



Office of the Secretary

45 CFR Parts 170 and 171

RIN 0955-AA03

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing; Correction

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

ACTION: Final rule; correction.

SUMMARY: This document corrects technical and typographical errors in the final rule entitled, “Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing” that was published in the Federal Register on January 9, 2024, and has a stated effective of February 8, 2024.

DATES: The corrections in this document are effective on March 11, 2024.

FOR FURTHER INFORMATION CONTACT: Kate Tipping, Office of Policy, National Coordinator for Health Information Technology, 202-690-7151.

SUPPLEMENTARY INFORMATION:

I. Background

In **Federal Register** document 2023-28857 (89 FR 1192) final rule entitled “Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing” (HTI-1) (hereinafter referred to as the HTI-1 Final Rule), we identified technical and typographical errors following publication in the Federal Register on January 9, 2024. We first published a notice correcting certain errors on February 8, 2024 (89 FR 8546). In this document, we summarize and correct additional errors in the “Summary of Errors” and “Corrections of Errors” sections below.

II. Summary of Errors

A. Regulation Text Errors – Part 170—Health Information Technology Standards, Implementation Specifications, and Certification Criteria and Certification Programs for Health Information Technology

1. **ONC Certification Criteria for Health IT.**

On page 1429, third column, top of page, within amendatory instruction 9 for § 170.315, sub-instruction h., paragraph “(g)(3) introductory text” should read paragraph “(g)(3)(i).”

On page 1432, third column, halfway down the page, we inadvertently added the language, “User-centered design processes must be applied to each capability technology includes that is specified in the following certification criteria: paragraphs (a)(1) through (5), (9) until the criterion’s expiration date, and (14), and (b)(2), (3), and (11) of this section.” to paragraph (g)(3) when the language should have been added to paragraph (g)(3)(i). While we had erroneously proposed (88 FR 23746, 23911) and then finalized the revision to paragraph (g)(3), we had intended to revise paragraph (g)(3)(i). This fact is evident by our discussion of revising the provision actually found in paragraph (g)(3)(i) to include the “DSI” certification criterion (45 CFR 170.315(b)(11)) in the preambles of the proposed (88 FR 23787) and final (89 FR 1256) rules. Paragraph (g)(3) only contains the title of the certification criterion (safety-enhanced design) and not the language referenced in preamble and specifically included in paragraph (g)(3)(i). Therefore, when we discussed revising the substance of paragraph (g)(3) to “apply to the new certification criterion proposed in § 170.315(b)(11) as well,” (88 FR 23787), we believe it was evident we intended to refer to (g)(3)(i), since there were no substantive requirements in paragraph (g)(3) that could be revised. We received no substantive feedback on the proposal (89 FR 1256) and then erroneously finalized the revised provision in (g)(3) rather than (g)(3)(i).

2. **Insights Condition and Maintenance of Certification.**

On page 1434, third column, beginning at the bottom half of the page, in § 170.407, and ending in the first column of page 1435, we inadvertently included incorrect paragraph

designators (i) within paragraphs (a)(3)(iv), (v), (vi) and (vii). The (i) in these paragraphs should be deleted. We also inadvertently included the word “of” after the word “distinct” and before “certified health IT” in paragraph (a)(3)(iv)(i), which should be removed.

B. Regulation Text Errors – Part 171—Information Blocking

On page 1437, third column, in amendatory instruction 22, we add subpart D. In subpart D, after the table of contents, we erroneously included the authority for the subpart, which is the same authority as for part 171 and all subparts under part 171, and was already included in amendatory instruction 17 on page 1435. Therefore, “Authority: 42 U.S.C. 300jj–52; 5 U.S.C. 552.” under subpart D table of contents should be removed.

III. Waiver of Proposed Rulemaking, Comment Period, and Delay in Effective Date

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rulemaking in the **Federal Register** before the provisions of a rule take effect. In addition, section 553(d) of the APA mandates a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the notice and comment and delay in effective date requirements. Section 553(b)(B) of the APA authorizes an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment process are impracticable, unnecessary, or contrary to the public interest. In addition, section 553(d)(3) of the APA allows the agency to avoid the 30-day delay in effective date where such delay is contrary to the public interest and an agency includes a statement of support.

We believe this final rule correction does not constitute a rule that would be subject to the APA notice and comment or delayed effective date requirements. This document corrects technical and typographical errors in the regulation text of the HTI-1 Final Rule, but does not make substantive changes to the policies that were adopted in the HTI-1 Final Rule. As a result, this final rule correction is intended to ensure that the information in the HTI-1 Final Rule accurately reflects the policies adopted in that document.

In addition, even if this were a rule to which the notice and comment procedures and delayed effective date requirements applied, we find that there is good cause to waive such procedures and requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the HTI-1 Final Rule would be contrary to the public interest because these corrections do not change the policies laid out in the HTI-1 Final Rule. This final rule correction is intended solely to ensure that the HTI-1 Final Rule accurately reflects the policies finalized in the HTI-1 Final Rule. Therefore, we believe we have good cause to waive the notice and comment and effective date requirements.

IV. Corrections of Errors

In FR Doc. 2023-28857 appearing on page 1192 in the **Federal Register** of January 9, 2024, for the reasons stated above, the Office of the Secretary corrects the following:

1. On page 1429, in the third column, top of page, instruction 9.h to § 170.315 is corrected to read as follows:

9. Amend § 170.315 by:

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h. Revising paragraphs (g)(3)(i), (g)(6)(i)(A) and (B), (g)(9)(i)(A)(I) and (2), (g)(10)(i)(A) and (B), (g)(10)(ii)(A) and (B), (g)(10)(iv)(A) and (B), (g)(10)(v)(A)(I)(i) and (ii), (g)(10)(v)(A)(2)(i) and (ii), (g)(10)(v)(B), and (g)(10)(vi) and (vii).

2. On page 1432, in the third column, in amendatory instruction 9, in § 170.315 correct paragraph (g)(3) by removing the text following the paragraph heading and adding paragraph (g)(3)(i) to read as follows:

§ 170.315 [Corrected]

* * * * *

(g) * * *

(3) *Safety-enhanced design.* (i) User-centered design processes must be applied to each capability technology includes that is specified in the following certification criteria: paragraphs

(a)(1) through (5), (9) (until the criterion's expiration date), and (14) and (b)(2), (3), and (11) of this section.

* * * * *

3. On page 1434, in the third column, beginning at the bottom half of the page, in amendatory instruction 13, in § 170.407, correct paragraphs (a)(3)(iv), (v), (vi) and (vii) to read as follows:

§ 170.407 [Corrected]

(a) * * *

(3) * * *

(iv) *Use of FHIR in apps through certified health IT.* If a health IT developer has a Health IT Module certified to § 170.315(g)(10), then the health IT developer must submit responses on the number of requests made to distinct certified health IT deployments that returned FHIR resources, number of distinct certified health IT deployments active at any time, the number of distinct deployments active at any time that returned FHIR resources in response to API calls from apps connected to certified health IT, including stratifying responses by the following:

(A) User type;

(B) FHIR resource; and

(C) US Core Implementation Guide version.

(v) *Use of FHIR bulk data access through certified health IT.* If a health IT developer has a Health IT Module certified to § 170.315(g)(10), then the health IT developer must submit responses for the total number of FHIR bulk data access requests completed through the certified health IT, and the number of distinct deployments of the certified health IT active at any time overall, and by whether at least one bulk data download request was completed.

(vi) *Immunization administrations electronically submitted to immunization information systems through certified health IT.* If a health IT developer has a Health IT Module certified to § 170.315(f)(1), then the health IT developer must submit responses for the use of certified health

IT to electronically send immunizations administered to immunization information systems (IIS), including stratifying responses based on the following subgroups:

(A) IIS; and

(B) Age group.

(vii) *Immunization history and forecasts through certified health IT.* If a health IT developer has a Health IT Module certified to § 170.315(f)(1), then the health IT developer must submit responses for the use of certified health IT to query immunization history and forecast information from immunization information systems (IIS), including stratifying responses based on the following subgroup:

(A) IIS.

(B) [Reserved]

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Subpart D [Amended]

4. On page 1437, in the third column, in amendatory instruction 22, correct subpart D by removing the authority.

Elizabeth J. Gramling,
*Executive Secretary to the Department,
Department of Health and Human Services.*

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