# Test Criteria: 170.315.a.5: Demographics

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| **Testing Result** |  |
| Participant and Product-with-version |  |
| Setting (Ambulatory or Inpatient) |  |
| Test Proctor |  |
| Test Date |  |
| Test Result | Pass:  Fail:  No Attempt: |
| Error Description (if applicable) |  |
| Modifications to Product Under Test |  |
| Additional Software Used |  |
| Additional Proctor Notes |  |

### Overview

In this document you will find:

* [Test Data and Test Tools](#_Test_Data_and)
* [Standards Support](#_Demonstrate_Standards_Support)
* [Drummond Test Report (Instructions, Expected Results, Points to Remember)](#_170.315(a)(5)(i)_Record,_Change,)
* [Test Procedures](#_Test_Procedures)
* [Appendix A: Testing Guide](#_Appendix_A:_Testing)
* [Appendix B: ONC Criteria](#_Appendix_B:_ONC)

### Version of ONC Test Method

1.3

### Scope of Proctoring Sheet

The ONC test method associated with this criterion is the only approved test method for EHR Meaningful Use certification. This Proctoring Sheet is not a replacement test method but a test procedure document for performing the ONC test method and recording the results. Proctoring Sheet describe test data, test criteria and expected results. It is assumed the Health IT Developer or Participant Under Test is familiar with the associated ONC test method.

# Robustness and Reliability Requirement

To satisfy the module criteria, it is expected that the Product-Under-Test is able to complete the testing requirements reliably, including repeat testing with the same result without error, and with a satisfactory level of robustness. This includes unexpected error messages produced through normal operation, multiple unintended restarts of the application or any other “buggy” facets of the product displayed while testing. These errors are record in the Additional Proctor Notes of the proctor sheet. Lack of reliability and robustness of design will result in failure of the module.

# Test Data and Tools

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| **Test Data Source:** | ONC-Supplied  DG-Supplied:  Developer-Supplied: |
| **Pre-Test Data Setup:**  Not applicable. | |
| **Test Data:**  DG-supplied demographics test data specified in test procedure below. | |
| **Test Tools:**  Not applicable. | |

# Demonstrate Standards Support

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| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **Instructions:** Implement standards to demonstrate recording of patient demographics. For additional references, click [here](https://www.healthit.gov/policy-researchers-implementers/meaningful-use-stage-2-0/standards-hub) for the ONC Standards Hub. | |

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|  | **Standard** |  |
|  | §170.207(f)(1) | [Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity](https://www.whitehouse.gov/omb/fedreg_1997standards) Statistical Policy Directive No. 15, as revised, October 30, 1997**.** The software must be able to aggregate each one of a patient’s race(s) and ethnicity(ies) to the OMB standard categories. The categories to which race and ethnicity selections must be aggregated and recorded include:   * American Indian or Alaska Native * Asian * Black or African American * Native Hawaiian or Other Pacific Islander * White |
|  | § 170.207(f)(2) | **Race and Ethnicity**. [CDC Race and Ethnicity Code Set Version 1 (March 2000)](http://www.cdc.gov/nchs/data/dvs/Race_Ethnicity_CodeSet.pdf). |
|  | §170.207(g)(2) | **Preferred Language**. [Request for Comments (RFC) 5646](REuehttp://www.rfc-editor.org/info/rfc5646) |
|  | §170.207(n)(1) | **Birth sex** must be coded in accordance with HL7 Version 3, Value Sets for AdministrativeGender and NullFlavor, attributed as follows:  (i) *Male.* M  (ii) *Female.* F  (iii) *Unknown. nullFlavor* UNK |
|  | §170.207(o)(1) | **Sexual orientation** must be coded in accordance with, at a minimum, the version of SNOMED CT® codes specified above for (i) through (iii) and HL7 Version 3, Value Sets for AdministrativeGender and NullFlavor, for (iv) through (vi), attributed as follows:  (i) Lesbian, gay or homosexual*.* 38628009  (ii) Straight or heterosexual*.* 20430005  (iii) Bisexual. 42035005  (iv) Something else, please describe. nullFlavor OTH  (v) Don’t know*.* nullFlavor UNK  (vi) Choose not to disclose. nullFlavor ASKU |
|  | §170.207(o)(2) | **Gender identity** must be coded in accordance with, at a minimum, the version of SNOMED CT® codes specified above for (i) through (v) and HL7 Version 3, Value Sets for AdministrativeGender and NullFlavor, for (vi) and (vii), attributed as follows:  (i) Identifies as Male*.* 446151000124109  (ii) Identifies as Female*.* 446141000124107  (iii) Female-to-Male (FTM)/Transgender Male/Trans Man. 407377005  (iv) Male-to-Female (MTF)/Transgender Female/Trans Woman. 407376001  (v) Genderqueer, neither exclusively male nor female*.* 446131000124102  (vi) Additional gender category or other, please specify. nullFlavor OTH  (vii) Choose not to disclose. nullFlavor ASKU |

# 170.315(a)(5) Demographics

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| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **Instructions:**   * User records patient demographic data according to applicable specified standards for Race and Ethnicity, Preferred Language, Sex, Sexual Orientation, Gender Identity, and Date of Birth. Additionally, for Inpatient Settings, the user records patient Preliminary Cause of Death and Date of Death. * User changes patient’s demographic data. * User accesses patient’s demographic data. | |
| **Expected Test Result:**   * Enable a user to record, change, and access a patient’s demographic data according to applicable specified standards that includes:   + Race and Ethnicity   + Preferred Language   + Sex   + Sexual Orientation   + Gender Identity   + Date of Birth * ***Inpatient Setting only*** : in addition to the list above, the user can record, change, and access a patient’s demographic data that includes:   + Preliminary Cause of Death   + Date of Death * The Health IT system correctly maps the more granular CDC concepts for Race to the appropriate OMB standard (See the [CDC Race and Ethnicity Code Set Version 1 (March 2000)](http://www.cdc.gov/nchs/data/dvs/Race_Ethnicity_CodeSet.pdf) for guidance):   + American Indian or Alaska Native   + Asian   + Black or African American   + Native Hawaiian or Other Pacific Islander   + White * The Health IT system correctly maps the more granular CDC concepts for Ethnicity to the OMB standard as applicable:   + Hispanic or Latino   + Not Hispanic or Latino * The OMB standard permits merging the ethnicity and race categories for a “combined format,” which would no longer require “not Hispanic or Latino” to be recorded. This alternative approach is also acceptable. Please notify your Proctor before your test event if you will be using this approach in order to prepare test data. * The user must be able to record whether the patient declined to specify Race, Ethnicity, Preferred Language, Sexual Orientation, and Gender Identity. * The user must be able to record multiple patient Races (at least two) and multiple Ethnicities (at least two). | |
| **Points to Remember:**   * Health IT Modules can present for certification to a more recent version of the “Race & Ethnicity” – CDC code system than Version 1.0. * Race and Ethnicity should be captured in separate field as other standards required these data to be exchanged as separate fields (e.g. CCDA). * A product does not need to display all of the race and ethnicity codes or the preferred language codes to the user in order to meet the certification criterion. The developer has the discretion to create a default selection set or enable customization choices for providers. However, for the purposes of testing, a developer should be prepared to show that the product can represent any of the races or ethnicities and preferred languages in the value set created by the standard. * Testing will only test the primary language tag and not test for the extension components specified in RFC 5646. Specifically, * Use alpha 2 character code if one exists (ISO 639-1); * Use alpha 3 character code if an alpha 2 character code does not exist (ISO 639-2); and * Region extensions (ISO 3166-1) are permitted but not required (however, if a region extension is used, it will be verified for accuracy as part of testing and must be correct). * There is no standard required for recording Date of Birth, Preliminary Cause of Death, and Date of Death (i.e. any format may be used). * While not required structured and coded questions for soliciting Sexual Orientation/Gender Identity (SO/GI), it is suggested that health care providers and institutions decide whether to include these questions in the collection of SO/GI information as “best practices”:   + Do you think of yourself as:     - [Straight or heterosexual;     - Lesbian, gay, or homosexual;     - Bisexual;     - Something else, please describe.     - Don’t know.]   + What is your current gender identity? (Check all that apply.)     - [Male;     - Female;     - Transgender male/Trans man/Female-to-male;     - Transgender female/Trans woman/Male-to-female;     - Genderqueer, neither exclusively male nor female;     - Additional gender category/(or other), please specify.     - Decline to answer.] | |

### Test Procedures

**1.1 Record Demographics**

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|  | User records demographics by charting the following three test patients and demonstrates health IT module can record codified entries listed:  Patient 1:   * + Date of Birth: **3/30/1977**   + Sex : **Female**   + Race: **Samoan** (CDC: 2080-0)   OMB standard: *Native Hawaiian or Other Pacific Islander* (CDC: 2076-8)   * + Ethnicity : **Not Hispanic or Latino** (CDC: 2186-5)   + Preferred Language : **English**, US (ISO: en)   + Sexual Orientation : **Lesbian, gay, or homosexual** (SNOMED: 38628009)   + Gender Identity : **Identifies as** **Female** (SNOMED: 446141000124107)   + (*Inpatient Only*) Preliminary Cause of Death: **Cardiac Arrest**   + (*Inpatient Only*) Date of Death: **10/1/2016**   Patient 2:   * + Date of Birth : **8/31/1938**   + Sex : **Male**   + Race :   **Haitian** (CDC: 2071-9)  OMB standard *Black or African American* (CDC: 2054-5)  **Dominica Islander** (CDC: 2070-1)  OMB standard: *Black or African American* (CDC: 2054-5)   * + Ethnicity : **Not Hispanic or Latino** (CDC: 2186-5)   + Preferred Language : **French** (ISO: fr)   + Sexual Orientation : **Straight or heterosexual** (SNOMED: 20430005)   + Gender Identity : **Identifies as** **Male** (SNOMED: 446151000124109)   + (*Inpatient Only*) Preliminary Cause of Death: **Head Trauma**   + (*Inpatient Only*) Date of Death: **9/1/2016**   Patient 3:   * + Date of Birth : **4/7/1980**   + Sex : **Female**   + Race : **Declined to Specify**   + Ethnicity : **Declined to Specify**   + Preferred Language : **Declined to Specify**   + Sexual Orientation : **Choose Not to Disclose** (HL7 v3: nullFlavor ASKU)   + Gender Identity : **Choose Not to Disclose** (HL7 v3: nullFlavor ASKU)   + (*Inpatient Only*) Preliminary Cause of Death: **Cerebrovascular Accident**   + (*Inpatient Only*) Date of Death: **8/1/2016** |

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**1.2 Change Demographics**

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|  | User changes demographics (highlighted in **bold**) for the following three test patients and demonstrates health IT module can record codified entries listed:    Patient 1:   * + Date of Birth : **9/17/1954**   + Sex : **Male**   + Race : **Declined to Specify**   + Ethnicity : **Declined to Specify**   + Preferred Language : **Declined to Specify**   + Sexual Orientation : **Don’t know** (HL7 v3: nullFlavor UNK)   + Gender Identity : **Genderqueer, neither exclusively male nor female (**SNOMED:446131000124102)   + (*Inpatient Only*) Preliminary Cause of Death: **Head Trauma**   + (*Inpatient Only*) Date of Death: **1/30/2016**   Patient 2:   * + Date of Birth : **3/15/1982**   + Sex : **Female**   + Race : **Dominican** (CDC: 2069-3)   OMB standard: *Black or African American* (CDC: 2054-5)   * + Ethnicity :   **Dominican** (CDC: 2184-0)  OMB standard: *Hispanic or Latino* (CDC: 2135-2)  **Latin American** (CDC: 2178-2)  OMB standard: *Hispanic or Latino* (CDC: 2135-2)   * + Preferred Language : **Spanish** (ISO: es)   + Sexual Orientation : **Bisexual (**SNOMED: 42035005)   + Gender Identity : **Male-to-Female (MTF)/Transgender Female/Trans Woman (**SNOMED: 407376001)   + (*Inpatient Only*) Preliminary Cause of Death: **Cerebrovascular Accident**   + (*Inpatient Only*) Date of Death: **4/10/2016**   Patient 3:   * + Date of Birth : **5/24/1964**   + Sex : **Male**   + Race :   **Blackfoot Sioux** (CDC: 1610-5)  OMB standard: *American Indian or Alaska Native* (CDC: 1002-5)  **French** (CDC: 2111-3)  OMB standard: *White* (CDC: 2106-3)   * + Ethnicity : **Not Hispanic or Latino** (CDC: 2186-5)   + Preferred Language : **French** (ISO: fr)   + Sexual Orientation : **Something else, please describe** (HL7 v3: nullFlavor OTH)   + Gender Identity : **Female-to-Male (FTM)/Transgender Male/Trans Man** (SNOMED: 407377005)   + (*Inpatient Only*) Preliminary Cause of Death: **Cardiac Arrest**   + (*Inpatient Only*) Date of Death: **7/30/2016** |

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**1.3 Access Demographics**

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|  | User accesses patient demographics and codified entries:  Patient 1:   * + Date of Birth : **9/17/1954**   + Sex : **Male**   + Race : **Declined to Specify**   + Ethnicity : **Declined to Specify**   + Preferred Language : **Declined to Specify**   + Sexual Orientation : **Don’t know** (HL7 v3: nullFlavor UNK)   + Gender Identity : **Genderqueer, neither exclusively male nor female (**SNOMED:446131000124102)   + (*Inpatient Only*) Preliminary Cause of Death: **Head Trauma**   + (*Inpatient Only*) Date of Death: **1/30/2016**   Patient 2:   * + Date of Birth : **3/15/1982**   + Sex : **Female**   + Race : **Dominican** (CDC: 2069-3)   OMB standard: *Black or African American* (CDC: 2054-5)   * + Ethnicity :   **Dominican** (CDC: 2184-0)  OMB standard: *Hispanic or Latino* (CDC: 2135-2)  **Latin American** (CDC: 2178-2)  OMB standard: *Hispanic or Latino* (CDC: 2135-2)   * + Preferred Language : **Spanish** (ISO: es)   + Sexual Orientation : **Bisexual (**SNOMED: 42035005)   + Gender Identity : **Male-to-Female (MTF)/Transgender Female/Trans Woman (**SNOMED: 407376001)   + (*Inpatient Only*) Preliminary Cause of Death: **Cerebrovascular Accident**   + (*Inpatient Only*) Date of Death: **4/10/2016**   Patient 3:   * + Date of Birth : **5/24/1964**   + Sex : **Male**   + Race :   **Blackfoot Sioux** (CDC: 1610-5)  OMB standard: *American Indian or Alaska Native* (CDC: 1002-5)  **French** (CDC: 2111-3)  OMB standard: *White* (CDC: 2106-3)   * + Ethnicity : **Not Hispanic or Latino** (CDC: 2186-5)   + Preferred Language : **French** (ISO: fr)   + Sexual Orientation : **Something else, please describe** (HL7 v3: nullFlavor OTH)   + Gender Identity : **Female-to-Male (FTM)/Transgender Male/Trans Man** (SNOMED: 407377005)   + (*Inpatient Only*) Preliminary Cause of Death: **Cardiac Arrest**   + (*Inpatient Only*) Date of Death: **7/30/2016** |

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**1.4 Verification of Preferred Languages**

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|  | Verify EHR supports ***all*** preferred languages present in ISO 639-2. See the “**2015E\_PrefLang**“tab within the “**Demographic\_PreferredLanguage**” list provided by Drummond Group as a reference for verification (available for download in Zendesk or inquire with your Test Proctor). Verification may include inspecting back end database or list of preferred languages in user interface according to the following standard:   * use alpha 2 character code if one exists (ISO 639-1); * use alpha 3 character code if an alpha 2 character code does not exist (ISO 639-2); and * region extensions (ISO 3166-1) are permitted but not required (however, if a region extension is used, it will be verified for accuracy as part of testing and must be correct) |

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# Appendix A: Testing Guide

*This appendix contains more details and background on the testing requirements, including explanation on underlying standards, notable issues and best practice suggestions.*

Rev 01-May-2016 Additions

* Testing for preferred language using the standard at § 170.207(g)(2) (RFC 5646) will focus on all the languages present in [ISO 639-2](http://www.loc.gov/standards/iso639-2/php/code_list.php).
* For any health IT module testing regional tags for Preferred Language, verification may be conducted using the ISO 3166 browser (https://www.iso.org/obp/ui/#search).

Rev 01-Mar-2016 Additions

* The demographic data can come from other sources (e.g., a registration system or practice management system) so long as testing demonstrates the Health IT Module can perform all required functions included in the demographics certification criterion.
* The “Race & Ethnicity: CDC” code system includes over 900 concepts for race and ethnicity. A health IT developer is free to determine how the user interface is designed, including how many race and ethnicity values are displayed. No default minimum number of visible selections is expected or implied. During testing, however, any of the concepts for race and ethnicity may be tested.
* The following OIDs are provided to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards.
  + “Race & Ethnicity” - CDC code system OID: 2.16.840.1.113883.6.238
  + Tags for Identifying Languages : Request for Comment (RFC) 5646 code system OID: 2.16.840.1.113883.6.316
  + SNOMED CT® code system OID: 2.16.840.1.113883.6.96
* Health IT Modules can present for certification to a more recent version of the “Race & Ethnicity” : CDC code system than Version 1.0.
* The OMB standard permits merging the ethnicity and race categories for a “combined format,” which would no longer require “not Hispanic or Latino” to be recorded. This alternative approach is also acceptable.
* RFC 5646 is compatible with C-CDA Release 2.1 and ISO 639-1, 639-2, and 639-3 can be mapped to it.
* Health IT Modules can present for certification to a more recent version of the U.S. Edition of SNOMED CT® than the September 2015 version.

# Appendix B: ONC Criteria and Standards

*This appendix contains copy of the relevant ONC criteria and standards for this proctor sheet as a reference. In the event of a discrepancy with the ONC Final Rule, the ONC Final Rule takes precedence.*

**§170.315(a)(5) Demographics**

(i) Enable a user to record, change, and access patient demographic data including race, ethnicity, preferred language, sex, sexual orientation, gender identity and date of birth.

(A) Race and ethnicity*.*

(*1*) Enable each one of a patient's races to be recorded in accordance with, at a minimum, the standard specified in §170.207(f)(2) and whether a patient declines to specify race.

(*2*) Enable each one of a patient's ethnicities to be recorded in accordance with, at a minimum, the standard specified in §170.207(f)(2) and whether a patient declines to specify ethnicity.

(*3*) Aggregate each one of the patient's races and ethnicities recorded in accordance with paragraphs (a)(5)(i)(A)(*1*) and (*2*) of this section to the categories in the standard specified in §170.207(f)(1).

(B) Preferred Language. Enable preferred language to be recorded in accordance with the standard specified in §170.207(g)(2) and whether a patient declines to specify a preferred language.

(C) Sex. Enable sex to be recorded in accordance with the standard specified in §170.207(n)(1).

(D) Sexual orientation. Enable sexual orientation to be recorded in accordance with the standard specified in §170.207(o)(1) and whether a patient declines to specify sexual orientation.

(E) Gender identity. Enable gender identity to be recorded in accordance with the standard specified in §170.207(o)(2) and whether a patient declines to specify gender identity.

(ii) Inpatient setting only*.* Enable a user to record, change, and access the preliminary cause of death and date of death in the event of mortality.

§ 170.207 Vocabulary standards for representing electronic health information.

(a) (4) Standard. IHTSDO SNOMED CT®, U.S. Edition, September 2015 Release.

(f) Race and Ethnicity —

(1) Standard. The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997.

(2) Standard. CDC Race and Ethnicity Code Set Version 1.0 (March 2000).

(g) Preferred language —

(2) Standard. Request for Comments (RFC) 5646.

(n) Sex —

(1) Standard. Birth sex must be coded in accordance with HL7 Version 3, Value Sets for AdministrativeGender and NullFlavor, attributed as follows:

(i) Male. M

(ii) Female. F

(iii) Unknown. nullFlavor UNK

(o) Sexual orientation and gender identity —

(1) Standard. Sexual orientation must be coded in accordance with, at a minimum, the version of SNOMED CT® codes specified in paragraph (a)(4) of this section for paragraphs (o)(1)(i) through (iii) of this section and HL7 Version 3, Value Sets for AdministrativeGender and NullFlavor, for paragraphs (o)(1)(iv) through (vi) of this section, attributed as follows:

(i) Lesbian, gay or homosexual. 38628009

(ii) Straight or heterosexual. 20430005

(iii) Bisexual. 42035005

(iv) Something else, please describe. nullFlavor OTH

(v) Don’t know. nullFlavor UNK

(vi) Choose not to disclose. nullFlavor ASKU

(2) Standard. Gender identity must be coded in accordance with, at a minimum, the version of SNOMED CT® codes specified in paragraph (a)(4) of this section for paragraphs (o)(2)(i) through (v) of this section and HL7 Version 3, Value Sets for AdministrativeGender and NullFlavor, for paragraphs (o)(2)(vi) and (vii) of this section, attributed as follows:

(i) Identifies as Male. 446151000124109

(ii) Identifies as Female. 446141000124107

(iii) Female-to-Male (FTM)/Transgender Male/Trans Man. 407377005

(iv) Male-to-Female (MTF)/Transgender Female/Trans Woman. 407376001

(v) Genderqueer, neither exclusively male nor female. 446131000124102

(vi) Additional gender category or other, please specify. nullFlavor OTH

(vii) Choose not to disclose. nullFlavor ASKU

# Change Log

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| --- | --- |
| Revision | Change Description |
| 01-Oct-2016 | Clarified at least two Races and at least two Ethnicities required. Updated inpatient cause of death test data. |
| 01-Sept-2016 | Added second ethnicity for test patient #2. Reformatted race and ethnicity listings. |
| 01-July-2016 | Updated link for “CDC Race and Ethnicity” within Standards section. Provided clarification regarding mapping to OMB standard. Re-numbered sections. Corrected the gender descriptors for "male" and "female" to "identifies as male" and "identifies as female" in § 170.207(o)(2). |
| 01-Jun-2016 | Updated race for patient #1 under section 1.1 to map to “Native Hawaiian or Other Pacific Islander”. Added hyperlinks under “Demonstrate Standards Support” section. |
| 01-May-2016 | Updated standard identifiers under “Demonstrate Standards Support” section. Added clarification for Preferred Language requirement and additional test step (4.1) for verification. Updated race and ethnicity test data to include mapping verification to OMB standard. Added optional reference for verifying regional tags under Appendix A. |
| 01-Apr-2016 | Corrected SNOMED for “straight or heterosexual” from ‘20730005’ to ‘20430005’. |
| 01-Mar-2016 | Initial Release. |
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**About Drummond Group LLC**

Drummond Group LLC is a global software test and certification lab that serves a wide range of vertical industries.  In healthcare, Drummond Group tests and certifies Controlled Substance Ordering Systems (CSOS), Electronic Prescription of Controlled Substances (EPCS) software and processes, and Electronic Health Records (EHRs) : designating the trusted test lab as the only third-party certifier of all three initiatives designed to move the industry toward a digital future. Founded in 1999, and accredited for the Office of the National Coordinator Health IT Certification Program as an Authorized Certification Body (ACB) and an Authorized Test Lab (ATL), Drummond Group continues to build upon its deep experience and expertise necessary to deliver reliable and cost-effective services. For more information, please visit <http://www.drummondgroup.com> or email [ehr@drummondgroup.com](mailto:ehr@drummondgroup.com)

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