ASTP Assistant Secretary
for Technology Policy

Overview of the HHS Health IT Alignment Policy: Aligning HHS-Adopted Standards Across the Department

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Background

- In 2022, the HHS Secretary instituted the HHS Health IT Alignment Policy.

- Policy goals:

  – Establish a consistent HHS-wide approach to standard health IT requirements across HHS agencies and programs to eliminate program and data silos and advance the effectiveness and efficiency of Department programs and policies

  – Fully exercise HHS authorities to promote cross-agency collaboration and better support each agency's mission

  – Reinforce department goals for nationwide interoperability through consistency in funding and policies related to health IT activities

  – Provide Secretary-level and cross-agency visibility and awareness of significant health IT activities

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Authorities Under The HITECH Act

- **Section 13111 of the Health Information Technology for Economic and Clinical Health (HITECH) Act** requires agencies…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, to utilize, where available, health IT systems and products that meet standards and implementation specifications adopted by ONC under section 3004 of the PHSA.

- **Section 13112 of the HITECH Act** specifies that agencies…shall require in contracts or agreements with health care providers, health plans, or health insurance issuers that as each provider, plan, or issuer implements, acquires, or upgrades health IT systems, it shall utilize, where available, health IT systems and products that meet standards and implementation specifications adopted under section 3004 of the PHSA.
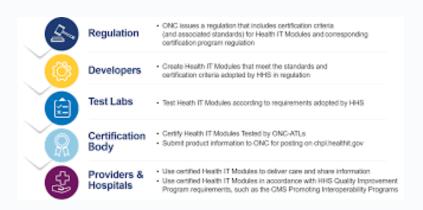

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Policy Description

Directed ASTP/ONC to establish and oversee a consistent HHS approach to the inclusion of health IT requirements in grants, cooperative agreements, contracts, and policy and regulatory actions

1. Institutes a Department-wide management policy to promote greater alignment of health IT-related activities.

2. Directs ASTP to engage with HHS agencies to align and coordinate health IT-related activities in support of HHS health IT and interoperability goals.

3. Directs Operating Divisions and Staff Divisions (OpDivs/StaffDivs):

   a. To the extent legally permissible, to include standard health IT language in applicable grants, cooperative agreements, contracts, and rulemaking to ensure alignment of the Department's health IT investments; and

   b. To maximize opportunities to align HHS's health IT requirements and investments by engaging with ONC when the OpDiv/StaffDiv initiates a major health IT-related activity.

What Do We Mean When We Say, "Health IT Related Activities?"

- Health IT-related activities are any activities and/or programs that involve health IT systems or adoption, health IT standards, or any activities that promote interoperability.

- Health information technology (IT) is defined in Section 3000 of the Public Health Service Act and codified at 45 CFR 170.102.
  - Health IT is 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.

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Policy Tailored to Complexity of Health IT Activities

Inclusion of Standard Health IT Language

ASTP and the HHS Assistance Secretary for Financial Resources (ASFR) developed standard language that, to the extent legally permissible, should be included in applicable grants, cooperative agreements, and contracts at HHS:

- Full use of HHS-certified health IT where available
- Support HHS-approved standards where applicable
- Use of other HHS-identified non-proprietary open-industry standards where applicable

ASTP will work collaboratively with agencies to modify or supplement this language where necessary to address unique program circumstances.

Major Activities Review and Technical Assistance

ASTP (in collaboration with the HHS Assistant Secretary for Financial Resources) will work with agency liaisons at each HHS division to develop and maintain a Department-wide inventory of major IT activities:

- HHS funding >$20M annually or >$100M over 5 years
- Economically significant rulemaking/guidance

ASTP will provide technical assistance to selected programs in collaboration with agencies.

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Examples of Technical Assistance (TA) for Health IT-related Activities

- ASTP sends out ongoing communications to the Department on standard language for contracts, grants, and cooperative agreements.

- ASTP worked with the Centers for Disease Control and Prevention to draft public health IT guidance for grants and cooperative agreements, which includes references to the current health IT certification criteria for public health activities as well as HHS-adopted health IT standards that support public health programs.

- ASTP also worked with the Centers for Medicare & Medicaid Services to incorporate language supporting HHS Health IT Alignment Policy into new initiatives, including an [innovation model focused on maternal health](#).

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Policy Timeline

July 2022

Policy instituted. ASFR released **Notice of Funding Opportunity (NOFO)** guidance on July 21, which included standard language that can be used in grants and cooperative agreements, starting in FY 2023.

October 2022

ASTP identification of **Agency Liaisons** from across the Department to support implementation of this new policy within every HHS Operating and Staff Division.

November 2022

ASTP worked across HHS Operating Divisions and Staff Divisions to identify health IT activities**.**

ASTP analyzes the health IT activities to determine alignment opportunities across HHS.

December 2022

ASFR released the **class deviation memo** for standard language to be included in applicable contracts beginning in December 2022, along with the release of standard resource materials.

January 2023- December 2023

Policy implementation under way across HHS and ASTP continues to engage with partners on the policy requirements.

ASTP developed **educational resources and training materials** for HHS procurement and program teams.

ASFR, supported by ASTP, developed a **planned HHSAR rulemaking and submitted to the Unified Agenda**.

January 2024 - Present

ASTP **launched educational resource materials and an HHS intranet page as a resource for** OpDivs/StaffDivs.

ASTP is also **developing a technical assistance (TA) resource center** for procurement activities.

HHSAR NPRM published to the **Federal Register** and is **open for public comment through October 8, 2024.**

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Additional Work in Progress

- Development of an HHS Health IT Alignment Policy Technical Assistance (TA) Resource Center

- Recently, ASFR released the HHS Acquisition Regulation (HHSAR): Acquisition of Information Technology; Standards for Health Information Technology proposed rule for [public comment](#) through October 8, 2024

Resources

Please see the [HHS Health IT Alignment webpage](#).

- The webpage includes the following:
  - General FAQs
  - [Summary Overview of Adopted Standards](#)
  - [HHS Health IT Alignment Policy Overview](#)

- Blogs:
  - [HHS Making Progress on Department-wide Alignment of Health IT Investments](#)
  - [E Pluribus Unum](#)

- HHS Health IT Alignment Resource Mailbox: onchealthitalignment@hhs.gov

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Contact ASTP

Send all questions about the HHS Health IT Alignment Policy to:
ONCHealthITAlignment@hhs.gov

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