

Clinical Laboratory Cancer Identification Program
Program Announcement & Teleconference Announcement
July 1, 2002

Florida's cancer surveillance and control programs have been established under the Florida Department of Health in order to reduce cancer-related morbidity and mortality in our state. As Dr. John Agwunobi, Florida's Secretary of the Department of Health, first announced in his February 8, 2002 letter to you, the Florida Cancer Data System (FCDS) will **activate** a new program, the **Clinical Laboratory Cancer Identification Program (CLIP)** on **July 1, 2002**.

Under this new program, data from surgical pathology reports will be confidentially forwarded to FCDS and used to verify that all cases of cancer have been reported to FCDS and to identify any new cases of cancer that have yet to be reported to FCDS. Unreported cancers will be followed back to individual attending physicians in order to complete a full cancer case report for FCDS as outlined in the Florida cancer reporting legislation and Florida Department of Health Administrative Rules.

This program announcement includes information on reporting legislation, rationale for reporting cancer cases, data requirements and other helpful information to assist you in program planning.

Program specifications including details for cancer case identification, case identification report requirements and instructions outlining procedures for forwarding case identification reports to the Florida Cancer Data System will be explained during a free **dial-up teleconference on Wednesday, June 26, 2002 from 2pm-3pm**. Please see the enclosed purple-copy Teleconference Announcement for more information or contact Betty Fernandez or Bleu Herard at FCDS for more information, **1-800-906-3034**.

Also, please take a few moments to complete the enclosed canary yellow-copy **Clinical Laboratory Information Verification Form** and return it to FCDS **on or before July 1, 2002**.

FCDS looks forward to a cooperative and supportive relationship with each of you. If we can be of any assistance now or in the future, please do not hesitate to contact us.

Thank you for your support.

FCDS

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Attachments

Attachment 1 -	February 8, 2002 letter from John O Agwunobi, MD,MBA Florida Secretary, Department of Health - Program Announcement
Attachment 2 -	Clinical Laboratory Information Verification Form – Yellow Copy – Please Complete and Return to FCDS on or before July 1, 2002 –
Attachment 3 -	Teleconference Announcement – Purple Copy

Florida Cancer Reporting Legislation and Department of Health Administrative Rules

The Florida Legislature has recognized the importance of maintaining a statewide cancer surveillance program since 1981. As a result, **cancer reporting is a legal requirement** for all healthcare facilities in the state of Florida (Florida Statutes - Chapter 381.0031 – Report of diseases of public health significance to department). Reports required by this section of the Florida Statutes “...must be in accordance with methods specified by rule of the department.”

All facilities licensed under Florida Statute 395, which includes pathology laboratories and freestanding radiation therapy centers as defined by Florida Statute 408.07, are required to report cancer incidence data to the Florida Cancer Data System (FCDS). Reportable cancer incidence information is defined by Rule 64D-3.006, which includes, but is not limited to, diagnosis, stage of disease, medical history, laboratory data, tissue diagnosis, radiation, or surgical treatment.

Copies of the referenced statutes and rules were included with the February 8, 2002 letter by John O. Agwunobi, MD. MBA, Secretary Department of Health included in this announcement. Additionally, Florida Statutes and Florida Department of Health Administrative Rules can be quickly and easily referenced using the Florida Online Sunshine website at <http://www.leg.state.fl.us>.

Florida Cancer Data System (FCDS)

The Florida Department of Health (DOH) has designated the **Florida Cancer Data System (FCDS)** as the managing entity under which all cancer cases must be reported. Please visit the FCDS website at <http://www.fcds.med.miami.edu> for more information on the various components that make up the full FCDS Program including cancer case identification and reporting from all healthcare facilities in the state of Florida, Education & Training Programs and numerous additional integrated program components.

Cancer Case Identification & Lab Reporting

A free phone-in teleconference will be held Wednesday, June 26, 2002 from 2pm-3pm to cover the specifics with regard to cancer case identification and lab reporting to FCDS under this new program. Each lab will be responsible for cancer case identification in accordance with HIPAA regulations. In short, there will be three options for case identification at the facility level. A nationally recognized 800-word search and word combination file will be available to electronically search text for identification of cancer cases. Additionally, a listing of both ICD-9 and SNOMED codes as they relate to cancer diagnoses will be made available to electronically search computerized codes for identification of cancer cases. Finally, instructions for manual case identification will also be covered if this is the only means by which your lab can identify cancer cases for submission to FCDS.

RATIONALE: Why Have Laboratories Identify and Report Cancer Cases?

Cancer surveillance activities spearhead Florida cancer research efforts by studying cancer trends and investigating alleged cancer clusters in our communities. Cancer control programs utilize data collected through surveillance efforts in order to target education, prevention and early detection activities toward populations found to be at higher risk for developing cancers. Furthermore, disease surveillance efforts assist in both resources and program planning aimed at improving the health of all Floridians.

The Florida Cancer Data System (FCDS) was established in 1981 to monitor cancer incidence in Florida. This program was originally established as a hospital-based reporting system. Over the past ten years the management and treatment of many cancers has shifted from the more traditional hospital setting where cancer patients historically have been diagnosed and treated for cancer, to the ambulatory patient care setting. Physician offices are increasingly being utilized for both diagnosis and treatment of certain types of cancers. Unfortunately, one result of this shift in settings for delivery of patient care is that the true picture of cancer in Florida can no longer be assessed utilizing only hospital and ambulatory treatment center cancer case reporting.

It is estimated that without case identification by pathology laboratories, including biopsies taken in the physician office setting, that Florida's cancer surveillance system is underestimating cancers in Florida by as much as ten percent overall and up to 50 percent for certain types of cancer. This in turn has an increasing impact on cancer control efforts as well as healthcare facility and patient care planning for our state.

Furthermore, the national Centers for Disease Control and Prevention has recognized these trends and now requires that state cancer surveillance programs receiving CDC funding must include cancer case identification by clinical laboratories in state cancer surveillance efforts as a part of the National Program of Cancer Registries (NPCR). Florida has been an active participant in the NPCR since its inception in 1995.

FCDS is working diligently to ease the burden of this new case identification and reporting program for all parties involved. We expect that the cost in terms of time, personnel, computing and other resources will be minimal.

Electronic Reporting (FCDS IDEA)

All cancer case identification data must be transmitted to FCDS electronically via the Internet using the "FCDS IDEA" (unless FCDS confirms that the facility meets the "fewer than 35 cancer cases" reporting option). Internet data transfer is the only means by which electronic reporting can be accomplished at this time. FCDS has established a secure Internet data transfer website and secure transfer protocol which includes data encryption and multiple password protection as well as a security firewall to insure patient confidentiality.

Data Requirements for Florida Laboratory Case Identification

Essentially, FCDS needs to receive only what is already printed on your existing surgical pathology reports. However, FCDS must receive these data in a specific file format and specific record layout. This file format and record layout is included as an attachment.

FCDS will follow the North American Association of Central Cancer Registries “Consensus Standards for Cancer Registries, Pathology Laboratory Electronic Reporting Recommendations for Data Items, Formatting and Data Transfer” - Version 1.1, September 2000 in establishing Florida case identification, record layout and file transfer requirements. These standards can be found on the NAACCR website, <http://www.naacr.org> in the Standards Section.

We have included the Florida required record layout and file specifications for laboratory case identification in this program announcement for your information. Files must be submitted in a tab-delimited format. The data items designated with an “R” are required to be reported to FCDS. Data items designated with an “O” are optional. Some of the required data items may not be available in your surgical pathology reporting information system. FCDS will provide ‘default’ values for any data items not readily available in your pathology record.

What If My Facility Already Has A Cancer Registry Performing Case Abstracting?

Case Identification under the Florida Clinical Laboratory Cancer Identification Program is a separate function from hospital or ambulatory care center cancer case abstracting. If your facility currently has a cancer registry that abstracts and reports cancer cases to FCDS, the cancer registry does utilize surgical pathology reports created by your laboratory to identify cases. However, not all surgical pathology reports are identified and reported to FCDS under the cancer registry. Therefore, all cancer and cancer-related pathology reports must be submitted to FCDS under this new program.

This new program is designed to close this known gap in case identification and reporting in order to ensure that all Florida cancer cases are being identified. Any new case identified and not previously reported by a cancer registry or contract abstractor will require follow-back to the attending physician who will assist in completing a full cancer case abstract.

Deadlines

All cases identified with histologically confirmed malignancy during the first six months of the year 2002 must be reported on or before **December 31, 2002**. The last six months of 2002 will be due on or before **June 30, 2003**. This is in compliance with the six-month reporting rule as outlined in the Florida Department of Health Administrative Rules for Cancer Reporting. Failure to comply may result in the revocation or suspension of your facilities’ operations licensure, as controlled and administered by AHCA.

Cancer Case Reporting - Administrative Options for Reporting

- 1) Laboratories with a History of Reporting to FCDS - Several hospital-based clinical pathology laboratories have been voluntarily identifying and reporting cancer cases to FCDS for several years utilizing a (now obsolete) DOS-based case identification and reporting program. Case identification by these facilities will continue as in the past with several important changes in the technology used for case identification as well as the technology used for case reporting.
- 2) Corporate Labs – FCDS understands that many clinical laboratories currently licensed and operating in Florida are owned and operated by larger corporate labs. Case identification and reporting by corporate labs can be either centralized through the corporate office or can be non-centralized (reported by each separate facility), depending on how each lab and corporation chooses to identify and report to FCDS. FCDS will be working closely with corporate labs to meet the necessary case identification and reporting requirements as outlined in this announcement and detailed during the June 26th teleconference.
- 3) Utilizing Existing Lab Information Systems Staff – This option will entail training existing lab information systems staff to either manipulate your current electronic information system to download pertinent data to FCDS or to train your existing staff to identify and report cancer cases utilizing the FCDS Internet-based case identification and reporting module.

General information regarding case identification and electronic submission of identified cancer cases is included in this program announcement. Details will be outlined during the June 26th teleconference. Additionally, details will be made available on the FCDS website on or before July 1, 2002, <http://www.fcds.med.miami.edu>.

- 4) Contractual Agreements – This option involves contracting with an established information systems or experienced cancer registry professional to manage all of your laboratories' cancer case identification and reporting needs. However, the Clinical Laboratory Cancer Identification Program is a new reporting program even to the experienced Florida cancer registrar. Most, if not all, of the clinical laboratory case identification and reporting procedures can be accomplished without an experienced cancer registrar. The only labs that might benefit from using an experienced cancer registry professional would be labs heavily dependent upon manual or word processing systems.

NOTE: FCDS maintains a list of independent contractors and contract abstracting services. The list is reviewed twice a year and may be used as a reference when seeking out contract services. (Disclaimer: Inclusion on this list does not imply any endorsement by FCDS. The list is provided only as a service to reporting facilities and should not be considered exclusive or inclusive.)

- 5) Centers with Fewer than 35 Cases - Any facility reviewing reports of fewer than 35 cancer cases per year will only be required to submit paper copies of selected pathology reports to FCDS. FCDS must confirm that your facility meets the criteria for limited reporting.