California AB 2325 Electronic Pathology Reporting

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Introduction

• CA State Assembly Bill 2325
  – Introduced by Assemblywoman Susan Bonilla, 14th District - Contra Costa, Solano Counties
  – Approved and signed by Governor Jerry Brown on September 14, 2016
Assembly Bill Text

This bill, on or after January 1, 2019, would, among other things, require a pathologist diagnosing cancer to report cancer diagnoses to the department by electronic means, including, but not limited to, either directly from an electronic medical record or using a designated Internet Web portal provided by the department.
Health and Safety Code Change Summary
CA HSC 103885

• (3) (A) On or after January 1, 2019, a pathologist diagnosing cancer shall report cancer diagnoses to the department utilizing the College of American Pathologists cancer protocols or any other standardized format approved by the department.

• (B) Reporting shall be by electronic means, including, but not limited to, either directly from an electronic medical record or using a designated Internet Web portal that the department shall provide for pathologists’ use. If a pathologist fails to report electronically and with an approved format, the department’s authorized representative may access the information from the pathologist in an appropriate alternative format. In these cases, the pathologist shall reimburse the department or the authorized representative for its cost to access and report the information.
Health and Safety Code Change Summary
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• (C) A **pathologist shall not be responsible for acquiring missing or inaccessible patient demographic information** not provided to him or her beyond the content of the required cancer-specific data elements.

• (D) For purposes of reports submitted pursuant to this paragraph, the **department shall prescribe the data required** to be included in the report, work collaboratively with stakeholders to designate a standardized electronic format for submission, and designate an Internet Web portal for electronic submission.

• (E) This paragraph shall not be interpreted to require a pathologist to submit the same pathology report to the department, regardless of format, more than once. If a pathology report is submitted by a pathologist electronically, pursuant to this paragraph, the same pathology report is not required to be submitted to the department by any other means.
Many Large Parts to the Plan

- Communications
- Data Standards
- Technical Support
- Software/Hardware/Network Development
- Testing/Implementation Support
- Operational Process Changes
Milestones

- Define Data Standard: January 15, 2017
- Release Implementation Guide: July 1, 2017
- Implementation Start: January 1, 2018
- Release of the Direct Entry Web Portal: June 8, 2018
- Effective Date: January 1, 2019
Path to Implementation

Registration

Manual Entry
- Direct Data Entry Web Portal
  - Direct Data Entry Account
    - Create an account
  - Training
    - Training as needed for use of the manual entry portal
  - Validation
    - Validation of message content by CCR staff

Electronic Data Submission
- HL7 Interface
  - Choose Transmission Method
    - REST, SOAP, MLLP, SFTP
  - Choose Data Format
    - Simple Narrative
    - Synoptically Structured
    - Synoptically Structured with CAP eCC
  - Self Testing
  - Onboarding

Ongoing data submission to CCR
Registration Process

• Registration with the California Cancer Registry is required for electronic pathology reporting

• A Laboratory or institution may register a single time on behalf of all of its pathologists

• https://pathreporting.ccr.ca.gov/registration/
Transmission Methods

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

1. Web Services (SOAP, REST)
2. Minimal Lower Layer Protocol (MLLP)
3. Secure File Transfer Protocol (SFTP)
4. Direct Data Entry Web Portal
Data Format

• CCR is limiting the formatting of pathology reports to the options presented within the CDC National Standard NAACCR Volume V:
  – Simple Narrative
  – Synoptically Structured
  – Synoptically Structured using College of American Pathologists (CAP) Electronic Cancer Checklist (eCC)
  – CAP eCC Structured Data Captured (SDC) Extensible Markup Language (XML)
Required Data Elements
Manual Web Portal Entry

• **Required**
  – Patient Information (First, Last)
  – Ordering Physician Information (First, Last, Provider NPI, CA License Number, Address)
  – Ordering Facility (Facility Name, NPI, Address)
  – Principal Result Interpreter (Last, First, CA License Number)
  – Cancer Diagnosis (Order Filler Number, Date Specimen collected, Date results reported, Report Text)

• **Required if available**
  – Patient Information (14 fields)
Required Data Elements
Electronic HL7

Please reference the California Cancer Registry NAACCR Volume 5 Version 4.0 – HL7 2.5.1 Constraints Document. Fields are designated as required or required if accessible.

- NAACCR Volume 5 Version 4.0 Link: https://www.naaccr.org/pathology-laboratory-electronic-reporting/

- California Cancer Registry NAACCR Volume 5 Version 4.0 HL7 2.5.1 Constraints Link: http://www.ccrcal.org/pdf/AB2325/CA_Volume_V_constraints.xlsx
Current State of Implementation

- 392 Labs have registered
- 107 Labs have completed onboarding
- 63 Labs are actively within the process of onboarding
  - 36 via a new interface
  - 27 to report via the Direct Entry Portal
- 221 Labs have yet to initiate onboarding
Implementation Resources

• CCR AB2325 Webpage
  – http://www.ccrcal.org/AB2325.shtml

• Registration
  – https://pathreporting.ccr.ca.gov/registration/

• Direct Data Entry Portal
  – https://pathreporting.ccr.ca.gov/directdataentry/

• Self-Testing
  – https://pathreporting.ccr.ca.gov/selftesting/
Reportable Diagnoses

1. Invasive malignancies
2. In Situ malignancies (excluding non genital skin)
3. Benign and borderline intracranial and/or Central Nervous System (CNS) tumors
4. All Hematopoietic and lymphoid neoplasms as outlined in the SEER HEMELYMPH DATABASE
5. Carcinoid Tumors, NOS of the Appendix
6. Neuroendocrine tumor when the diagnosis is insulinoma
7. Cystic Pancreatic Endocrine Neoplasm (CPEN), grades 1 and 2
8. Solid pseudopapillary neoplasm of pancreas.
9. Non-Invasive Mucinous Cystic Neoplasm (MCN) of pancreas with high grade dysplasia
10. Mature teratoma of the testes in adult
Criteria for Reporting

Specimen types:

- Biopsies, resections, re-excisions, cytology

Report types:

- primary diagnosis, consults, addendums, molecular testing and IHC results
Criteria for Reportable Diagnoses

• “In the event an ambiguous term precedes a reportable cancer diagnoses, the case is to be considered reportable.”

Examples of ambiguous terminology include:

• suspicious, consistent with, typical (of), probable, presumed, malignant appearing.
Non Reportable Diagnoses

1. Basal and squamous cell carcinoma of the skin, unless it occurs on vulva, scrotum and penis

2. Neoplasms, malignant, NOS of the skin
   *Melanoma is reportable

2. Carcinoma in situ or CIN III of the cervix.

3. Benign and borderline neoplasms that are not primary intracranial and/or CNS neoplasms
St. Joseph Health (SJH) System

- Includes hospitals in California, Texas and New Mexico
- Now part of Providence Health System, but still using Meditech
- Have been using mTuitive’s CAP eFRM to report all CAP electronic cancer checklists (eCC) for ~5 years
- Have already been electronically reporting all eCC synoptics to CCR for ~2 years
SJH CCR Reporting

• Because this CCR reporting was established using Meditech, SJH implementation of AB2325 differs from rest of Providence
• Pathologists from each institution met by webinar to discuss best way to comply
• Sending eCC resection data alone encompasses only about 20% of cases required by CCR
SJH CCR Compliance Plan

- Determined that best approach is to have pathologist decide for each case need to send to CCR
- New Y/N field in draft report
- Sent in HL7 format via Secure File Transfer Protocol (sFTP)
mTuitive-eFRM

The basic concept behind AB2325 was our original vision (Dr. William O’Ttoole 2003)

• Frustrated with the inefficiency of registry process
• Little scientific validity to the quality of the data

Plan for pathologist workstation

• Capture diagnosis at microscope
• Validate, standardize, code
• “Database ready”
• Use for downstream purposes- staging, trials eligibility, further testing, peer review, teaching, CANCER REGISTRY
• Found the CAP protocols- 1st to license
• Simplify usability and maintenance, vendor/technology independent, truly interoperable
Why mTuitive

Complete compliance
  • Not just software, not a form filler or a checklist tool
  • Maintenance of the checklist changes, corrections, additions

Experience, focus, eCC development and QA

Relationship with CAP

Interoperability- integration capabilities

Vendor and technology neutral

Not competitive- not a pathology system
Criteria for Reporting

Specimen types:
  Biopsies, resections, re-excisions, cytology
Report types:
  primary diagnosis, consults, addendums, molecular testing and IHC results
Some pre- and non-cancer conditions
### AB 2325 Plan for Compliance: Structured (synoptic reports)

<table>
<thead>
<tr>
<th>Report Type</th>
<th>CAP eCC</th>
<th>New checklists (mTuitive Community)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Surgicals (resections, excisions, bone marrow)</strong></td>
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<tr>
<td><strong>Lymphoma and leukemia</strong></td>
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<tr>
<td><strong>Biopsies</strong></td>
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<td>&gt;</td>
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<tr>
<td><strong>Cytology</strong></td>
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<tr>
<td><strong>Non or pre-malignant</strong></td>
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<tr>
<td><strong>Bio-markers, molecular ....</strong></td>
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<tr>
<td><strong>Anything else</strong></td>
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<td>Generic checklist</td>
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Standalone eFRM Portal
<table>
<thead>
<tr>
<th>Feature/ function</th>
<th>Best approach eFRM</th>
<th>CCR web module (standalone)</th>
<th>Free synoptic (structured) AB 2325 completion only</th>
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<tbody>
<tr>
<td>Electronic Cancer Checklist (eCC) &amp; AB 2325 Compliance</td>
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<td>Reporting database</td>
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<tr>
<td>Integrated decision support- Immunoquery and Expert Path from Elsevier</td>
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<tr>
<td>Training and support at no charge</td>
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<td><strong>Interfaces</strong></td>
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<td>Bi-directional with AP Systems</td>
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<td>Outbound to CCR</td>
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<td>Correlation with molec. &amp; genomic</td>
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<td>Transmission to oncology systems</td>
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<tr>
<td>Requires manual registration</td>
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<td>yes</td>
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</table>
Translating eCC Data to NAACCR

mTuitive Translation Engine

Central Data Repository (CDR) → Translation Service → NAACCR Registry

NAACCR Registry

Translation Rules Created by Subject Matter Experts

Translation Service

eCC Data (NAACCR Vol 5 HL7, SDC) → mTuitive Translation Engine → Central Data Repository (CDR) → eCC
Translation Designer