Plan Report ID Number:	
Developer Name:	**Updox LLC**
Product Name(s):	**Updox LLC**
Version Number(s):	**2016.0**
	2016.1
Certified Health IT:	**July 20, 2017**
Product List (CHPL) ID(s):	**(v2016.0)15.04.04.2484.Updo.16.00.0.17072**
Product List (CHPL) ID(s):	**(v2016.1)15.04.04.2484.Updo.61.01.0.170720**

Product List:

170.315 (d)(1): Authentication, Access Control, Authorization

170.315 (d)(2): Auditable Events and Tamper-Resistance

170.315 (d)(3): Audit Report(s)

170.315 (d)(5): Automatic Access Time-out

170.315 (d)(7): End-User Device Encryption

170.315 (d)(9): Trusted Connection

170.315 (e)(1): View, Download, and Transmit to 3rd Party

170.315 (e)(2): Secure Messaging

170.315 (g)(1): Automated Numerator Recording

170.315 (g)(4): Quality Management System

170.315 (g)(5): Accessibility-Centered Design

170.315 (g)(6): Consolidated CDA Creation

170.315 (h)(2): Direct Project, Edge Protocol, and XDR/XDM

Real World Testing (RWT) was created so Certified Health IT Developers could demonstrate conformance with the ONC Cures Act Final Rule. As a Condition of Certification and ongoing Maintenance of Certification, developers with one or more Health IT modules certified to any of the certification criteria outlined in §170.405 (a) of ONC Cures Act Final Rule must successfully test the real-world use of those modules. By using settings and scenarios in a production environment vs a testing environment Updox can demonstrate functionality and interoperability of their certified health IT. RWT in “real-life” settings also shows transparency to compliance of certification criteria made available to the public via the CHPL.

A Certified Health IT Developer’s demonstration of interoperability-focused functionality is critical to advancing transparency on the Health IT Modules’ performance and provides information that could help users decide which certified health IT to acquire. As defined in§170.102 of the ONC Cures Act Final Rule, “Interoperability is, with respect to health information technology, such health information technology that—

1) Enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user.

2) Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable state or federal law; and

3) Does not constitute information blocking as defined in § 171.103."

For 2022 RWT, Updox will be demonstrating compliance and interoperability within two certification criteria. The first is the Patient Engagement §170.315 (e)(1) view, download and transmit to 3rd party and the second is Electronic Exchange §170.315 (h) (2) Direct Project, Edge Protocol, and XDR/XDM.

Measurement/Metric	**Associated Certification Criteria**
Conformance to this criterion by using the DT (DirectTrust) interoperability testing between HISPS performed biannually.	Patient Engagement §170.315 (e)(1) view, download and transmit to 3rd party
Conformance to this criterion by using Direct Secure Messaging for sending "Transitions of Care" documents via secure messaging to a 3rd party.	Electronic Exchange §170.315 (h) (2) Direct Project, Edge Protocol, and XDR/XDM.

Updox primarily markets to EHR vendors (not end users) in order to integrate our products into their EHR. We market our secure messaging products to our partners, which is a valuable tool that aligns with ONC's push for interoperability. Secure messaging allows providers to communicate securely with patients and other providers. This promotes interoperability, gives consumers/patients more control of their own health and follows Privacy and Security rules for keeping patient health information within a secure environment.

Care Setting	**Justification**
DirectTrust	*Promotes interoperability *Is a trusted and reliable source for exchange and reporting of Direct Secure Messaging *Continues to improve and work with regulating authorities to promote interoperability and reducing SDOH
EHR Vendors	*Demonstrates interoperability between HISPS and top EHR vendors *Primary target market for Updox *Proves interoperability between providers exchanging PHI/PII in secure environments

RWT Multiple Criteria

Updox has developed a system to ensure providers can share PHI (personal health information) of their patients in a secure environment in which messages and documents can be shared by using Direct Secure Messaging via our API, UI, Edge protocol or XDR/XDM. Through our patient portal, which is integrated into our Partners EHR systems, patients have the ability to

view, download, and transmit. ePHI/PII is always encrypted and hashed to prevent unauthorized access or tampering. encryption standard is AES 256. The hashing standard is SHA-2. TLS 1.2 is used when transmitting information over the internet. Updox is currently Web Content Accessibility supported by the Health IT Module: Web Content Accessibility Guideline (WCAG) 2.0, Level A Conformance as specified in § 170.204(a)(1).

Justification for RWT Approach:

Certification Criteria	Requirement
Patient Engagement §170.315 (e)(1) view, download and transmit to 3rd party	*(I)(B)(2) Download ambulatory summary or inpatient summary using CCD Template *(I)(C)(1) Transmit to third party
Electronic Exchange §170.315 (h) (2) Direct Project, Edge Protocol, and XDR/XDM.	*Applicability Statement for Secure Health Transport, Version 1.2 (the "Direct Project" specification). *The ONC XDR and XDM for Direct Messaging Specification, Version 1, including support for both limited and full XDS metadata profiles. *And both protocols in the ONC Implementation Guide for Direct Edge Protocols, Version 1.1

Updox will apply its testing to other companies that are promoting interoperability since that is the primary market for our products at this time. Other HISPs and EHR vendors will apply to this care setting. Updox will include all criteria to demonstrate conformance involving §170.315 (e)(1) view, download and transmit to 3rd party and Electronic Exchange §170.315 (h) (2) Direct Project, Edge Protocol, and XDR/XDM.

Using this approach helps promote interoperability by testing with other vital HISPs and several major EHR vendors to demonstrate compliance with all rules, regulations and laws pertaining to these two testing criteria. We will demonstrate conformance by providing logs of "real-world" processes in a production environment and will rely on two accrediting bodies Direct Trust and EHNAC to validate results. Direct Trust's HISP to HISP testing with the Accredited Trust Bundle is also used to assess potential interoperability issues in the field and to evaluate new HISP participants entering the Accredited Trust Bundle. Members of DT share details about their findings during the bi-annual interop testing within a Security and Trust Compliance Workgroup.

The formal discussion of these issues within the workgroup leads to progress and consensus interpretation of standards and policies, identification of the causes of variability and the shortcomings of the existing specifications brought to light through the deployment of Direct exchange at scale, and eventual determination of the best practices for improved interoperability.

The Updox system includes these functionalities of interest: (A) Send Direct Secure message summaries (B) receive Direct Secure message summaries (C) Edge Protocol used for processing or if EHI was shared through the patient portal using downloads and encrypted and unencrypted transmissions.

Standard (and version)	USCDI v2 C-CDA Companion Guide (Release 2.1) ASTM Updates E1247-18 WCAG v2.0 Level A 2015 Edition Cures Update
Updated certification criteria and associated product	Patient Engagement §170.315 (e)(1) view, download and transmit to 3rd party
Health IT Module CHPL ID	**(v2016.0)15.04.04.2484.Updo.16.00.0.170720** **(v2016.1)15.04.04.2484.Updo.61.01.0.170720**
Date of ONC ACB notification	April 2022
Date of customer notification (SVAP only)	Not Applicable
Conformance measure	Conformance to this criterion by using the DT (DirectTrust) interoperability testing between HISPS performed biannually.
USCDI updated certification criteria (and USCDI version)	The plan documents the support of all USCDI v2 data elements. The plan documents the support of all USCDI v2 data elements.

Expected Outcomes:

1. Real World Testing will demonstrate that Updox is conformant to the following certification criteria: §170.315 (e)(1) view, download and transmit to 3rd party.

Regulation Text § 170.315 (e)(1) View, download, and transmit to 3rd party—Patients (and their authorized representatives) must be able to use internet-based technology to view, download, and transmit their health information to a 3rd party in the manner specified below. Such access must be consistent and in accordance with the standard adopted in § 170.204(a)(1) and may alternatively be demonstrated in accordance with the standard specified in § 170.204(a)(2).

and Electronic Exchange §170.315 (h) (2) Direct Project, Edge Protocol, and XDR/XDM.

Regulation Text §170.315 (h)(2) Direct Project, Edge Protocol, and XDR/XDM— (i) Able to send and receive health information in accordance with: (A) The standard specified in §170.202(a)(2), including formatted only as a “wrapped” message; (B) The standard specified in §170.202(b), including support for both limited and full XDS metadata profiles; and (C) Both edge protocol methods specified by the standard in §170.202(d). (ii) Delivery Notification in Direct. Able to send and receive health information in accordance with the standard specified in §170.202(e)(1).

2. Real World Testing will demonstrate the ability of direct secure messaging between HISPs and between providers in our provider directory that are vetted and have a certified address or domain bound certificate issued to them.

3. Real World Testing will demonstrate that Updox supports the Electronic Exchange §170.315 (h) (2) by using Edge protocol technology.

Key Milestones:

Release of documentation for the Real-World Testing to be provided to EHR vendors, especially ones that use Updox as relied upon software for their certifications and participating HISPs. Specific instruction on what to look for, how to record issues encountered, and other relative agreements/notifications.	December 1, 2021
Begin collection of information and testing as documented in the RWT plan.	January 1, 2022
Implement any fixes or updates for collection of all data as they arise	March 1, 2022
Follow-up with HISPs and EHR vendors on a regular basis to understand issues arising with the data collected.	March 2022 (Qtrly)
HISP to HISP testing with the Accredited Trust Bundle.	April 2022
Follow-up with HISPs and EHR vendors on a regular basis to understand issues arising with the data collected.	June 2022 (Qtrly)
Follow-up with HISPs and EHR vendors on a regular basis to understand issues arising with the data collected.	Sept. 2022 (Qtrly)
HISP to HISP testing with the Accredited Trust Bundle	October 2022
Create a New Testing Plan with new certified criteria included. Submit to Drummond Group:	November 15,2022
Follow-up with HISPs and EHR vendors on a regular basis to understand issues arising with the data collected.	December 2022 (Qtrly)
End of Real-World Testing period. Have all data collected.	January 1, 2023
Analysis and report creation. Submit all documentation.	January 15,2023

Testing Procedure/Process between Accredited HISPs:

HISP to HISP testing with the Accredited Trust Bundle is used to assess potential interoperability issues and as a Condition of Certification with Direct Trust (DT). This testing is done twice a year in the months of April and October. Results must be sent to DT. HISP to HISP Direct Secure Messaging includes both criteria, §170.314(e)(1), View/Download/Transmit and Electronic Exchange §170.315 (h) (2) Direct Project, Edge Protocol, and XDR/XDM. This testing is performed in “real-world” settings and promotes interoperability.

To initiate interoperability testing, Updox will send a wrapped, DT compliant message from our Updox Accredited Trust Bundle address to each HISP’s interop testing address which will be in a production environment using a “test” account so that no ePHI is involved. Within the message and out of band, we will indicate that we are performing RWT and request a received & readable confirmation. When a message is received from another testing participant, we will reply to the message indicating whether the message was received and readable and (if

receiving into an EMR system and a C-CDA was included in the message) whether the attached C-CDA could be incorporated into our system).

RESULTS OF SENDING FROM MY ADDRESS TO THE COUNTERPARTY ADDRESS:

•Message was sent to this counterparty (left my system without immediate fail) AND

•Processed MDN was Received and Usable by my system

ONLY IF DISPATCHED REQUESTED (Updox always requests Dispatched MDN):

Dispatched MDN was received and usable by my system.

If our system successfully receives the dispatched MDN from the Counterparty, then we will answer “Yes.” If our system does not receive the dispatched MDN from the Counter Party during our system’s allowed timeout interval, then we will answer “No.” In our report to DT we will report successful or not successful transmission and the same in our Real-World Testing report which will be submitted in January of 2023.

•Beyond the MDN: Counterparty confirmed the message I sent to them was received and its payload could be incorporated (if the receiving system is an EHR endpoint) OR was readable (if the receiving system is a HISP endpoint). Counterparty may alternatively confirm this in their own report.

In August 2017 during a meeting of the Security and Trust Compliance workgroup with DirectTrust the following guideline was established:

If the receiving party does not reply and confirm the message, the sending party must make two attempts and allow three business days per attempt to confirm the received and readable confirmations.

If there is no reply after following the guideline, we will include the dates of our attempts in the Comments section to DT so that our test results will reflect a positive test. We will also include all results successful or otherwise in our Real-World Testing Report.

The following list are the likely reasons for a failed test:

1. Processed MDN not received

2. Out of band received and readable confirmation not yet available

3. Certificate expired

4. Certificate revoked

5. Unsolicited Dispatched MDN received

6. Processed MDN not received when C-CDA payload attached

7. Dispatched MDN not received when requested

8. Message Digest Issue in sent message preventing trust validation

9. Could not determine revocation status

10. Message contained additional stray content not expected.

The Payload Archive is used to store the files that are sent and/or received. No PHI should be in the sample files. Sample files should be either C-CDA or XDM Zip files and available in the DT Payload Archive. The C-CDA sample filename, XDM Zip sample filename, or another sample filename from the DT payload archive should be entered in the report to DT.

A factor complicating XDM transmission is the choice of MIME type to identify the attachment. To facilitate interoperability, DT recommends that all senders of XDM Zip attachments label the attachment with the MIME type application/zip. Recipients should examine attachments labeled as either application/zip or application/octet-stream for potential XDM content, however, as the latter MIME type is also encountered in the field.

The payloads systems may receive are the C-CDA and human readable versions thereof, as part of §**170.314(e)(1), View/Download/Transmit**. Certification standards are more flexible for this measure, and may include, for example, PDF, HTML, and XML+XSL as the human-readable file types. This use case introduces situations in which EHR summaries of care may be sent to provider recipients in many different potential file formats that the receiving systems are not necessarily prepared to accept.

Examples of additional content/payload-related practices which **may hinder interoperability** include:

-Accepting messages that contain a text part or a payload attachment, but not both

- Accepting only messages that contain a MU2 payload (This condition would not cause a secure messaging failure in Updox, however, an EHR system may have a limitation.)

- Expecting the text part before the C-CDA or not accepting a message if sender adds message parts out of the expected order. (This condition would not cause a secure messaging failure in Updox, however, an EHR system may have a limitation.)

-Sending a payload referencing a proprietary, privately hosted, or unconventionally named style sheet which may not be universally accessible due to recipient's firewall settings or may introduce security risks to the recipient

-Sending broken or invalid HTML as part of the XDM container, the message body itself, or one of the attachments, potentially making the content non-viewable by some recipients

-Self-imposed C-CDA or other structural data or metadata validation causing receivers to accept too narrowly--such that C-CDAs or XDM Zip files that would have been declared valid by certification testing are not incorporated or entire messages are dropped.

Testing Process for testing with Partners/EHR vendors-

Testing will be conducted between 2-3 of our EHR Partners and will be conducted once every quarter. We will first need to ensure that each Partner has a "test" account set up (at partners request) in a production environment at no charge but for testing purposes only.

The Updox system includes these functionalities of interest:

(A) Send Direct Secure message summaries

(B) receive Direct Secure message summaries

(C) Edge Protocol used for processing or if EHI was shared through the patient portal using downloads and encrypted or unencrypted transmissions.

Patient Portal 1:

To test with Amazing Charts as an EHR we will use the company Eye Care Leaders, LLC as they use Updox for transmission of their "transitions of Care."

Scenario 1: A patient is experiencing severe eye pain and is referred to an Ophthalmologist by their Primary Care Provider (PCP). The PCP needs to generate a summary document to provide to the Ophthalmologist.

This use case exhibits the "Transition of Care" criterion in action: § 170.314 (b)(2) Transitions of care – create and transmit transition of care/referral summaries.

In this scenario, treatment has been provided by a PCP: • Given that this treatment is in an ambulatory setting, a Discharge Summary would not be appropriate. • Since the PCP HAS NOT been providing care at the request of another provider, a Consultation Note would not be appropriate. • Given the clinical scenario to be described, a Continuity of Care Document (CCD) is the most appropriate C-CDA Document Template to use.

Continuity of Care Document (CCD)- The CCD is a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters.

In this particular scenario this information contained in the C-CDA will **always** be clinically relevant. Pt. Demographics, Allergies, Medications, Problem, Results

This information contained in the C-CDA will **sometimes** be clinically relevant. Encounters, Plan of Care, and Vital Signs

These are the additional criteria that are required by USCDI (other than already listed items). Care team members, Laboratory tests/results, Procedures, Smoking Status, Provider Name & Office Contact, Reason for Referral, Encounter Diagnosis, Cognitive Status, Functional Status, and Immunizations that can be added if needed.

View- The patient via the Pt. Portal, must be able to use technology to download at a minimum, the following data as applicable:

- The data classes in accordance with § 170.213 United States Core Data for Interoperability Standard (USCDI) as specified in section (e)(1)(i)(A)(*1*) and
    i. Assessment and Plan of Treatment as specified in section (e)(1)(i)(A)*(3)(i)*;
    ii. Goals as specified in section (e)(1)(i)(A)*(3)(ii)*;
    iii. Health Concerns as specified in section (e)(1)(i)(A)*(3)(iii)*;
- Ambulatory setting only: the provider's name and office contact information as specified in section (e)(1)(i)(A)(*4*);
- Laboratory test report(s) as specified in section (e)(1)(i)(A)(*6*), when available; and
- Diagnostic Imaging report(s) as specified in section (e)(1)(i)(A)(*7*), when available.

Download- The patient via the Pt. Portal must be able to use technology to download an ambulatory summary in the following formats: Human readable format; and the format specified in accordance with the standard specified in § 170.205(a)(4) following the CCD document

template. The user uses the internet-based technology health IT function(s) to download an ambulatory summary document in section (e)(1)(i)(B) that is formatted as a CCD document according to the standard specified in § 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes with Errata, DSTU Release 2.1 and § 170.205(a)(5) HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes R1 Companion Guide, Release 2.

Transmit to a third party- The patient via the Pt. Portal will transmit the ambulatory summary of care by these two methods: Email transmission to any email address(unencrypted) and an encrypted method of electronic transmission.

Unencrypted Email Method

1. For each data set viewed in section (e)(1)(i)(A), the user, with the role of patient, uses the Health IT Module's internet-based technology to transmit, via email, an ambulatory summary as created in section (e)(1)(i)(B)(2) as a CCD document according to the standards specified in § 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes with Errata, DSTU Release 2.1 and § 170.205(a)(5) HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes R1 Companion Guide, Release 2 to a valid, third-party email address identified by the user.
2. The user accesses the third-party email account and verifies that the transmission was received, and the correct ambulatory summary is attached.

Encrypted Method

1.For the data set viewed in (e)(1)(i)(A), a user, with the role of patient, uses the Health IT Module's internet-based technology to transmit an ambulatory summary or inpatient summary as created in section (e)(1)(i)(B)(*2*) as a CCD document according to the standards specified in § 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes with Errata, DSTU Release 2.1 and § 170.205(a)(5) HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes R1 Companion Guide, Release 2 to any third party using the developer-identified encrypted method of transmission.

2. The user accesses the account to which the encrypted message has been sent and verifies that the transmission was received with the correct ambulatory and/or inpatient summary.

Updox would transmit the CCD (Summary document) to the Ophthalmologist's EHR system which would complete the requirements for create and transmit transition of care/referral summaries.

Scenario 2: The Ophthalmologist, after consulting with the patient, schedules surgery to be performed and provides an ambulatory summary to the patient including the care plan to be followed leading up to the surgery.

This use case exhibits the "View/Download/Transmit" criterion in action: § 170.314 (e)(1) View, download, and transmit to 3rd party.

In this scenario, treatment has been provided by a PCP: • Given that this treatment is in an ambulatory setting, a Discharge Summary would not be appropriate. • The Continuity of Care Document (CCD) is intended to summarize a full episode of care, and as such may be too cumbersome for this scenario. • Since the Ophthalmologist is providing care at the request of the PCP, a Consultation Note is the best fit for the clinical workflow.

The patient via the Pt. Portal will have the ability to view, download, and transmit the Consultation Note and the Care Plan to another provider or keep for their own records.

When the user utilizes the view, download, or transmit to a third-party capability as specified in sections (e)(1)(i)(A) through (e)(1)(i)(C), the Health IT Module records a new activity log entry for the following actions related to electronic health information:

- View of patient information.
- Download patient information; and
- Transmit patient information.

For each action, the activity log entry includes:

- Type of action.
- Date and time of event in accordance with the standard specified in § 170.210(g) RFC 5905
- User identification; and
- To whom the transmission was sent (if applicable).

Updox will include all documentation and results in our Real-World Testing Results Report due in January of 2023. The results submitted will be based on and directly related to this plan and will address each required element in this plan. The results report will reflect what we state in this plan. If Updox Developers discover during Real World Testing that methods/methodologies, measurements/metrics, and other approaches selected do not produce the anticipated expected outcomes or issues arise during the collection of data that require a developer to adjust their strategies then developers will adjust their methods/methodologies and report this adjustment in our results report. The developer would then submit the data derived from its original approaches with a statement indicating that in retrospect a more appropriate approach was established. The results report will clearly indicate the adjustments made, when they were made, and how the results reflect the new approaches, if they are necessary.

Attestation:

This Real-World Testing plan is complete with all required elements, including measures that address all certification criteria and care settings. All information in this plan is up to date and fully addresses the health IT developer's Real World Testing requirements.

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