Historical information must be completed starting with the eight fields in HISTORY1. Every additional historical case would use the next sequential group of eight fields (i.e. HISTORY2 through HISTORY5). No gaps in the groups can exist.

Examples:

One Historical Case – MUST use Historical #1 group of nine fields.

Two Historical Cases – MUST use Historical #1 and Historical #2 groups of nine fields.

In the example of Two Historical cases, if Historical #1 and Historical #3 groups of nine fields are populated, then the abstract will not be accepted due to a gap in the Historical #2 group.

- b. All nine fields must be filled When selecting a group (Historical #1).

The current standards must complete historical data. If any of these fields are left blank, the abstract and possibly the entire batch will be rejected.

Examples:

Historical #1: Sequence Number,

Historical #1: Dx Date,

Historical #1: Primary Site,

Historical #1: Histology,

Historical #1: Behavior,

Historical #1: Laterality,

Historical #1: Dx State Abbreviation,

Historical #1: Dx County FIPS

Historical #1: Schema Discriminator 1

Historical #1: Schema Discriminator 2

Once these historical groupings pass structure check edits, a full abstract will be generated from the data provided. The derived Historical abstracts will be subject to our full edit checks. If any failures exist, the abstract and batch will be rejected.

7. Annual Reporting Deadline – June 30th

The June 30th Deadline is an annual milestone for cancer reporting in Florida. Florida law requires that all cancer cases diagnosed/treated for cancer, having a cancer-related health visit while undergoing cancer treatment, or having any evidence of disease at the time of encounter must be abstracted and transmitted to FCDS within 6 months of the date of first encounter for cancer. FCDS reinforces the 6-month reporting standard with a June 30th Deadline each year.

Compliance and Data Quality Reports are run following the annual June 30th Deadline.

FCDS will notify facilities not in compliance with the 6-month reporting rule of the delinquency. Each facility will be asked to develop a remedial plan to bring the facility back into compliance with state statutes and a plan

to remain compliant. If no action is taken or delinquency continues, FCDS will notify the Florida Department of Health that the facility is non-compliant and further action will be taken. The Florida Department of Health and FCDS must approve any remediation or other action plan. FCDS will monitor the plan.

8. Making changes to existing abstracts from Field Coordinator Inquiry (corrections) or QC Review (Visual Editing)

You must comply with the messaging requirements for the FCDS Systems for FCDS to be able to view and process corrections, inquiries, deletions, or visual editing updates to abstracts.

Your Facility has 21 days to complete any Field Coordinator Correction/Inquiry or QC Review Correction Inquiry. This FCDS Policy is loosely enforced but important to good quality abstracting and timeliness of operations and practices. Do not wait months to answer inquiries, make corrections, or update text and messaging in your facility queue.

9. Required and Recommended Desktop References

Also refer to the document ‘2024 References and Resources for Cancer Registrars’ in Appendix P of this manual.

REQUIRED DESKTOP REFERENCES

| REQUIRED REFERENCE | ORDERING INFORMATION/LINKS |
|---|---|
| FCDS <i>Data Acquisition Manual, 2025</i> | FCDS, Florida Cancer Data System PO Box 016960 (D4-11) Miami, FL 33101 The Florida Cancer Data System - Downloads (miami.edu) |
| FCDS IDEA – FCDS Secure Web-Based Software to abstract cases, upload batched cases, access FLccSC, QC Review, Audits | The Florida Cancer Data System Home Page (miami.edu) |
| FLccSC Learning Management System FCDS Abstractor Code Test, FCDS Continuing Education Webcast Series, NAACCR Webinar Recordings, FCDS Annual Conference, etc. | The Florida Cancer Data System - FLccSC (miami.edu) |
| FCDS v25 EDITS Metafile | The Florida Cancer Data System - Downloads (miami.edu) |
| 2025 Instructional Manuals/Guidelines | https://apps.naaccr.org/data-dictionary/data-dictionary/version=24/chapter-view/ |
| Current Solid Tumor Manual | https://seer.cancer.gov/tools/solidtumor/ |
| Current Grade Coding Manual | https://www.naaccr.org/wp-content/uploads/2022/10/Grade-Coding-Instructions-and-Tables-v3.pdf?v=1688673341 |
| Current Site-Specific Data Items Manual | https://apps.naaccr.org/ssdi/list/ |
| Current SEER Program Coding and Staging Manual | SEER Program Coding and Staging Manual |
| Cancer PathChart | Cancer PathCHART - Tumor Site-Morphology Surveillance Standards Initiative |
| Current SEER RSA – Registrar Staging Assistant – online staging assistant | https://seer.cancer.gov/tools/staging/rsa.html |
| Current SEER*Rx – Interactive Drug Database | https://seer.cancer.gov/tools/seerrx/ |
| Current Hematopoietic and Lymphoid Neoplasm Case Reportability and Coding Manual and Hematopoietic Database (desktop or web-based versions available) | https://seer.cancer.gov/tools/heme/ |
| Current NAACCR ICD-O-3 Coding Guidelines, Annotated Histology List | https://www.naaccr.org/icdo3/ |
| ICD-O-3.2 Excel Table downloaded from the IACR/WHO Website | Downloadable Excel File Version of ICD-O-3.2 SEER ICD-O-3 Coding Materials |
| International Classification of Diseases for Oncology, 3rd ed. Geneva, World Health Organization: 2000 | The World Health Organization WHO Publications Center USA; 49 Sheridan Avenue; Albany, NY 12210 https://www.who.int/standards/classifications/other-classifications/international-classification-of-diseases-for-oncology |

RECOMMENDED DESKTOP REFERENCES

| RECOMMENDED BOOK | ORDERING INFORMATION/LINKS |
|--|---|
| 2025 CoC STORE Manual - CoC Standards for Oncology Registry Entry | American College of Surgeons (ACS) 55 East Erie Street Chicago, IL 60611-2797 store-manual-2025.pdf |
| 2025 SEER Program Code Manual | National Cancer Institute Publications Ordering Service P.O. Box 24128, Baltimore, MD 21227, 301-330-7968 SEER Program Coding and Staging Manual |
| Cancer Registry Management Principles and Practice for Hospitals and Central Registries, 4th Edition, 2021 | National Cancer Registrars Association https://www.ncra-usa.org/About/Store/Store-Professional-Resources/BKctl/ViewDetails/SKU/NCRCRMtXbK4ED |
| NAACCR Standards for Cancer Registries Volume II: Data Standards and Data Dictionary, current edition (v25) | North American Association of Central Cancer Registries, Inc. (NAACCR) 2121 West White Oaks Drive, Suite B Springfield, Illinois 62704-7412 Phone: (217) 698-0800 Fax: (217) 698-0188 https://www.naaccr.org/ |
| EDITS Software – EditWriter 6 and GenEdits Plus | https://www.cdc.gov/cancer/npcr/tools/edits/index.htm |
| NAACCR v25 EDITS Metafile | https://www.naaccr.org/standard-data-edits/ |
| FCDS v25 EDITS Metafile | The Florida Cancer Data System - Downloads (miami.edu) |
| Cancer Principles and Practice of Oncology, 10th edition | Lippincott Williams & Wilkins Publishers 227 East Washington Square Philadelphia, PA 19106-3780 ISBN-10: 1451192940 ISBN-13: 9781451192940 |
| American Cancer Society Textbook of Clinical Oncology | American Cancer Society Vermont Division, Inc. 13 Loomis Street Montpelier, VT 05602 https://www.cancer.org/ ISBN-13: 978-0944235072 ISBN-10: 0944235077 |
| CA: A Cancer Journal for Clinicians | Lippincott Williams & Wilkins Publishers P.O. Box 1600 Hagerstown, MD 21741-9910 301-223-2300 (Voice) https://acsjournals.onlinelibrary.wiley.com/journal/15424863?journalRedirectCheck=true |
| AJCC Cancer Staging System Products AJCC Cancer Staging Manual, 8 th ed AJCC Cancer Staging, Version 9 | https://www.facs.org/quality-programs/cancer-programs/american-joint-committee-on-cancer/cancer-staging-systems/cancer-staging-system-products/ |

D. DATA TRANSMISSION

All cases must be transmitted to FCDS electronically using the FCDS secure information and data sharing portal: the FCDS IDEA, and by all FCDS Data Submission Policies and Procedures and Transfer Protocols. Appendix Q for FAQs on FCDS IDEA.

RELEASE OF INFORMATION – FCDS will not release patient information directly to any contractor due to liability and confidentiality issues regarding contractual agreements not involving FCDS. Furthermore, new guidelines under HIPAA (Health Insurance Portability and Accountability Act) have introduced additional restrictions regarding releasing and re-releasing patient information under many circumstances. FCDS understands that this policy may present some challenges to some contractors. Any contract between a healthcare facility and a private contractor where FCDS is not a party to the contract cannot include allowances for FCDS to release patient information to anyone other than the reporting facility.

Contractors must arrange with their clients (facilities) to forward any FCDS correspondence that includes patient information to them (contractors). This includes, but is not limited to edit discrepancies, quality control inquiries, verification of patient information, death certificate notification, AHCA casefinding audits, etc. Any discrepancies or omissions discovered after an abstract has been transmitted and processed will be posted to FCDS IDEA for review and/or correction. A *SAMPLE* FCDS Discrepancy Journal is provided at the end of this Section.

As a courtesy, FCDS will attempt to inform contractors of outgoing edits, quality control inquiries, verification of patient information, death certificate notification, casefinding audits, etc. However, the contractor and the reporting facility are ultimately responsible for assuring these reports and inquiries reach the contractor through appropriate channels.

CONFIDENTIALITY - Patient information, personal health information, medical records and healthcare facility data are all confidential and continue to be a concern about cancer and other disease reporting. Please do not fax or email patient information to FCDS. Also, please take care when discussing cases over the phone with FCDS staff.

DO NOT E-MAIL, FAX OR MAIL PATIENT INFORMATION (PHI) TO FCDS UNDER ANY CIRCUMSTANCES unless you are provided specific instructions for using our Secure Fax Service.

CONFIDENTIAL INFORMATION includes any HIPAA-defined Protected Health Information.

PHI information in the healthcare includes:

- Patient name, address including street, city, county, zip code and equivalent geo codes,
- Name of relatives,
- Name of employers,
- All elements of date about patient (ex-admission, discharge, and birthdate)
- Telephone numbers
- Fax numbers
- Electronic email addresses
- Social Security number, medical record number,
- Health plan beneficiary number,
- Account number
- Certificate and license number,
- Any vehicle or other device serial number
- Web Universal Resource Locator (URL)
- Internet Protocol (IP) address number
- Finger or voice prints
- Photographic images

1. Quarterly Reporting

FCDS requires that facilities transmit data at least quarterly.

Monthly data submission is highly recommended for large facilities reporting over 500 cases annually.

FCDS requires that QC Visual Review of Cases, Corrections, and Field Coordinator inquiries be completed within 21 days of receipt.

2. Electronic Submissions**Record Layout**

All data must be submitted in the current NAACCR Version.

All Cancer Registry Vendors and Cancer Registries transitioned to an XML Format.

This includes any electronic submission and utilization of the current FCDS EDITS Metafile.

The FCDS field positions and field lengths are standardized using the NAACCR transfer record layout, data definitions and data exchange guidelines. All fields identified in the FCDS Record Layout Appendix as Core ('C') must be completed. Historical cases may retain old standards.

3. Receipt on Upload

An Upload Receipt is generated after the upload is successfully transmitted. Please validate that the Upload Receipt and the expected upload are the same number of cases as a quick easy QC check.

4. Data Acceptance Policy – FCDS EDITS

Batch submissions will be edited immediately during uploading using the standard FCDS EDITS metafile. This metafile is published on the FCDS website and is available for software vendors and other interested parties who wish to run edits before data submission.

Each record must pass all inter and intra-item edits before acceptance by FCDS.

Records requiring a NAACCR edit override (FORCE) will pass the edit check process and be accepted. However, upon review at FCDS, it may be determined that the case does not meet the criteria for edit override (FORCE), and a correction may be made to the case.

For cases requiring an edit override or Force, FCDS staff will review the submitted text to determine whether sufficient information has been provided to override the edit in question.

Suppose the information in text is insufficient, unclear, equivocal, incomplete or incorrect. In that case, the reporting facility will have two weeks from case transmission to send FCDS the appropriate information from the patient's medical records to support the code(s) assigned. FCDS QC Staff will use documentation provided to validate coding and set relevant override flag(s).

E. PSYCHIATRIC, MILITARY, AND VETERANS ADMINISTRATION FACILITIES

United States military and Veterans Administration healthcare facilities are requested to report cancer under Rule 64D-3.006 of the Florida Administrative Code.

F. AMBULATORY SURGERY CENTERS

In July 1997, the Florida legislature amended state cancer reporting legislation to include cancer case reporting by ambulatory patient care facilities. The Florida Department of Health and FCDS agreed that to ease the burden of reporting by ambulatory centers, FCDS would take on the responsibility of cancer case identification, the critical first step in reporting cancer cases.

Administrative Options for Reporting for Ambulatory Surgical Centers:

1. Facilities with a History of Reporting – Several ambulatory surgical centers voluntarily report complete cancer cases to FCDS. Reporting by these facilities will continue as in the past. The FCDS notification of cases for cancer reporting for these facilities will be a quality control exercise. Cases identified through the notification process will be considered ‘Missed Cases’ and must be reported promptly.
2. Annual reporting through the FCDS Notification of Cases (Annual Consolidated Follow Back Audit) - The AHCA (Agency for Healthcare Administration) discharge data from the surgical centers is matched with the complete FCDS Master-file database regardless of the type of cancer or the discharge date. Records are matched on Social Security Number, Date of Birth, Sex, Race and County of Residence. Each AHCA record that does not match with a case in the FCDS Master-file is identified on the Consolidated Follow Back Unmatched Cancer Records Request listing for reporting.
3. Unmatched Ambulatory Surgery Center Cases are posted to the FCDS IDEA. Cases must be reviewed for reportability and abstracted using FCDS IDEA Single Entry. If the case is “not reportable” the appropriate AHCA Disposition Code must be entered in FCDS IDEA to explain why the facility will not report the case.

| Code | Description |
|------|---|
| 1 | Reportable-Missed Case-Case to be Abstracted & Reported by Facility |
| 2 | N/R - Tumor was Not Malignant - Behavior = 0 or 1 |
| 3 | N/R - NonReportable Skin Cancer - Site=C44.* and Morph = 8000 to 8110 |
| 4 | N/R - No Evidence of Cancer at This Time - NED |
| 5 | N/R - Consultation Only |
| 6 | N/R - Cancer Not Proven - Equivocal |
| 7 | Case Previously Reported to FCDS by this Facility |
| 8 | N/R - Outpatient Record with No Active Cancer Documented in Record |
| 9 | N/R - Insitu Cancer of Cervix or CIN III |
| 10 | N/R - Other |
| 11 | Reportable-Case Abstracted BUT Not found in FCDS files - Abst Requested |
| 12 | N/R - No Cancer Mentioned in Medical Record |
| 13 | Skins we elected not to FB since most of them turn out N/R |
| 14 | N/R - Hematopoietic Diseases Dx Prior to 2001 |
| 15 | N/R - Case DX Prior to FCDS Reference Date - Same Cancer/Same Facility |
| 16 | N/R - Benign or Borderline Brain/CNS Tumor Dx Prior to 2004 |
| 20 | Unknown if Reportable - No Record of this Patient at this Facility |
| 21 | Unknown if Reportable - Lost Medical Record |
| 30 | Unknown if Reportable - No Follow-Back Ever Returned by this Facility |
| 40 | N/R - Special Case - Other |
| 50 | Hospice Case - Not A Hospital |
| 51 | Transitional Care Center - Not A Hospital |

G. FREESTANDING RADIATION THERAPY CENTERS

Those facilities that do not voluntarily report full cancer abstracts to FCDS must upload minimal data on all cancer patient encounters for casefinding using the FCDS IDEA. FCDS will match the cancer records identified by each facility against the FCDS Master file. Each record that does not match with a case in the FCDS Master file will be identified for reporting.

H. PRIVATE PRACTICE PHYSICIAN OFFICES

Practitioners licensed under Chapters 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. Each physician office shall submit each cancer case report electronically. FCDS requires physician office (claims) reporting from medical oncology, hematology, urology, and other physician practices. Dermatology practices report under the Dermatology Reporting Module (abbreviated reporting mechanism designed to report skin cancers).

CAPIS: Electronic Reporting Options for Physicians delivering non-surgical treatment to cancer patients is an option that minimizes physician requirements to report cancers and streamlines the data submission process. This would include medical oncologists, hematologists, radiation therapy programs, and other non-surgical cancer treatment physician practices and centers. Electronic Reporting of Physician Claims is processed through the CAPIS System at FCDS. Please contact Meg Herna, FCDS Manager of Data Acquisition for more information on how to report claims from your physician office and help FCDS complete reporting of all therapies administered in physician offices.

I. CLINICAL LABORATORY CANCER IDENTIFICATION PROGRAM

Every anatomic pathology laboratory that reads biopsy specimens and/or surgical resection specimens collected from patient encounters within Florida MUST electronically submit the specified data for every malignant cancer case. This includes ALL hospital labs and ALL non-hospital labs.

FCDS continues to add new labs every year and consistently works with the larger labs to improve the reporting of e-pathology reports to FCDS. Please contact FCDS to learn about automated reporting of electronic pathology reports to FCDS.

Complete information, reporting specifications and pathology lab case report record layout can be found on the FCDS website at <http://fcds.med.miami.edu>. Each pathology laboratory has multiple submission choices; generating a tab delimited file from their existing database, using the web-based software provided by FCDS, generating an HL7 formatted file for download or generating an HL7 formatted file for transmission using PHINMS. Click on the PATH LAB icon then scroll down to the Path Labs File Layout. The document describes in detail the various formats that are acceptable to FCDS. The rest of the PATH LAB page includes important information for reference, including; the NAACCR/FCDS cancer terms, SNOMED codes and ICD-9 code files you should use to filter and select only the lab records that identify cancer as specified in these standard files.

J. FCDS RESPONSIBILITIES

1) Data Acquisition

To support the data acquisition aspect of the statewide registry, FCDS will:

- a. Provide manuals, which specifically define data collection and reporting requirements,
- b. Provide a data collection tool(s) and user manual(s) for electronic/web-based data submission,
- c. Train facility staff and interested parties in incidence data collection via FCDS sponsored training programs (NAACCR Webinars), FCDS web-based training modules, teleconferences, FCDS web broadcasts or recorded educational events and programs. All FCDS-originated training materials and web broadcasts are recorded and free on the FCDS website.
- d. Provide Alternate Resources for Self-Instruction in Cancer Abstracting.
- e. Provide Information regarding preparing for and writing the ODS Exam.
- f. Provide specific routine reports to verify data submission and resolve data discrepancies.

2) Training and Education

FCDS develops, teaches, and supports a full range of Education and Training Options including:

- FCDS hosts a 2-day Annual Conference to Inform Registrars of New Initiatives and Standards
- FCDS hosts 4-6 educational webinars each year focusing on special topics
- Appendix P provides multiple resources for a beginner to advanced hospital and central cancer registry training: cancer surveillance, cancer registry, abstracting and coding cancers, etc.
- FCDS hosts 12 NAACCR Educational Webinars, allowing 110 Florida Registrars to view the live sessions.
- ALL 12 NAACCR Educational Webinars are available in recorded sessions in FLccSC
- Additional free resources are advertised through the FCDS Memo and blast e-mail.

3) Quality Control

The primary objective of the Florida Cancer Data System (FCDS) is to maintain a high-quality database of useable, timely, complete, and accurate data for every case of cancer identified in the state of Florida.

- a. **Completeness** is the extent to which all required cases have been reported to FCDS. Completeness is also the extent to which each abstract includes all the FCDS Required Data

Completeness is assessed using:

- i. Historical data from facilities
- ii. On-Site or Remote Access Casefinding Audits
- iii. Annual Linkage to Florida's Agency for Health Care Administration statewide patient encounter files – AHCA Casefinding Audits (AHCA Match)
- iv. Annual Linkage to Florida's Bureau of Vital Statistics statewide death files - Mortality Casefinding Audits (Death Certificate Notifications)
- v. FCDS Audits and Visual Editing (QC Review)
- vi. NPCR Audits and Visual Editing Evaluations (DQE)

- b. **Accuracy** is the extent to which the data submitted have been correctly coded and match the information in the medical record. Accuracy encompasses correctly interpreting and applying coding rules and guidelines, identifying data entry and submission errors and evaluating case correctness.

Accuracy is assessed using:

- i. FCDS Abstractor Code Testing

- ii. FCDS Abstractor Code Annual Renewal Testing
- iii. Field-Item, Inter-Item and Intra-Item Data Edits
- iv. QC Visual Review Sampling of Every 25th Record – Visual Editing
- v. On-Site Re-Abstracting Audits
- vi. Remote Access Re-Abstracting Audits – Visual Editing
- vii. Mail-In Re-Abstracting Audits
- viii. FCDS Management Reports

- c. **Timeliness** involves how quickly each reporting facility submits cases to FCDS once a patient enters the health care system. The standard set forth by NAACCR, CDC/NPCR, ACOS/COC and FCDS is that 95% of all new reportable cancer cases seen at any facility must be abstracted, submitted and any corrections for edit failures be completed within 6 months from the service date. 100% of cases must be submitted by June 30 of any given year.

Timeliness is assessed using:

- i. Admissions by Facility Report
- ii. Facility Timeliness Report
- iii. Monitoring the number of cases reported to FCDS after each annual deadline
- iv. Monitoring the number of cases reported to FCDS after Certification of Completeness
- v. AHCA Audits – All In-Patient and Ambulatory Care Facilities in Florida
- vi. FAPTP Audits – Most Pediatric Facilities in Florida

Timeliness: Case Abstracting Requirements

Individual cases must be abstracted no later than six months after the date of first contact with the reporting facility. The only exceptions to this reporting timeline are the free-standing ambulatory surgical centers reporting under the Ambulatory Centers Cancer Reporting Program.

Cases may be abstracted earlier than six months after the date of first contact, but only if the required information regarding first course of therapy is available and complete.

All cases meeting the reporting requirements outlined in Section I.A must be abstracted following the guidelines outlined in Section II of this document. Questions regarding interpreting individual data items should be referred to the FCDS office.

Florida Statute requires that cases be completely abstracted (all information must be included regarding the diagnosis, staging, first course of treatment, cancer progression or recurrence) within 6-months of first patient encounter for cancer at your facility.

The CoC STORE Manual instructs registrars from CoC Programs that the data item “Date Case Completed” should not be filled in until the case has been completed and all data required have been abstracted/coded.

The case is “pending completion” until all first-course treatments have been investigated and documented in the original abstract sent to FCDS and the final abstract sent to the NCDB.

4) FCDS Quality Control Program Components**a) FCDS/Agency for Health Care Administration (AHCA) Casefinding Audits**

FCDS staff will perform annual matching of the FCDS Master File to the Florida Agency for Health Care Administration (AHCA) files for both inpatient and outpatient/ambulatory patient encounters. FCDS will provide the reporting facility with an electronic list of Unmatched AHCA Cases (cases that appear in the AHCA files but have no matching record in the FCDS Master File) available on the FCDS website.

Consolidated AHCA and Vital Statistics Follow-Back (Casefinding Audits).

The Consolidated AHCA and Vital Statistics Follow-Back will be available via FCDS IDEA.

The facility abstractor must compare the Unmatched Follow Back Cases list to the facility “Not Reportable List”. Cases that appear on the Unmatched listing but do not appear on the “Not Reportable List” will need to be reviewed by the facility abstractor.

Upon review, if any case is found to meet the cancer reporting requirements outlined in Section I, the case must be abstracted and reported to FCDS. These cases are a priority reporting item and must be abstracted immediately. Please reference the AHCA Disposition Codes List for “reason not reported to FCDS”.

| Code | Description |
|------|---|
| 1 | Reportable-Missed Case-Case to be Abstracted & Reported by Facility |
| 2 | N/R - Tumor was Not Malignant - Behavior = 0 or 1 |
| 3 | N/R - NonReportable Skin Cancer - Site=C44.* and Morph = 8000 to 8110 |
| 4 | N/R - No Evidence of Cancer at This Time - NED |
| 5 | N/R - Consultation Only |
| 6 | N/R - Cancer Not Proven - Equivocal |
| 7 | Case Previously Reported to FCDS by this Facility |
| 8 | N/R - Outpatient Record with No Active Cancer Documented in Record |
| 9 | N/R - Insitu Cancer of Cervix or CIN III |
| 10 | N/R - Other |
| 11 | Reportable-Case Abstracted BUT Not found in FCDS files - Abst Requested |
| 12 | N/R - No Cancer Mentioned in Medical Record |
| 13 | Skins we elected not to FB since most of them turn out N/R |
| 14 | N/R - Hematopoietic Diseases Dx Prior to 2001 |
| 15 | N/R - Case DX Prior to FCDS Reference Date - Same Cancer/Same Facility |
| 16 | N/R - Benign or Borderline Brain/CNS Tumor Dx Prior to 2004 |
| 20 | Unknown if Reportable - No Record of this Patient at this Facility |
| 21 | Unknown if Reportable - Lost Medical Record |
| 30 | Unknown if Reportable - No Follow-Back Ever Returned by this Facility |
| 40 | N/R - Special Case - Other |
| 50 | Hospice Case - Not A Hospital |
| 51 | Transitional Care Center - Not A Hospital |

b) FCDS/Bureau of Vital Statistics Casefinding Audits (Death Clearance Audit)

FCDS staff will annually match the FCDS Master File to the Florida Bureau of Vital Statistics death files. FCDS will provide the reporting facility with a list of unmatched Vital Statistics cases (deaths) that show the place of death as the reporting facility.

Consolidated Vital Statistics and AHCA Follow-Back Casefinding Audits

The Integrated Vital Statistics and AHCA Follow-Back will be available via FCDS IDEA.

The facility abstractor will need to research these cases to determine if the patient did expire at the facility and whether the case meets the cancer reporting requirements. If any case meets the reporting requirements, the case must be abstracted and reported to FCDS.

For each case that will not be reported to FCDS or did not expire at the reporting facility, FCDS requires a brief statement be submitted that sufficiently explains why the case will not be reported. Please reference the Death Clearance Disposition Codes Listing below for “reason not reported to FCDS”.

| Code | Description |
|------|--|
| 0 | Pending Follow Back |
| 1 | Missed Case - Case Abstracted & Reported by Facility |
| 2 | N/R - Tumor was Not Malignant - Behavior = 0 or 1 |
| 3 | N/R - NonReportable Skin Cancer - Site=C44.* and Morph = 8000 to 8110 |
| 4 | N/R - No Evidence of Cancer at This Time - NED |
| 5 | N/R - Consultation Only |
| 6 | N/R - Cancer Not Proven - Equivocal |
| 7 | Case Previously Reported to FCDS by this Facility |
| 8 | N/R - Outpatient Record with No Active Cancer Documented in Record |
| 9 | N/R - Insitu Cancer of Cervix or CIN III, VIN III, VAIN III, PIN III |
| 10 | N/R - Other |
| 11 | Case Abstracted by Facility but Not found in FCDS Masterfile |
| 12 | N/R - No Mention of Cancer in Medical Record |
| 13 | This follow-back code no longer valid |
| 14 | N/R - Non-Reportable Myeloproliferative Disease - Dx Prior to 2001 |
| 15 | N/R - Case DX Prior to FCDS Reference Date - Same Cancer/Same Facility |
| 16 | N/R - Benign or Borderline Brain/CNS Tumor Dx Prior to 2004 |
| 20 | Unknown if Reportable - No Record of this Patient at this Facility |
| 21 | Unknown if Reportable - Lost Medical Record |
| 30 | Unknown if Reportable - No Follow-Back Info ever Returned by Facility |
| 40 | N/R - Special Case - Other |
| 41 | This Vital Statistics Record Matches an AHCA Record- For FCDS Use Only |
| 50 | Hospice Case - Not A Hospital |
| 51 | Transitional Care Center - Not A Hospital |
| 52 | Not A Hospital, NOS |
| 53 | Closed Facility - No Records Available |
| 54 | Nursing Home Death or Residence Death, Not A Hospital Death |
| 55 | DCO Replaced by Non-DCO- For FCDS Use Only |
| 56 | Report Source 7 or 8 is corrected and does not link back to proper Pt. |
| 57 | Demographic information changed. Death Certificate linkage was lost. |

c) FCDS EDITS Metafile includes Field-Item, Inter-Item and Intra-Item Data Edits

FCDS uses a standard EDITS Metafile modified to meet Florida requirements. The FCDS EDITS Metafile can be found on the FCDS website, and a master listing of changes by date. FCDS EDITS include data edits to validate codes, cross-check related data items and records, and check for blank fields. The Florida-specific data edits were created for all Florida-only fields, and common abstracting errors were identified through re-abstracting audits. Edits are reviewed as needed (monthly). New edits are added as needed.

d) QC Visual Review Sampling of Every 25th Record – Visual Editing

FCDS Quality Control staff visually review at least one in every 25th record submitted by each reporting facility. The Quality Control Visual Review is designed to facilitate visual editing of abstracted data. It allows a trained eye to detect inconsistent coding that electronic edit checks cannot identify; it is a tool to identify deficiencies in abstractors' understanding of abstracting concepts, data definitions and coding selections that may require additional training.

The QC Abstract Review Case Selection Process is fully automated and randomly selects one of every 25th record processed, which accounts for 4% of cases being visually reviewed for accuracy. Each case selected is placed in a QC file and is ready for visual review by the FCDS QC staff. Records with discrepant data must be resolved by the reporting facilities through FCDS IDEA by making return comments on each case (agree/disagree/add documentation to support original coding/other rationale).

The case is then reviewed again by FCDS QC staff (different staff than the original FCDS Reviewer), and a final decision is made based on all available information.

This three-step process provides the registry every opportunity to dispute identified “errors” or “deficiencies” in the abstract by having three ODS or ODS-eligible staff review each case and provide documented input to what they interpret from the documentation provided in the original abstract.

This process also serves as an educational tool for new and experienced registrars, providing comments on

a case-by-case basis about where they have deficiencies in their abstracting tool kit and what they should be doing when abstracting specific cases.

Registry Managers should always share results with the staff members responsible for the original abstract. Otherwise, they will continue to make the same error without knowledge they are doing something incorrectly, inconsistently, or out of sync with national reporting standards and guidelines.

e) QC Facility Analysis Report Available in IDEA

The QC Facility Analysis Report is accessible to users with HOSPADMIN or FAA User Roles. We hope this new report will help to meet CoC Requirement 6.1.

The user can select the period for the report. The report will display every case that FCDS Visually Edited (QC Every 25th Case) and the result of that Review (See Below).

This report has been designed specifically to address CoC Cancer Program Requirement 6.1 by giving you a total of cases quality controlled by FCDS in any given period, the accession number and sequence of each case reviewed, and the outcome from each review, including the Turnaround Time in days with totals at the bottom of the report. The report is exportable to Excel or you can print it in PDF format.

If your program manages multiple facilities, you must run a separate report for each facility. The Report is not set up for a multi-facility network of facilities to be combined.

FCDS has no plans to add the FCDS Abstractor Code to this report. We want to keep this information at the facility level, not the individual abstractor level. The QC Sample is not a large enough sample of a person's work for performance evaluation.

| Accession | Receipt | Completed | Turnaround | Corrected | Forced | Deleted | No Changes |
|-----------|------------|------------|------------|-------------------------------------|--------------------------|--------------------------|-------------------------------------|
| | 04/16/2020 | 08/10/2020 | 116 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | 12/30/2020 | 01/17/2021 | 18 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| | 05/04/2020 | 07/01/2020 | 58 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| | 01/20/2020 | 03/02/2020 | 42 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| | 12/22/2020 | 01/13/2021 | 22 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| | 12/14/2020 | 01/10/2021 | 27 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| | 07/30/2020 | 10/02/2020 | 64 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| | 08/27/2020 | 10/19/2020 | 53 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

f) FCDS Follow-Up Reports in IDEA

FCDS makes updated/consolidated First Course of Treatment Data and Follow-Up Dates (including Dates of Death) available via the FCDS Follow-Up Inquiry and Batch Reports Menu. This inquiry/report system has been available since 2014 in IDEA, but is often overlooked as a resource for patient follow-up for CoC Accredited Facilities, and as a way to find and complete First Course of Therapy received in a physician's office or other setting (not at your facility). This report is available to HOSPADMIN and FAA roles in FCDS IDEA.

All you need to do is provide the inquiry system with your 4-digit Facility Number, Accession Number, and Sequence Number. The system will find your case to verify that you have reported the cancer to be matched. Then the system will pull down all of the First Course of Therapy Data (including start dates) from all facilities that have reported the cancer and have provided treatment data; this is via the Consolidated Tumor Record, a single-source FCDS Record that provides a summary of all of the data submitted to FCDS for this person for this cancer.

This report may provide you with more treatment data than you could access while the patient was at your facility, including physician-office treatment, other facility treatment, radiation therapy, or other cancer-directed therapies. The system cannot provide you with any outpatient pharmacy data as these data are not part of the FCDS Cancer Reporting System, but it will give you a complete course of treatment for this cancer.

The report can be run one case at a time or in a batch mode. To batch cases, you must create a file that includes the 4-digit facility number, 9-digit Accession Number, and 2-digit Sequence Number. These data must be in a comma-delimited file with no spaces between items. You load the file and wait for the result. You will get individualized treatment by case for all treatment reported on this person/cancer to FCDS from any source. You will not know the source of the treatment, only that it was given and the date it started. You will also receive a date of last contact from AHCA and/or a State of Florida Death Certificate.

The report will also tell you which cases matched or did not match or if you have a problem with the file format. Any of these inconsistencies will result in a no-match for the case. You can either display the results on your screen, export them to a comma-delimited or tab-delimited file, or export them to an Excel-formatted file for review & entry.

g) On-Site or Remote Access Re-Abstracting Audits

The FCDS Quality Control staff and/or outside contract agents working on behalf of FCDS will perform on-site or remote access review of abstracting procedures by auditing individual reports and/or entire medical records of cases previously submitted to FCDS. The data validation or re-abstracting audit verifies that coded data submitted to FCDS can be validated compared to source documents at the hospital or central registry level. Discrepant data are followed back to the originating institution for clarification.

Reconciliation of the Re-abstracting Audit: Key data items will be evaluated, and any discrepancy noted between the auditor's findings and the original abstract findings will be returned to the facility for reconciliation. Documentation must be submitted to clarify the originally abstracted codes if the auditor's findings are disputed.

These audits allow assessment regarding the standardized interpretation of data definitions, coding rules, guidelines, policies, and procedures, and identify areas that may require further education and training.

Remote Access Re-Abstracting Audits

FCDS may substitute On-Site Re-Abstracting Audits with Remote Access Re-Abstracting Audits. Should FCDS decide to perform Remote Online audits, facilities will be asked to make pertinent reports from medical records and/or other data sources available to FCDS for review. FCDS will utilize existing source documents used in routine reporting.

h) FCDS Abstractor Code Policy

Every abstractor planning to work in the State of Florida is required to obtain an individual FCDS Abstractor Code. FCDS assigns this code to persons who successfully pass the FCDS Abstractor Code On-Line Test, regardless of certification by NCRA as an ODS, experience in the registry industry, or other factors. As of January 1, 2013, any individual planning to acquire a New FCDS Abstractor Code or to renew an existing FCDS Abstractor Code must take and pass the FCDS Abstractor Code Exam. Registration for testing and real-time online testing can be found on the FCDS website.

The FCDS Abstractor Code test requirement applies to every cancer registrar in Florida (ODS or non-ODS, Florida resident or out-of-state contractor, regardless of the number of years of experience. FCDS will not accept cases from individuals without an active or current FCDS Abstractor Code.

While the FCDS Abstractor Code Requirement Policy remains unchanged, the FCDS Abstractor Code Test is a tool introduced to help FCDS expedite FCDS Abstractor Code approvals, renewals, and monitoring. Tests are short (20 multiple choice or T/F questions) with a variable mix of content questions weighted differently depending on whether this is an exam for a New FCDS Abstractor Code or Renewal of an existing FCDS Abstractor Code.

Questions are updated annually to ensure the tester is familiar with the most current standards. They are randomly selected from a pool of more than 350 questions covering 7 major topic areas. No two exams will be alike.

Tests (20 multiple-choice or T/F questions) with a variable mix of content questions are short.

Questions are updated annually to ensure the most current standards are familiar to the tester.

Questions are randomly selected from a pool of more than 350 questions covering 7 major topic areas. No two exams will be alike.

The 7 topic areas include:

- Florida Reporting Requirements
- General Abstracting Knowledge
- Anatomy and Physiology
- Primary Site/Histology/Grade
- Stage at Diagnosis (SS2018, SSDI, Grade Coding Instructions)
- Latest Rule Changes
- Treatment and Survival

Before taking the test, please read through and become familiar with the FCDS DAM to ensure you understand all the Florida abstracting and data collection requirements. The current version FCDS DAM can be found on our website, <http://fcds.med.miami.edu>. There are a few Florida-specific requirements critical to complete reporting in Florida that many out-of-state registrars miss – reporting non-analytic cases and all historical cancers.

FCDS monitors use of individual codes and is alert to the practice of sharing abstractor codes for new staff, temporary staff, and even permanent staff. Please be secure with your abstractor code, abstracted data, personal information, and all confidential materials.

i) Admissions by Facilities Report

FCDS Data Acquisition staff will regularly review the Admissions by Facilities Report (an internal FCDS report). This report compares observed to expected numbers of cases reported by each facility for any period requested.

The report is based on a five-year historical summary of cases reported to FCDS by each facility. The ratio of observed to expected is reported as a percent of completeness. These same data are included in the Quarterly Activity Report.

FCDS Staff will notify facilities that have not reported the expected cases.

j) Facility Timeliness Report

FCDS Data Acquisition staff will review the Facility Timeliness Report regularly. This report shows the average time (in days) it takes the reporting facility to submit a case to FCDS.

It specifically; 1) calculates the difference between the date the reporting facility had the first contact with the patient and the date the case was abstracted, 2) calculates the difference between the date the case was abstracted and the date the case entered the FCDS Master File, and 3) calculates the difference between the date the reporting facility first had contact with the patient and the date the case entered the FCDS Master File.

The time between the date the reporting facility had contact with the patient and the date the case entered the FCDS Master File should be 180 days or less. These same data are included in the Quarterly Activity Report (see Section Forms).

k) Other Quality Control Studies and Audits

FCDS Quality Control staff will run quarterly reports to help identify areas of concern regarding reporting by individual facilities. These quarterly reports will be used to identify trends in case reporting that may need to be addressed at a facility or the state level. Similar analyses may be conducted for individual abstractors within the facility. The FCDS Quality Control staff will perform ad-hoc inquiries to the FCDS Master File when data requests are made. Any unusual data will be reviewed, and facility-abstracting staff may be requested to review individual cases to confirm the reporting of certain data items.

l) Facility Evaluation Report

The report is a graphical and numerical representation of a reporting facility's performance over a given period, detailing the three principles of data appraisal: Timeliness, Completeness and Accuracy.

m) FCDS Data Quality Indicator Report (DQIR)

The FCDS Data Quality Indicator Report is designed to provide feedback to registries on the completeness of case abstracts by examining the frequency of coding “unknown” or “ill-defined” values in key analytic data items. Data must meet rigorous national quality standards to be included in local, regional, state, and national cancer rates, reports to Congress, numerous surveillance-related publications and for registry certification.

The percent of “unknown” and “ill-defined” values is an indicator used in ranking Florida’s overall data quality and completeness of case reporting. It is used when comparing Florida data to other states for overall data validity and reliability.

These data are also early indicators of problem areas and areas where FCDS and local registries can improve cancer reporting, as data are available.

The report includes the Florida state and National distribution of “unknown” values used for comparison. The report uses data from analytic cases only.

This report is a scaled-down model of a similar report the CDC National Program of Cancer Registries (NPCR) provides to Florida and each NPCR state to assess our state-wide data.

5) Data Requests

Before applying to data, you should review the new Automated Data Request instructional videos on the FCDS Data Request Web page. The tutorials explain how to navigate the DREAMS system. FCDS will no longer accept paper applications.

Procedures for Data Release

All data requests, regardless of the nature of the request, must be submitted to FCDS via the FCDS Data Request Automated Management System (DREAMS) module on the FCDS Website. All requests require an FCDS IDEA account; if a researcher does not have an FCDS IDEA account, he or she must first establish one. Please refer to the video 'New IDEA User' instructions on the Data Requests page of the FCDS Website.

Requests for data fall into five broad categories: (1) stat data, (2) tabular, (3) ad hoc, (4) data linkage and (5) hospital specific requests. There are specific procedures and fees for each category. This document provides a description for each of the categories as well as the fee. You should read this document before filling out a DREAMS application.

Instructional videos are available for each request category. Please refer to the FCDS Data Request web page video before you begin your automated data request.

Four separate and distinct entities are involved in the data release approval process. The number of entities involved in processing your request depends on several factors. Please refer to the specific category to see which entities are involved.

- 1) Florida Cancer Data System (FCDS) maintains and collects the data. FCDS performs data extracts after approvals are obtained from the Florida DOH Cancer Registry Program (CRP) and, if required, from the Florida DOH IRB (IRB).
- 2) The Florida DOH Cancer Registry Program (CRP) decides what variables will or will not be released based on scientific merit, and if variables are available that will meet the research needs of the proposed research. The CRP will also decide whether the application will require Florida DOH IRB approval. CRP approval must be obtained before submitting for IRB approval.
- 3) **Florida DOH IRB (IRB)** reviews data applications to ensure they are ethical and protect participants. *The DOH IRB submission is **outside** of DREAMS.*
- 4) **Florida DOH Vital Statistics (VS)** requires the requestor to apply for approval of data items derived from death certificates. This is also outside DREAMS.

| Request Category | Approval Required by | | | |
|--------------------------|----------------------|----------------|----------------|----------------|
| | FCDS | CRP | IRB | VS |
| Stat | X | | | |
| Tabular | X | X ¹ | | X ¹ |
| Ad hoc | X ² | X | X ¹ | X ¹ |
| Linkage | X ² | X | X ¹ | X ¹ |
| Hospital Specific | X | | | |

1 May or may not be required, depending on cell size, geographic level, source, requested variable(s), etc.

2. The application is reviewed to ensure that it is complete and that all information has been submitted before it is forwarded to the CPR for approval; it is not reviewed for scientific merit.

DATA REQUEST CATEGORIES**(1) Stat Data Request**

Currently, FCDS provides one static dataset. This is a flat file. You will need some software to read in the data and analyze it (i.e. SAS, SPSS, SQL). For a complete list of variables in the dataset, please refer to the “Variables available for request”. The list of variables in the Stat dataset file is fixed; it is strongly recommended that the requester review the STAT layout.pdf before applying for a Stat dataset.

The stat dataset is free of charge. It contains county-level case data for all sites, with many demographic variables collapsed into aggregate groups, such as age, race, marital status, etc. Refer to the Stat layout.pdf for the dataset and aggregated demographic variables. Please log in to DREAMS, select Stat Dataset, and follow the submission instructions for this type of request.

Note: if your study requires record-level data and the variables needed are not contained in the Stat dataset, or the aggregated groups will not meet your research needs, you must apply for an Ad Hoc/ type request. Refer to the Ad hoc category for more information.

The Stat dataset is updated annually, with the most recent year added as it becomes available.

FCDS will fill data requests for the Stat Dataset within 30 business days once the application is complete and approved.

Please view the Stat Data Request Video before filling out the DREAMS application for this type of request.

Entities involved in approving the Stat dataset: FCDS.

(2) Tabular Data

These requests concern requests requiring output in tables or some specific statistical output. An example of tabular data in a table could be a table such as

| | Gender | |
|-------------|--------|--------|
| Cancer Site | Male | Female |
| Colon | A | B |
| Rectum | C | D |

An example of tabular data could also be statistical output such as the mean age at diagnosis for brain cancer.

To protect the indirect identification of the patient, the "rule of ten" is applied; this rule suppresses any counts containing fewer than 10 cases. Tabulated data may be released at or above the county code level with a count of 10 or greater; for counts less than 10 or data below the county level, approval will be required from the CRP.

If data with counts fewer than 10 or below the county are needed, be sure to specify why in your application; the CRP will need this information.

In addition, if you request output in the form of tables, it is highly recommended that the requestor submit templates of how the data will be displayed.

FCDS will fill most tabular data requests within 30 business days once the application has been completed and the cost has been approved; tabular requests are invoiced by the hour. For additional information, refer to the fee and billing procedure section.

Please watch the Tabular Request Video before making this type of request.

Entities involved in approving tabular requests: FCDS and possibly CRP and VS. VS approval is only

required for those studies wanting to obtain variables derived from death certificates

(3) Ad hoc

In DREAMS, this category is also referenced as Ad hoc/patient.

Research requiring record-level data for secondary analysis or patient contact will need to make this request. Please review the available variables for release to ensure that FCDS has the variables to meet your research needs. Note: date of birth, month, and day are NOT releasable.

Note: The Florida Department of Health (CRP & IRB) can approve ad hoc/patient requests in 8 weeks to 18 months, depending on the request's complexity and the application's thoroughness. Please plan accordingly.

FCDS will fill most ad hoc/patient requests within 30 business days once the application has been completed and the cost has been approved. Ad hoc requests are invoiced by the hour, and patient contact studies are invoiced according to the number of records extracted. Refer to the fee and billing procedure section for additional information.

Please watch the Ad Hoc Request Video before making this request.

Entities involved in approving ad hoc/patient requests: CRP and possibly VS and IRB. The CRP will determine whether or not IRB approval is required. VS approval is only required for those studies wanting to obtain variables derived from death certificates.

(4) Data Linkage

A data linkage project is a request that involves linking internal FCDS data to an external data set.

Fields used in the linkage must be consistent in both data sets. The researcher should send FCDS the data in a fixed-length ASCII file with the proper record layout and format. (Refer to Data Linkage Record Layout document). Any deviations from the record layout or format that require adjustment to the external data set will be charged to the requestor according to the fee schedule (Refer to Fees and Billing Procedure below).

At a minimum one of the following combinations are required to link records with FCDS:

- 1) First Name, Last Name, Sex, Date of Birth, Zip Code and Street Address
- 2) First Name, Last Name, Sex, Date of Birth, and Social Security Number

Additional information such as Middle Initial, Alias Name, Maiden Name, City, State, and Birthplace improve chances of successfully linking your records to FCDS. We strongly encourage you to submit these data items if available.

FCDS will fulfill data linkage requests within 8 weeks once the request and cost have been approved. Currently, FCDS utilizes a combination of R and Stata for data linkages. Requests using other software can be considered but may result in additional fees and increased time, in which case the 8-week timeframe does not apply, and the researcher may incur extra charges. A copy of the required record layout, "Data Linkage Record Layout," is available under the "Data Request" link on the FCDS website <http://fcds.med.miami.edu>.

All linkages must occur at the Florida Cancer Data System office. No offsite linkages are permitted.

Please watch the Data Linkage Request Video before making this request.

Entities involved in approving linkage requests: CRP and possibly VS and IRB. The CRP will determine whether or not IRB approval is required. VS approval is only required for those studies wanting to obtain variables derived from death certificates

(5) Hospital Data Requests

Hospital data requests refer to requests for data downloads that your facility has submitted.

To access this module, you must be the Facility Access Administrator (FAA).

You can select the admission year(s) you would like to have extracted, and the download will be available in the latest NAACCR version record layout.

Please watch the Hospital Specific Request Video before making this request.

Entities involved in approving hospital-specific requests: FCDS

Fees and Billing Procedure

Most requests generate a fee. The FCDS does not receive additional funding to perform special, ad-hoc data analysis; therefore, actual costs are passed on to the research applicant. The fees are as follows:

- STAT Dataset - No Charge
- Minimum charge - \$150.00
- Ad Hoc: Statistical analysis/programming/data coordination - \$150.00 per hour

- Data Linkage:

| | <i>Number of Records</i> | <i>Cost</i> |
|----------------|--------------------------|--|
| Sliding scale: | <10,000 | \$3,000 |
| | 10,000 – 24,999 | \$2,500 fee plus .05 cents per record |
| | 25,000 – 49,999 | \$3,000 fee plus .03 cents per record |
| | 50,000 – 99,999 | \$3,500 fee plus .02 cents per record |
| | 100,000 – 249,999 | \$4,000 fee plus .015 cents per record |
| | 250,000+ | \$5,000 fee plus .011 cents per record |

- Geocoded & Patient Contact lists

| | <i>Number of Records</i> | <i>Cost</i> |
|----------------|--------------------------|-------------|
| Sliding scale: | <10,000 | \$1,500 |
| | 10,000 – 24,999 | \$2,000 |
| | 25,000 – 49,999 | \$2,500 |
| | 50,000 – 99,999 | \$3,000 |
| | 100,000 – 249,999 | \$3,500 |
| | 250,000+ | \$4,000 |

Please note:

The billing procedure follows once approval is granted and the data request is processed, the researcher will be notified in DREAMS when the dataset is available for download. An invoice will be downloaded along with DREAMS's data request results or linkage. Payment may be made by check, purchase order or credit card.

Data linkage fees are charged for projects matching an outside data source to the Florida Cancer Data System database.

Other Information:

Additional information, such as published resources and statistics, is available on the FCDS website: <http://fcds.med.miami.edu>.

All media requests should be directed to The FL DOH Office of Communications Director at 850-245-4111.

FCDS maintains a list of all published articles using FCDS Data. Please provide information on any scientific publications resulting from a data request. Thank you

K. FCDS MANAGEMENT REPORTS

FCDS Quarterly Activity Status Report

This report summarizes the FCDS file activity for each facility every quarter. Every facility should have some file activity during every quarter of the year. The report documents information about the number and quality of cases submitted during the previous quarter and the timeliness of reporting. Also, it provides an annual incidence and completeness summary, which compares observed-to-expected numbers of cases reported for the year. (See Forms Section)

FCDS Data Quality Indicator Report

This report is a scaled-down version of a similar report provided by the CDC National Program of Cancer Registries (NPCR) to Florida and each NPCR state as an assessment of statewide data. The report reflects five years of data and examines the frequency of assigning “unknown” or “ill-defined” values to key analysis variables over those five years, with a comparison to national data.

The percent of “unknown” and “ill-defined” values in certain variables is a data quality indicator used to rank Florida’s overall data quality and completeness for each case reported and is used when comparing Florida data to other states for overall data reliability. These data are also indicators of problem areas where FCDS and local registries can improve upon cancer reporting as data are available.

Annual AHCA Unmatched Report

The AHCA Unmatched Report and subsequent follow-back procedures are used to assess casefinding completeness at the facility level.

Annual Bureau of Vital Statistics Unmatched Report

FCDS staff will annually match the FCDS Master File to the Florida Bureau of Vital Statistics death files. FCDS will provide the reporting facility with a list of unmatched Vital Statistics cases (deaths) that show the place of death as the reporting facility.

Consolidated Vital Statistics and AHCA Follow-Back Reports (Casefinding Audits).

Consolidated Reports Vital Statistics and AHCA Follow-Back Reports will be available via FCDS IDEA.

FCDS EDITS Master List

This list includes all FCDS edits in the latest FCDS EDITS Metafile and includes the edit number, category, and message. The current list can be found under Downloads on the FCDS website. This list is updated regularly and can be found under Downloads on the FCDS Website.

L. AWARDS

Jean Byers Memorial Award for Excellence in Cancer Registration

Pat Strait Award for Excellence in Cancer Registry Abstracting – The Pat Strait Award for Excellence in Cancer Registry Abstracting is awarded to individuals who contribute to a facility achieving the annual Jean Byers Memorial Award.

The criteria for receiving the Jean Byers Award and the Pat Strait Award are based on a standard set of benchmarks that meet or exceed the requirements for completeness, timeliness, and accuracy as determined by FCDS and CDC. These criteria may change from year to year, depending on annual reporting conditions, but are generally influenced by a combination of successful data quality metrics, including Reporting Deadline, the percentage of missed cases determined using AHCA and Vital Statistics Matching and Follow-Back Results (missed cases cannot exceed 10% of the facility's annual caseload), and other established data quality indicators.

M. FCDS CORRESPONDENCE

DO NOT MAIL ANY MATERIALS CONTAINING PERSONAL HEALTH INFORMATION

To protect and properly handle all packages, FCDS is making the following recommendations:

1. If you are mailing a package to FCDS, use Federal Express, UPS, Airborne Express, or any other courier service.
 - a. The FCDS street address below must be used for courier packages:

FCDS
University of Miami School of Medicine
1550 NW 10 AVE
Suite 406
Miami, FL 33136
 - b. Always request a signature upon delivery.
 - c. Make sure the addressee at FCDS knows that she/he is to expect a package.
 - d. Track the package to ensure that it has reached its destination. You may want to explore the e-mail tracking and notification features that the courier of choice offers.
2. **For non-confidential information**, if using the US Postal Service, which may include Express mail, Priority mail, and Certified mail, you must use the FCDS PO Box address below:

FCDS
University of Miami School of Medicine
PO BOX 016960 (D4-11)
Miami, FL 33101

3. All shipments must adhere to the [FCDS Confidential Information Security Policy](#).

N. CALENDAR/FORMS/TEMPLATES/SAMPLE REPORTS

- FCDS Profile Modification Form - Sample
- FCDS Annual Reporting Calendar
- FCDS Discrepancy Journal - Sample
- Not Reportable List - Template
- FCDS Quarterly Activity Status Report – Sample
- FCDS Data Quality Indicator Report – Sample