Indiana State Department of Health

INDIANA STATE CANCER REGISTRY
2 North Meridian Street, Section 6-B
Indianapolis, IN 46204-3010

POLICIES AND PROCEDURES

FOR NON-HOSPITAL CANCER REPORTING

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NON-HOSPITAL CANCER REPORTING

POLICIES AND PROCEDURES

I. INTRODUCTION

State legislation (IC 16-38-2, 410 IAC 21-1) made cancer a reportable disease in Indiana, effective January 1, 1987. The law requires all health care providers, as described in section II. A. below, to report confirmed cases of cancer and other specified tumors and precancerous diseases so that the Indiana State Department of Health can conduct epidemiologic surveys of cancer and apply appropriate preventive and control measures. In addition, federal legislation (PL102-515) established the National Program of Cancer Registries, whose goal is to develop a national comprehensive cancer prevention and control strategy. Because the State receives funds through this national program, the federal law also requires reporting by all Indiana health care providers who diagnose or treat cancer patients. Compliance with reporting requirements by all providers will ensure complete and accurate surveillance data and enable the registry to produce meaningful cancer statistics for public use.

Note: The term "cancer" is used throughout this document to describe all reportable tumors defined in section III of these policies and procedures.

II. WHO MUST REPORT

A. Health Care Providers Who Must Report

All health care providers who diagnose or treat cancer patients must report confirmed cases of cancer to the State Cancer Registry. The types of providers listed below are included in this requirement.

- hospitals
- physicians
- dentists
- medical laboratories
- freestanding radiation or medical oncology clinics
- ambulatory outpatient surgical centers
- nursing homes
- other health facilities, such as freestanding radiation or medical oncology clinics, mammography or other radiology facilities, or nursing homes

B. Determining Responsibility for Reporting

1. Physicians must report all required cancer cases that are not referred to a hospital for further diagnosis or treatment. This includes:

   a. Patients who are clinically diagnosed and receive no further work-up or treatment;
   b. Patients who are newly diagnosed in the physician's own laboratory facility or by sending a specimen from the office to an outside laboratory, whether hospital based or independent;
   c. Patients whose first course treatment is initiated in the physician's office or clinic. This includes cancer treatment by surgery, radiation, chemotherapy, immunotherapy, or hormones.

   Exception: If a hospital reports cases diagnosed and treated in a staff physician's office, the

physician need not duplicate reporting this case to the State.

2. Dentists must report all required cancer cases that are not referred to a hospital for further diagnosis or treatment. This includes:

   a. Patients who are diagnosed or treated by a dentist who performs a biopsy and/or receives a pathology report of a malignant diagnosis;
   b. Cases also reported by either hospital based or private/independent medical laboratories as described in paragraph 2 above.

3. Medical Laboratories: Hospital based laboratories and private or independent laboratories licensed in Indiana must report all required cancer cases diagnosed in the lab for patients that are not referred to a hospital for further diagnosis and treatment. This includes cases also reported by physician or dentist offices as described in paragraph 1.b. above and paragraph 6 below. For hospital based laboratories these are "path only" cases that are reported by the hospital registry staff, but not necessarily included in the hospital registry.

4. Freestanding Radiation or Medical Oncology Clinics must report any patient initially diagnosed with reportable cancer or when first course treatment is initiated at the non-hospital based facility. This includes cancer treatment by surgery, radiation, chemotherapy, immunotherapy, or hormones.

5. Surgery Centers
   Freestanding surgery centers (independent centers not affiliated with any hospital) must report any patient undergoing a biopsy or other surgical procedure at the facility for a newly diagnosed reportable cancer. This includes cases also reported by either a hospital based or a private/independent medical laboratory as described in paragraph 3 above.

   Surgery centers affiliated with a hospital must report any patient undergoing a biopsy or other surgical procedure at the facility for a newly diagnosed reportable cancer if the patient was not referred to the hospital for further diagnosis or treatment. This includes cases also reported by either hospital based or private/independent medical laboratories as described in paragraph 3 above.

6. Nursing Homes
   a. Nursing homes must report the following types of newly diagnosed required cancer cases:
      - Cases clinically diagnosed but not confirmed through biopsy, cytology, or other microscopic methods;
      - Cases for whom the first course of cancer treatment is initiated at the facility. Treatment may include chemotherapy, immunotherapy, or hormone therapy.
   b. Nursing homes should identify all patients with a cancer diagnosis at the time of admission, even if diagnosed and treated prior to the admission. The facility should send copies of pertinent medical records relating to the diagnosis to the State Cancer Registry. Section VIII. A. 1. of this policy and procedure manual describes the records to send, as available.

7. Mammography or Other Radiology Facilities: Facilities that provide screening, diagnostic, or therapeutic cancer services must report confirmed cases of reportable cancer.

III. REQUIRED CASES

A. General

All confirmed cases of cancer that have been diagnosed or treated in Indiana January 1, 1987 or later must be reported to the State Cancer Registry. This includes solid and hematopoietic malignancies. A clinical diagnosis or any case that is stated to be cancer by a recognized medical practitioner is reportable, even if there is no histologic or cytologic confirmation. Any cancer or malignancy listed on the death certificate is reportable. In addition:

- Juvenile astrocytoma is reportable.
- Basal or squamous cell carcinoma of the skin of genitalia is reportable.
- All benign and borderline neoplasms of the brain and central nervous system diagnosed January 1, 2004 or later are reportable.
- All neoplasms with behavior code two (in situ) or three (malignant) in the most current edition of the *International Classification of Diseases for Oncology* (*ICD-O*) are reportable.

Exceptions are described in section B. below.

B. Exceptions: Cases That Are Not Required or Reportable

1. Basal or squamous cell carcinoma of nongenital skin;
2. Preinvasive cervical neoplasia, including carcinoma in situ of the cervix or cervical intraepithelial neoplasia, grade III (CIN III);
3. Prostatic intraepithelial neoplasia, grade III (PIN III);
4. A patient whose primary malignancy has previously been reported and who is receiving subsequent or second line/salvage treatment for recurrence or progression of disease;
5. A patient who was diagnosed or treated at a hospital and is receiving additional or follow-up treatment at the physician's office or clinic. The hospital should report this information on the first course of treatment, so it is important to get the information to the hospital for reporting.

C. Terminology

1. Diagnoses that include the following terms are malignant neoplasms and are reportable:

cancer	leukemia
carcinoma	lymphoma
carcinoma in situ	melanoma
malignant	sarcoma

2. Malignant diagnoses that are not histologically confirmed, but are described by one of the following ambiguous terms, are considered confirmed cases and are reportable:

apparent, apparently	presumed
compatible with	probable, probably
consistent with	suspect, suspected
most likely	suspicious

Diagnoses described as "possible," questionable," "suggests," "rule out," "worrisome," "potentially malignant," etc., are not to be reported.

3. The most common types of cancer diagnosed or treated outside a hospital setting include: melanoma, prostate, leukemia, lymphoma, multiple myeloma, other bone marrow primaries, some breast tumors, noninvasive bladder tumors, tumors in colorectal polyps, oral or genital tumors, and small eye tumors.

IV. WHEN TO REPORT

Cases must be reported to the State Registry no later than six (6) months after the date of diagnosis or the date you first saw the patient for this tumor, whichever is earlier.

V. WHERE TO REPORT

The reporting forms and supporting documentation, as described in Section VIII below, should be mailed in a sealed envelope that is clearly labeled "CONFIDENTIAL" to:

Cancer Registry
Indiana State Department of Health
2 North Meridian Street, Section 5-L
Indianapolis, IN 46204-3010

Questions may be directed as follows:

Telephone	(317) 233-7158
Fax	(317) 233-7722
E-mail	mlundy@isdh.IN.gov

VI. CONFIDENTIALITY ISSUES

A. Reporting

State law requires the reporting of cancer cases. The law does not require patient consent to report a case.

In addition, federal law includes provisions for state registry access to patient records of all health care providers whose services involve identifying, establishing the characteristics of, treating, or assessing the medical status of cancer cases.

B. State Registry Disclosure

State Cancer Registry disclosure of confidential information that could lead to the identification of an individual cancer patient, except to other state cancer registries and local and State health officers, is strictly prohibited by state and federal regulations. Those regulations are reflected in the Indiana State Cancer Registry policies and procedures and in their operating practices.

C. HIPAA

The State Cancer Registry is considered an exempt entity according to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR 164.512(a) because state law mandates cancer reporting. Therefore, HIPAA covered entities, such as the health care providers described in Section II.A, are permitted to disclose protected health information (PHI) to the State Registry without patient (or their personal representative's) consent.

VII. DATA QUALITY

State Registry staff perform extensive visual and computerized edits of reports for the completeness and accuracy of the data submitted. State Registry staff may contact reporting entities when the edits identify incomplete or unclear information or discrepancies in data reported by multiple providers for one patient. Contact will be made in writing or by telephone.

VIII. INSTRUCTIONS FOR REPORTING CANCER DATA

A. General

Cases may be reported by: 1) sending records electronically; 2) sending copies of medical records; or 3) completing the Cancer Reporting Form attached to these policies and procedures using the general instructions below.

1. Records to Send
   a. Registration or Face Sheet with demographics, including **ADDRESS at diagnosis** and **RACE**. If available, please also include Hispanic origin, occupation, and industry.
   b. Dictations pertaining to cancer, such as discharge summary, history and physical, consultations, or correspondence. **(Please include DATE OF INITIAL DIAGNOSIS or an approximation.)**
   c. Diagnostic tests or other staging information
   d. Biopsy, pathology, cytology, laboratory, or operative reports
   e. Treatment records (surgery, chemotherapy, radiation, hormones, immunotherapy, etc.)

2. Electronic Submission
   Reporters interested in electronic submission should contact the State Cancer Registry.

3. Cancer Reporting Form
   a. Make additional copies of the form as needed. Please duplex (copy back to back) the two pages. The form is provided as two separate pages so that it can be duplexed in the position that is appropriate for the reporter's record system (top-to-top or top-to-bottom).
   b. Print legibly or type all entries on the form.
   c. Record an "X" or the requested information, as appropriate, for each item.
   d. Record "NA" (not available) if you do not know or do not have the information. Blanks will be interpreted as "not available." Complete as much of the form as possible.
   e. The code numbers in parentheses after some of the options are for use by the State Registry. They are also used in some of the instructions below to identify specific options.
   f. Attach copies of the pathology report and other medical documentation that support the information being reported on the form, as described above in VIII.A.1.

B. Patient Identification Data

1. Patient Last Name: Record the patient's full last name (surname). If the name is hyphenated, include both names with the hyphen (Johnson-Brown).

2. Patient First and Middle Names: Record the patient's first (given) name and middle name or initial, if known.

3. Other Last Names, Maiden Names, or Aliases: Record, as known, any other *last* names the patient has had, including maiden name, aliases, and names from previous marriage(s).

4. Other First Names or Nicknames: Record, as known, any other first names or nicknames the patient has used.

5. Street Address at Diagnosis: Record the patient's usual home address at the time of diagnosis. Report the street address of residence instead of post office box number or mailing address, if different.

6. City at Diagnosis: Record the city of the patient's usual home address at the time of diagnosis.

7. State and ZIP Code at Diagnosis: Record the state and ZIP Code of the patient's usual home address at the time of diagnosis.

8. County at Diagnosis: Record the county name of the patient's usual home address at the

time of diagnosis.

9. Medical Record Number: Record the patient's medical record number, if available.
10. Social Security Number: Record the patient's Social Security Number. Do not record the spouse's number.
11. Date of Birth: Record the patient's birth date (month-day-year). If you do not know the patient's date of birth, record an estimated age in years, if known.
12. Race: Record an "X" in the box that indicates the patient's race. If the race is neither white nor black, record the race after "Other, specify." If mixed, specify the race of each parent, if known.
13. Hispanic Origin (Ethnicity): Record an "X" in the applicable box if the patient is not Hispanic or if ethnicity is unknown. If the patient is of Hispanic origin, record the type after "Hispanic, specify" (e.g., Mexican, Puerto Rican, Cuban, etc.).
14. Sex: Record an "X" in the box that indicates the patient's sex. If sex is neither male nor female, record the type after "Other, specify." (e.g., transsexual).
15. Occupation: Record the kind of work the patient performed during most of his/her working life. This may be different from the occupation at the time of diagnosis. Do not record "retired."
16. Industry: Record the primary type of activity carried on by the business/industry of the patient's usual occupation. This may be different from the company or industry at the time of diagnosis. Record the type of industry and not the name of the industry.
17. Previous Malignancies Over the Patient's Lifetime: Record the sites or types of primary malignant tumors the patient has had over the course of his/her lifetime (e.g., breast, melanoma, lymphoma, etc.) and the dates of diagnosis, if known (month/year).

    Do not record metastatic sites (e.g., for a lung cancer that has metastasized/spread to the brain, record "lung," with the diagnosis date).

C. Tumor Data

18. Date of First Contact (For This Cancer at Your Location): Record the date the patient was first seen at your location or facility for this malignancy. If the contact involved a specimen, rather than the patient, record the date the specimen was obtained. If the exact month, day, and year are unavailable, approximate the date.
19. Date of Initial Diagnosis: Record the date the patient was first diagnosed for this malignancy by any recognized medical practitioner. If you did not physically see this patient, record the date the specimen was obtained. If the exact month, day, and year are unavailable, approximate the date.
20. Laterality (Side of Origin): Record an "X" in the box that indicates the side of origin for the cancer being reported. Report (1) for right or (2) for left.
    - Report (0) if the organ is a non-paired site or if the primary site is unknown.
    - Report (3) if the only one side is involved, but right or left is not specified.
    - Report (4) if there is bilateral involvement, but side of origin is unknown.
    - Report (4) if there is bilateral involvement, but stated to be a single primary. (e.g., bilateral retinoblastomas, bilateral Wilms' tumors, and simultaneous bilateral ovary tumors with the same histology)
    - Report (9) if the organ is a paired site, but there is no information on laterality.
    - Report (9) if the organ is a paired site, but the tumor is on the midline.
21. Diagnosis Confirmed By: Record an "X" in all the boxes that indicate the method(s) used to

confirm this diagnosis of cancer.

Box (1) includes peripheral blood smears for leukemia and tissue from autopsies.
Box (6) includes diagnosis from gross autopsy report only.

22. Primary Site (Where Cancer Started): Record the specific site of origin of the tumor (e.g., upper-outer quadrant of right breast, skin of left forearm). Identify the primary site and not a metastatic site. The primary site for leukemia is always bone marrow.

23. Histologic Cell Type: Record the cell morphology type (e.g., papillary transitional cell carcinoma, superficial spreading melanoma, chronic lymphocytic leukemia).

24. Behavior of Neoplasm: Record an "X" in the box that indicates the cell behavior type according to the definitions provided below.

    In situ. The behavior of a neoplasm that has all the characteristics of malignancy except invasion through the basement membrane of the organ. Some synonyms are intraepithelial, noninvasive, and noninfiltrating. For breast cancer, intraductal is in situ behavior.

    Malignant. The behavior of a neoplasm that has the properties of anaplasia, invasion, and metastasis; invasive.

25. Tumor Grade/Differentiation: Record an "X" in the box that indicates the grade or differentiation of the malignancy. If the diagnosis includes more than one grade of tumor, record the highest grade (e.g., for moderately well differentiated, record moderately differentiated, code 2). Note that codes 5 through 8 (T-cell, B-cell, Null cell, NK cell) are for leukemia and lymphoma.

26. Stage at Diagnosis: Record an "X" in the box that indicates how far the disease has spread from the site of origin at the time of diagnosis according to the definitions provided below. Consider only information available within 2 months of diagnosis (or within 4 months of diagnosis for prostate primaries only). Do not change stage as the disease progresses. If AJCC Staging (TNM Elements and/or Stage group) is available, record it in item 46, Comments.

    In situ (0). The tumor has not invaded through the basement membrane of the organ involved; noninvasive, noninfiltrating, or intraepithelial. Intraductal breast cancer and Clark's Level 1 melanoma are in situ.

    Local (1). The tumor is limited to the primary site of origin. It has progressed through the basement membrane but not beyond the walls of the organ involved. Clark's Level 2-5 melanomas and stage I lymphoma are local.

    Regional. The tumor has spread beyond the original primary site. There are four types of regional spread. Record the specific type of regional spread, if known, according to the definitions provided below.

        Regional by direct extension (2). Tumor has extended or spread directly into adjacent organs or tissues only.

        Regional to nodes (3). Tumor involves regional lymph nodes only.

        Regional both to adjacent organs and lymph nodes (4). Tumor involves both adjacent organs or tissues and regional lymph nodes.

        Regional, *Not Otherwise Specified* (5). Tumor has spread beyond original primary site to regional areas, but is not distant. Stage II lymphomas are stage 5.

    Distant (7). The tumor extends beyond adjacent organs or tissues, or has metastasized (spread) to distant sites or distant lymph nodes through blood or the lymphatic system. Leukemia and Stage III and IV lymphoma are distant.

Unknown (9). No information is available to determine stage or extent of disease.

27. Largest Tumor Size: Record the largest dimension of the largest tumor. Specify whether the measurement is in centimeters or millimeters (e.g., 4.2 cm or 6 mm). Record only the largest measurement reported and do not add together measurements recorded in biopsy and resection reports.

    For melanomas, record both the depth of invasion **and** the diameter of the lesion.

    Size is not applicable for lymphoma, leukemia, Kaposi's sarcoma, multiple myeloma, unknown primary site, etc. Leave the item blank for these diagnoses.

28. Number of Regional Lymph Nodes Positive: Record the number of regional lymph nodes surgically removed, examined by a pathologist, and reported as containing tumor.

29. Number of Regional Lymph Nodes Examined: Record the total number of regional lymph nodes surgically removed and pathologically examined.

30. Sites of Distant Metastasis: Record the distant sites to which this cancer has spread. Distant sites are those organs or tissues that are not adjacent to the original primary site.

    - Report None (0) if the cancer is local or regional and has not metastasized (spread) to distant sites.
    - Report CNS/Brain (6) for central nervous system metastasis.
    - Report Systemic/Carcinomatosis (9) for leukemia.
    - If the distant site is not listed, record it after "Other, specify."

D. First Course of Treatment and Follow-Up Data

Definitions

Cancer-directed treatment. Treatment that is tumor directed. Its purpose is to modify, control, remove, or destroy primary or metastatic cancer tissue. Cancer-directed treatment is given to minimize the size of tumor or to delay the spread of disease. Report all first course cancer-directed treatment.

Non cancer-directed treatment. Treatment that prolongs the patient's life, alleviates pain, makes the patient comfortable, or prepares the patient for cancer-directed therapy. It is not meant to reduce the size of the tumor or delay the spread of disease. Procedures include diagnostic procedures and supportive care. Diagnostic procedures are the only non cancer-directed treatment that should be reported.

First course treatment. Cancer-directed treatment that is planned by the physician(s) during or after the first diagnosis of cancer. Administration of the treatment may span a year or more. If the plan or protocol is not available, consider treatment that begins within four months after the initial diagnosis date as the first course of treatment. Treatment that is part of the first course plan, but is initiated more than four months after diagnosis, is still considered first course treatment. Report all first course cancer-directed treatment.

Subsequent treatment. Treatment for recurrence or progression of disease. Treatment that is administered after the first course is stopped is subsequent treatment. Do not record subsequent treatment.

31. Diagnostic or Surgical Procedure(s) Performed: Record cancer-directed surgical procedures or diagnostic procedures. Examples: Incisional biopsy of (site), lumpectomy, polypectomy, wide resection or excision.

32. Date(s) Performed: Record the date each procedure was performed.

33. Cancer Therapy Drugs: List any drug given to the patient for the purpose of modifying, controlling, removing, or destroying cancer tissue. Do not list drugs given for palliation (relief of pain or symptoms) only.

- Examples of chemotherapy: 5-FU, Cytoxan, Platinum.
- Examples of hormone therapy: Tamoxifen, Nolvadex, Lupron. Prednisone is hormone therapy only when administered in combination with chemotherapy, such as MOPP.
- Examples of immunotherapy drugs: Interferon, Levamisole, monoclonal antibodies.

34. Date(s) Started: Record only the first date the drug therapy recorded in item 33 was started. If reporting more than one drug, record each date.

35. Other Cancer Treatment: Record other types of treatment given for the purpose of modifying, controlling, removing, or destroying cancer tissue. Examples: Radiation therapy (RT), immunotherapy procedures (e.g., bone marrow transplant), experimental drugs. For RT, describe whether beam, radioactive implants, radioisotopes, or a combination was administered.

36. Date(s) Started: Record the date the other treatment recorded in item 35 was started. If reporting more than one other treatment, record each date.

37. Date of Last Patient Contact: Record the last date that you had any contact with the patient. If the patient has expired, record the date of death. If the exact month, day, and year are unavailable, approximate the date.

38. Patient Status at Last Contact: Record an "X" in the box that indicates whether the patient was alive (1) or dead (0) at the time of your last contact with him/her. If the patient has expired after the last contact, report dead.

39. Cancer Status at Last Contact: Record an "X" in the box that indicates whether the patient was without (1) or with (2) this cancer at the time of your last contact with him/her.

40. Source of Information: Record an "X" in the box that indicates the source used to obtain the information on this report. (E.g., if a hospital were collecting information from a physician's office, the source would be Physician (4) since the information came from physician records.) If the reporting source used is not listed, record the source after "Other, specify." Enter the physician's 8-digit medical license number if a physician is the source of information.

41. Was the patient seen or referred elsewhere for further diagnosis or treatment? If "Yes" is reported, record the name of the health care provider and city to which the patient was referred.

42. Name, Address, and Phone Number for Reporting Provider: Record the name, address, and telephone number of the physician, clinic, dentist, or nursing home reporting this case. If the case is being reported by a laboratory, record the ordering physician's address and number for this item. This item provides contact information for the State Registry.

43. Person Completing Form: Record the name of the individual who actually completed the form.

44. Date Report Completed: Record the date (month-day-year) the form was completed.

45. Laboratory Name, Address, and Phone Number: Record the name, address, and telephone number of the laboratory involved in reading or interpreting the histologic or cytologic results of this case. This item provides contact information for the State Registry.

46. Comments: Record any additional information available that may help in the coding and staging of this cancer case (e.g., how far the cancer has spread or AJCC staging).

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