



December 20, 2022

MEMORANDUM TO: Heads of the Contracting Activities

FROM: H. Katrina Brisbon
Deputy Assistant Secretary for the Office of Acquisitions
Senior Procurement Executive

SUBJECT: Department of Health and Human Services Acquisition Regulation
(HHSAR) Class Deviation (2023-01) from Part 339, Acquisition of
Information Technology; Standards for Health Information Technology

EFFECTIVE DATE: December 20, 2022

EXPIRATION DATE: This class deviation is effective until either incorporated into the HHSAR or otherwise rescinded.

PURPOSE: This HHSAR class deviation implements requirements to procure health information technology (health IT) that meets standards and implementation specifications (“standards”) adopted by the Office of the National Coordinator for Health Information Technology (ONC), consistent with Sections 13111 and 13112 of the Health Information Technology for Economic and Clinical Health Act (“HITECH Act”) (Pub. L. 111-5, Title XIII, §§ 13111 and 13112).

DEVIATION: This class deviation adds a new HHSAR subpart 339.70, Standards for Health Information Technology, which provides definitions, policy, and a prescription for a new HHSAR clause to implement requirements of the HITECH Act, to include: 1) when contracting officers must procure health IT that complies with the HITECH Act; and 2) when to require use of health IT that complies with the HITECH Act in contracts and agreements with health care providers, health plans, or health insurance issuers.

BACKGROUND: Section 13111 of the HITECH Act focuses on the use of health IT systems and products that meet standards adopted pursuant to Section 3004 of the Public Health Service Act (PHSA) when implementing, acquiring, or upgrading health IT systems used for the direct exchange of individually identifiable health information between agencies and with non-Federal entities. Section 13112 of the HITECH Act focuses on requiring the use of health IT systems and products that meet such standards in contracts or agreements with health care providers, health plans, or health insurance issuers that are implementing, acquiring, or upgrading health IT systems.

On behalf of HHS, ONC adopts standards and implementation specifications under Section 3004 of the PHS Act in 45 CFR Part 170, Subpart B. The standards adopted under Section 3004 expand over time as ONC works with HHS and other federal agencies to identify updated or new standards for adoption. Standards adopted under Section 3004 support are included in certification criteria for health IT in the ONC Health Information Technology Certification Program.

AUTHORITY: This class deviation is issued under the authority of the Federal Acquisition Regulation (FAR) 1.404, and HHSAR 301.401, for the purpose of implementing policy in the HHSAR to comply with requirements for standards alignment specified under the HITECH Act (Title XIII, §§ 13111 and 13112).

APPLICABILITY: This requirement applies to all solicitations and contracts, issued by or on behalf of HHS entities, that involve implementing, acquiring, or upgrading health IT used (1) for the direct exchange of individually identifiable health information between agencies and non-Federal entities, and (2) by health care providers, health plans, or health insurance issuers.

ACTION REQUIRED: Contracting officers shall comply with this class deviation to ensure the policy set forth in HHSAR subpart 339.70 is followed, and the prescribed clause is inserted in new solicitations issued and contracts awarded on or after the effective date of the deviation. Contracting officers should consider amending existing applicable solicitations or modifying existing applicable contracts to include the prescribed clause.

SUMMARY OF HHSAR CHANGES. To implement the standards requirement, HHSAR part 339, Acquisition of Information Technology (DEVIATION) is revised, and subpart 339.70, Standards for Health Information Technology (DEVIATION), and affected part 352 section 352.239-70 (DEVIATION) are added, as summarized in the following and provided in Attachment 1:

339.70, Standards for Health Information Technology (DEVIATION). This subpart is added to implement standards alignment under the authority of the HITECH Act, Pub. L. 111-5, Title XIII, §§ 13111 and 13112 for applicable HHS contracts.

339.7000, Scope of subpart. This section is added to provide the scope of the Standards for Health Information Technology.

339.7001, Definitions. This section is added to include the definitions for the Certified Health IT Product List, health information technology, individually identifiable health information, and the ONC Health Information Technology Certification Program.

339.7002, Policy—certification of health information technology. This section is added to implement the Standards for Health Information Technology in HHS contracts.

339.7003, Contract clause. This section is added to prescribe a new clause 352.239-70, Standards for Health Information Technology in solicitations and contracts, issued by or on behalf of HHS entities, that involve implementing, acquiring or upgrading health IT used —

(a) for the direct exchange of individually identifiable health information between agencies and with non-Federal entities; and

(b) by health care providers, health plans, or health insurance issuers.

SUMMARY OF HHSAR PGI CHANGES. As a result of new HHSAR part 339 (DEVIATION), the following summarizes updates provided to the HHSAR PGI, as provided in Attachment 2:

PGI Subpart 339.70, Standards for Health Information Technology. This subpart is added to provide policy and procedure on Standards for Health Information Technology in applicable HHS contracts.

PGI 339.7002, Policy—standards for health information technology. This section is added to advise contracting officers and requiring activities to consult with ONC if they have questions regarding the use of the new clause at 352.239-70, Standards for Health Information Technology, and provides additional available ONC resources.

ADDITIONAL INFORMATION: Direct any questions or comments regarding this deviation to the HHS Office of Acquisition at OAP@hhs.gov.

Attachments

Attachment 1 – Class Deviation to HHSAR Part 339, Acquisition of Information Technology

Attachment 1

Class Deviation to the Department of Health and Human Services Acquisition Regulation Part 339

HHSAR Text Baseline is 48 CFR chapter 3 dated May 24, 2022.

Changes to baseline shown as [**bolded, bracketed additions**] and strikethrough deletions.
HHSAR text unchanged shown as asterisks.

[PART 339—ACQUISITION OF INFORMATION TECHNOLOGY (DEVIATION)]

Subpart 339.70 – Standards for Health Information Technology (DEVIATION)

339.7000 Scope of subpart. (DEVIATION)

(a) This subpart implements standards for health information technology (health IT) pursuant to the Health Information Technology for Economic and Clinical Health Act (“HITECH Act”), Pub. L. 111-5, Title XIII, sections 13111 and 13112.

(b) This subpart provides policies and procedures for solicitations and contracts that involve implementing, acquiring, or upgrading health IT used—

(1) For the direct exchange of individually identifiable health information between agencies and with non-Federal entities; and

(2) By health care providers, health plans, or health insurance issuers.

339.7001 Definitions. (DEVIATION)

As used in this subpart—

Health information technology (health IT) means hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information. (42 U.S.C. 300jj)

Individually identifiable health information means information that is a subset of health information, including demographic information collected from an individual, and:

(1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health condition of

an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(i) That identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual. (42 U.S.C. 300jj, 1320d)

***ONC Health Information Technology Certification Program* means the certification program administered by the HHS Office of the National Coordinator for Health Information Technology (ONC) using a third-party conformity assessment program for health IT. Certification criteria for the Program, which incorporate standards and implementation specifications in 45 CFR part 170 subpart B, are found in 45 CFR part 170, subpart C.**

339.7002 Policy—standards for health information technology. (DEVIATION)

(a) Pursuant to the HITECH Act, Pub. L. 111-5, Title XIII, sections 13111 and 13112, health IT procured by or on behalf of HHS entities, or when contracting with health care providers, health plans, or health insurance issuers that are implementing, acquiring, or upgrading health IT, shall meet standards and implementation specifications adopted in 45 CFR part 170, subpart B, if applicable.

(b) Contracting officers shall not award a contract unless the offeror/contractor agrees that—

(1) For work performed under the contract that involves implementing, acquiring, or upgrading health IT used for the direct exchange of individually identifiable health information between agencies and with non-Federal entities the contractor will utilize health IT that—

(i) Meets standards and implementation specifications adopted in 45 CFR part 170, subpart B, if such standards and implementation specifications can support work performed under the contract; and

(ii) Is certified under the ONC Health Information Technology Certification Program, if certified technology can support work performed under the contract (see certification criteria in 45 CFR part 170, subpart C), when the contractor is an eligible professional in an ambulatory setting, or a hospital, eligible under sections 4101, 4102, and 4201 of the HITECH Act, or when the contractor is implementing, acquiring, or upgrading technology to be used by an eligible professional in an ambulatory setting, or hospital, eligible under sections 4101, 4102, and 4201 of the HITECH Act.

(2) If the contractor is a health care provider, health plan, or health insurance issuer, or is establishing an agreement with a health care provider, health plan, or health insurance

issuer, for work performed under the contract that involves implementing, acquiring, or upgrading health IT, the contractor will utilize health IT that—

(i) Meets standards and implementation specifications adopted in 45 CFR part 170, subpart B, if such standards and implementation specifications can support work performed under the contract; and

(ii) Is certified under the ONC Health Information Technology Certification Program, if certified technology can support work performed under the contract (see certification criteria in 45 CFR part 170, subpart C), when the contractor is an eligible professional in an ambulatory setting, or a hospital, eligible under sections 4101, 4102, and 4201 of the HITECH Act, or when the contractor is implementing, acquiring, or upgrading technology to be used by an eligible professional in an ambulatory setting, or hospital, eligible under sections 4101, 4102, and 4201 of the HITECH Act.

(c) If standards and implementation specifications adopted in 45 CFR part 170, subpart B, cannot support the work as specified in the contract, the contractor is encouraged to use health IT that meets non-proprietary standards and implementation specifications developed by consensus-based standards development organizations. This may include standards identified in the ONC Interoperability Standards Advisory, available at <https://www.healthit.gov/isa/>.

339.7003 Contract clause. (DEVIATION)

The contracting officer shall insert the clause at 352.239-70, Standards for Health Information Technology, in solicitations and contracts issued by or on behalf of HHS entities that involve implementing, acquiring, or upgrading health IT used —

(a) For the direct exchange of individually identifiable health information between agencies and with non-Federal entities; or

(b) By health care providers, health plans, or health insurance issuers.

PART 352—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

Subpart 352.2—Text of Provisions and Clauses

[352.239-70 Standards for Health Information Technology. (DEVIATION)

As prescribed in 339.7003, insert the following clause:

**STANDARDS FOR HEALTH INFORMATION TECHNOLOGY
(DEC 2022) (DEVIATION)**

(a) *Definitions.* As used in this clause—

***Health information technology (health IT)* means hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information. (42 U.S.C. 300jj)**

***Individually identifiable health information* means information that is a subset of health information, including demographic information collected from an individual, and:**

(1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(i) That identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual. (42 U.S.C. 300jj, 1320d)

***ONC Health Information Technology Certification Program* means the certification program administered by the HHS Office of the National Coordinator for Health Information Technology (ONC) using a third-party conformity assessment program for health IT. Certification criteria for the Program, which incorporate standards and implementation specifications in 45 CFR part 170 subpart B, are found in 45 CFR part 170, subpart C.**

(b) Pursuant to the Health Information Technology for Economic and Clinical Health Act (HITECH Act), Pub. L. 111-5, Title XIII, sections 13111 and 13112, by submission of an offer and execution of a contract, the Contractor agrees that—

(1) For any work performed under the contract that involves implementing, acquiring, or upgrading health IT used for the direct exchange of individually identifiable health information between agencies and with non-Federal entities, the Contractor will utilize health IT that—

(i) Meets standards and implementation specifications adopted in 45 CFR part 170, subpart B, if such standards and implementation specifications can support the work performed under the contract; and

(ii) Is certified under the ONC Health Information Technology Certification Program, if certified technology can support the work performed under the contract (see certification criteria in 45 CFR part 170, subpart C), when the Contractor is an eligible professional in an ambulatory setting, or a hospital, eligible under sections 4101, 4102 and 4201 of the HITECH Act, or when the Contractor is implementing, acquiring or upgrading technology to be used by an eligible professional in an ambulatory setting, or a hospital, eligible under sections 4101, 4102 and 4201 of the HITECH Act.

(2) If the Contractor is a health care provider, health plan, or health insurance issuer, or is establishing an agreement with a health care provider, health plan, or health insurance issuer, for work performed under the contract that involves implementing, acquiring, or upgrading health IT, the Contractor will utilize health IT that—

(i) Meets standards and implementation specifications adopted in 45 CFR part 170, subpart B, if such standards and implementation specifications can support the work performed under the contract; and

(ii) Is certified under the ONC Health Information Technology Certification Program, if certified technology can support the work performed under the contract (see certification criteria in 45 CFR part 170, subpart C), when the Contractor is an eligible professional in an ambulatory setting, or a hospital, eligible under sections 4101, 4102 and 4201 of the HITECH Act, or when the Contractor is implementing, acquiring or upgrading technology to be used by an eligible professional in an ambulatory setting, or a hospital, eligible under sections 4101, 4102 and 4201 of the HITECH Act.

(c) If standards and implementation specifications adopted in 45 CFR part 170, subpart B, cannot support the work as specified in the contract, the Contractor is encouraged to use health IT that meets non-proprietary standards and implementation specifications developed by consensus-based standards development organizations. This may include standards identified in the ONC Interoperability Standards Advisory, available at <https://www.healthit.gov/isa/>.

(End of clause)]

Attachment 2

Changes to HHSAR PGI Due to HHSAR Part 339 Class Deviation

Changes to baseline shown as [**bolded, bracketed additions**] and strikethrough deletions. HHS Acquisition PGI text unchanged shown as ***** asterisks.

[PGI Subpart 339.70 – Standards for Health Information Technology

339.7002 Policy— standards for health information technology.

Contracting officers and requiring activities—

(a) Should consult with the Office of the National Coordinator for Health Information Technology (ONC) if they have questions regarding the use of the clause at 352.239-70, Standards for Health Information Technology. Contracting officers and requiring activities can email onhealthitalignment@hhs.gov with questions;

(b) May access educational materials and resources regarding available standards and certification criteria can support health care activities are available from ONC at <https://www.healthit.gov/topic/hhs-health-it-alignment-policy>; and

(c) May access the ONC Certified Health IT Product List at <https://chpl.healthit.gov/> to validate certified health IT has been tested and certified by the ONC Health Information Technology Certification Program.