ONC | HealthIT ADVISORY COMMITTEE

Adopted Standards Task Force 2022 Recommendations to the HITAC

Hans Buitendijk, Task Force Co-Chair

Steven Eichner, Task Force Co-Chair

Adopted Standards Task Force 2022 Recommendations Overview

- 21st Century Cures Act Requirement
- Charge
- Membership
- Approach
- Groups
- Recommendations

21st Century Cures Act Requirement

Review of Adopted Standards

- Beginning 5 years after the date of enactment *[December 13, 2016]* of the 21st Century Cures Act and every 3 years thereafter, the National Coordinator shall convene stakeholders to review the existing set of adopted standards and implementation specifications and make recommendations with respect to whether to-
  - (A) maintain the use of such standards and implementation specifications; or
  - (B) phase out such standards and implementation specifications.

- Reference: 42 U.S. Code § 300jj–13 - Setting priorities for standards adoption

Adopted Standards Task Force 2022 Charge

Review the existing set of ONC adopted standards and implementation specifications and make recommendations to maintain or phase out such standards and implementation specifications, as required by 42 U.S. Code § 300jj–13 (*Setting Priorities for Standards Adoption*). The current set of ONC adopted standards and implementation specifications are maintained on the ONC Standards Hub.

This charge does not include seeking recommendations for new standards or implementation specifications for ONC to adopt through rulemaking.

Adopted Standards Task Force 2022 Roster

Name	Organization	Name	Organization
Hans Buitendijk* (Co-Chair)	Oracle Cerner	Eliel Oliveira*	Dell Medical School, University of Texas at Austin
Steven Eichner* (Co-Chair)	Texas Dept. of State Health Services	Vassil Peytchev	Epic
Jeff Danford	Altera Digital Health	Samantha Pitts	Johns Hopkins University School of Medicine
Rajesh Godavarthi*	MCG Health	Alexis Snyder*	Individual
Jim Jirjis*	HCA Healthcare	Fillipe Southerland*	Yardi Systems, Inc.
John Kilbourne**	Veterans Affairs (VA)	Ram Sriram**	National Institute of Standards and Technology (NIST)
Hung Luu*	Children's Health (Dallas)	Raymonde Uy	National Association of Community Health Centers (NACHC)
Clem McDonald*	National Library of Medicine	Debi Willis	PatientLink Enterprises, Inc.
Deven McGraw	Invitae		

* HITAC Member
** HITAC Federal Representative

Approach

- Identified 55 standards for review
- Group standards into blocks for review
- Developed and managed grid for input tracking from across the Task Force, noting where subject matter experts from across the HIT community would be beneficial
- Conducted Task Force Meetings, including community-based subject matter experts, to ensure that all Task Force members understand the impact of the standards
- Draft dispositions and rationales for each standard

Presenters

Laura Conn, CDC
- Electronic Lab Reporting

Carmela Couderc, ONC
- CDC Race and Ethnicity Code Set differences between v1.0 and v1.2
- USCDI

Rosa Ergas, MA Department of Health
- Syndromic

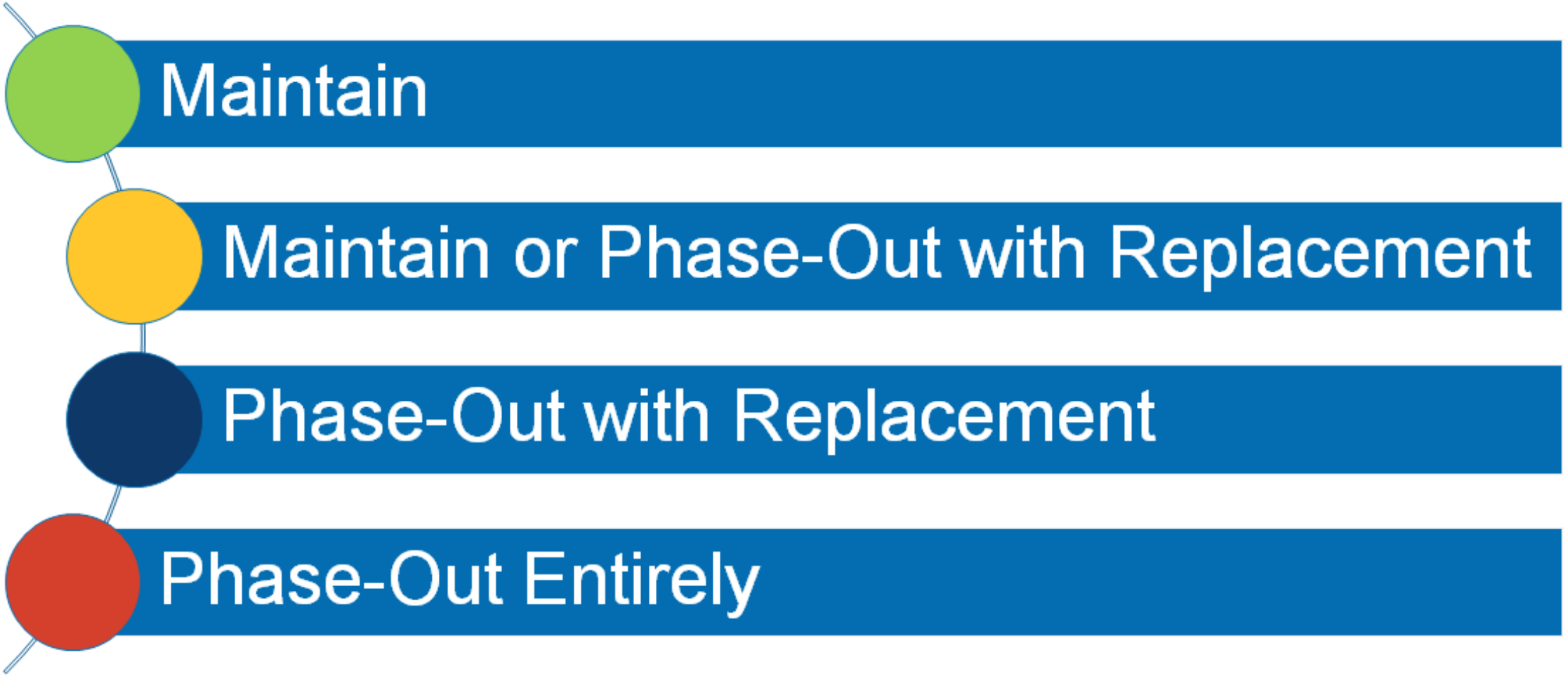
Riki Merrick, APHL
- Electronic Lab Reporting

Al Taylor, ONC
- USCDI

Caleb Wiedeman, TN Dept of Health
- Syndromic

Margaret Weiker, NCPDP
- NCPDP SCRIPT Standard

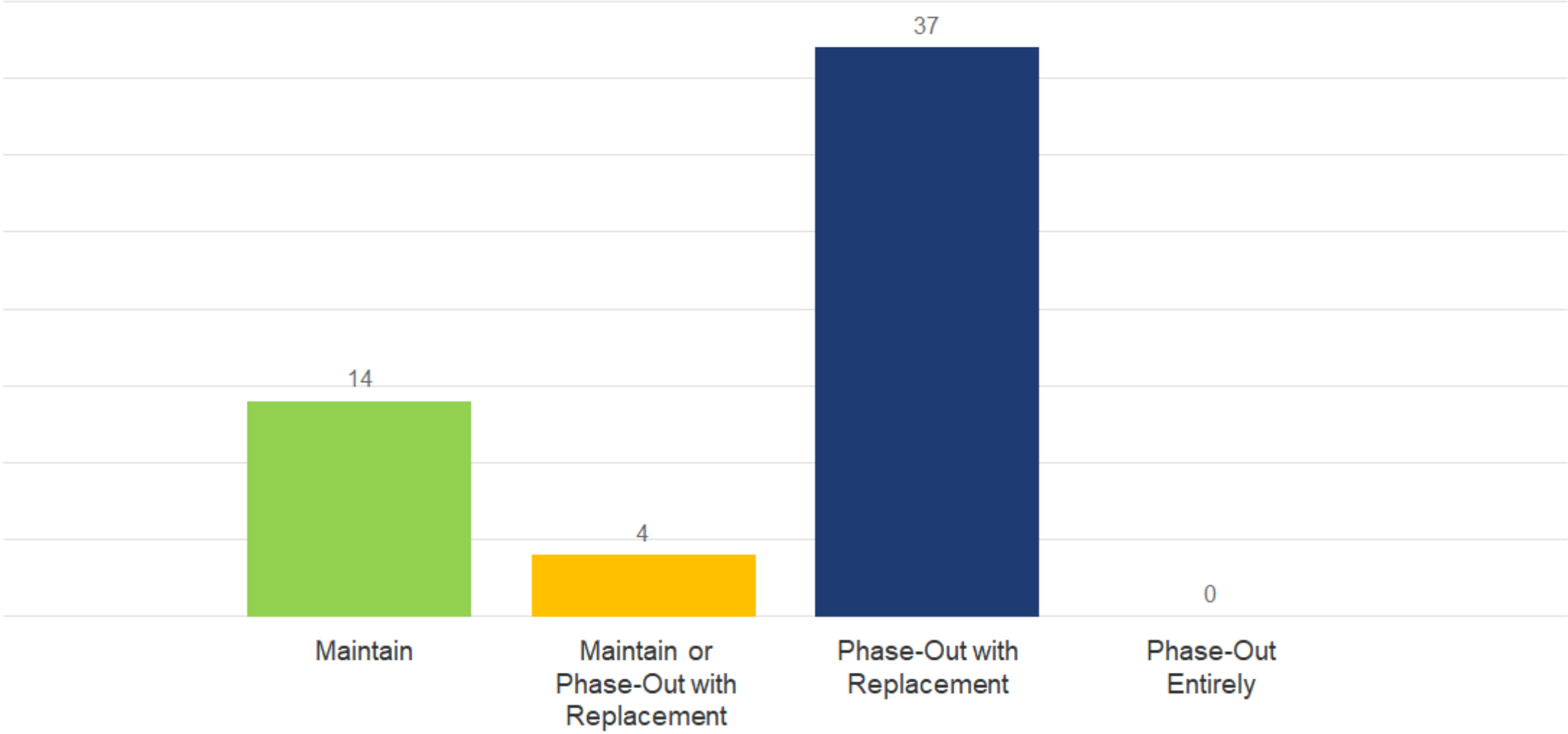
Disposition States



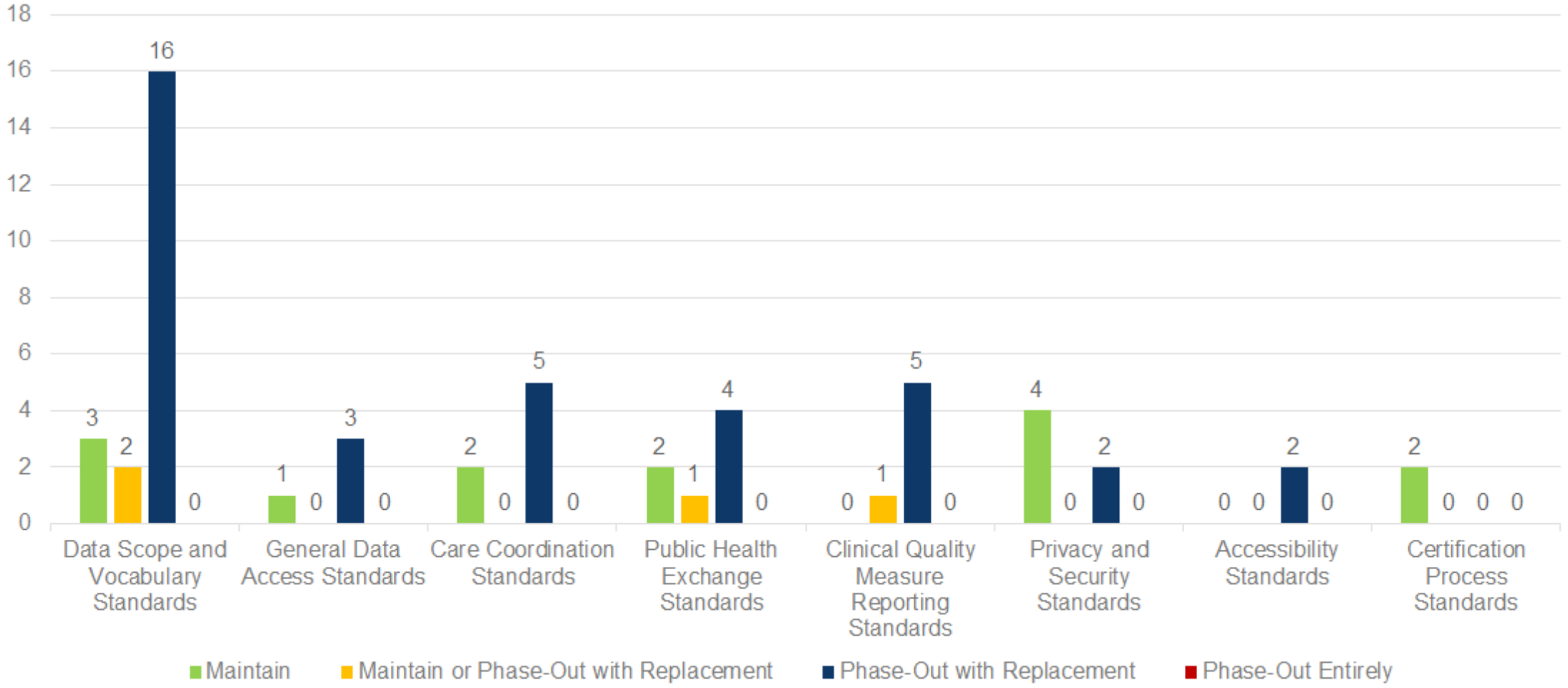
Standards Groups

- Data Scope and Vocabulary Standards
- General Data Access Standards
- Care Coordination Standards
- Public Health Exchange Standards
- Clinical Quality Measurement Reporting Standards
- Privacy/Security Standards
- Accessibility Standards
- Certification Process Standards

Summary of Task Force Recommendations by Disposition



Summary of Disposition Recommendations by Standards Grouping



Data Scope and Vocabulary Standards

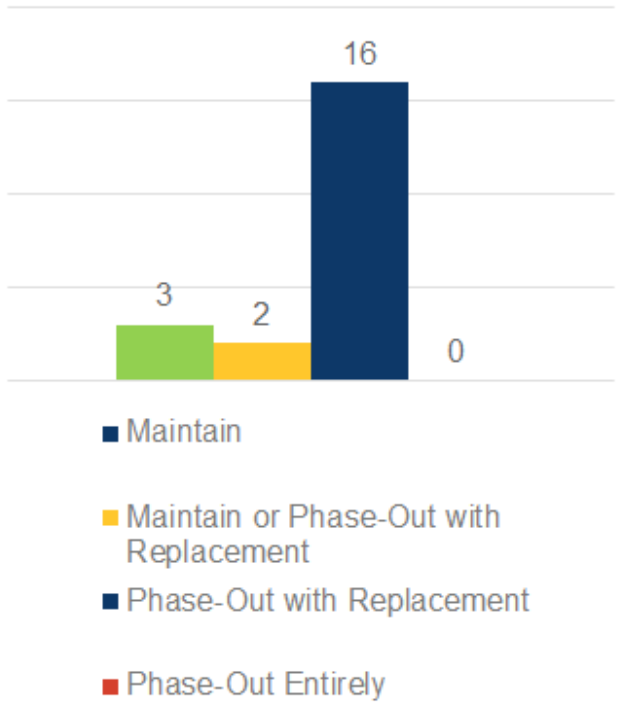
Description

The standards in this section reference the scope of data for specific certification criteria and the vocabulary referenced in the Cures Act Final Rule that in turn are used by standards in the subsequent sections of this report.

Group Highlights

- USCDI can advance, but must be aligned with supporting interoperability standards
- SNOMED and LOINC can advance, while reduce references to different versions
- Ambiguous reference to OMB Race and Ethnicity should be clarified
- Vocabulary advancement process is very valuable

Dispositions



Data Scope and Vocabulary Standards

#	Standard	Disposition Recommendation
1	United States Core Data for Interoperability (USCDI)	Phase-Out with Replacement
2	Code on Dental Procedures and Nomenclature (CDT)	Phase-Out with Replacement
3	Current Procedural Terminology, Fourth Edition (CPT-4)/Healthcare Common Procedure Coding System (HCPCS)	Phase-Out with Replacement
4	ICD-10 CM Encounter Diagnoses: Code Set for the following conditions: Diseases, Injuries, Impairments, Other health problems and their manifestations, Causes of injury, disease, impairment, or health problems.	Phase-Out with Replacement
5	International Classification of Diseases ICD-10-PCS 2020	Phase-Out with Replacement
6	RxNorm, September 8, 2015 Full Release Update	Phase-Out with Replacement
7	SNOMED International, Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) U.S. Edition, September 2019 Release	Phase-Out with Replacement

Data Scope and Vocabulary Standards

#	Standard	Disposition Recommendation
8	Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) International Release July 31, 2012 and US Extension to SNOMED CT® March 2012	Phase-Out with Replacement
9	Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), U.S. Edition, September 2015 Release	Phase-Out with Replacement
10	RFC 5646, “Tags for Identifying Languages,” September 2009	Maintain or Phase-Out with Replacement
11	Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52, Released June 2015.	Phase-Out with Replacement
12	Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40, Released July 2012.	Phase-Out with Replacement
13	HL7® Standard Code Set CVX— Vaccines Administered, updates through August 17, 2015	Phase-Out with Replacement
14	Public Health Data Standards Consortium Source of Payment Typology Code Set Version 5.0 (October 2011)	Phase-Out with Replacement

Data Scope and Vocabulary Standards

#	Standard	Disposition Recommendation
15	National Drug Code (NDC) Directory–Vaccine NDC Linker, updates through August 17, 2015	Phase-Out with Replacement
16	CDC Race and Ethnicity Code Set Version 1.0 (March 2000)	Phase-Out with Replacement
17	HL7® Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor	Maintain
18	Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997	Maintain or Phase-Out with Replacement
19	The Unified Code of Units of Measure, Revision 1.9	Phase-Out with Replacement
20	E.123: Notation for national and international telephone numbers, e-mail addresses and web addresses	Maintain
21	E.164: The international public telecommunication numbering plan	Maintain

General Data Access Standards

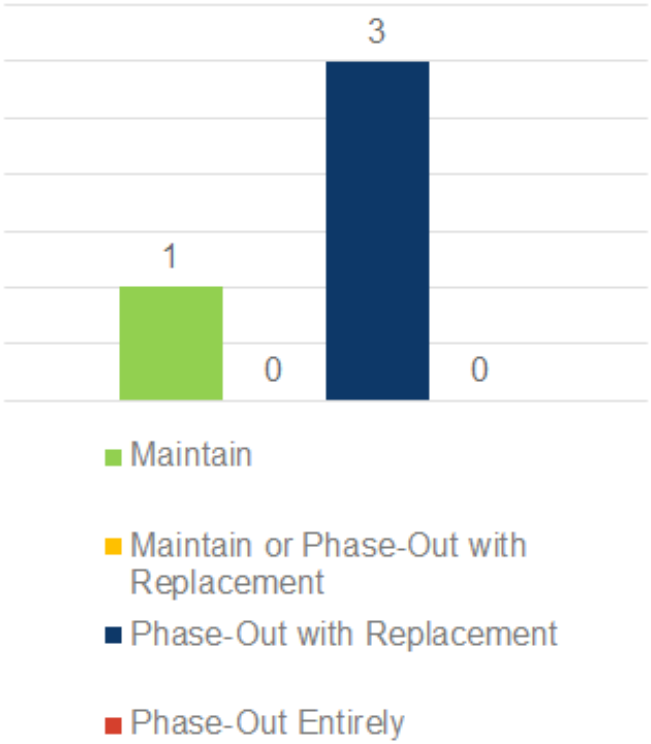
Description

The standards in this section reference the ability to generally access data using FHIR based Application Programming Interfaces (APIs).

Group Highlights

- Recommend to maintain HL7® FHIR® standard while starting to explore when advancement is appropriate

Dispositions



General Data Access Standards

#	Standard	Disposition Recommendation
22	HL7® Version 4.0.1 FHIR® Release 4, October 30, 2019	Maintain
23	FHIR® US Core Implementation Guide STU V3.1.1	Phase-Out with Replacement
24	HL7® FHIR® Bulk Data Access (Flat FHIR®) (V1.0.0:STU 1)	Phase-Out with Replacement
25	HL7® SMART Application Launch Framework Implementation Guide Release 1.0.0	Phase-Out with Replacement

Care Coordination Standards

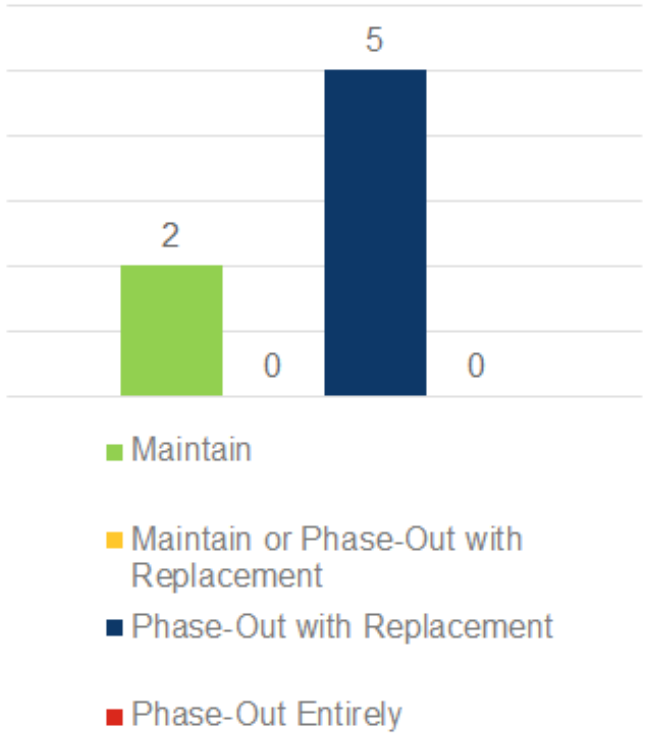
Description

The standards in this section reference the ability to support coordination of care specific transactions. Some are used for general access as well, but the Task Force opted to only list them in this section to avoid redundancy.

Group Highlights

- Maintain HL7® CDA® C-CDA version as primary guidance is in the companion guides
- Continue maintaining older HL7® CDA® C-CDA IHE Health Story Consolidation or HL7® CDA® guidance for viewing, reconciling, and incorporating, not generating.

Dispositions



Care Coordination Standards

#	Standard	Disposition Recommendation
26	HL7® CDA R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019, IBR approved for § 170.205(a)(5).	Phase-Out with Replacement
27	HL7® Implementation Guide (IG) for CDA Release 2 Consolidation CDA Templates for Clinical Notes (US Realm),Draft Standard for Trial Use Release 2.1 C-CDA 2.1, August 2015, June 2019 (with Errata).	Maintain
28	HL7® Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012	Maintain
29	Direct Project: ONC Applicability Statement for Secure Health Transport, Version 1.2 August 2015	Phase-Out with Replacement
30	ONC Implementation Guide for Direct Edge Protocols, Version 1.1, June 25, 2014	Phase-Out with Replacement
31	IHE IT Infrastructure Technical Framework Volume 2b (ITI TF- 2b)	Phase-Out with Replacement
32	NCPDP SCRIPT Standard, Implementation Guide, Version 2017071	Phase-Out with Replacement

Public Health Exchange Standards

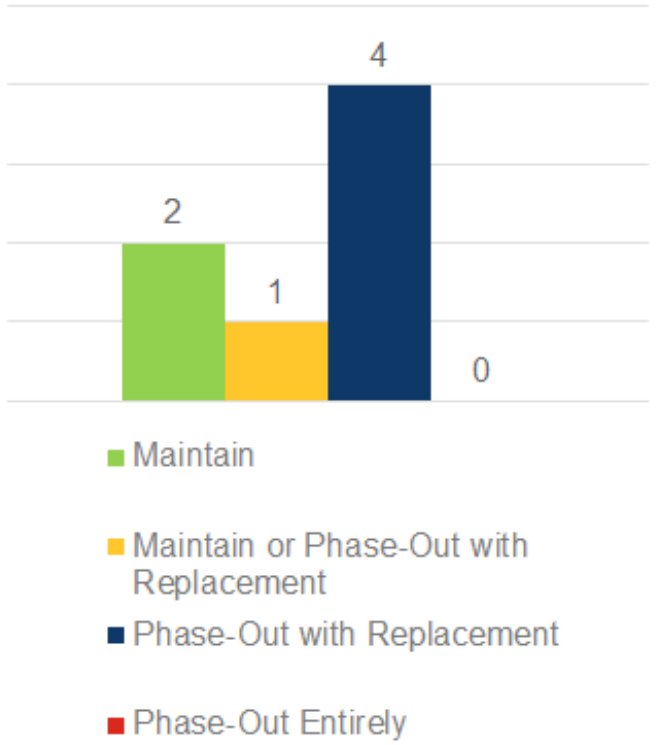
Description

The standards in this section reference the ability to exchange data with public health authorities.

Group Highlights

- Alignment of when to advance is critical across stakeholders (ONC, STLT, CDC/NHSN)
  - Immunization Registry reporting
  - Cancer Registry
  - Laboratory Reporting
- Laboratory Reporting presents opportunities to advance with multiple choices

Dispositions



Public Health Exchange Standards

#	Standard	Disposition Recommendation
33	HL7® Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5)—Addendum, July 2015	Maintain
34	PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent, Care, Inpatient and Ambulatory Care, and Inpatient Settings, Release 2.0, April 21, 2015	Phase-Out with Replacement
35	HL7® Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm)	Phase-Out with Replacement
36	Electronic Laboratory Reporting (ELR) 2.5.1 Clarification Document for EHR Technology Certification	Maintain or Phase-Out with Replacement
37	HL7® Implementation Guide for CDA© Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1, April 2015	Maintain
38	HL7® Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection Reports	Phase-Out with Replacement
39	HL7® Implementation Guide for CDA Release 2: National Health Care Surveys (NHCS), Release 1 – US Realm, Draft Standard for Trial Use, December 2014	Phase-Out with Replacement

Clinical Quality Measure Reporting Standards

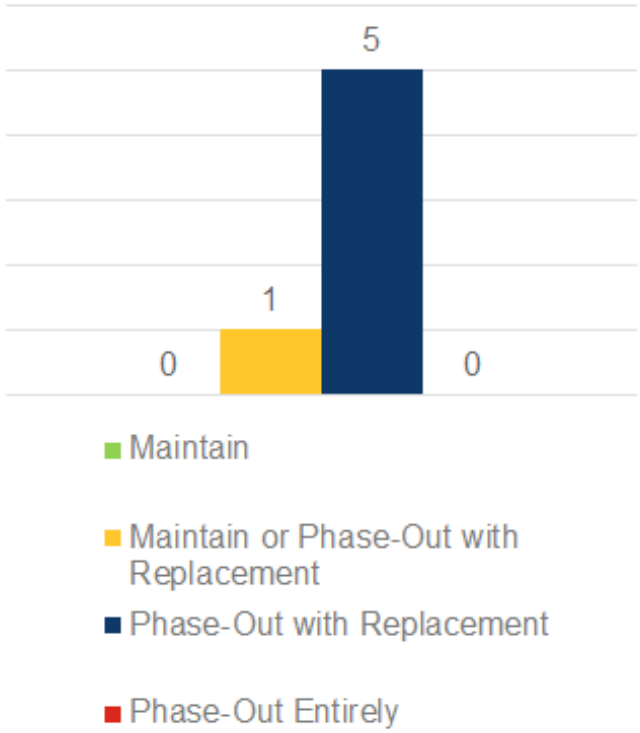
Description

The standards in this section support the various clinical quality measure reporting requirements, primarily to the Centers for Medicare and Medicaid Services (CMS).

Group Highlights

- Update of QRDA standards to the extent necessary to support CMS quality reporting implementation guides.

Dispositions



Clinical Quality Measures Reporting Standards

#	Standard	Disposition Recommendation
40	HL7® CDA® Release 2 Implementation Guide for: Quality Reporting Document Architecture – Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 1 and 2	Phase-Out with Replacement
41	Quality Reporting Document Architecture Category III, Implementation Guide for CDA Release 2	Phase-Out with Replacement
42	Errata to the HL7® Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture—Category III, DSTU Release 1 (US Realm), September 2014	Maintain or Phase-Out with Replacement
43	Crosswalk: Medicare Provider/Supplier to Healthcare Provider Taxonomy, April 2, 2015	Phase-Out with Replacement
44	CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2020	Phase-Out with Replacement
45	CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2020	Phase-Out with Replacement

Privacy and Security Standards

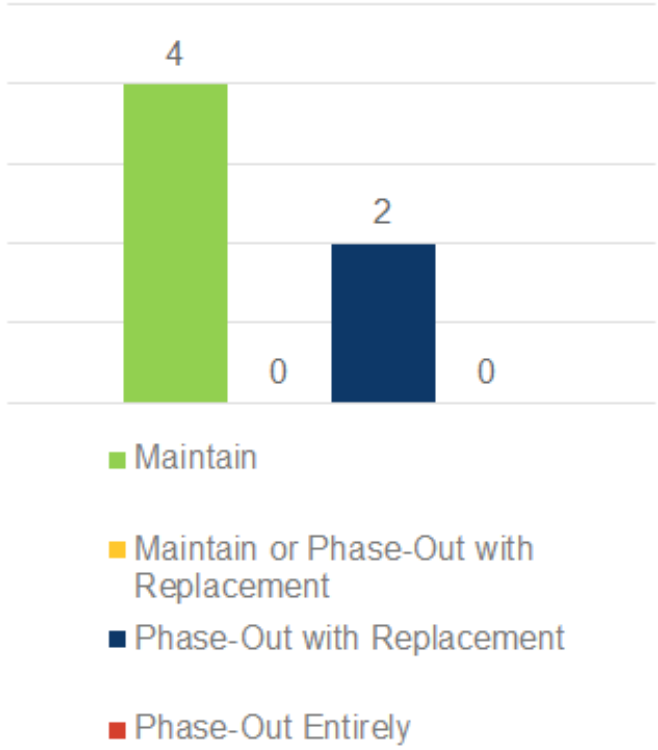
Description

The standards in this section support the ability to communicate various privacy and security related capabilities and attributes, while providing a consistent audit log.

Group Highlights

- Standards are well established
- The Secure Hash standard is under review. If it needs to be maintained, should clarify that SHA-1 is disallowed.

Dispositions



Privacy and Security Standards

#	Standard	Disposition Recommendation
46	HL7® Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1	Maintain
47	(RFC 5905) Network Time Protocol Version 4	Maintain
48	Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2, October 8, 2014 (incorporated by reference in § 170.299).	Phase-Out with Replacement
49	ASTM E2147-18 Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems.	Maintain
50	OpenID Connect Core 1.0 incorporating errata set 1	Maintain
51	Secure Hash Standard, 180-4 (August 2015).	Phase-Out with Replacement

Accessibility Standards

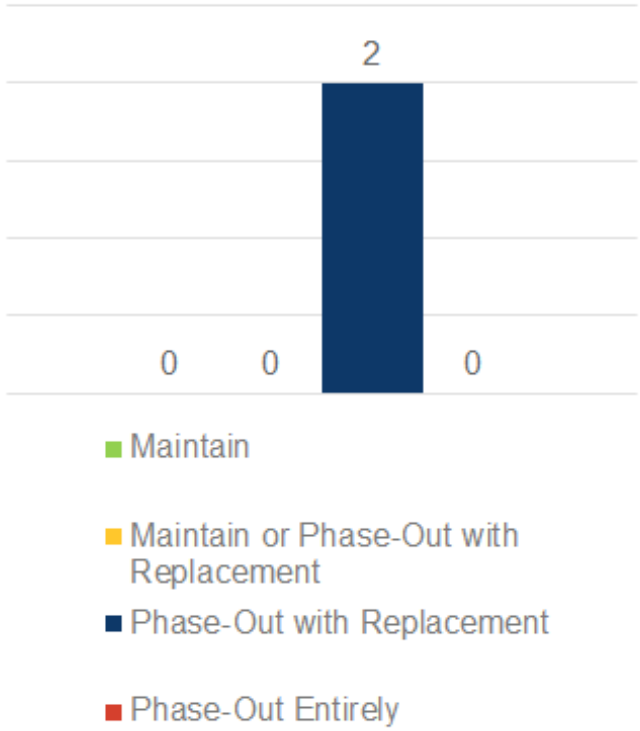
Description

The standards in this section address accessibility guidelines related to supporting the ability of individuals with disabilities to successfully interact with HIT.

Group Highlights

- The Task Force consulted with the HHS Office of Civil Rights (OCR) to align regulatory standards related to ONC with other accessibility issues being addressed by OCR

Dispositions



Accessibility Standards

#	Standard	Disposition Recommendation
52	Web Content Accessibility Guidelines (WCAG) 2.0, Level A Conformance	Phase-Out with Replacement
53	Web Content Accessibility Guidelines (WCAG) 2.0, Level AA Conformance	Phase-Out with Replacement

Certification Process Standards

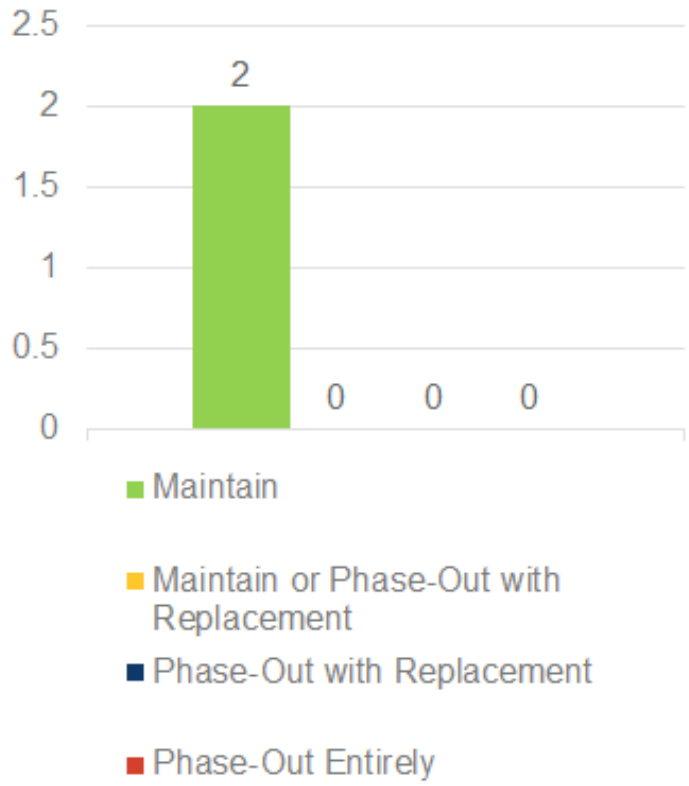
Description

The standards in this section address the ability to establish the necessary processes and controls to implement ONC HIT certification program.

Group Highlights

- N/A

Dispositions



Certification Process Standards

#	Standard	Disposition Recommendation
54	ISO/IEC 17025:2017(E)—General Requirements for the Competence of Testing and Calibration Laboratories, (Third Edition), November 2017	Maintain
55	ISO/IEC 17065:2012 (E)—Conformity Assessment—Requirements for Bodies Certifying Products, Processes and Services (First Edition), September 2012	Maintain

Key Takeaways

- All the regulated areas supported by the 55 referenced standards have ongoing need for continued support through established standards.
  - No standard references should be retired without a suitable replacement and transition plan.
  - Regular reviews and updates are necessary to continue advancing capabilities for these regulated areas.

- Recommending only whether to Maintain or Phase-Out a reference to a standard would have been insufficient to address the intent of the Task Force's charter. This led the Task Force including a rationale for the recommendation with a focus on viable alternatives for ONC to consider in future rulemaking. The Task Force also added sub-categories distinguishing between phasing out because there is a viable alternative or that no reference to a standard is further necessary. The Task Force recommends this approach to be part of future task force assignments.

Key Takeaways (Continued)

- The Cures Act review process results in duplicative reviews: one review to identify references that may need updates and for which a reasonable update is available to determine whether to maintain the reference or not, and a second review at the time of preparing a subsequent rulemaking update to specifically identify the standard that should then be referenced in regulation. It is inefficient to only be able to discuss retiring references to standards without considering viable replacements at the same time.

- The Task Force understands that the SVAP process enables voluntary adoption of interoperability standards by certified HIT developers before future regulations would raise the floor for all. This process may inadvertently create interoperability challenges where a new version is not fully backwards-compatible and/or not all trading partners adopt the same SVAP-included interoperability standards.

- A couple of referenced standards and viable alternatives were not available at no cost to Task Force members, limiting the ability perform a review by all members. Presentations by subject matter experts enabled productive discussions and review.

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Discussion

HITAC Vote