Office of the National Coordinator for Health Information Technology

Health Data, Technology, and Interoperability: Decision Support Intervention

HTI-1 Proposed Rule Subgroup 2

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April 26, 2023

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Agenda

1. HITAC TF Meeting #1 – April 25, 2023
   - Policy Overview
   - Context and Background
2. HITAC TF Meeting #2 – April 26, 2023
   - Proposed Revisions and Criterion Mechanics
   - Source Attributes
3. HITAC TF Meeting #3 – May 3, 2023
   - Intervention Risk Management
   - Oversight & Implementation

Proposed Revisions

Decision Support And Certified Health IT

- Since 2010, the Program has maintained a CDS certification criterion, consistent with the “qualified electronic health record” definition in section 3000(13) of the PHSA,
  - An electronic record of health-related information on an individual that has the capacity to “provide clinical decision support” (42 U.S.C. § 300jj(13)(B)(i)).

- The initial CDS criterion required that a Health IT Module could:
  - Implement rules, “according to specialty or clinical priorities;”
  - “Automatically and electronically generate and indicate in real-time, alerts and care suggestions based upon clinical decision support rules and evidence grade;” and
  - Track, record, and generate reports on the number of alerts responded to by a user (75 FR 2046)

- HITPC recommendations in 2012 provided the framework for our current CDS criterion, including requirements that Health IT Modules support CDS that :
  - Displays source or citation of CDS
  - Is configurable based on patient context (e.g., inpatient, outpatient, problems, meds, allergies, lab results)
  - Is presented at a relevant point in clinical workflow
  - Include alerts presented to users who can act on alerts (e.g., licensed professionals);
  - Is integrated with the EHR (i.e., not standalone)

Scope of Certification and Decision Support Criterion

- The decision support intervention does not get certified, the Health IT Module supporting decision support does
- Current CDS criterion for Health IT Modules is part of the “Base EHR” definition
  - The “Base EHR” is referenced in CMS payment policy
  - We propose to update the “Base EHR” definition to include the new DSI criterion
- Current requirements are for Health IT Modules to:
  - Enable interventions based on (1) specific data elements and (2) when meds, allergies, and problems are incorporated from a transition of care/referral summary received
  - Enable “evidence-based decision support interventions” based on a set of data elements
  - Identify for a user diagnostic or therapeutic reference information based on set of data elements
  - Enable a user to review “source attributes”
    - Bibliographic citation, developer details, funding source, release/revision information

Proposed New Requirements for All Health IT Modules Certified to the DSI Criterion

- Source Attributes must be available as a “plain language description” to users “via direct display, drill down, or link out from a Health IT Module”
  - This would make a historic expectation explicitly required
- If DSI is developed by a developer of certified health IT, all attributes are required, unless otherwise noted as “if available”
- For DSIs that are developed by other parties, clearly indicate when any attribute is not available for the user to review
  - Other parties include health systems, third-party software developers, medical education publishers, etc.
- Health IT Modules must enable users to “author and revise source attributes and information” beyond source attributes listed
  - This would provide flexibility for users to design DSI information unique to their circumstances
- Enable end users to provide feedback regarding the intervention and make available such feedback data for export, in a computable format, including the intervention, action taken, user feedback provided (if applicable), user, date, and location
  - This would support quality improvement for all DSIs

Predictive DSI Definition and Related Request for Comment

Predictive Decision Support Intervention Means:

"Technology intended to support decision-making based on algorithms or models that derive relationships from training or example data and then are used to produce an output or outputs related to, but not limited to, prediction, classification, recommendation, evaluation, or analysis."

- Request for comment:
  - Predictive DSI definition would not include
    - Simulation models that use modeler-provided parameters rather than training data
    - Unsupervised machine learning techniques that do not predict an unknown value among other technologies.
  - Are there prominent models (e.g., simulation models, unsupervised learning models) used to support decision-making in healthcare that are not effectively captured under the proposed definition of a predictive DSI?
  - If so, is it is feasible and appropriate to include such models in the scope of this proposed rule?

Proposed Predictive DSI Attestation

- Health IT Modules certified to § 170.315(b)(11) **are not required to enable or interface** with predictive DSIs, but developers of certified health IT must make one of the following attestations:
  - Yes – the Health IT Module enables or interfaces with a predictive decision support intervention(s) based on any of the data expressed in the USCDI
  - No – the Health IT Module does not enable or interface with a predictive decision support intervention(s) based on any of the data expressed in the USCDI
- If the developer attests "yes," to this statement, the developer and its certified Health IT Module are subject to applicable predictive DSI requirements
- If the developer attests "no" to this statement, the developer would be subject to applicable general DSI requirements

Proposed Scope of Covered Technologies

Developers of certified health IT should attest "yes," if any of the following are true:

- Developer self-develops predictive DSIs for use in their certified Health IT Module; or
- Developer's Health IT Module enables or interfaces with predictive DSIs developed by its users or customers, such as a health care organization or medical center; or
- Developer's Health IT Module enables or interfaces with predictive DSIs developed by an "other party," such as a separate software developer(s)

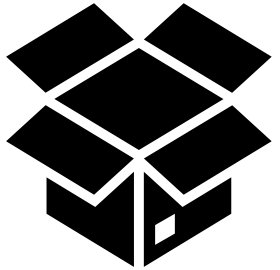
AND

- Predictive decision support intervention is based on any of the data expressed in the USCDI standards (§ 170.213)

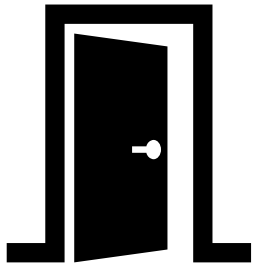
“Enabled by or Interfaced with”

- Enables = The developer of certified health IT has the technical capability to support a predictive model or DSI within the developer’s Health IT Module
  - User-, third-party, and self-developed applications
  - Standalone applications used within or as a part of a Health IT Module
    - For example, if the calculations for a predictive DSI occur within the Health IT Module, either to or through a standalone app used within a Health IT Module or an app developed by a developer of certified health IT for use within a Health IT Module, we would consider this “enabling”
  - Includes instances where predictive DSIs are enabled by default and instances where they can be enabled by users

- Interfaces with = The Health IT Module facilitates either (1) the launch of a predictive model or DSI or (2) the delivery of a predictive model or DSI output(s) to users when such a predictive model or DSI resides outside of the Health IT Module
  - For example, scenarios where the calculations for a predictive DSI occur outside the Health IT Module, and the predicted value or output gets sent to or through a Health IT Module (or to or through an app used within or as part of a Health IT Module) would be considered to “interface with”
  - A Health IT Module would also “interface with,” a predictive DSI in scenarios where an application is launched from a certified Health IT Module, including through the use of a single sign-on functionality



“enables” is about the certified health IT being a container within which a predictive model or DSI can be used (either as an app or as part of the Health IT Module)

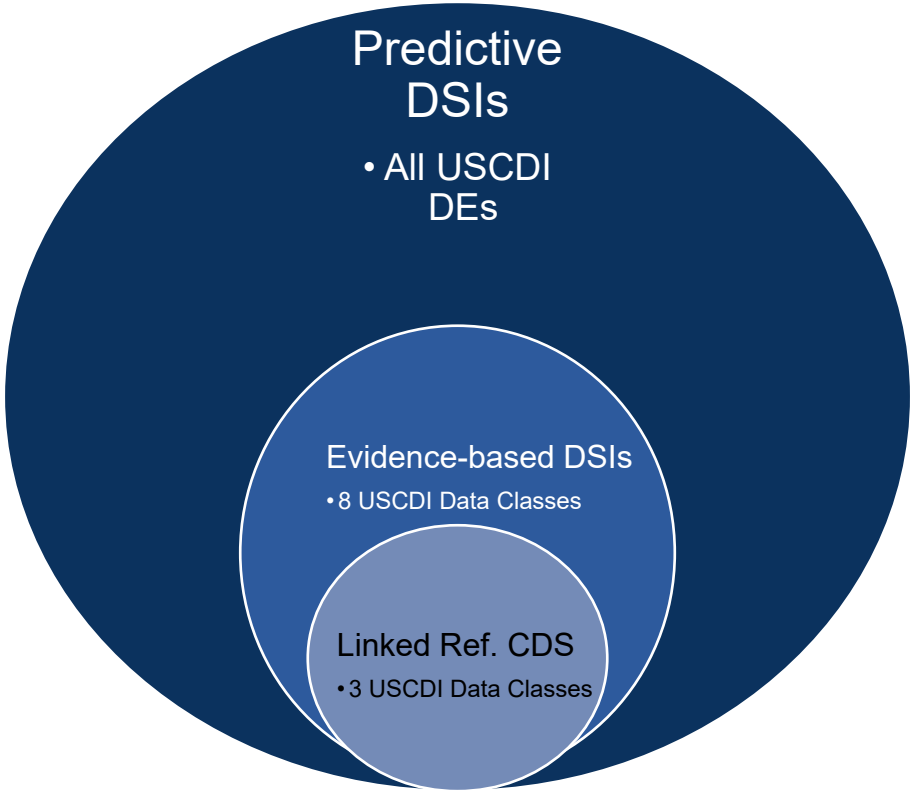


"interface with" is about the certified health IT being a door, through which actions can be taken to launch or deliver a predictive model or DSI

Which DSIs Would Need to Adhere to Relevant ONC Proposed Requirements?

- ***For predictive decision support interventions***: All DSIs that use any USCDI Data Elements (DEs) at § 170.213
  - This is established in 170.315(b)(11)(v)
  - Yes – the Health IT Module enables, or interfaces with, electronic predictive decision support interventions based on **any of the data classes expressed in the standard in § 170.213**
- ***For evidence-based decision support interventions***: All DSIs that use:
  - Problems; Meds; Allergy and intolerances; Demographics; Labs; Vital Signs; and Procedures, according to USCDI at § 170.213
- ***For Linked referential CDS***: All DSIs that use
  - Problems, Meds, Demographics (no change to current reg)

Scope of relevant DSIs is not based on function/intended use, but on data elements used by the DSIs



Proposed Implementation Timeline and RWT Implications

- Health IT Modules certified to § 170.315(a)(9) would need to update and provide their customers with technology certified to § 170.315(b)(11) and comply with these new requirements by December 31, 2024
  - Health IT Modules may be certified to (a)(9) and/or (b)(11) until December 31, 2024
- Propose to modify the Base EHR definition in § 170.102 to include § 170.315(b)(11)
  - (a)(9) will expire January 1, 2025, and (b)(11) will replace (a)(9) in the Base on and after January 1, 2025
- Developers of certified health IT with Health IT Module(s) certified to § 170.315(b)(11) would be required to submit real world testing plans and corresponding real world testing results, consistent with other "(b)-criteria" in § 170.405(a)
  - RWT for all DSI types (predictive, evidence-based, and linked referential) beginning for 2023 plans
  - Measures demonstrating conformance to requirements, self-identified by developer
  - Annual cycle of RWT plans and results publicly available via CHPL
- Propose to add (a)(9) to the list of applicable criteria for Real World Testing, effective as of a final rule until it expires

Source Attributes

Snapshot of Proposals to Promote Transparent & Trustworthy DSIs through the ONC Health IT Certification Program

Technical & Performance

- Information about how the predictive DSI "works" made available to users, in plain language and via direct display, drill down, or link out:
  - Output and intended use, out of scope use(s), description of training data, external validation, update schedule, etc.
  - Like a "nutrition label"; leverage existing "source attributes" certification requirement
- Supportive of health equity by design:
  - Identification of REL, SOGI, SDOH, & Health Status data elements used
  - Information on validity and fairness of prediction in test and local data (if available)
- Additional enhancements that enable:
  - Authoring and revision capability for users
  - User feedback capabilities and feedback exports for quality improvement of DSIs

Governance

- Public disclosure regarding how certified health IT developer manages risks and govern predictive DSIs:
  - Risk analysis (8 risk types): validity, reliability, robustness, fairness, intelligibility, safety, security, and privacy
  - Risk mitigation of those risks
  - Governance processes, including data management
- Summary documentation must be:
  - Publicly accessible through hyperlink without precondition
  - Reviewed annually for updates
- Detailed documentation must be:
  - Available to ONC upon request from ONC for each predictive DSI the certified health IT enables or interfaces with
  - Reviewed annually for updates

Oversight

- Conformance to proposed new requirements through Real World Testing (RWT) Program:
  - RWT for all DSI types (predictive, evidence-based, and linked referential) beginning for 2024 plans
  - Annual cycle of RWT plans and results publicly available via the Certified Health IT Product List (CHPL)
  - Measures demonstrating conformance to requirements, self-identified by developer
- Summary of intervention risk management practices made publicly available
- Detailed risk management practices made available to ONC upon request from ONC

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Transparency: Emerging guidelines and best practices

- Academia and industry are developing ways to demonstrate technical and performance dimensions of predictive algorithms in health care
  - Reporting guidelines, such as model cards & datasheets for datasets (aka algorithmic nutrition labels) that provide information on
    - Predictive model details, development processes, performance, and maintenance requirements (to identify “model drift”)
      - Model Cards for Model Reporting
      - Datasheets for Datasets

- Government, academia, and industry are coalescing on the need to manage risks at the organizational level
  - AI Governance Models
    - Duke Algorithm-Based Clinical Decision Support (ABCDS) Oversight
  - Risk management practices
    - Office of the Comptroller of the Currency handbook for the financial sector
    - NIST Risk Management Framework that sector agnostic

Sources of Source Attributes

We emphasized source attribute information that

1. Were most commonly included in existing, reviewed reporting guidelines
2. Would be most meaningful and interpretable in the context of health IT users and developers
3. Were focused on health equity, fairness, and identifying issues of bias
4. Were intended to show that the model would perform effectively outside of the specific context in which it was developed

Goals

- Identify minimum necessary attributes
- Based on existing model reporting guidelines
- Balance prescriptiveness and flexibility to accommodate varied applications, contexts, and use cases
- Align with existing reference material (e.g., NIST AI RMF, WH Blueprint, WH E.O.s)
- Support emerging industry-led efforts (e.g., CHAI and Health AI Partnership)

DSI - Health IT Modules are not required to enable or interface with predictive DSIs, but…

If a Health IT Module enables or interfaces with predictive DSIs, we are proposing that the module must make information about additional Source Attributes available to provide users transparency on how the predictive DSI was designed, developed, trained, evaluated, and should be employed.

- **Intervention Details**
  1. Output of the intervention
  2. Intended use of the intervention
  3. Cautioned out-of-scope use of the intervention
- **Intervention Development**
  1. Input features of the intervention including description of training and test data
  2. Process used to ensure fairness in development of the intervention
  3. External validation process, if available
- **Quantitative Measures of Intervention Performance**
  1. Validity of prediction in test data
  2. Fairness of prediction in test data
  3. Validity of prediction in external data, if available
  4. Fairness of prediction in external data, if available
  5. References to evaluation of use of the model on outcomes, if available
- **Ongoing Maintenance and Use**
  1. Update and continued validation/fairness assessment schedule
  2. Validity of prediction in local data, if available
  3. Fairness of prediction in local data, if available

Intellectual Property

- The proposals in § 170.315(b)(11)(vi)(C) would not require disclosing or sharing intellectual property (IP) existing in the developer's health IT (including other parties' IP)
- The proposed requirement would not provide information about or report any details of the specific code, pipeline, statistical processes, or algorithms used to generate model predictions, which might be considered the developer's intellectual property

Source Attributes Prescriptiveness

- We request comment on whether there are items contained within the proposed source attributes that we should explicitly require as elements of source attributes information.
  - Specific attention to three Source Attributes with multiple “should” components:
    - “Intended use of the intervention,”
    - “Input features of the intervention including description of training and test data”
    - “External validation process, if available”

Intervention Details

Output of the intervention is a description of the value that the model produces as an output, including whether the output is a prediction, classification, or other type of output

- Users evaluating the model or deciding whether to use it should know what the model is predicting to ensure that the output is directly relevant to the way in which the users intend to use it

Intended use of the intervention is a description of the intent of the model developers in how the model is meant to be deployed and used, including its intended role in the identified use case. This information should clarify:

- Whether the model is intended for specific or general tasks and what those tasks are;
- Who the intended patient population is;
- Who the intended users of the model are, as well as the intended action of the user;
- The role of the model (e.g., whether it informs, augments, or replaces clinical management), which may be most clearly conveyed through use of a taxonomy such as those described by the International Medical Device Regulators Forum (IMDRF), American Medical Association, Consumer Technology Association, and others; and
- The logic underlying the model; for instance, the exact question the algorithm is supposed to answer, how it fits into specific clinical decision-making, and in what ways the inputs are appropriate to answer that question and, if appropriate, how that logic is associated with how the model should be used.

Intervention Development

Cautioned out-of-scope use of the intervention is a description of tasks, situations, or populations to which the model developer cautions a user against applying the predictive model. This description should include:

- Known risks, inappropriate settings, inappropriate uses, or known limitations of the model
- Description should inform users about tasks, situations or populations related to the intended use of the model in which the model may not perform as expected

Input features of the intervention including description of training and test data should include:

- Exclusion and inclusion criteria that influenced who was included in data sets;
- Statistical characteristics—including sample size—of the demographic and other key variables in these data to assess representativeness;
- The source and clinical setting from which the data was generated
- The extent of missing values in the training and testing data sets; and
- Other attributes related to data quality, such as the comprehensiveness of the data and the process of collecting the data should be included as the developer determines what is relevant while examining the data during pre-processing, creation, and testing of the model.

Intervention Development

Process used to ensure fairness in development of the intervention is a description of the approach the model developer has taken to ensure that the model output is fair. This should include:

- Approaches to manage, reduce, or eliminate bias in models and could be similar to a brief synopsis of risk mitigation practices and outcomes related to fairness for this DSI
- Many such approaches exist; however, there is no universal best process to ensure fairness
- For example, this attribute might state that in pre-processing the data before training the model, the developers employed a “disparate impact remover” transformation across race or ethnicity groups based on a well-known approach

External validation process, if available is a description of how and in what source, clinical setting, or environment a model’s validity and fairness has been assessed other than the source training and testing data. This should include:

- Who conducted the external testing (e.g., the model developer, developer of certified health IT, or an independent third party);
- The setting from which the external data was derived;
- The demographics of patients in external data; and
- A brief description of how external validation was carried out.

Quantitative Measures of Intervention Performance

- **Validity of prediction**
  - In test data and, if available, external data and local data is the presentation of the measure or set of measures related to the model's validity (often referred to as performance) tested, respectively, in data derived from the same source as the initial training data, in data from an external source, and in data local relative to its current use.
    - This proposal would not prescribe the specific performance or validation measures to be used or included as part of the source attributes requirements but would require that some performance or validation measure(s) be used and included in the source attribute.

- **Fairness of prediction**
  - In test data and, if available, external data and local data is the presentation of the measure or set of measures related to the model's fairness (evaluation of fairness in a model) in terms of the accuracy of its output across certain groups in data derived from the same source as the initial training data, in data from an external source, and in data local relative to its current use.
    - Numerous approaches and related measures exist to measure the fairness of model outputs. Examples of potential fairness measures include positive predictive parity, false positive error rate balance and false negative error rate balance, equivalent calibration within groups, and mean residual difference

- **References to evaluation of use of the model on outcomes, if available** are bibliographic citations or links to evaluations of how well the intervention, or model on which it is based accomplished specific objectives such as reduced morbidity, mortality, length of stay or other important outcomes

Ongoing Maintenance and Use

- **Update and continued validation or fairness assessment schedule** is a description of the process and frequency by which the model's performance is measured and monitored in the local environment and corrected when risks related to validity and fairness are identified
  - Information should also include how often performance is evaluated and how often the model is updated to provide users with insight into the likelihood that the model may have degraded (i.e., no longer provides valid or accurate predictions) since it was last updated

- **Validity and Fairness in Local Data**
  - As previously described

Additional Considered Source Attributes Example

- Intervention Details
  - Information on explainability and interpretability
  - Whether a DSI meets the definition of a medical device under the FDA definition
- Intervention Development
  - Details on how model prediction and classification cut-points were selected
  - Security and privacy-preserving approaches included in model development
- Quantitative Measures of Intervention Performance
  - Model calibration or calibration curve
  - Confidence or prediction intervals or other measures of uncertainty
- Ongoing Maintenance of Intervention Implementation and Use
  - Whether the model is ‘online’ or ‘unlocked’
    - Any additional organizational or technical controls in place to evaluate the impact of the online or unlocked updating and results of that evaluation.
    - The controls in place to update the descriptions of source data to reflect the changing composition of the data.

Availability of Source Attributes to the Public

- We solicit comment on whether we should require developers of certified health IT with Health IT Modules certified to proposed § 170.315(b)(11) to make all source attributes information publicly available or accessible, for example, on a website, similar to the existing API documentation requirement in § 170.315(g)(10)(viii)(B).

- We solicit comment on whether having this information publicly available would be beneficial for potential users that purchase models or associated technology or software, and would help inform them prior to procurement of certified health IT and procurement of predictive DSIs integrated with certified health IT.

- We also solicit comment on whether having this information publicly available would improve public confidence in predictive DSIs by enabling research on source attribute information.

Patient Access to Source Attributes

- Patients want to know if AI is being used in their care, and understand how and why it is being used in their care. We understand an emerging trend is for health care providers to inform patients about the use of these technologies, including predictive DSIs, in making decisions about their care.

- We solicit comment on whether existing Program requirements in the Communications condition and maintenance of certification requirements in § 170.403 are sufficient to ensure open and transparent discussion regarding the use of predictive DSIs in patient care – including discussion between users of certified health IT and patients. We are especially interested in whether we should require developers of certified health IT to provide the technical capability for users to support patients electronically accessing underlying source attribute information (e.g., through a patient portal) for predictive DSIs or otherwise indicate to a patient when a predictive DSI was used to make decisions about the patient in the course of the patient's care.

Consensus Metrics and Standards

- We also solicit comment on testing or assessment tools that might further support transparency and trustworthiness including
  - Consensus metrics and technical standards for evaluating fairness (assessing for bias) and validating performance (including testing performance in different populations and evaluating applicability or generalizability) of predictive models that are enabled by or interface with Health IT Module(s) prior to and during deployment
  - Development and engineering of algorithmic impact assessments (AIAs)
  - Development of documentation of datasets used, such as datasheets for datasets and data cards as well as tools that could be useful in these areas so that Health IT Modules certified to §170.315(b)(11) can demonstrate it meets a given requirement on an ongoing basis

Authoring and Revising Source Attributes

- We propose in § 170.315(b)(11)(vi)(E) that Health IT Modules enable users to author attributes and revise attributes beyond what is proposed in to support the ongoing evolution of what source attributes are important to users to make informed decisions regarding the DSI's recommendation(s).
  - Pertains to both evidence-based DSIs and predictive DSIs
  - Means that a Health IT Module would need to support the technical ability for a limited set of identified users to create new or revised attribute information alongside other source attribute information proposed
  - Example: a hospital that develops its own predictive DSI that is interfaced with a certified Health IT Module would be able to create new or revise existing source attributes information related to that predictive DSI that is made available through the certified Health IT Module without the developer of certified health IT's direct involvement.

DSI Feedback Loops

- In the 2015 Edition Proposed Rule, we proposed to adopt new functionality that would require a Health IT Module to be able to record at least one action taken, and by whom it was taken, when a CDS intervention is provided to a user
  - For example, whether the user viewed, accepted, declined, ignored, overrode, provided a rationale or explanation for the action taken, took some other type of action not listed here, or otherwise commented on the CDS intervention) (80 FR 16821).
  - We also proposed that a Health IT Module certified to § 170.315(a)(9) be able to generate either a human readable display or human readable report of the responses and actions taken and by whom when a CDS intervention is provided (80 FR 16821).
- In the 2015 Edition Final Rule, we noted that many commenters stated that current systems already provide a wide range of functionality to enable providers to document decisions concerning CDS interventions and that such functionality is unnecessary to support providers participating in the EHR Incentive Programs (80 FR 62622).

DSI Feedback Loop Proposal

- We propose that a Health IT Module certified to § 170.315(b)(11) must be able to export such feedback data, including but not limited to the intervention, action taken, user feedback provided (if applicable), user, date, and location, so that the exported data can be associated with other relevant data.

- We propose that such feedback data be available for export by users for analysis in a computable format, so that it can be associated with other relevant data, such as diagnosis, other inputs into the DSI, and the outputs of the DSI for a particular patient, to evaluate and improve DSI performance.

- In addition to quality improvement of the DSI, such an export would facilitate research, associating feedback data with other relevant data, and linking the DSI to patient health outcomes, including assisting in identifying and reducing health disparities and possible discriminatory outcomes.

Office of the National Coordinator for Health Information Technology

Contact ONC

Phone: 202-690-7151

Health IT Feedback Form: https://www.healthit.gov/form/healthit-feedback-form

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