REVISED PROPOSED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R057-16

August 4, 2016

With additional proposed revisions

EXPLANATION – Matter in italics is new; matter in brackets [omitted material] is material to be omitted. Matter in green are additional changes to the document dated August 4, 2016.

AUTHORITY: §§1, 2, 4-8 and 10-14, NRS 457.065 and 457.240; §3, NRS 457.065 and 457.250; §9, NRS 457.065; §15, NRS 439.150, 457.065, 457.250 and 457.260.

A REGULATION relating to cancer; revising provisions relating to certain publications adopted by reference by the State Board of Health; revising provisions governing the system for reporting information on cancer and other neoplasms established and maintained by the Chief Medical Officer; establishing the amount and the procedure for the imposition of certain administrative penalties by the Division of Public and Behavioral Health of the Department of Health and Human Services; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law defines the term "cancer" to mean "all malignant neoplasms, regardless of the tissue of origin, including malignant lymphoma and leukemia" and, before the 78th Legislative Session, required the reporting of incidences of cancer. (NRS 457.020, 457.230) Pursuant to Assembly Bill No. 42 of the 78th Legislative Session, the State Board of Health is: (1) authorized to require the reporting of incidences of neoplasms other than cancer, in addition to incidences of cancer, to the system for reporting such information established and maintained by the Chief Medical Officer; and (2) required to establish an administrative penalty to impose against any person who violates certain provisions which govern the abstracting of records of a health care facility relating to the neoplasms the Board requires to be reported. (Sections 2, 3 and 4 of Assembly Bill No. 42, chapter 103, Statutes of Nevada 2015, at page 385 (NRS 457.230-457.250)) **Section 3** of this regulation establishes the amount of and the procedures for notice and appeal with regard to the imposition of such an administrative penalty. **Sections 4-15** of this regulation revise existing regulations to comport with the statutory changes made by Assembly Bill No. 42. (Sections 2, 3 and 4 of Assembly Bill No. 42, chapter 103, Statutes of Nevada 2015, at page 385)

Existing law, as amended by Assembly Bill No. 42, requires, with certain limited exceptions, a provider of health care who diagnoses or provides treatment for cancer or other neoplasms and a hospital, medical laboratory or other facility that provides screening, diagnostic or therapeutic services to patients with respect to cancer or other neoplasms to report information on cases of cancer and other neoplasms to the system. A provider of health care who has directly referred or previously admitted a patient to a hospital, medical laboratory or other facility that provides screening, diagnostic or therapeutic services to patients with respect to cancer or other neoplasms is excepted from the requirement of reporting information concerning that case to the system. (Section 2 of Assembly Bill No. 42, chapter 103, Statutes of Nevada 2015, at page 385 (NRS 457.230))

Section 9 of this regulation sets forth the limited information that a provider of health care who has directly referred or previously admitted a patient to a hospital, medical laboratory or other facility that provides screening, diagnostic or therapeutic services to patients with respect to cancer or other neoplasms is required to provide to the Chief Medical Officer. Section 9 does <u>not</u> require such a provider of health care to report information on cases of cancer and other neoplasms involving such a patient to the system, rather, it requires such a provider of health care to provide limited information to the Chief Medical Officer which the Chief Medical Officer may use to obtain the required reports from the hospital, medical laboratory or other facility that provides screening, diagnostic or therapeutic services to patients with respect to cancer or other neoplasms to which the patient was referred or admitted.

Existing law authorizes an agency to adopt by reference in a regulation material published by another authority if certain requirements are satisfied. (NRS 233B.040) Under existing regulations, the State Board of Health has adopted by reference the Registry Operations and Data Standards (ROADS) Manual, 1996 edition. (NAC 457.050) **Section 2** of this regulation provides instead that the Board adopts by reference the most current version of certain volumes of the Standards for Cancer Registries, the International Classification of Diseases for Oncology and the Facility Oncology Registry Data Standards (FORDS), and any subsequent revision of those publications that have been approved by the Chief Medical Officer for use in this State.

Existing regulations specify the types of neoplasms that are required to be reported pursuant to state statute. (NAC 457.040, 457.045) **Sections 5 and 6** of this regulation amend existing regulations to instead reference the neoplasms listed in one of the publications adopted by reference in **section 2** of this regulation as the types of neoplasms which are required, with certain limited exceptions, to be reported pursuant to existing law.

Existing regulations require health care facilities to abstract information concerning malignant neoplasms and provide that information to the Chief Medical Officer. (NAC 457.050) **Section 7** of this regulation expands: (1) the scope of the information abstracted to include information on cases of cancer and other neoplasms; and (2) the applicability of the requirement to certain providers of health care and other facilities that provide screening, diagnostic or therapeutic services to patients with respect to cancer and other neoplasms.

Section 15 of this regulation: (1) increases from \$32 to \$250 the fee that the Chief Medical Officer must collect from a health care facility from whose records regarding cases of neoplasms the Division of Public and Behavioral Health of the Department of Health and Human Services abstracts information pursuant to **section 7**; (2) expands the applicability of that fee to certain providers of health care and other facilities that provide screening, diagnostic or therapeutic services to patients with respect to cancer and other neoplasms; (3) removes the fee imposed on a health care facility that abstracts information from its own records at the request of the Division; and (4) increases from \$35 to \$200 the fee that the Chief Medical Officer must collect from a medical researcher who obtains data from the registry.

Section 1. Chapter 457 of NAC is hereby amended by adding thereto the provisions

set forth as sections 2 and 3 of this regulation.

Sec. 2. 1. The State Board of Health hereby adopts by reference the most

current version of:

(a) The following volumes in the <u>Standards for Cancer Registries</u> published by the North

American Association of Central Cancer Registries:

(1) Volume I, Data Exchange Standards and Record Description:

(2) Volume II, Data Standards and Data Dictionary;

(3) Volume III, <u>Standards for Completeness, Quality, Analysis, Management,</u> <u>Security</u>,

and Confidentiality of Data:

- (4) Volume IV, Standard Data EDITS; and
- (5) Volume V, Pathology Laboratory Electronic Reporting.

 \neg A copy of each volume adopted by reference may be obtained, free of charge, from the North American Association of Central Cancer Registries at the Internet address <u>http://www.naaccr.org.</u>

(b) The <u>International Classification of Diseases for Oncology</u>, published by the World Health Organization. A copy of this publication may be obtained, free of charge, from the World Health Organization at the Internet address <u>http://codes.iarc.fr/usingicdo.php.</u>

(c) The <u>Facility Oncology Registry Data Standards (FORDS)</u>, published by the Commission on Cancer of the American College of Surgeons. A copy of this publication may be obtained, free of charge, from the American College of Surgeons at the Internet address

https://www.facs.org/quality-programs/cancer/ncdb/registrymanuals/cocmanuals.

2. If a publication adopted by reference in subsection 1 is revised, the Chief Medical Officer shall review the revision to determine its suitability for this State. If the Chief Medical Officer determines that the revision is not suitable for this State, the Chief Medical Officer shall file an objection to the revision with the State Board of Health within 30 days after the standards are revised. If the Chief Medical Officer does not file such an objection, the revision becomes part of the publication adopted by reference pursuant to subsection 1. If the Board determines that the revision is not suitable for this State, it will hold a public hearing to review its determination and give notice of that hearing within 6 months after the date of the publication of the revision. If, after the hearing, the Board does not revise its determination, the Board will give notice that the revision is not suitable for this State within 30 days after the hearing. If the Board does not give such notice, the revision becomes part of the publication adopted by reference pursuant to subsection 1.

Sec. 3. 1. For the failure of a person covered by this regulation to correct a violation of NRS 457.250 within the time set forth in the notice provided pursuant in subsection 2, the [The] Division may impose an administrative penalty of not more than

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[\$25,000] \$5,000 against [a] the person. [who violates any provision of NRS 457.250 and fails to correct the violation within the time set forth in the notice provided pursuant to subsection 2.] For the purpose of this section, if a facility or aggregate of facilities is the reporting entity, it will be the "person" to which any penalty will attach, and reporting by the facility covers all providers included in the report.

2. Before imposing an administrative penalty pursuant to this section, the Division shall give notice in the manner forth in NAC 439.345 which includes, without limitation, a time determined by the Chief Medical Officer within which the person must correct the violation of NRS 457.250. *The Division may amend and extend the deadline for corrective action in its discretion for the primary purpose of obtaining full corrective action in the best interests of the reporting system.*

3. If a person is aggrieved by a decision of the Division relating to the imposition of an administrative penalty pursuant to this section, the aggrieved person may appeal the decision pursuant to the procedures set forth in NAC 439.300 to 439.395, inclusive.

4. For the purpose of reporting under NRS 457.250 subsection 5, a company with multiple facilities can report its data compiled across all facilities, covering all providers included therein, and the company will be the responsible person for purposes of subsection 3 above.

Sec. 4. NAC 457.010 is hereby amended to read as follows:

457.010 As used in NAC 457.010 to 457.150, inclusive, and sections 2 and 3 of this regulation, unless the context otherwise requires:

1. "Cancer" has the meaning ascribed to it in NRS 457.020.

2. "Division" means the Division of Public and Behavioral Health of the Department of

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Health and Human Services.

- 3. "Health care facility" has the meaning ascribed to it in NRS 457.020.
- 4. ["Malignant neoplasm" means a virulent or potentially virulent tumor, regardless of

the tissue of origin.

5.] "Medical laboratory" has the meaning ascribed to it in NRS 652.060.

[6. "Physician" means a physician licensed pursuant to chapter 630 or 633 of NRS.

7.] 5. "Provider of health care" has the meaning ascribed to it in NRS 629.031.

6. "Registry" means the office in which the Chief Medical Officer conducts the program

for reporting information on cancer and other neoplasms and maintains records containing

that information.

Sec. 5. NAC 457.040 is hereby amended to read as follows:

457.040 Except as otherwise provided in NAC 457.045, the types of [malignant] neoplasms

which must be reported pursuant to NRS 457.240 are as follows:

[1. Neoplasms, not otherwise specified:

- Neoplasm, malignant

-Neoplasm, metastatic

-Neoplasm, malignant, uncertain whether primary or metastatic

- Tumor cells, malignant

Malignant tumor, small cell type

- Malignant tumor, giant cell type

- Malignant tumor, fusiform cell type

- Malignant tumor, spindle cell type

2. Epithelial neoplasms, not otherwise specified:

- -Carcinoma, in situ, not otherwise specified
 - Intraepithelial carcinoma, not otherwise specified
- Carcinoma, not otherwise specified
 - Epithelial tumor, malignant
- Pleomorphic carcinoma
- Giant cell and spindle cell carcinoma
- -Giant cell carcinoma
- -Spindle cell carcinoma
- Pseudosarcomatous carcinoma
- Polygonal cell carcinoma
- -Small cell carcinoma, not otherwise specified

Reserve cell carcinoma

Round cell carcinoma

- Oat cell carcinoma
- 3. Papillary and squamous cell neoplasms:
 - Papillary carcinoma, in situ
 - Papillary carcinoma
 - Verrucous carcinoma
 - Squamous cell carcinoma
 - Epidermoid carcinoma
 - Spinous cell carcinoma

Squamous cell carcinoma, keratinizing type
Squamous cell carcinoma, large cell, nonkeratinizing type
Squamous cell carcinoma, small cell, nonkeratinizing type
Squamous cell carcinoma, spindle cell type
Adenoid squamous cell carcinoma
Squamous cell carcinoma, micro-invasive
Queyrat's erythroplasia
Bowen's disease
Intraepidermal squamous cell carcinoma, Bowen's type
Basal cell carcinoma, fibroepithelial type
Basosquamous carcinoma
Transitional cell carcinoma, in situ
Schneiderian carcinoma
Basaloid carcinoma
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6. Adenocarcinomas:
Adenocarcinoma
Adenocarcinoma, metastatic
Islet cell adenocarcinoma
Insulinoma, malignant
Beta-cell tumor, malignant
Alpha cell tumor, malignant
Gastrinoma, malignant
G cell tumor, malignant
Mixed islet cell and exocrine adenocarcinoma
Bile duct carcinoma
Bile duct adenocarcinoma
Bile duct cystadenocarcinoma
Liver cell carcinoma
Hepatocarcinoma
Hepatoma, malignant

Combined hepatocellular carcinoma and cholangiocar-cinoma
Hepatocholangiocarcinoma
Adenocarcinoma, cylindroid type
Cribriform carcinoma
Adenocarcinoma in adenomatous polyp
Adenocarcinoma in tubular adenoma
Carcinoma in adenomatous polyp
Adenocarcinoma in polypoid adenoma
Adenocarcinoma in adenomatous, polyposis coli
Carcinoma simplex
Carcinoid tumor, malignant
Carcinoid tumor, argentaffin, malignant
Carcinoid tumor, nonargentaffin, malignant
Goblet cell carcinoid
Composite carcinoid
Bronchiolo-alveolar adenocarcinoma
10- -

Alveolar adenocarcinoma
Adenocarcinoma in villous adenoma
Chromophobe adenocarcinoma
Acidophil adenocarcinoma
Eosinophil adenocarcinoma
Oxyphilic adenocarcinoma
Oncocytic carcinoma
Oncocytic adenocarcinoma
Hurthle cell carcinoma
Hurthle cell adenocarcinoma
Basophil carcinoma
Basophil adenocarcinoma
Clear cell adenocarcinoma, mesonephroid type
Renal cell adenocarcinoma

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Grawitz tumor
Hypernephroma
Granular cell carcinoma
Granular cell adenocarcinoma
Water-clear cell adenocarcinoma
Water-clear cell carcinoma
Mixed cell adenocarcinoma
Papillary and follicular adenocarcinoma
Nonencapsulated sclerosing carcinoma
Nonencapsulated sclerosing adenocarcinoma
Adrenal cortical adenocarcinoma
Adrenal cortical tumor, malignant
Endometrioid adenocarcinoma
Endometrioid cystadenocarcinoma
Endometrioid adenofibroma, malignant
Endometrioid cystadenofibroma, malignant

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Apocrine adenocarcinoma
Sebaceous adenocarcinoma
Serous adenocarcinoma
Papillary cystadenocarcinoma
Papillocystic adenocarcinoma
Papillary serous cystadenocarcinoma
Papillary serous adenocarcinoma
Serous surface papillary carcinoma
Mucinous cystadenocarcinoma
Pseudomucinous adenocarcinoma
Papillary mucinous cystadenocarcinoma
Papillary pseudomucinous

Cystadenocarcinoma
Colloid adenocarcinoma
Colloid carcinoma
Gelatinous adenocarcinoma
Krukenberg tumor
— 10. Ductal, lobular and medullary neoplasms:

Comedocarcinoma, noninfiltrating
Comedocarcinoma
Secretory carcinoma of the breast
Noninfiltrating intraductal papillary adenocarcinoma
Noninfiltrating intracystic carcinoma
Parafollicular cell carcinoma
Medullary carcinoma with amyloid stroma
Solid carcinoma with amyloid stroma
Medullary carcinoma with lymphoid stroma
Lobular carcinoma, in situ
Lobular carcinoma, noninfiltrating
Lobular adenocarcinoma
Infiltrating lobular carcinoma
Infiltrating ductular carcinoma
Inflammatory carcinoma
Inflammatory adenocarcinoma

Paget's disease, mammary
Paget's disease of breast
Paget's disease and infiltrating duct carcinoma of breast
Acinar adenocarcinoma
Acinar carcinoma
— 11. Complex epithelial neoplasms:
Adenosquamous carcinoma
Adenocarcinoma with squamous metaplasia
Adenoacanthoma
Adenocarcinoma with cartilaginous and osseous metaplasia
Adenocarcinoma with spindle cell metaplasia
Adenocarcinoma with apocrine metaplasia
Granulosa cell tumor, malignant
Granulosa cell carcinoma
Androblastoma, malignant
Arrhenoblastoma, malignant
Leydig cell tumor, malignant

<u>14. Nevi and melanomas:</u>
Malignant melanoma
<u>Nevocarcinoma</u>
Balloon cell melanoma
Amelanotic melanoma
Malignant melanoma in junctional nevus
Precancerous malanosis
Malignant melanoma in precancerous melanosis
Hutchinson's melanotic freckle
Superficial spreading melanoma
Malignant melanoma in giant pigmented nevus
Epithelioid cell melanoma

Epithelioid cell melanosarcoma
Spindle cell melanoma
Mixed epithelioid and spindle cell melanoma
Blue nevus, malignant
—15. Soft tissue tumors and sarcomas:
Sarcomatosis
Giant cell sarcoma
Small cell sarcoma
Infantile fibrosarcoma
Congenital fibrosarcoma

Dermatofibrosarcoma protuberansMyxosarcomaLiposarcomaFibroliposarcomaLiposarcoma, well differentiated typeMyxoid liposarcomaMyxoliposarcomaMyxoliposarcomaMyxoliposarcomaMyxoliposarcomaMyxoliposarcomaPembryonal liposarcoma17. Myomatous neoplasms:LeiomyosarcomaSarcomaMyosarcomaPithelioid leiomyosarcomaMyosarcomaMyosarcomaMyosarcomaMyosarcomaMyosarcomaMyosarcomaMyosarcomaSarcoma botryoidesBotryoid sarcoma	
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 — Pleomorphic rhabdomyosarcoma — Mixed type rhabdomyosarcoma — Embryonal rhabdomyosarcoma — Sarcoma botryoides 	
— Mixed type rhabdomyosarcoma — Embryonal rhabdomyosarcoma — Sarcoma botryoides	Rhabdosarcoma
Botryoid sarcoma	
	Botryoid sarcoma

- Alveolar rhabdomyosarcoma

Stromal sarcoma
Adenosarcoma
Embryonal hepatoma
Carcinosarcoma
Carcinosarcoma, embryonal type
Pneumoblastoma
— 19. Fibroepithelial neoplasms:
-Brenner tumor, malignant
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Synovial sarcoma
Synovial sarcoma, spindle cell type
Synovial sarcoma, epithelioid cell type
Clear cell sarcoma of tendons and aponeuroses
<u>—21. Mesothelial neoplasms:</u>
Epithelioid mesothelioma, malignant
Epithelioid mesothelioma
Mesothelioma, biphasic type, malignant
Mesothelioma, biphasic type
<u>— 22. Germ cell neoplasms:</u>
Seminoma, anaplastic type
Spermatocytic seminoma
Embryonal carcinoma

Endodermal sinus tumor
Orchioblastoma
Embryonal carcinoma, infantile type
Polyembryoma
Embryonal carcinoma, polyembryonal type
Malignant teratoma, undifferentiated type
Malignant teratoma, anaplastic type
Malignant teratoma, intermediate type
Chorionepithelioma
Choriocarcinoma combined with teratoma

Malignant teratoma, trophoblastic type
<u>—24. Mesonephromas:</u>
Angiosarcoma
Kupffer cell sarcoma
Kaposi's sarcoma
Osteosarcoma
Osteochondrosarcoma

Juxtacortical osteosarcoma
Juxtacortical osteogenic sarcoma
Parosteal osteosarcoma
27. Chondromatous neoplasms:
Juxtacortical chondrosarcoma
Giant cell sarcoma of bone
<u>—29. Miscellaneous bone tumors:</u>
Ewing's sarcoma
Ewing's tumor
Intraosseous carcinoma
Ameloblastic odontosarcoma
Ameloblastoma, malignant24-

Ameloblastic fibrosarcoma
Ameloblastic sarcoma
Pineloma
Pinecytoma
Pineoblastoma
Glioma, malignant
Gliomatosis cerebri
Mixed oligo astrocytoma
Subependymal glioma
Subependymoma
Subependymal astrocytoma
Subependymal giant cell astrocytoma
Choroid plexus papilloma, malignant
Choroid plexus papilloma, anaplastic type
Ependymoma
Epithelial ependymoma
Ependymoma, anaplastic type

Protoplasmic astrocytoma
Gemistocytic astrocytoma
Pilocytic astrocytoma
Juvenile astrocytoma
Glioblastoma multiforme
Glioblastoma with sarcomatous component
Primitive polar spongioblastoma
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Oligodendroblastoma Medulloblastoma Desmoplastie medulloblastoma Circumscribed arachnoidal cerebellar sarcoma Medullomyoblastoma Cerebral sarcoma Monstrocellular sarcoma 33. Neuroepitheliomatous neoplasms: Ganglioneuroblastoma Neuroblastoma Sympathicogonioma Sympathicogonioma Diktyoma Terotoid medulloepithelioma Olfactory neurogenie tumor Esthesioneuroblastoma Olfactory neuroblastoma Olfactory neuroblastoma	Oligodendroglioma, anaplastic type
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EsthesioneuroblastomaOlfactory neuroblastoma	Olfactory neurogenic tumor
	Esthesioneuroepithelioma

<u>—34. Meningiomas:</u>
Leptomeningeal sarcoma
<u>35. Nerve sheath tumors:</u>
Neurofibrosarcoma
Neurosarcoma
Neurilemmoma, malignant
Granular cell tumor, malignant
Granular cell myoblastoma, malignant
Alveolar soft part sarcoma
Malignant lymphoma, undifferentiated cell type

Malignant lymphoma, stem cell type
Malignant lymphoma, convoluted cell type
Malignant lymphoma, lymphoblastic, convoluted cell type
Malignant lymphoma, lymphoplasmacytoid type
Immunoblastic lymphosarcoma
Malignant lymphoma, mixed lymphocytic histiocytic, not otherwise specified
Malignant lymphoma, follicular center cell
Malignant lymphoma, lymphocytic, well differentiated
Malignant lymphoma, lymphocytic, intermediate differentiation
Malignant lymphoma, follicular center cell, cleaved
Malignant lymphoma, lymphocytic, poorly differentiated

Reticulosarcoma, pleomorphic cell type
Malignant lymphoma, Hodgkin's type
Hodgkin's disease, lymphocytic predominance
Hodgkin's disease, mixed cellularity
Hodgkin's disease, lymphocytic depletion, reticular type
Hodgkin's disease, nodular sclerosis
Hodgkin's disease, nodular sclerosis, cellular phase
— 40. — Lymphomas, nodular or follicular:

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Giant follicular lymphoma
Lymphocytic lymphoma, nodular
Malignant lymphoma, mixed lymphocytic-histiocytic, nodular
Malignant lymphoma, centroblastic-centrocytic, follicular
Malignant lymphoma, lymphocytic, well differentiated, nodular
Malignant lymphoma, lymphocytic, intermediate differentiation, nodular
Malignant lymphoma, follicular center cell, cleaved, follicular
Germinoblastic sarcoma, follicular
Malignant lymphoma, follicular center cell, noncleaved, follicular
—41. Mycosis fungoides:
Sezary's disease
Sezary's syndrome
-42. Miscellaneous reticuloendothelial neoplasms:
Histiocytic medullary reticulosis
Letterer Siwe's disease
-43. Plasma cell tumors:
Plasma cell myeloma

Plasmacytic myeloma
Myeloma, not otherwise specified
Plasma cell tumor, malignant
Systemic tissue mast cell disease
<u>45. Burkitt's tumor:</u>
Burkitt's tumor
Burkitt's lymphoma
Malignant lymphoma, undifferentiated, Burkitt's type
Malignant lymphoma, lymphoblastic, Burkitt's type
<u>46. Leukemias:</u>
Leukemia
Acute leukemia
Stem cell leukemia
Blast leukemia
Blastic leukemia
Subacute leukemia
Aleukemic leukemia
-

Lymphocytic leukemia
Lymphatic leukemia
Acute lymphoid leukemia
Subacute lymphoid leukemia
Chronic lymphoid leukemia
Aleukemic lymphoid leukemia
-49. Plasma cell leukemias:
<u></u>
Erythremic myelosis
Acute erythremia
Guglielmo's disease
Acute erythremic myelosis
Granulocytic leukemia
Acute myeloid leukemia

Acute granulocytic leukemia
Blastic granulocytic leukemia
Acute Myelogenous leukemia
Acute myelocytic leukemia
Acute myelomonocytic leukemia
Acute myelosis
Subacute myeloid leukemia
Chronic myeloid leukemia
Chronic granulocytic leukemia
Chronic myelogenous leukemia
Aleukemic granulocytic leukemia
Aleukemic myelogenous leukemia
Aleukemic myelosis
Acute promyelocytic leukemia
Basophilic leukemia
— 54. Eosinophilic leukemias:
— 55. Monocytic leukemias:
Monocytic leukemia

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Acute monocytic leukemia
Acute monocytoid leukemia
Subacute monocytic leukemia
Aleukemic monocytic leukemia
Aleukemic monocytoid leukemia
— 56. Miscellaneous leukemias:
Mast cell leukemias
Granulocytic sarcoma
— 57. No microscopic confirmation of tumor:
No microscopic confirmation; clinically malignant tumor (cancer)
- No microscopic confirmation; clinically metastatic tumor (cancer)

1. Any neoplasm that is listed in the <u>International Classification of Diseases for Oncology</u>, as adopted by reference in section 2 of this regulation, with a behavior code of in situ or malignant; and

2. Any solid tumor of the brain or central nervous system, including, without limitation, the meninges and intracranial endocrine structures, that is listed in the <u>International</u> <u>Classification of Diseases for Oncology</u>, as adopted by reference in section 2 of this regulation, with a behavior code of benign, uncertain malignant potential, in situ or malignant.

Sec. 6. NAC 457.045 is hereby amended to read as follows:

457.045 Carcinoma in situ of the cervix uteri and [noninvasive] cervical intraepithelial neoplasia, basal and squamous cell carcinomas of the skin and prostatic intraepithelial neoplasia are not required to be reported pursuant to NAC 457.040.

Sec. 7. NAC 457.050 is hereby amended to read as follows:

457.050 1. Each provider of health care who is required to report information on cases of cancer and other neoplasms pursuant to NRS 457.230, each health care facility and any other facility that provides screening, diagnostic or therapeutic services to patients with respect to cancer and other neoplasms shall, within 6 months after a patient is admitted, initially diagnosed with or treated for cancer or another neoplasm,- provide to the Chief Medical Officer information concerning [malignant] such neoplasms by [abstracting] :

(a) Abstracting information on a form prescribed by the Chief Medical Officer or a designee thereof [.]; and *Information must include, without limitation:*

(1) The patients name, address, date of birth, gender, race and ethnicity, and if available, primary payer and social security number;

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(2) The name, address, and National Provider Identification number of the provider of health care or health care facility making the report;

(3) The date and final diagnosis of the patient;

- (4) The anatomical site of the lesion; and
- (5) Vital status and date of last contact with the patient.

(b) Except as otherwise provided in subsection 6, submitting that information on a [monthly] quarterly basis using an electronic means approved by the Chief Medical Officer or the designee.

(c) If a reporting entity cannot provide the required cancer abstract information required pursuant to subsection 1(a)(1)-1(a)(5), the reporting entity may file a request for a variance with the State Board of Health pursuant to NRS 439.200.

(d) A variance is not necessary if the information required is not made available by the patient or is not readily obtainable by the reporting entity.

(e) To the extent that any possible variance is the subject of a notice of corrective action, the reporting entity may defer requesting a variance until the corrective action process has been finished.

(f) For purposes of reports aggregated pursuant to Section 3(4), the only required address that a provider of health care or health care facility will be required to report is the address of the aggregate reporting entity.

2. Except as otherwise provided in subsection 3, each provider of health care described in subsection 1, each health care facility and any other facility that provides screening, diagnostic or therapeutic services to patients with respect to cancer and other neoplasms shall abstract information in conformance with the standards for abstracting information concerning

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[malignant] neoplasms [of the Commission on Cancer of the American College of Surgeons as] set forth in [the Registry Operations and Data Standards (ROADS) Manual, 1996 edition, which is hereby adopted by reference, and any subsequent revision or amendment to the standards established by the Commission on Cancer of the American College of Surgeons. A copy of the manual may be obtained from the American College of Surgeons, 633 North Saint Clair-Street, Chicago, Illinois 60611-3211, for the price of \$25.

3. The Chief Medical Officer shall review any revision or amendment to the standards specified in subsection 2 to determine whether the revision or amendment is appropriate for this State. Ten]:

(a) Volumes I to V, inclusive, of the <u>Standards for Cancer Registries</u>, as adopted by reference in section 2 of this regulation; and

(b) The <u>Facility Oncology Registry Data Standards (FORDS)</u>, as adopted by reference in section 2 of this regulation.

3. Thirty Ninety days after [the standards] a publication specified in subsection 2 [are] is revised,

[or amended,] a provider of health care described in subsection 1, a health care facility or other facility that provides screening, diagnostic or therapeutic services to patients with respect to cancer and other neoplasms shall abstract information in conformance with the revision [or amendment] unless the Chief Medical Officer files an objection to the [amendment or] revision [with the State Board of Health within 10 days after the standards are revised or amended.] pursuant to section 2 of this regulation.

4. A provider of health care described in subsection 1, a health care facility or other facility that provides screening, diagnostic or therapeutic services to patients with respect to cancer and other neoplasms which does not use the staff of the Division to abstract

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information from its records shall cause to have abstracted and reported to the Division the [malignant neoplasms listed] neoplasms described in NAC 457.040 in the manner required by this section.

5. If a provider of health care, a health care facility *or other facility that provides screening, diagnostic or therapeutic services to patients with respect to cancer and other neoplasms* [with 100 beds or more does not use the staff of the Division to abstract information from itsrecords concerning malignant neoplasms, it shall cause to have abstracted and reported to the-Division, pursuant to subsection 4, the malignant neoplasms listed in NAC 457.040 using anelectronic means approved by the Chief Medical Officer or the designee, unless an exemptionfrom this requirement is granted by the] or other facility] fails to comply with subsection 4, the Division shall give the provider of health care, health care facility or other facility *that provides screening, diagnostic or therapeutic services* at least 30 days to comply with subsection 4 before the Division abstracts information from the records of the provider of health care, health care facility or other facility *that provides screening, diagnostic or therapeutic services* and the Chief Medical Officer [-] charges the fee set forth in NAC 457.150.

6. The Chief Medical Officer may waive the requirement of submitting the information by electronic means pursuant to subsection 1 if the Chief Medical Officer determines that such a waiver is in the best interests of the general public.

7. For purposes of reporting responsibilities under NRS 457.230(4), the responsibilities for each reporting entity will be generally described and allocated as follows:

(a) For a provider of health care described in subsection 1 who diagnoses but does not provide treatment, their responsibility is to report the diagnosis of cancer and if they do not treat further, their reporting responsibilities end. For the purpose of this regulation

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"diagnosis of cancer" attaches to the provider who first designates a cancer code in the patient's medical record and inform the patient of their diagnosis.

a. Diagnosis does not include the preparation of a diagnostic tool, such as an image, where that tool will be interpreted by another provider of health care for the purpose of diagnosing cancer.

b) Each provider of health care required to report pursuant to NRS 457.230 (4) shall submit [reports] information pursuant to section 7(a) as follows:

(1) Diagnosis made, or treatment initiated in the first quarter shall be due on or before June 30 of the same calendar year;

(2) Diagnosis made, or treatment initiated in the second quarter shall be due on or before September 30 of the same calendar year:

(3) Diagnosis made, or treatment initiated in the third quarter shall be due on or before December 30 of the same calendar year; and

(4) Diagnosis made, or treatment initiated in the fourth quarter shall be due on or before March 30 of the following calendar year.

Sec. 8. NAC 457.053 is hereby amended to read as follows:

457.053 1. A medical laboratory that obtains a specimen of human tissue which, upon examination, shows evidence of cancer or other neoplasms shall, within 10 working days after the date that the pathology report is completed, provide information concerning its findings to the Chief Medical Officer using an electronic means approved by the Chief Medical Officer or a designee thereof.

2. The information provided by a medical laboratory pursuant to subsection 1 must include, without limitation [:], for each specimen which shows evidence of cancer or other neoplasms which are subject to reporting pursuant to NAC 457.040:

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(a) The name, address, date of birth, gender and social security number of the person from whom the specimen was obtained;

(b) The name and the address or telephone number of the [physician] provider of health care who ordered the examination of the specimen;

(c) The name and the address or telephone number of the medical laboratory that examined the specimen;

(d) The final diagnosis from the pathology report; and

(e) Any other relevant information from the pathology report, including, without limitation:

(1) The anatomical site of the lesion;

(2) The size of the lesion;

(3) The stage of the disease and the grade of

tumor; (4) The lesion margin status, if available;

and

(5) Lymphatic involvement, if available.

Sec. 9. NAC 457.057 is hereby amended to read as follows:

457.057 1. [Except as otherwise provided in subsection 3, a physician] A provider of health care who has a case of cancer or another neoplasm in which he or she [diagnoses] has directly referred or previously admitted a patient [as having cancer or provides treatment to a patient with cancer] to a hospital, medical laboratory or other facility that provides screening, diagnostic or therapeutic services to patients with respect to cancer and other neoplasms is not required to provide information to the Chief Medical Officer pursuant to NAC 457.050 but [shall] may, within [10] 30 working days after the date of the [diagnosis or the date of the first treatment,] referral or admission, provide information to the Chief Medical Officer concerning

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the case on a form prescribed by the Chief Medical Officer or a designee thereof, or by an electronic means approved by the Chief Medical Officer or the designee.

Information provided by a [physician] provider of health care pursuant to subsection 1
 [must] may include, without limitation:

(a) The name, address, date of birth, *and* gender, [race or ethnicity, and social security-number] of the patient;

(b) The name and the address or telephone number of the [physician] provider of health care making the report;

(c) The date and final diagnosis [from the pathology report; and] of the patient;

(d) [Any other relevant information from the pathology report, including, without limitation:

(1)] [The anatomical site of the lesion];

[(2) The size of the lesion;

(3)]

[(e) The stage of the disease ,] [and the grade of tumor;

(4) The lesion margin status, if available; and

(5) Lymphatic involvement,] if available [.]; and

[(f)](d) The name and the address or telephone number of the hospital, medical laboratory or other facility that provides screening, diagnostic or therapeutic services to patients with respect to cancer and other neoplasms to which the patient was referred or admitted.

3. [A physician is not required to provide information pursuant to this section if the patient is directly referred to or has been previously admitted to a hospital, medical laboratory or other facility which is required to report similar information pursuant to this chapter.] [The Chief Medical Officer or a designee thereof shall notify a provider of health care who fails to comply with this section of the fact that the provider of health care is not in compliance

with the provisions of this section.]

[4.] 3. The Chief Medical Officer or a designee thereof may contact a provider of health care regarding a patient who was directly referred to or previously admitted to a hospital, medical laboratory or other facility that provides screening, diagnostic or therapeutic services to patients with respect to cancer and other neoplasms if the Chief Medical Officer determines it is necessary for the abstraction of the required data relating to the incidence of neoplasms.

Sec. 10. NAC 457.060 is hereby amended to read as follows:

457.060 All documents in the possession of the registry which contain names of patients, [physicians, hospitals] providers of health care, health care facilities, other facilities that provide screening, diagnostic or therapeutic services to patients with respect to cancer and other neoplasms or medical laboratories are confidential except the list of names of [hospitals] health care facilities or other facilities that provide screening, diagnostic or therapeutic services which report information to the registry and the list of names of medical laboratories which report information to the registry.

Sec. 11. NAC 457.090 is hereby amended to read as follows:

457.090 1. If confidential information of the registry is to be mailed to a [physician] provider of health care or health care facility, the envelope or container must be addressed directly to the [physician] provider of health care or to the person designated by the health care facility to receive such information.

2. The Chief Medical Officer shall keep a list of the persons who have been designated by the chief administrator of the health care facility to receive confidential information of the registry.

Sec. 12. NAC 457.110 is hereby amended to read as follows:

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457.110 1. The Chief Medical Officer or person employed in the registry shall not disclose the existence or nonexistence in the registry of a record concerning any patient or disclose other information about the patient except to:

(a) The [physician] provider of health care who treated the patient;

(b) The health care facility, medical laboratory or other facility that provides screening, diagnostic or therapeutic services to patients with respect to cancer and other neoplasms where the patient was treated;

(c) A health care facility, medical laboratory or other facility that provides screening, diagnostic or therapeutic services to patients with respect to cancer and other neoplasms, or a registry connected with [that facility] one of those entities which has participated or is participating in treating the patient; [or]

(d) A qualified researcher in cancer[-]; or

(e) Other state cancer registries or federal organizations with which the department has data sharing agreements that ensure confidentiality.

2. If a request for information about a patient is made over the telephone by the [physician] provider of health care who treated the patient or by a representative of the health care facility, medical laboratory or other facility that provides screening, diagnostic or therapeutic services to patients with respect to cancer and other neoplasms in which the patient was treated, and the caller is not known to the employee who receives the call at the registry, the employee must verify the identity of the caller in the manner described in NAC 457.130.

Sec. 13. NAC 457.120 is hereby amended to read as follows:

457.120 The Chief Medical Officer or person employed in the registry may provide confidential medical information in the registry concerning a patient's medical treatment for cancer with any health care facility, medical laboratory or other facility that provides screening,

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diagnostic or therapeutic services to patients with respect to cancer and other neoplasms, or registry connected with [the facility] one of those entities which has participated or is participating in treating that patient's illness if the person seeking the information:

1. Has been identified in the manner described in NAC 457.130;

2. Furnishes the employee of the registry with specific information, other than the patient's name, which is sufficient to identify the patient without using his or her name; and

3. Gives assurances to the employee of the registry that the confidentiality of the information will be maintained to the same extent as is required in NAC 457.010 to 457.150, inclusive [-], and sections 2 and 3 of this regulation.

Sec. 14. NAC 457.140 is hereby amended to read as follows:

457.140 1. A person who desires to use the confidential records of individual patients or the statistical data of the registry for the purpose of scientific research into cancer must apply in writing to the Chief Medical Officer. The applicant must:

(a) Set forth in the application:

(1) His or her qualifications as an epidemiologist, [physician] provider of health care or employee of a bona fide program of research into cancer or other qualification for using confidential information and statistical data in the registry; and

(2) A description of the research project in which that information will be used.

(b) Sign a statement, on a form furnished by the Chief Medical Officer or a designee thereof, in which the applicant agrees not to make any copies of the records, and to maintain the confidentiality of the information in the records in the manner required by NAC 457.010 to 457.150, inclusive [1], and sections 2 and 3 of this regulation.

(c) Agree to [submit]:

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(1) Submit to the Chief Medical Officer or the designee for review and approval any proposed publication which is based on or contains information obtained from the registry [..];

(2) Notify the Chief Medical Officer if, at any time during the research project or before publishing any results, the applicant finds an increased risk or decreased survival for cancer as compared to other states in either:

(I) A geographical area of this State; or

(II) A particular group of persons in this State, including, without limitation, a group of persons identifiable by age, gender, race, ethnicity, occupation, lifestyle or place of residence; and

(3) Include in any publication which is based on or contains information obtained from the registry the following disclosure in substantially the following form: The views expressed herein are solely those of the author and do not necessarily reflect the views of the Division.

2. The Chief Medical Officer or the designee must:

(a) Before a researcher is allowed access to information in the registry, make a written finding that he or she is qualified as a researcher and has a need for the information; and

(b) [Before any material based on or containing information from the registry is published by the researcher, examine and give written approval for the proposed publication.] Notify the Division as soon as practicable after the Chief Medical Officer receives notice of a finding described in subparagraph (2) of paragraph (c) of subsection 1 so that the Division may independently assess the validity of the finding before the material is published or released by the researcher.

Sec. 15. NAC 457.150 is hereby amended to read as follows:

457.150 The Chief Medical Officer shall charge and collect from:

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1. A provider of health care who is required to report information on cases of cancer and other neoplasms pursuant to NRS 457.230, a health care facility [,] or other facility that provides screening, diagnostic or therapeutic services to patients with respect to cancer and other neoplasms, a fee of [\$32] \$250 for each abstract prepared by the Division from the record of the provider of health care, health care facility [and a fee of \$8 for each abstract prepared by the health care facility from its own records.] or other facility.

2. A medical researcher [or other person] who obtains [information] data from the registry, a fee of [\$35] \$200 or the actual cost of [furnishing the information,] providing the data, whichever is [larger.] more.