TheraDoc 2025 Real World Testing Plan

General Information

Developer Name	Premier, Inc.
Product Name	TheraDoc
Version Numbers	v5.4.4 and higher
Certified Health IT Product List (CPHL) Product Numbers	v5.4.4: 15.99.04.3033.TH03.05.18.0.240814
Developer Real World Testing Plan Page URL	https://www.theradoc.com/certifications/real-world-testing-plan-and-results/

Overview

This document covers the TheraDoc 2025 Real World Testing plan for the following criteria:

- 170.315(f)(5): Transmission to public health agencies - electronic case reporting
- 170.315(f)(6): Transmission to public health agencies - antimicrobial use and resistance reporting

170.315(f)(5): Transmission to public health agencies- electronic case reporting

Justification for Real World Testing Approach

The objective of 170.315(f)(5) is electronic transmission of case reports to public health agencies. For TheraDoc customers who report eCR data, our testing approach evaluates this objective by counting the monthly number of electronic initial case reports (eICRs) sent to public health agencies and the monthly number of “Reportable” and “No Rule Met” Reportability Responses (RRs) received from those agencies, as mediated by the eCR Now Fast Health Interoperability Resources (FHIR®) application.

Standards Updates

Standard and Version	ASTM E1247-18
Updated Certification Criteria and Associated Product	ASTM E1247-18 for (d)(2) and (d)(3) for TheraDoc v5.4.4 and higher
Health IT Module CHPL ID	v5.4.4: 15.99.04.3033.TH03.05.18.0.240814
Date of ONC ACB Notification	v5.4.4: August 14, 2024
Date of Customer Notification (SVAP only)	N/A
Conformance Method and Measurement/Metrics	Attestation

Metrics Used

Metric Description	Monthly counts of the following: • Total number of unique initial case reports (eICRs) submitted to public health agencies (this excludes any records requiring resubmission due to technical problems with transmission). • Total number of records dispositioned by public health agencies with a Reportability Response (RR) of "Reportable" (RRVS1) or "No Rule Met" (RRVS4). • Total number of unique patients for whom eICR records were sent for evaluation. • Total number of unique facilities using TheraDoc for eICR submission. NOTE: The Electronic Reporting and Surveillance Distribution (eRSD) system version(s) in effect for each month is also included.
Associated Certification Criteria	170.315(f)(5)

Justification for Selected Measurement/Metric	• Counts of eICRs and RRs created against specific eRSD versions demonstrate ongoing interoperability as eCR reporting criteria evolve. • Counts of "Reportable" and "No Rule Met" reportability conditions reflect the quality of data sent for electronic case reporting.
Care Settings	Customers can configure TheraDoc to report eCR for select care settings in accordance with their needs. Testing will include all location types that have been configured to report eCR data.
Expected Outcomes	TheraDoc creates case reports containing expected data based on trigger codes and electronically transmits them to public health agencies; reportability responses appropriately reflect conditions met or not met for reporting criteria.

Schedule of Key Milestones

NOTE: The milestones below pertain to all care settings that have been configured in TheraDoc to report eCR.

Milestone	Date
Begin collection of data as specified in plan	January 1, 2025
Data collection and review	Monthly, 2025
Complete final data collection per end of 2025 Real World Testing period	January 2026
Complete 2025 data analysis and report creation	January 19, 2026
Submit 2025 Real World Testing report to ACB	February 9, 2026

170.315(f)(6): Transmission to public health agencies – antimicrobial use and resistance reporting

Justification for Real World Testing Approach

The objective of 170.315(f)(6) is electronic transmission of Antimicrobial Use (AU) and Antimicrobial Resistance (AR) data to NHSN. Our testing approach evaluates this objective by providing a de-duplicated count of the number of successful and failed submissions for each AUR document type in a monthly reporting period for TheraDoc customers who report AUR data to NHSN. (De-duplication accounts for submission failures unrelated to document content, such as DirectCDA outages.)

Standards Updates

Standard and Version	ASTM E1247-18
Updated Certification Criteria and Associated Product	ASTM E1247-18 for (d)(2) and (d)(3) for TheraDoc v5.4.4 and higher
Health IT Module CHPL ID	v5.4.4: 15.99.04.3033.TH03.05.18.0.240814
Date of ONC ACB Notification	v5.4.4: August 14, 2024
Date of Customer Notification (SVAP only)	N/A
Conformance Method and Measurement/Metrics	Attestation

Metrics Used

Metric Description	Monthly counts of successful and failed AR numerator, AR denominator, and AU summary submissions to NHSN.
Associated Certification Criteria	170.315(f)(6)
Justification for Selected Measurement/Metric	Monthly success/failure rate of submissions demonstrates ongoing interoperability
Care Settings	Care settings considered for NHSN AUR submission are specified in the NHSN AUR protocol (https://www.cdc.gov/nhsn/pdfs/pscmanual/11pscaurcurrent.pdf)
Expected Outcomes	NHSN accepts TheraDoc AUR submissions that comply with the AUR protocol.

Summary of Key Milestones

NOTE: The milestones below pertain to the AUR-eligible inpatient locations and select outpatient locations as defined in the 2025 NHSN AUR protocol.

Milestone	Date
Begin collection of data as specified in plan	January 1, 2025
Data collection and review	Monthly, 2025
Complete final data collection per end of 2025 Real World Testing period	January 2026
Complete 2025 data analysis and report creation	January 19, 2026
Submit 2025 Real World Testing report to ACB	February 9, 2026

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 TheraDoc's Real World Testing requirements.

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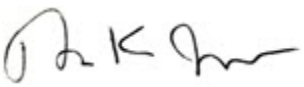
Authorized Representative Signature	
Date	October 10, 2024

