California Cancer Registry Electronic Pathology Reporting Standards Manual Volume V

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1 Introduction

California passed legislation which requires all pathologists diagnosing cancer to report cancer pathology reports to the California Cancer Registry (CCR) pursuant to California Health and Safety Code (HSC) 103885. Assembly Bill (AB) 2325 signed by California Governor Jerry Brown on September 14, 2016, revised HSC 103885 to require pathologists to report cancer diagnoses electronically to CCR beginning January 1, 2019.

2 Background

CCR is a statewide population-based cancer registry authorized by HSC 103885. CCR is recognized as one of the leading cancer registries in the world and has been the cornerstone of a substantial amount of research on cancer in the California population.

Prior to passage of AB 2325, most cancer cases were reported to CCR by hospitals and treatment facilities through hospital abstracting services and were not reported to CCR for 6-12 months or more after cancer diagnosis. The delay in receiving these cases limited the uses of this data to more historical, retrospective surveillance research purposes. With the passage of AB 2325, CCR receives a cancer incidence case electronically in near-time, which allows a broader use of the data including responding to community cancer concerns with more timely data, identifying data for research studies requiring rapid identification of cancer cases, and clinical trials matching.

3 Purpose

This CCR Electronic Pathology Reporting Standards Manual-Volume V contains the necessary specifications for standardized data transmissions from a pathology lab or pathology lab information system to CCR. A single standardized method will allow efficient and accurate transmission of cancer information while reducing the burden on laboratory system specific implementations. This reporting manual defines the specific data elements to be retrieved and included in the cancer pathology reports; describes how to create the appropriate, valid electronic message for transmission; and details how to transmit the cancer pathology report to CCR over a secure electronic transmission mechanism (see Data Format section for details). Transport mechanisms between a Laboratory Information Systems (LIS) or Electronic Health Record (EHR) to CCR have also been defined and included in this manual.

4 Effective Date of Electronic Reporting of Pathology Reports

Pathologists began reporting cancer diagnoses electronically to CCR January 1, 2019. National standard setters add and/or revise data requirements on an annual basis. This manual will reflect all data changes that result from national standard setters new and/or revised data items impacting pathology data.

5 Pathologist Reporting Requirements

It is the responsibility of the original pathologist to report all cancer diagnoses, as detailed under Reporting Criteria within two weeks of the final diagnosis (signoff/signout). Any slide review, second opinion, report correction, addendums,

etc. related to the original specimen diagnosis that either change the original incidence of cancer (i.e., reportable to non-reportable, or vice versa) or changes the histology and/or behavior of the original specimen are to be electronically transmitted to CCR by the original pathologist within two weeks of finalizing the revised pathology documentation.

Dermatopathologists Reporting Requirements

- If patients are diagnosed/treated **AND** corresponding pathology reports are created by you that are not sent automatically via an electronic interface, then report via the Physician Reporting Portal and attach a copy of the patient's pathology report.
  https://cancerreporting.ccr.ca.gov/

- If you only create pathology reports and you do not diagnose/treat patients, then report via the Pathologists Reporting Portal
  https://pathreporting.ccr.ca.gov/directdataentry/

5.1 Registration Process

Pathology labs and/or facilities are required to register for reporting on behalf of represented pathologists within an organization or lab. Registration information includes specific contact information, inclusive of a lead physician contact, lab management contact, and a technical interface contact, as well as LIS and/or EHR vendor information for the purpose of providing a certificate for submission to the web service where applicable.

5.2 Transmission Methods

CCR will accept electronic pathology reports through four methods of transmission:

- A web service
- Secure File Transfer Protocol (SFTP)
- Minimal Lower Layer Protocol (MLLP)
- Direct Data Entry Web Portal

5.3 Data Format

CCR is limiting the formatting of pathology reports to four options:

- Simple Narrative
- Synoptically Structured Health Level Seven (HL7)
- Synoptically Structured HL7 using College of American Pathologists (CAP) Electronic Cancer Checklist (eCC)
- CAP eCC Structured Data Captured(SDC) Extensible Markup Language (XML)

5.4 Reportable Diagnoses Criteria

All reportable neoplasms meeting the criteria below are to be transmitted to the CCR. Neoplasms outlined under the Non-Reportable Diagnoses are not to be transmitted. In the event an ambiguous term(s) precedes a reportable cancer diagnoses, the case is to be considered reportable. Examples of ambiguous terminology include, but are not limited to the following: apparently, appear to,

suspicious, likely or most likely, favors, comparable, consistent with, typical (of), probable, presumed, malignant appearing.

2018 ICD-O-3 (International Classification of Diseases for Oncology, Third Edition) histology coding changes: Updates include new and revised histology terms, codes, and behaviors for cases diagnosed January 1, 2018 and forward. Please see the 2018 ICD-O-3 – Coding tables.

Reportable Diagnoses

Reportable Malignant Diagnoses
• Invasive Malignancies
• In Situ Malignancies*
• Severe or High-grade Dysplasia documented as synonymous with carcinoma
• High grade squamous intraepithelial invasion
• Intraepithelial neoplasia, grade III
• All hematopoietic and lymphoid neoplasms as outline in the following link: http://seer.cancer.gov/seertools/hemelymph
• Carcinoid tumors, NOS
• Gastrointestinal Stromal Tumors (GIST) when documents as in situ, NOS with multiple foci, lymph node involvement or metastasis OR patient is undergoing treatment as if GIST is malignant
• Liver with LR-5 or LR-5V
• Ovary: Noninvasive low grade (Micropapillary) serous carcinoma
• Pancreas: Neuroendocrine tumor when diagnosis is insulinoma; cystic pancreatic endocrine neoplasm (CPEN); cystic pancreatic endocrine specified as neuroendocrine tumor, grades 1 and 2; solid pseudopapillary neoplasm of pancreas; or non-invasive mucinous cystic neoplasm (MCN) of pancreas with high-grade dysplasia
• Pituitary: Rathke pouch tumor
• Testis: Mature teratoma of the testes in adult (adult defined as post-puberty)
• Thymoma, NOS with multiple foci, lymph node involvement, or metastasis
• Thyroid: Non-invasive follicular thyroid neoplasm with papillary like nuclear features
• Skin: Basal and squamous cell carcinoma of skin of genital organs (vagina, clitoris, labium, vulva, prepuce, penis and scrotum; adnexal carcinomas (sweat glands, sebaceous gland, ceruminous gland and hair follicle); adenocarcinomas, lymphomas, melanomas, sarcomas and Merkel cell tumors of the skin (regardless of site); any carcinoma arising in a hemorrhoid is reportable as hemorrhoids arise in mucosa, not skin
Reportable Non-Malignant Diagnoses
• All benign and borderline intracranial and/or Central Nervous System (CNS) tumors

*NOTE: See Appendix C for a list of in situ terms.

Non-Reportable Diagnoses

Non-Reportable Diagnoses
• Skin: Basal and squamous cell carcinomas of the skin unless it occurs on genital organs. Non-reportable skin cancers includes the following ○ Neoplasms, malignant, NOS of the skin ○ Epithelial carcinomas of the skin ○ Papillary and squamous cell carcinomas of the skin ○ Basal cell carcinomas of the skin ○ Early or evolving melanoma of any type
• Cervix: Carcinoma in situ (CIS) or intraepithelial neoplasia grade III (CIN III)

5.5 Reportable Pathology Report Types

The following types of pathology reports that provide information on reportable neoplasms are to be transmitted to CCR:

- **Surgical Pathology Reports:**
  - Biopsy (Needle Core, Excisional, Incisional, Bone Marrow Aspirates)
  - Surgical Resection
  - Surgical Re-excision
    NOTE: All pathology reports for Surgical Resection or Surgical Reexcision of malignant melanoma or lentigo should be submitted. This includes both positive and negative findings (i.e., Wide Re-Excision: No residual melanoma; or negative for melanoma, etc.)

- **Cytology Reports:**
  - Biopsy (fine needle aspiration)
  - Brushings (e.g., endoscopic evaluation of pancreas, Papanicolaou (PAP) smear)
  - Fluids (Urine, Peritoneal, Pleural, Cerebrospinal Fluid, Broncheoalveolar lavage)
  - Hematologic Specific Reports
    - Immunohistochemistry (IHC)
    - Peripheral Blood Count
    - Flow Cytometry
  - Molecular Reports
    - Molecular Diagnosis Polymerase Chain Reaction (PCR)
    - Reverse Transcription (RT)-PCR
    - Sequencing (Next-Generation Sequencing [NGS], Pyrosequencing, etc.)
    - In Situ Hybridization (ISH)
    - Fluorescent In Situ Hybridization (FISH)
    - Gene Array

- **Consults**
- **Slide Reviews**
- **Biomarker results**
- **Pathology Report Addenda**

5.6 Required Data Elements

CCR requires various facility and patient information in order to successfully match pathology information to existing patients in its database and/or to match to the criteria for research studies/clinical trials. Other patient demographic items are also essential for epidemiological incidence and mortality research. CCR recognizes that not all facility/patient information may be available to all pathologists. Thus, to help CCR serve its public health mission to improve cancer patient outcomes, a cooperative effort is encouraged to provide this kind of data. It is likely that ordering facility/office EHR systems will contain many of these facility/patient data elements, so CCR recommends that LIS vendors work with ordering facilities/offices and their EHR vendors to enable these kinds of data elements to be transmitted to CCR. Given different work flows and different levels of integration between EHR systems and LIS systems, there may be multiple facility-specific methods to achieve this goal.

5.7 Annual Review and Revision

The CCR Electronic Pathology Standards Reporting Manual-Volume V will be available on line to serve as the reference document for pathologists and pathology. This manual will be revised and updated on an annual basis in order to incorporate required North American Association of Central Cancer Registries (NAACCR) changes and updates. CCR will notify pathologists, pathology labs, and LIS vendors when the final manual is published and when updates to the manual are released.

5.8 Quality Control

The CCR will routinely monitor compliance with regard to pathology report completeness, accuracy and timeliness in the following manner:

- Completeness: Pathology labs with identified issues in the HL7 message (i.e., out of compliance with the Constraints document) will be contacted by CCR with the expectation that the identified issues will be corrected.
- Accuracy: Pathology labs will be monitored for compliance with the reportable/non-reportable criteria outlined in this manual. CCR will work with pathology labs that have significantly high numbers of non-reportable pathology reports to identify and correct issue(s).
- Timeliness: Pathology reports will be monitored for compliance with the two week turnaround time from date of finalized pathology report to date transmitted to CCR.

6 Technical Implementation

6.1 Registration Portal

Pathology labs and/or facilities are required to register for reporting on behalf of represented pathologists within an organization or lab. Registration information includes specific contact information, inclusive of a lead physician contact, lab management contact, and a technical interface contact, as well as LIS and/or EHR vendor information. Registration also requires an organization or laboratory to select a preferred method of reporting. Methods of Reporting Include:

- HL7 Standard Protocol version 2.5.1, using North American Association of Central Cancer Registries Volume 5 and California defined constraints
- SDC Technical Framework using CAP ECC
- Direct Data Entry Web Portal

Please note that the Direct Data Entry Web Portal is only an option for Pathology labs and/or facilities that are not able to report electronically via an interface using HL7 2.5.1 or IHE SDC CAP ECC.

The Registration Portal can be accessed via the URL:

https://pathreporting.ccr.ca.gov/registration/

6.2 Identifying Reportable Cancers

Pathology labs reporting to CCR are required to implement filtering for reportable cancer cases. There are multiple approaches in which to implement filtering logic to disseminate reportable cancers. Options include using an ICD-10 list, ICD-02/ICD-03 list or a Cancer Case Finding Selection Criteria Word List. Specific codes associated with ICD reportable lists are referenced below please click on the hyperlink to view. Specifics relative to the NAACCR Path Lab Search Terms are referenced below please click on the hyperlink to view. CCR is not authorized to retain information on non-reportable neoplasms.

6.2.1 International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM):

http://www.ccrcal.org/pdf/AB2325/CA_ICD-10-CM.xlsx

6.2.2 NAACCR Path Lab Search Terms:

https://www.naaccr.org/naaccr-path-lab-search-terms/

6.2.3 International Classification of Diseases for Oncology (ICDO-3)

ICDO-3 is used by National Cancer Institute (NCI)

INCLUSIONS:

- All neoplasms diagnosed prior to the year 2001 with a behavior code of '2' or '3' in the International Classification of Diseases for Oncology, Second Edition (ICD-O-2) are reportable.
- All neoplasms diagnosed in 2001 and later with a behavior code of '2' or ‘3’ in the International Classification of Diseases for Oncology, Third Edition (ICD-O-3) are reportable.

- Epithelial carcinomas (8010-8046) in ICD-O-2 or ICD-O-3 are reportable for sites other than skin (C44.0-C44.9) including but not limited to vagina, clitoris, vulva, prepuce, penis and scrotum (sites C52.9, C51.0-C51.9, C60.0, C60.9, and C63.2).
- If a '0' or '1' behavior code term in ICD-O-2 or ICD-O-3 is verified as in situ, '2', or malignant, '3', by a pathologist, these cases shall be reportable.
- Tumors of the brain and central nervous system (C70.0-C72.9, C75.1-C75.3) with a behavior code of '0' or '1' beginning with January 1, 2001 diagnoses are reportable.

EXCLUSIONS:

- Cervix carcinoma in situ are not reportable after January 1, 1996.
- The following exclusions based on histology and site and are not reportable:
    - 8000-8005: Neoplasms, malignant, NOS of the skin (C44.0-C44.9)
    - 8010-8046: Epithelial carcinomas of the skin (C44.0-C44.9)
    - 8050-8084: Papillary and squamous cell carcinomas of the skin (C44.0-C44.9)
    - 8090-8110: Basal cell carcinomas of the skin (C44.0-C44.9)

6.3 Required Data Elements

All data elements contained in the California Cancer Registry NAACCR Volume V Version 4.0 – HL7 2.5.1 Constraints Document are required or required if accessible. If a data element is required, it must be transmitted with a value other than empty, blank, or null. For a data element that is required if available, it must be sent when a known value is accessible, although an empty value is allowed when no other allowable value is accessible. However, if a data element has an allowable code for "unknown", then that code should be transmitted for that element instead of an empty value.

See Appendix A: California Cancer Registry NAACCR Volume 5 Version 4.0 HL7 2.5.1 Constraints or access via the following Link:
http://www.ccrcal.org/pdf/AB2325/CA_Volume_V_constraints.xlsx

NAACCR Volume V Version 4.0 Link:
https://www.naaccr.org/pathology-laboratory-electronic-reporting/

6.4 Data Format

Laboratory-based cancer reports are to be formatted in accordance with federal standards for data format as defined by the NAACCR and the Office of the National Coordinator for Health Information Technology (ONC HIT). NAACCR publishes a version of the HL7 2.5.1 standard protocol which is named the Standards for Cancer Registries Volume V - Pathology Laboratory Electronic Reporting Version 4.0. There are three specific defined formats for reporting within NAACCR Volume

V. CCR also supports XML data transmission via the ONC HIT standard for SDC using CAP eCC.

6.5 Supported Report Format Styles using HL7

CCR is limiting the format of path reports to three options via HL7 outlined in NAACCR Volume V.

- Link to NAACCR Volume 5: https://www.naaccr.org/pathology-laboratory-electronic-reporting/
- Link to Appendix A: CA Constraints: http://www.ccrcal.org/pdf/AB2325/CA_Volume_V_constraints.xlsx

6.5.1 Narrative Report

Cancer pathology reports in a text-based or narrative-style format with specific information contained in the narrative. These reports are generally dictated by a pathologist and then transcribed by a transcriptionist. Please reference NAACCR Volume V Appendix D: 7.1 for example: https://www.naaccr.org/pathology-laboratory-electronic-reporting/

6.5.2 Synoptically Structured Report

Narrative cancer pathology reports that are formally divided into explicit items covering specific observations on a specimen, and laid out in a predefined format. Please reference NAACCR Volume 5 Appendix D: 7.2: https://www.naaccr.org/pathology-laboratory-electronic-reporting/

6.5.3 Synoptic Structured Report Using the CAP eCC

Cancer pathology reports that are structured synoptically and the data is also fully encoded, captured, and stored in the AP/LIS or synoptic reporting application as discrete question-and answer pairs. Please reference NAACCR Volume V Appendix D: 7.3: https://www.naaccr.org/pathology-laboratory-electronic-reporting/

6.5.4 SDC Technical Framework using CAP eCC

CCR supports the IHE Quality, Research, and Public Health Technical Framework Supplement SDC Rev. 2.1 Implementation as a role of 'Form receiver' for ITI-35 Transactions. Link to SDC Technical Framework Implementation Guide: https://ihe.net/uploadedFiles/Documents/QRPH/IHE_QRPH_Suppl_SDC.pdf

Upon successful registration selecting IHE SDC as a method of reporting a service interface implementation guide will be provided.

6.6 Supported Transmission Methods

CCR supports the following data transmission methods for pathology lab electronic reporting. After a provider or pathology lab registers with CCR to

send pathology data electronically to the state, CCR will work in priority order to establish appropriate connections for data submission.

6.6.1 Web Services - RESTful

RESTful web service interface for submitting for pathology laboratory electronic reports. Upon successful registration, the RESTful technical interface guide will be provided.

6.6.2 Web Services – Simple Object Access Protocol (SOAP)

SOAP 1.2 web service interface for submitting for pathology laboratory electronic reports. Upon successful registration, the SOAP 1.2 web service interface implementation guide will be provided.

6.6.3 SFTP

SSH File Transfer Protocol SFTP for uploading pathology laboratory electronic reports. Upon successful registration, the SFTP login information will be provided.

6.6.4 MLLP

MLLP for submitting pathology laboratory electronic reports. Upon successful registration, the MLLP implementation guide will be provided.

6.7 Direct Data Entry Web Portal

A Direct Data Entry Web Portal will be provided for pathologists who do not have the ability to output and send an electronic message to CCR. The Direct Data Entry Web Portal will have functionality to support direct entry of required and required if accessible data fields. The Direct Data Entry Web Portal will also have functionality associated with cut and paste of narrative text to support the direct entry data fields. The Direct Data Entry Web Portal will be deployed to serve as the low cost option for pathologists to meet the California cancer pathology reporting requirement without having to invest in software and technology. The Direct Data Entry Web Portal will require manual input of data fields and additional case information and may not be the most efficient solution for pathologists and pathology labs who receive orders to examine a moderate to high level of specimens which may result in an incidence of cancer and need to be reported to CCR.

Pathologists desiring to utilize this method for reporting will need to first establish their intent to report via the Direct Data Entry Web Portal by registering their provider information with CCR on the California Pathology Registration Portal. CCR will be using the registration list to subsequently work with providers to establish an account on the Direct Data Entry Web Portal. The Direct Data Entry Web Portal will be a secured website conforming to state level security requirements for the data entry and output of confidential patient information to CCR. A user name and password will be issued to each user and the password will be required to be changed upon first use. A second form of authentication will be required and will consist of a

code sent to the user, either by cell phone or email, which the user must then enter in the web page. Once authenticated, an upload page will be available to send pathology data to CCR.

Direct Data Entry Web Portal Link:
https://pathreporting.ccr.ca.gov/directdataentry/

6.8 Vendor Self-Initiated Testing

CCR has developed a web page and associated service to upload test files for automatic evaluation and feedback on pathology reports with any identified issues. The self-testing tool will validate test messages for structure and format. The file will be checked to determine that it is parsable, and that the required fields are completed. Edits will then be run against the submitted file.

Multiple record types from pathology laboratory vendors may be needed. If the files pass, the service will update their user account allowing them to send that version of the record to CCR. If the file fails, a list of errors will be returned and/or displayed.

Vendor Self-Initiated Testing Link: https://pathreporting.ccr.ca.gov/selftesting/

6.9 On-boarding Process

CCR will conduct outreach to entities registering to begin pathology reporting to the CCR and conduct organization and laboratory specific testing. Organization and laboratory specific testing will require a defined method of reporting to be finalized. Depending upon the method of reporting, subsequent tasks involved to create and establish a direct connection with CCR may be required. Pathology labs submitting data on behalf of pathologists will be required to participate in a testing and validation process with CCR. CCR will work with pathology labs and their representatives and/or vendor representatives to ensure the data being submitted to CCR meets formatting and completeness requirements.