

HITSP

Healthcare Information Technology Standards Panel

Report on HITSP/TN905 – Safe? Effective? Say what?!

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THE WHITE HOUSE
PRESIDENT
GEORGE W. BUSH

For Immediate Release
Office of the Press Secretary
August 22, 2006

Executive Order:

Promote Quality and Efficient Health Care in Federal Government
Administered or Sponsored Health Care Programs

Sec. 3. Agencies shall perform the following functions:

Health Information Technology -

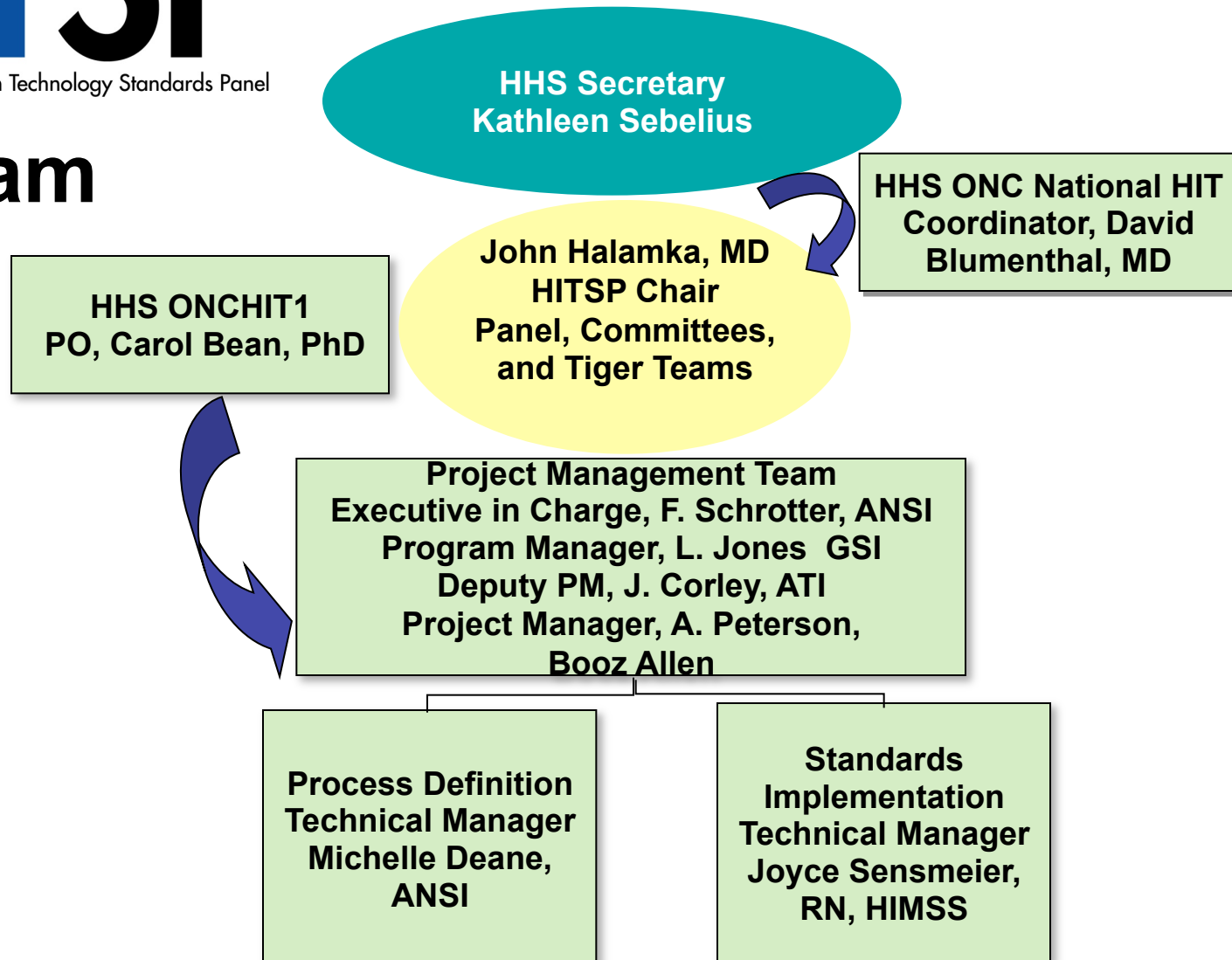
For Federal Agencies. As each agency implements, acquires, or upgrades health information technology systems used for the direct exchange of health information between agencies and with non-Federal entities, it shall utilize, where available, health information technology systems and products that meet recognized interoperability standards.

HITSP- Harmonized standards promote interoperability, enhance healthcare quality and contain costs

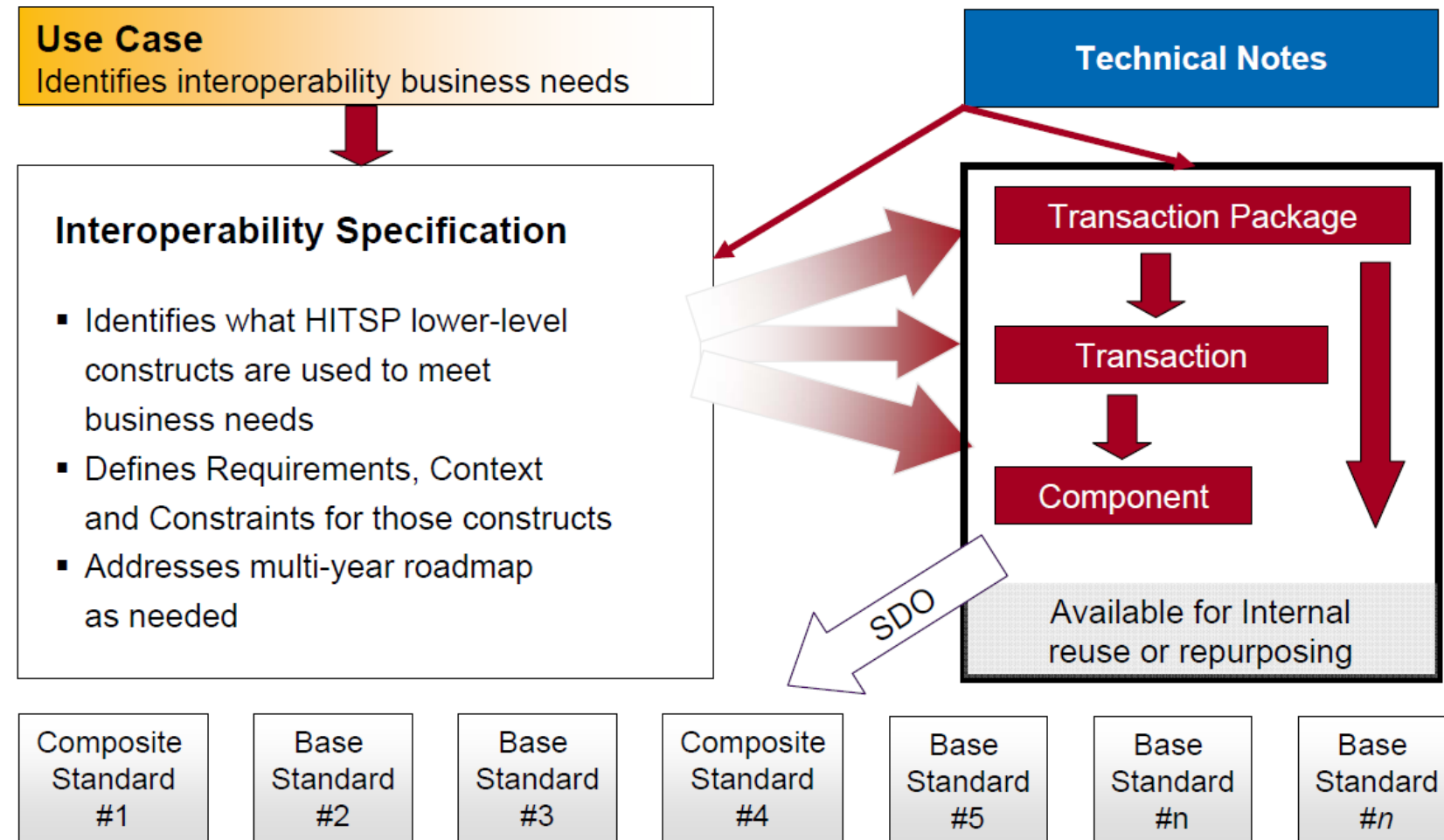


HITSP – *enabling healthcare interoperability*

Team



Harmonization Framework



HITSP Priorities and Use Case Roadmap

AHIC Priorities and Use Case Roadmap

2006	2007 Use Cases		2008 Use Cases		2009 Use Case
Consumer Empowerment <ul style="list-style-type: none"> •Registration •Medication History 		Consumer Access to Clinical Information <ul style="list-style-type: none"> •Access to Clinical Data •Provider Permissions •PHR Transfer 	Remote Monitoring <ul style="list-style-type: none"> •Remote Monitoring of Vital Signs and Labs (Glucose) 	Patient – Provider Secure Messaging <ul style="list-style-type: none"> •Structured email •Reminders 	Newborn Screening
EHR (Lab) <ul style="list-style-type: none"> •Laboratory Result Reporting 	Emergency Responder EHR <ul style="list-style-type: none"> •On-Site Care •Emergency Care •Definitive Care •Provider Authentication and Authorization 	Medication Management <ul style="list-style-type: none"> •Medication Reconciliation •Ambulatory Prescriptions •Contra-indications 	Consultations and Transfers of Care <ul style="list-style-type: none"> •Referrals •Problem Lists •Transfer of Care 	Personalized Healthcare <ul style="list-style-type: none"> •Laboratory Genetic / Genomic Data •Family Medical History 	2009 Use Case Ext/Gaps
Biosurveillance <ul style="list-style-type: none"> •Visit •Utilization •Clinical Data •Lab and Radiology 		Quality <ul style="list-style-type: none"> •Hospital Measurement and Reporting •Clinician Measurement and Reporting •Feedback to Clinicians 	Public Health Case Reporting <ul style="list-style-type: none"> •Case Reporting •Bidirectional Communication •Labs •Adverse Events 	Immunizations & Response Management <ul style="list-style-type: none"> •Resource Identification •Vaccine •EHR Data 	Medication Gaps
					Common Device Connectivity
					Clinical Encounter Notes
					Order Sets
					Scheduling
					Common Data Transport
					Consumer Preferences
					Medical Home: Co-Morbidity and Registries
					Maternal and Child Health
					Long Term Care - Assessments
					Prior Auth for Treatment, Payment, & Operations
					Consumer AE Reporting



2009 – Obama vows to continue the HIT Plan begun by President Bush

- President Barack Obama announces an audacious plan: *Computerize all health records within five years.*

- January 12, 2009



- February 17, 2009 – the American Reinvestment and Recovery Act (ARRA) is signed into law
 - HITECH Act component of ARRA provides a \$19 billion program to stimulate the adoption and use of HIT, with a focus on meaningful use of certified EHR-S



What about device connectivity?

HITSP Device Connectivity Technical Note

HITSP/TN905



Why a Technical Note?

- **Lack of medical device literacy in general HIT community**
- **Multiple sources of HITSP device connectivity requirements – some overlapping, some missing**
- **Lack of understanding about regulatory ... *opportunities!***
- **Safety? Effectiveness? Huh?!**



HITSP Device Connectivity Technical Note

HITSP/TN905

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1.6.3 ADDITIONAL DEFINITIONS

1.6.3.1 MEDICAL DEVICE

The U.S. Food and Drug Administration (FDA) provides the following descriptions of medical devices⁴:

"An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:



HITSP Device Connectivity Technical Note

HITSP/TN905 2.0 ARRA/HITECH AND DEVICE INFORMATICS

Table 2-1 ARRA/HITECH References for Device Connectivity

ARRA/HITECH Ref	Key Deliverable	Specific Requirement
Section 3002(b)(2)(C)(iv)	Monitoring of Patients	Technologies that facilitate home healthcare and the monitoring of patients recuperating at home
Section 3002(b)(2)(C)(v)	Medical Errors	Technologies that help reduce medical errors
Section 3001(b)(3)	Inefficiency and medical errors	Reduces healthcare costs resulting from inefficiency, medical errors, inappropriate care, duplicative care, and incomplete information
Section 3002(b)(2)(C)(x)	Efficiency	Any other technology that the HIT Policy Committee finds to be among the technologies with the greatest potential to improve the quality and efficiency of healthcare
Section 3017(a)(2)	Safety	An analysis of the impact of the project on healthcare quality and safety
Section 3001(b)(9)	Chronic Care	Promotes early detection, prevention, and management of chronic diseases;
Section 3011(a)(4)	Telemedicine	Infrastructure and tools for the promotion of telemedicine, including coordination among Federal agencies in the promotion of telemedicine



HITSP Device Connectivity Technical Note

HITSP/TN905 2.0 ARRA/HITECH AND DEVICE INFORMATICS

Table 2-2 Meaningful Use Matrix Device Connectivity Requirements

Outcome	Year	Objective/Measure	Requirement
Improve quality, safety, efficiency, and reduce health disparities	2015	Goal is to achieve and improve performance and support care processes on key health system outcomes	Medical device interoperability
			Implement clinical decision support for national high priority conditions
	2013	Goal is to electronically capture in coded format and to report health information and to use that information to track key clinical conditions	Conduct closed loop medication management, including eMAR and computer-assisted administration
			Use clinical decision support at the point of care (e.g., reminders, alerts)
Engage patients and families			Implemented ability to incorporate data uploaded from home monitoring devices
Improve care coordination	2013/2015	Goal is to facilitate the coordination of care across all providers serving a patient or a particular medical condition for the patient	Access comprehensive patient data from all available electronic sources on a timely basis



- ☐ **General Considerations**
- ☐ **Application Integration**
- ☐ **Clinical Pathways and Workflow**
- ☐ **Highly-Integrated Patient-Centric
Point-of-Care & “ICE”**



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✓ **Content provides a “heads up” only!**



Charting a path forward...

- ✓ **Consolidated list of connectivity requirements**
- ✓ **Roadmap section charts a course for meeting device connectivity requirements**
- ✓ **“Gaps” table identifies foundational deliverables + time frame + organizations**
- ✓ **Not included: *Addressing regulatory issues!***



Regulatory issues NOT considered in the roadmap...

- ✓ **Education ... especially HIT community**
- ✓ **CE-IT Convergence + 80001 ...**
- ✓ **Regulatory model for safe & effective enterprise heterogeneity**
- ✓ **Ensure ONC/HITSP Capabilities & Constructs support safe & effective interoperability**



Thanks to key contributors...

- ✓ **John Donnelly (HITSP Facilitator)**
- ✓ **Ken Fuchs**
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- ✓ **John Zaleski**

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www.HITSP.org => View All Documents**



Questions?

