AMIA Public Policy and Government Relations Update

Meryl Bloomrosen, Vice President, Public Policy AMIA
Margo Edmunds, Chairperson, AMIA PPC
Leslie Irvine, Washington Health Strategies Group

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Today’s Discussion Topics

1. Congressional Update
2. Upcoming Regulatory Activities
3. Requests for Comment and Information
4. Update on Legislation and Potential Implications for AMIA
5. AMIA PPC Activities
6. Ongoing Hot Topics HIT/Informatics
7. Outreach and Collaborative Activities
8. Information and Resources
1. Congressional Update: 2012 Hill Day

• Coincided with AMIA BOD meeting (April)
• Panel Discussions
  • Senate Staff – Health, Education, Labor and Pensions (HELP) and Finance Committee
  • Federal Agency Staff- FDA, NIST, ONC, NIH
• Meetings:
  • 16 Meetings in Member offices
• Scheduling follow-on meetings
2. Upcoming Regulatory Activities

- Health Information Technology for Economic and Clinical Health Act (HITECH) Omnibus Final Rule: privacy revisions, security, enforcement, breach notification (not Accounting of Disclosures)
- De-identification guidance from Office of Civil Rights (OCR)
- Data segmentation initiative
- Comprehensive privacy and cybersecurity legislation-HIPAA carve-out language
- ICD-10 implementation
3. Requests for Comments and Information

- CMS and ONC Meaningful Use Stage 2 – Submitted May 7
- ONC Nationwide Health Information Network (NwHIN) Request for Information – due June 29
3. Requests for Comments and Information: NwHIN

Set of standards, services, and policies that enable secure health information exchange over the Internet

- Creation of a voluntary program under which entities that facilitate electronic health information exchange could be validated with respect to their conformance to certain ONC-established ‘conditions for trusted exchange (CTEs)
- The scope and requirements included in the initial CTEs
- The processes that could be used to revise, adopt new, and retire CTEs
- A process to classify the readiness for nationwide adoption and use of technical standards and implementation specifications to support interoperability related CTEs
3. Requests for Comments and Information: NwHIN cont

- Nationwide Health Information Network Validated Entities (NVEs)
- 16 proposed Conditions of Trusted Exchange (CTEs)
  - 10 Safeguards – 3 Interoperability – 3 Business Practices
  - CTEs S-3 and S-10 would have the effect of requiring Consent for uses/disclosures via an NVE, including uses/disclosures for treatment, payment and healthcare operations (TPO).
  - CTE S-6 would prohibit the use or disclosure of de-identified health information by an NVE “for any commercial purpose”
  - CTEs S-8 and S-9 would provide access and annotation/correction rights for individuals to any “unique IIHI” aggregated by an NVE

Comments due to ONC by June 29
4. Update on Legislation and Potential Implications for AMIA

- Supreme Court decision on the Affordable Care Act (ACA) is imminent; Supreme Court heard challenges on federalism and commerce clause grounds, (special attention focused on the Individual Mandate on March 26-28)

- Independent Payment Advisory Board (IPAB) a very hot issue with Republicans and some Democrats looking to scuttle before it begins
4. Update on Legislation and Potential Implications for AMIA

- HR 3239: Safeguarding Access For Every Medicare Patient Act
- Hatch-Bennet PDUFA Amendment - FDA User Fees Reauthorization
- Rep. Ellmers letter on HIT oversight at HHS
- HIT Standards and Policy Committees continue to weigh in on a broad range of topics, from MU to ACOs
4. Prescription Drug User Fee Act (PDUFA)

- Authorizes FDA to collect fees from companies that produce certain human drug and biological products. The House and Senate have passed their respective versions of “PDUFA V.” The two bills, S. 3187, “The Food and Drug Administration Safety and Innovation Act” in the Senate and H.R. 5651, “Food and Drug Administration Reform Act of 2012”.

- Senate bill, Section 616 details that the would need to convene a working group of stakeholders and then submit a report to Congress. Puts an 18 month “de facto moratorium” on rulemaking in regards to mobile medical applications.

- House bill takes a broader look at HIT, including mobile medical applications. In Section 773 of the House, HHS would be required to collaborate with the FDA, ONC and the FCC to submit a regulatory strategy to Congress within 18 months of passage. However, the House bill does not preclude FDA from issuing the mobile applications guidance

4. HIT Oversight at HHS

Rep. Renee Ellmers (R-N.C.) sent a letter to HHS Secretary Kathleen Sebelius asking whether HHS has taken steps to create a federal agency to oversee safety of health IT systems, as recommended in the 2011 IOM report "Health IT and Patient Safety: Building Safer Systems for Better Care"

5. AMIA Public Policy Committee

- 2012 Work Plan
  - Engage Membership
  - Develop DRAFT 2013 Public Policy Priorities for BOD
  - Create Policy Issue Briefs
  - Maintain and Update Web Site
6. Ongoing Hot Topics

- Meaningful Use 2
- Breach reporting – a new case every day
- HIPAA enforcement by state Attorneys General
- HIPAA enforcement on BAs
- Administration's Privacy Bill of Rights
- “The learning healthcare system”
- “Big Data" in health care
- Workforce and education/training issues
- Quality initiatives: bundled payments, medical home, ACOs
- Comparative effectiveness research (CER)- PCORI
- Patient safety and HIT
- Consumer engagement
7. AMIA Public Policy Collaboration

Activities

• Patient Identity Coalition
• ICD-10 Coalition
• Confidentiality Coalition
• National Priorities Partnership (NPP)
  • CMS Partnership for Patients (PfP)
    [http://innovations.cms.gov/initiatives/Partnership-for-Patients/index.html](http://innovations.cms.gov/initiatives/Partnership-for-Patients/index.html)
• (NIH) Public Private Sector Partnership on mHealth
8. Public Policy Information and Resources

• Agency Announcements
• Meetings
• Publications
• Funding Opportunities
8. Public Policy Information and Resources

- **AHRQ Seeks Volunteers for ICD-10 Workgroups.** The Agency for Healthcare Research and Quality is seeking volunteers to serve on one of about 10 workgroups to advise on converting AHRQ Quality Indicators from ICD-9-CM to ICD-10-CM/PCS. See: [https://www.federalregister.gov/articles/2012/06/04/2012-13306/ahrq-workgroups-on-icd-10-cmpcs-conversion-of-quality-indicators-qis](https://www.federalregister.gov/articles/2012/06/04/2012-13306/ahrq-workgroups-on-icd-10-cmpcs-conversion-of-quality-indicators-qis)

- **AHRQ Toolsets to Help Pharmacists and Physicians Implement E-Prescribing.** Two toolsets, one for physicians in small practices and one for independent pharmacies, for supporting e-prescribing implementation are now available

- **AHRQ Hazard Tracker Final Report.** The Hazard Manager is a tool to proactively identify and categorize health IT hazards. The Final Report discusses the development process, testing, and considerations for national deployment of such a tool. [http://healthit.ahrq.gov/portal/server.pt/community/ahrq_national_resource_center_for_health_it/650](http://healthit.ahrq.gov/portal/server.pt/community/ahrq_national_resource_center_for_health_it/650)
8. Public Policy Information and Resources


8. Information and Resources

- **ONC** has created two new offices—the Office of the Chief Medical Officer (CMO) and the Office of Consumer eHealth.

- **ONC** launched its new standards and interoperability framework, for Clinical Decision Support (CDS) - Health eDecisions.
  
  [http://wiki.siframework.org/Health+eDecisions+Homepage](http://wiki.siframework.org/Health+eDecisions+Homepage)
8. Public Policy Information and Resources

• Institute of Medicine (IOM) Releases a CEO Checklist for High-Value Health Care. Released an IOM Discussion Paper that offers the personal views and experiences (with supportive case material) of the authors, and presents what they've learned about the key components of care that both improves outcomes and lowers costs. www.iom.edu/CEOChecklist

• IOM Workshop on the Role of Telehealth In An Evolving Health Care Environment. Workshop will be held on August 8-9, 2012 in Washington, DC. An IOM panel will examine how the use of telehealth technology can fit into the U.S. health care system. services. http://iom.edu/Activities/HealthServices/Telehealth.aspx
8. Public Policy Information and Resources

- **Office for Civil Rights (OCR) Memo on Patients' Legal Rights To Access Health Data.** OCR released a memo and a Youtube video to help patients understand their legal right to access their health information. See: [http://www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/righttoaccessmemo.pdf](http://www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/righttoaccessmemo.pdf) [http://www.youtube.com/watch?v=JY1l5s8ED5c](http://www.youtube.com/watch?v=JY1l5s8ED5c)

- **OCR Releases Findings from Privacy and Security Audits**
8. Public Policy Information and Resources

• Centers for Medicare and Medicaid Services (CMS) Data and Information Initiative. New data and information initiative as part of the agency’s evolution from a fee-for-service based payer to a value-based purchaser of care. The initiative will be administered through a new Office of Information Products and Data Analytics (OIPDA) that will oversee CMS’s portfolio of data and information.

• Website to Clarify Health Information Laws. Developed at George Washington University's Hirsh Health Law and Policy Program, Health Information and the Law with support from the Robert Wood Johnson Foundation, and is designed to serve as a practical online resource to federal and state laws governing access, use, release, and publication of health information www.HealthInfoLaw.org.
8. Public Policy Information and Resources


- Observational Medical Outcomes Partnership (OMOP) is a multi-year research initiative managed by the Foundation for the National Institutes of Health (FNIH) that has developed a network of administrative claims and electronic health records databases and established a community of methodologists to test the feasibility and utility of large-scale observational analyses. The third annual OMOP Symposium will be held on June 28, 2012 in Bethesda, Maryland http://omop.fnih.org/
8. Information and Resources: Funding Opportunities

- Health Resources and Services Administration (HRSA) National Coordinating Center for Interprofessional Education and Collaborative Practice. to help accelerate teamwork and collaboration among health professionals by developing and evaluating interprofessional education programs, and identifying and disseminating best practices and lessons learned.
  http://www.grants.gov/search/search.do;jsessionid=h15tPJ3WbVRSr7wKc4GWvp7I9p8pQLxj3VVT226gK62hQtfjDSD6!-253887325?oppId=173954&mode=VIEW

- Department of Agriculture Announces Funding To Improve Health and Safety, and Increase Educational Opportunities in Rural Communities. Funding for 52 distance learning and telemedicine projects that will increase access to healthcare and enhance educational opportunities in 29 states.
8. Information and Resources: Funding Opportunities

- **Innovative Health Information Technology for Broad Adoption by Healthcare Systems and Consumers (SBIR) (R44) PA-12-196** invites Small Business Innovation Research (SBIR) applications from small business concerns (SBCs) to develop and disseminate evidence-based health information technology (health IT) products that have the potential to 1) prevent or reduce the risk of cancer, 2) facilitate patient-provider communication, and/or 3) improve disease outcomes. [http://grants.nih.gov/grants/guide/pa-files/PA-12-196.html](http://grants.nih.gov/grants/guide/pa-files/PA-12-196.html)

- **Community Transformation Grant (CTG) program** HHS announced available funding of $70 million to improve the health of small communities across the nation. [http://www.grants.gov/search/search.do;jsessionid=RgW1PFPFQshPqDGLW5sBW8ZQTmTpXQwjMLlqTy7zJdwfc1QLpXP!-1021879135?oppId=173114&mode=VIEW](http://www.grants.gov/search/search.do;jsessionid=RgW1PFPFQshPqDGLW5sBW8ZQTmTpXQwjMLlqTy7zJdwfc1QLpXP!-1021879135?oppId=173114&mode=VIEW)
8. Information and Resources

• **MedPAC Releases Reports to the Congress.** MedPAC has released its June 2012 Report to Congress. In addition, they have issued several Fact Sheets including MedPAC's mandated report on serving rural Medicare beneficiaries and MedPAC's congressionally requested report on home infusion therapy. For more information see: [http://www.medpac.gov](http://www.medpac.gov).
Questions? Comments?

Meryl Bloomrosen
http://www.amia.org/public-policy
meryl@amia.org
301 657-1291