The Changing Health Care Delivery Landscape
Implications for Supply Chain

Natalia Wilson, MD, MPH

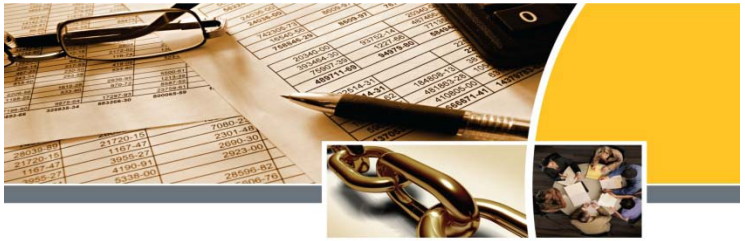
Co-director HSRC-ASU

November 16, 2011

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS

ARIZONA STATE UNIVERSITY

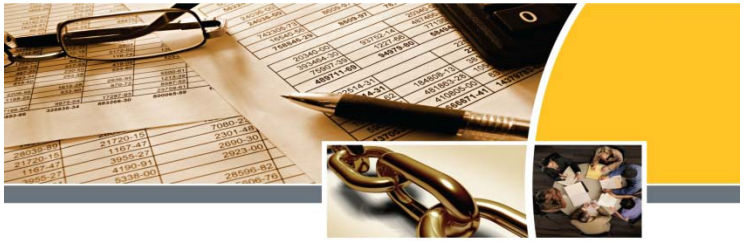


The Changing Face of Health Care

- Regulatory changes
- Refocus of the patient in the center
- Focus on quality, safety, value, efficiency & accountability

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY

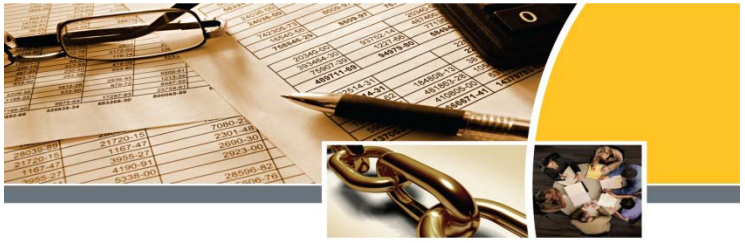


The Changing Face of Health Care – Supply Chain Moving Forward

- Regulatory drivers
- New models & priorities
- Focus on IT & data
- Data Standards
- Clinical integration
- Relationship building & new relationships
- Collaboration & trust
- Global expansion & global considerations

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

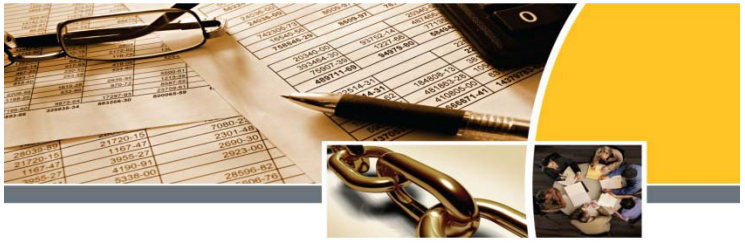
ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY



Regulatory Change

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY

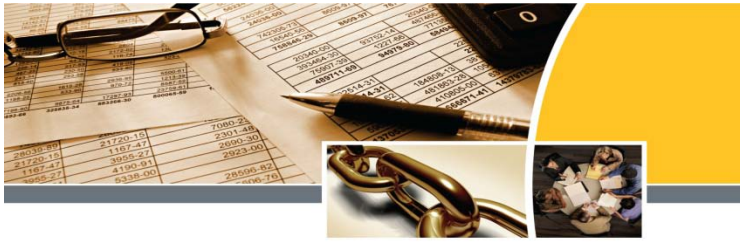


Regulatory Changes

- 2007 FDA Amendments Act
- American Reinvestment & Recovery Act 2009
  - HITECH Act
  - Appropriation for CER
- Affordable Care Act 2010

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY



2007 FDA Amendments Act

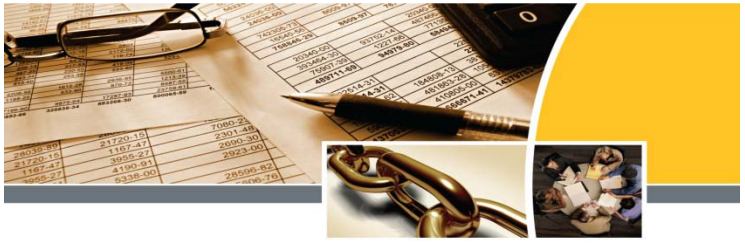
- Directed FDA to develop a unique device identification (UDI) system
- Draft rule expected at any time
- Final rule will require manufacturers to assign unique identifiers to all marketed devices

U.S. Food and Drug Administration. Medical Devices. Unique Device Identification. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentifiers/default.htm

Federal Register Volume 76, Number 130 (Thursday, July 7, 2011) http://www.gpo.gov/fdsys/pkg/FR-2011-07-07/html/2011-15487.htm

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS ARIZONA STATE UNIVERSITY

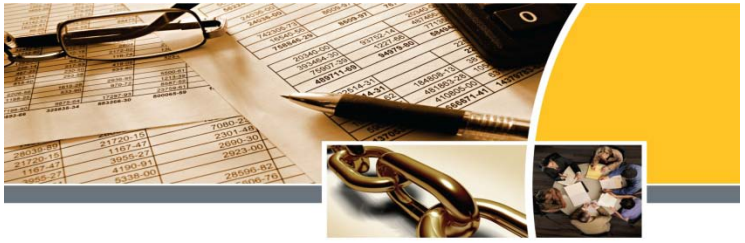


FDA UDI Initiative

- Components of UDI
  - Device Identifier (DI): [static] Manufacturer, make, model [i.e., each catalogue number]
  - Production Identifier (PI): [dynamic] however product is currently controlled – serial, lot number; expiration, manufacturing date

Jay Crowley, Senior Advisor for Patient Safety, FDA

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM
ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY



FDA UDI Initiative

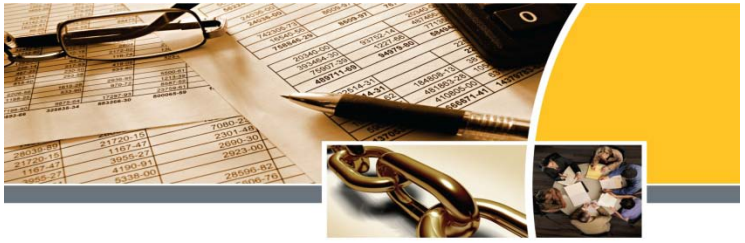
- Will start with Class III devices
- Timeline:
  - –class III – 12 months after final rule (implants)
  - –class II – 36 months after final rule (equipment)
  - –class I – 60 months after final rule (disposables)

U.S. Food and Drug Administration. Medical Devices. Unique Device Identification http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification

Jay Crowley, Senior Advisor for Patient Safety, FDA

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS ARIZONA STATE UNIVERSITY



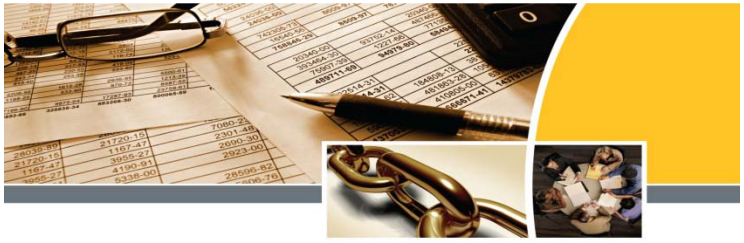
FDA UDI Initiative

- FDA developing a Unique Device Identification database (UDID)
- Will contain extended product attributes
- Discussion about appropriate attributes ongoing
- Pilots have been done to assess manufacturer and provider thoughts

U.S. Food and Drug Administration. Medical Devices. Unique Device Identificationhttp://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY



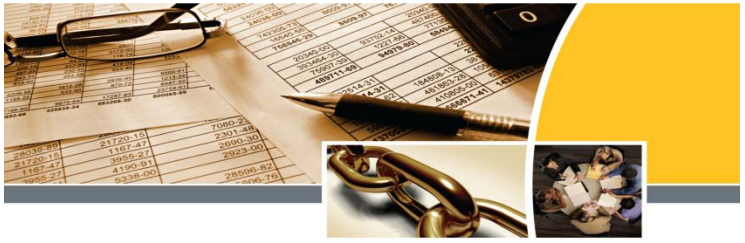
Global Level

- FDA involved on global level to achieve global harmony surrounding UDI
- Global Harmonization Task Force (GHTF)
  - Final Guidance on UDI for Medical Devices available
- International Consortium of Orthopaedic Registries
  - FDA initiative
  - Goal = develop international registry network
  - Data for enhanced research, comparative effectiveness, patient care & safety

Global Harmonization Task Force http://www.ghtf.org/ahwg/ahwg-proposed.html

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY

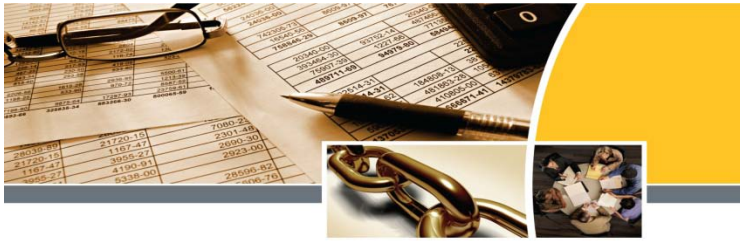


What will this do for SCM?

- Set the foundation for
  - Standard system to identify & record devices across supply chain & in hospital systems
  - Efficiency & transparency in transactions
  - Efficiency in recalls
  - Traceability
  - Standard for anti-counterfeiting
- Create the ability to link SC, clinical & finance

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY

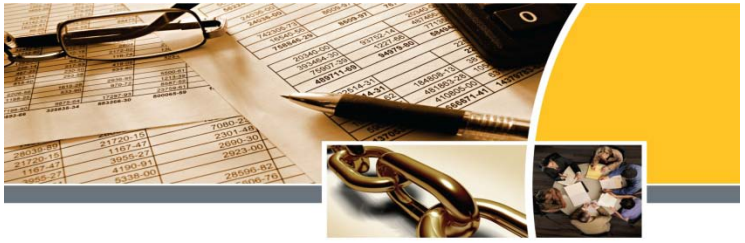


What will this do for clinical care?

- Set the foundation for
  - A standard to document devices used in patient care
  - A standard to identify implanted devices
  - A standard for device information @ point of use
  - A standard for input of device info into clinical registries
  - A standard for adverse event reporting & product recalls
  - A standard in post-market surveillance
- Facilitate quality, safety & efficiency

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY



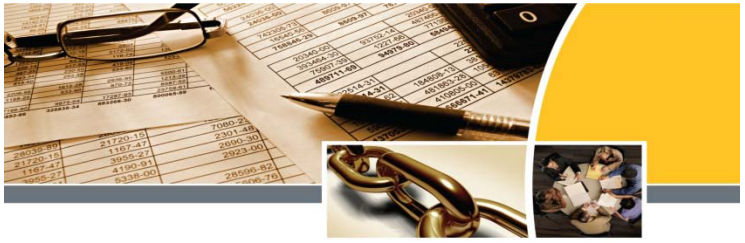
American Reinvestment & Recovery Act 2009 – HITECH Act

- $22.6b for adoption of HIT
- Goals = improve health care quality, safety, & efficiency thru use of HIT
- Stage 1 Meaningful Use criteria & incentives by Medicare & Medicaid

The Office of the National Coordinator for Health Information Technology . http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__home/1204

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS ARIZONA STATE UNIVERSITY



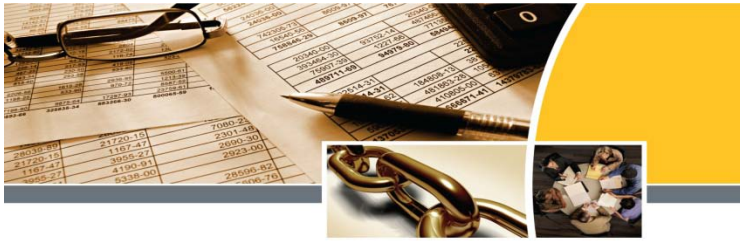
CMS EHR Meaningful Use

- Meaningful Use
  - Use of certified EHR in meaningful way
  - Use of certified EHR for electronic exchange of health info
  - Use of certified EHR to submit quality measures
- To qualify for incentive payments
  - Certified EHR vendor
  - Demonstrate meaningful use
  - Meet all core objectives
  - Meet required # menu objectives

CMS Meaningful Use EHR Overview. https://www.cms.gov/ehrincentiveprograms/30_Meaningful_Use.asp#BOOKMARK1

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS ARIZONA STATE UNIVERSITY

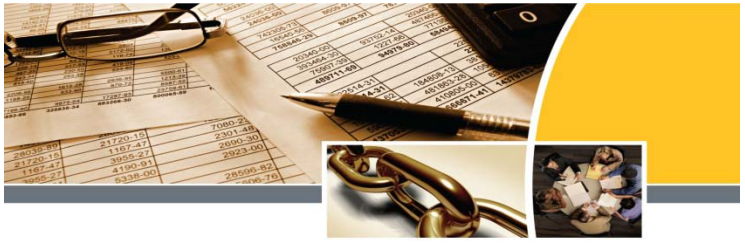


Impact on Health Care

- More comprehensive documentation
- Improved access to health information
- Opportunity for less medical error
- Better coordination of patient care
- Improved quality
- More efficiency…moving away from paper

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY

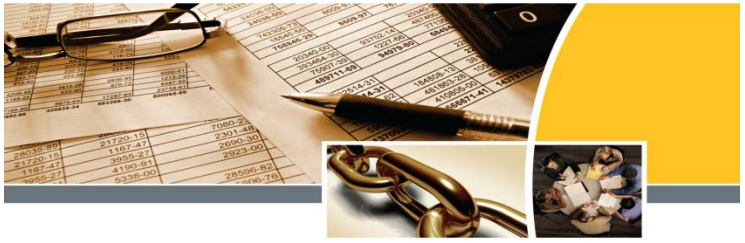


How will this impact supply chain?

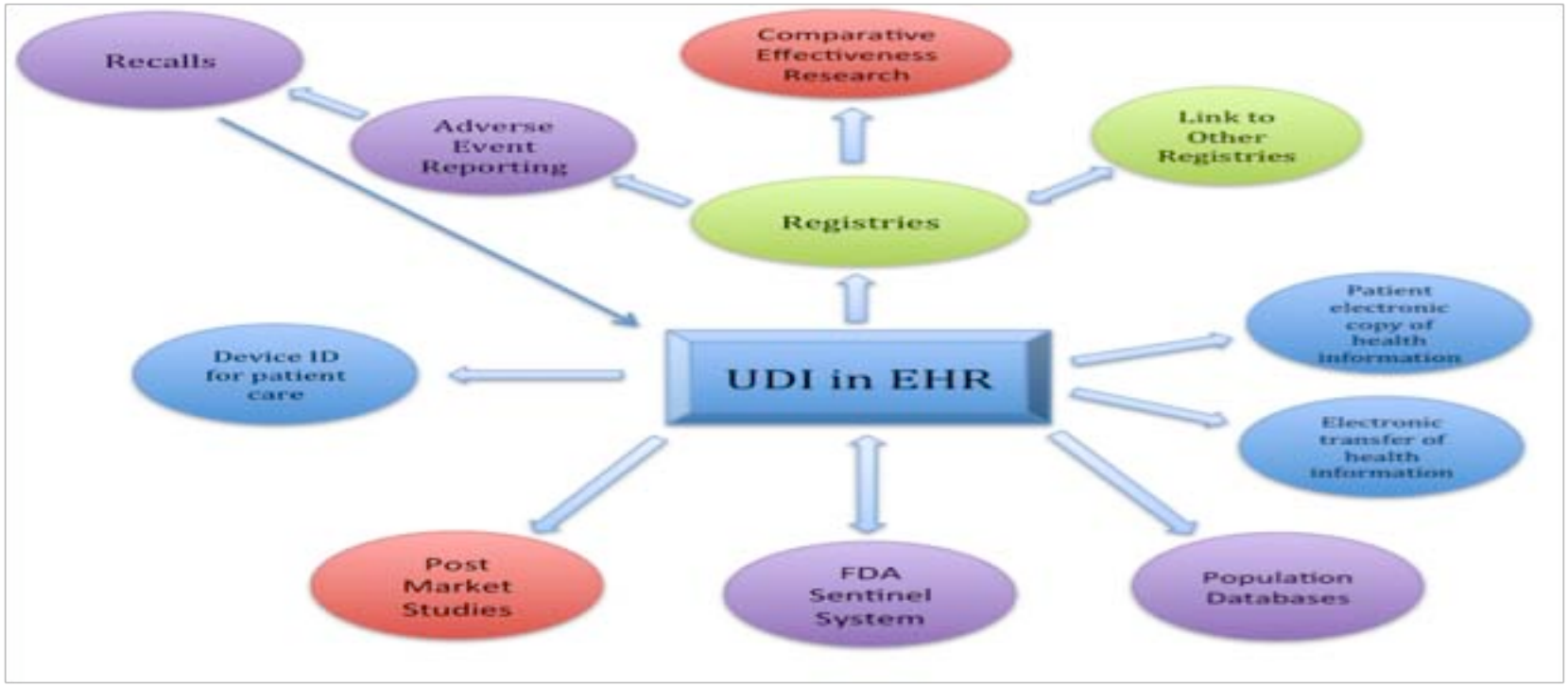
- Currently quite clinically focused
- Discussions on UDI in EHR as meaningful use criteria but unclear of status
  - Ability to link supply chain & clinical systems
  - Ability to access EHR for device info in recall
  - Ability for much expanded data analytics

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY

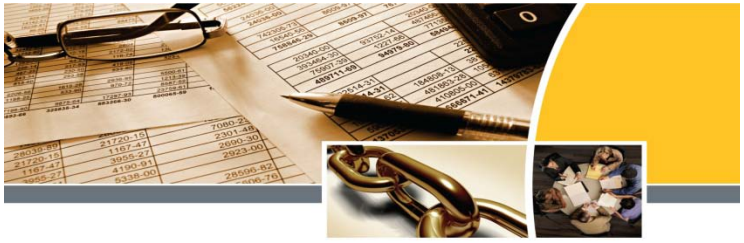


How will this impact supply chain?



HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY



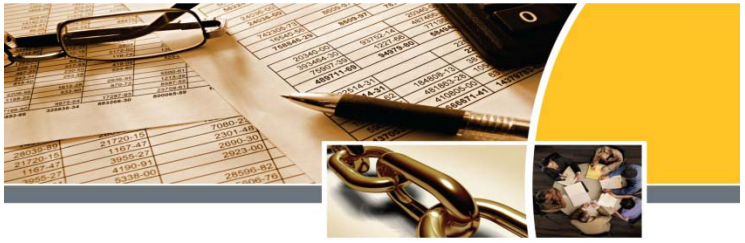
American Reinvestment & Recovery Act 2009 - CER

- Appropriated $1.1b for CER
  - $300m to AHRQ
  - $400m to NIH
  - $400m to Office of Secretary of HHS
- Established Federal Coordinating Council for CER
- Institute of Medicine Top 100 Initial Research Priorities

Text of Recovery Act Related to Comparative Effectiveness Funding. http://www.hhs.gov/recovery/programs/cer/recoveryacttext.html

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS ARIZONA STATE UNIVERSITY

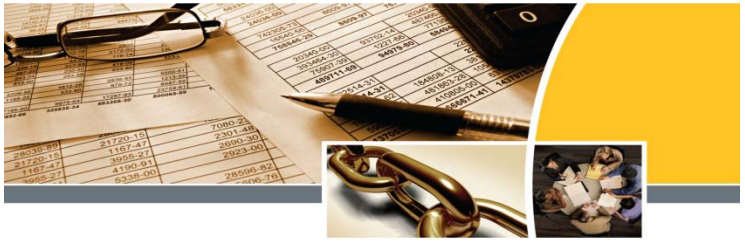


Plan for CER

- Funding for research on spectrum of treatments for clinical conditions
- Goals
  - Fill in Gaps in clinical knowledge
  - Rigorous comparison of different treatment options
  - Make more “real world”

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY



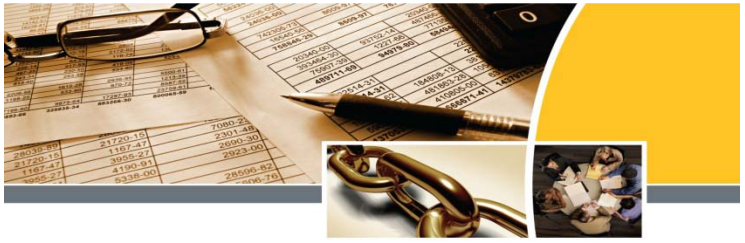
Definition of CER

"Comparative effectiveness research is the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in "real world" settings."

Federal Coordinating Council for Comparative Effectiveness Report to The President & The Congress. June 30, 2009

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY

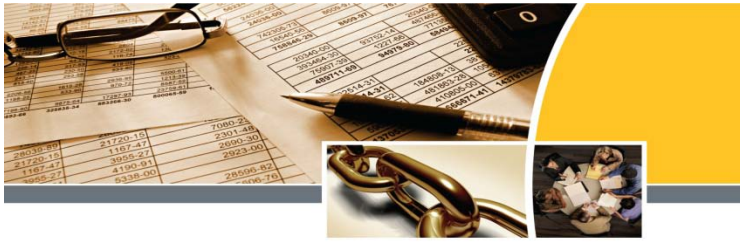


Potential Impact on Health Care

- Fill in gaps in clinical knowledge
- Expand use of EBM in decision-making
- Put focus on clinical practice patterns & respective products that are grounded in EBM
- Consider EBM, quality, cost together
- Opportunity to return to patient-centered health care across the spectrum

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY

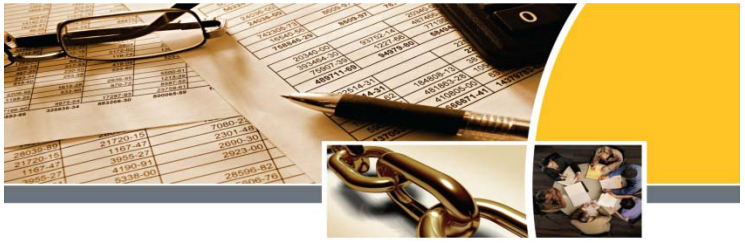


Implications for supply chain

- Supply chain & collaboration
  - Organizational
  - Physician engagement
  - Suppliers
- Requirements for evidence basis & evidence of value
- Guide purchasing
  - Contracting based on EBM
  - Clinical outcomes as part of contract?
- New model for innovation

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY



Affordable Care Act

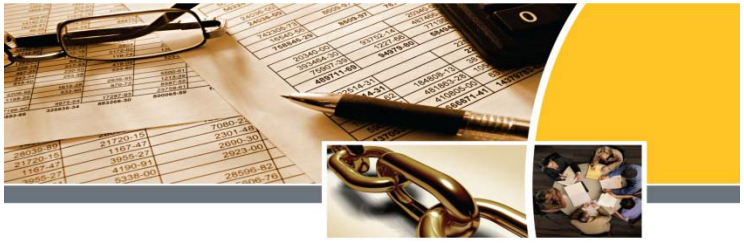
- Components
  - Increase access
  - Insurance regulation
  - Cost-containment
  - Improved quality
  - Improved public health
- Created the Patient Centered Outcome Research Institute (PCORI)
- Medical Device Tax

HealthCare.gov http://www.healthcare.gov/law/introduction/

http://healthreform.kff.org/Timeline.aspx

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS ARIZONA STATE UNIVERSITY

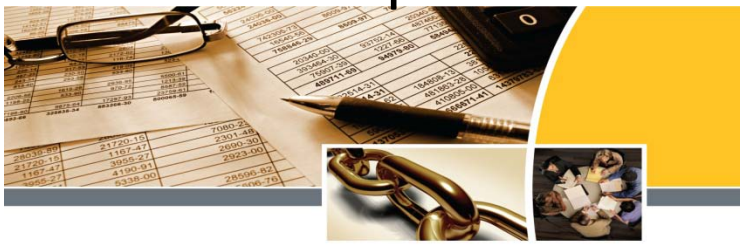


Accountable Care Organizations

- Group of providers (hospitals, physicians, others) working together to care for patients across care settings
- Accountability for quality, cost & overall patient care
- Goals = not fragmented care, patient-centered, EBM
- Can share savings if meet quality & performance standards and per capita cost
- But if don't provide effective cost-efficient care responsible for pay back
- Efficiency, value, good data, collaboration important

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY



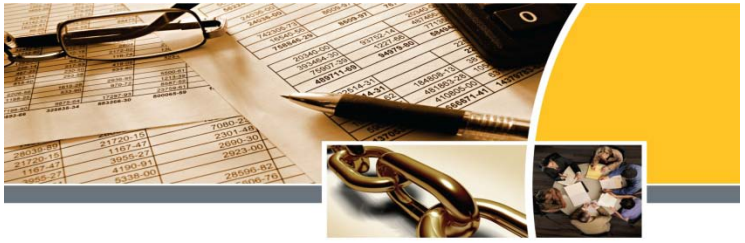
Bundled Payments

- CMS Innovation Center seeking applicants for 4 bundled payment models
  - Payments bundled for multiple services & providers during patient's episode of care
  - Gainsharing may be involve
- SC opportunity for supply chain-clinical interface through data, evidence

CMS Innovation. http://innovations.cms.gov/areas-of-focus/patient-care-models/bundled-payments-for-care-improvement.html

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY

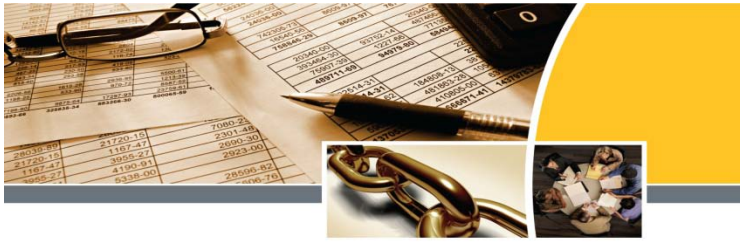


Value Based Purchasing

- Hospitals eligible for value-based incentive payments starting FY2013
- Funded by 1% reduction in DRG payments
- 70% determined by clinical process of care measures
- 30% determined by patient experience of care measures
- Clinical focus

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY

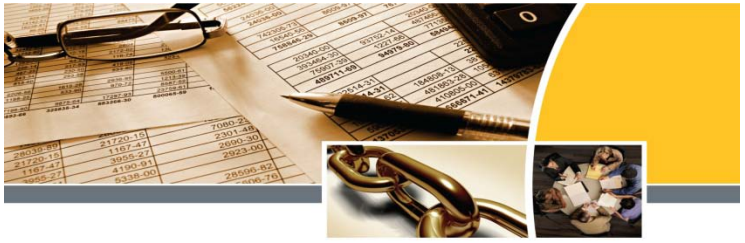


Value Based Purchasing – Implications for Supply Chain Moving Forward

- Consideration of clinical outcomes & care given including products used
- New relationships across the supply chain and into the clinical realm to realize this
- Moving beyond just price of products to consideration of products, process and outcomes

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY



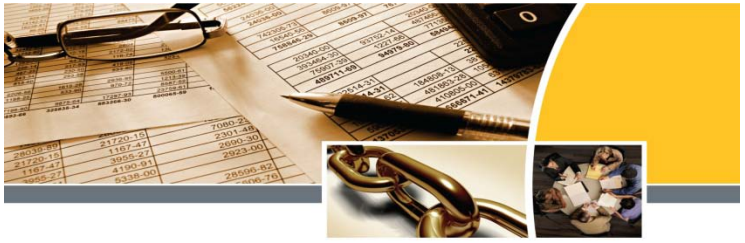
Patient Centered Outcomes Research Institute (PCORI)

- Permanent structure for CER
- Duties: research agenda, standards, award contracts, public input, dissemination
- CMS data & registry data made available to researchers
- Evidence basis for clinical care
- Registry data involving devices allows CE between devices

http://www.pcori.org/

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY

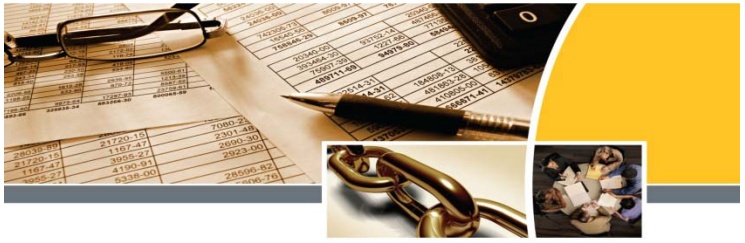


Medical Device Tax

- 2.3% excise tax on sale of taxable medical devices
- Roll out 2013
- Lots of controversy

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY

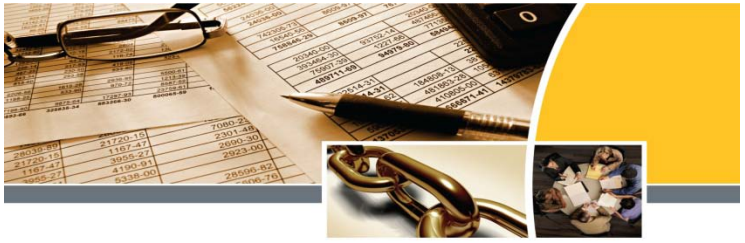


Other Considerations

- Co-management
- Increasing employment of physicians by hospital systems
- Increased focus on physician-industry relationships
  - Sunshine Act
  - Conflict of interest statements

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY

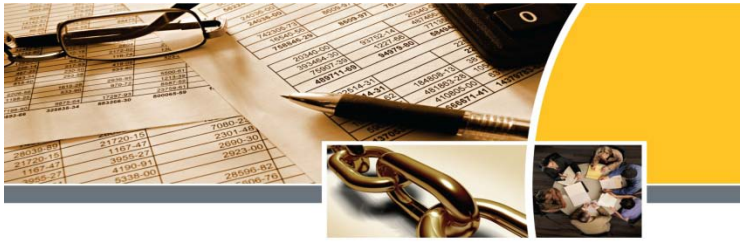


The Changing Face of Health Care - Supply Chain Moving Forward

- Regulatory drivers
- New models & priorities
- Prominence of IT & data
- Data Standards
- Clinical integration
- Relationship building
- Collaboration & trust
- Global expansion & global considerations

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY



Thank you!

Natalia.wilson@asu.edu

Our website:

http://wpcarey.asu.edu/hsrc

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY