Shifting Sands
How Policymakers Are Addressing the COVID-19 Pandemic and What It Means for Health Informatics Professionals

April 2, 2020
Health Informatics is the science of how to use data, information, and knowledge to improve human health, including the execution of scientific research, the delivery of health care services, and the promotion of public health.

AMIA is the multi-disciplinary, inter-professional home for 5,400+ health informatics experts.
Where AMIA Works

PRIMARY WORK SETTING

- Health System / Hospital: 37.2%
- Academia: 11.1%
- Non-Profit / Community: 6.3%
- Government / Military: 5.5%
- Industry: 4.8%
- Private Practice: 1.3%
- Health Plan: 33.9%
Working Groups of AMIA

- Biomedical Imaging Informatics
- Clinical Decision Support
- Clinical Information Systems
- Clinical Research Informatics
- Consumer and Pervasive Health Informatics
- Dental Informatics
- Education
- Evaluation
- Bioinformatics
- Ethical, Legal and Social Issues
- Genomics and Translational Global Health Informatics
- People and Organizational Issues

Intensive Care Informatics
Knowledge Discovery and Data Mining
Knowledge Representation and Semantics
Nursing Informatics
Open Source Student
Pharmacoinformatics
Primary Care Informatics
Public Health Informatics
Regional Informatics Action
Visual Analytics
Natural Language Processing
The Globe of Health Informatics & COVID-19

- Analysis of Coronavirus
- Development of Therapeutics and symptom identification
- Treatment of patients via EHRs & Information Exchange
- Tools for contact tracing and for study of transmission

DNA
Small Molecules
Disease
Patient
Practice
Population
Global

10^{-9} 10^{-6} 10^{-3} 10^{0} 10^{3} 10^{6} 10^{9}

TBI
CRI
Public Health
Clinical
Consumer Health
Panel

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Disclosure

Dr. Kannry and Mr. Smith have no relevant relationships with commercial interests to disclose.

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The Game Plan

• Health Informatics Policy
• Key provisions in recent legislation of importance to the health informatics community
• Key federal actions in response to COVID-19
• A discussion of what’s needed next from policymakers
Health Informatics Policy

A domain of public policy which seeks to:

- **Optimize** care delivery for **providers** & care experience for **patients**;
- **Improve** public and population health; and
- **Advance** basic and translational biomedical research through the science and tools of informatics
COVID-19 Legislative Updates
Big Picture

• Largest Stimulus package in US history
  • Spread across three bills (and counting)
    • H.R.6074 - Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 ($7.7B)
    • H.R.6201 - Families First Coronavirus Response Act ($104.8B in tax breaks)
    • H.R. 748 - Coronavirus Aid, Relief, and Economic Security (CARES) Act ($2.2T)
• Major funding implications for key agencies important to health informatics
  • NIH, FDA, CDC, NSF, CMS, FCC, VA
• Major programmatic and policy implications
  • HIPAA, 42 CFR Part 2, Medicare Telehealth authority
"Phase 1" Bill

- FDA – $61 million
- CDC - $2.2 billion
- NIH - $836 million
- Emergency Telehealth Waiver
  - Allows HHS to permit Medicare providers to furnish telehealth services to Medicare beneficiaries regardless of where the patient is located
Families First Coronavirus Response Act

"Phase 2" Bill

• Requires health plans to provide coverage for COVID-19 testing

• Provides a temporary increase to states’ federal medical assistance percentage (FMAP) for the duration of the public health emergency
"Phase 3" Bill

• Billions more in stimulus and supplemental appropriations for federal agencies

• Numerous new policy provisions
  • Clears way for telehealth provisions at CMS
  • Changes 42 CFR Part 2
  • Seeks Guidance on use of PHI during emergencies
Supplemental Appropriations

- Public Health and Social Services Emergency Fund - $88 billion
- CDC - $4.3 billion
  - $500M COVID-19 tools & state/local public health data surveillance infrastructure
- NIH - $945.5M for vaccine, therapeutic, and diagnostic research
  - NLM - $10M
  - NCATS - $36M
- CMS - $100 million
  - Infection control surveys for COVID-19
- VA - $19 billion
  - $2.25B for telework, telehealth, and call center capabilities
Policy Changes

• 42 CFR Part 2 Update
  • Patients can give consent to share records once, at which point data is shared within the health care system along HIPAA standards
  • Patients can revoke their consent if they choose

• Guidance on PHI – Section 3224
  • Requires the HHS to issue guidance (within 6 months) on what is allowed to be shared of patient record during the public health emergency related to COVID-19

• Removes cap for OTA during public health emergencies
  • Allows the Biomedical Advanced Research and Development Authority (BARDA) to more easily partner with private sector on research and development
COVID-19 Agency Updates

Telehealth
Telehealth: HIPAA Flexibilities

- HHS OCR will exercise "enforcement discretion" against covered health care providers during the public health emergency
  - Providers may use consumer technology, such as Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, or Skype
    - Facebook Live, Twitch, TikTok, and similar video communication applications are public facing, and should not be used
Telehealth: Reimbursement

- Per Phase 1 bill, Medicare will pay for office, hospital, and other visits furnished via telehealth across the country and including in patient's places of residence.
- CMS allowing private individual and small group market insurers to alter plans mid-year to expand or provide telehealth services.

- Interim CMS final rule permitting 80 additional telehealth services:
  - Audio-only visits
  - Inpatient rehab, hospice, and home health facilities
  - Remote patient monitoring
  - Prior provider-patient relationship no longer needed
Telehealth: Licensure

Generally, provider must be licensed in the state where the patient is located at the time of treatment.

- CMS has waived this requirement for Medicare patients
- States may request a waiver for Medicaid patients

HHS Secretary Azar sent letter to governors (3/24) urging them to modify licensure reqs to facilitate cross-border practice

- FSMB is tracking which states have relaxed requirements
- 29 states, DC, and Guam are currently members of Interstate Medical Licensure Compact
COVID-19 Agency Updates

HHS OCR/HIPAAFlexibilities
OCR: Other HIPAA Flexibilities

• Bulletin to ensure that HIPAA covered entities and their business associates are aware of the ways that patient information may be shared in an outbreak of infectious disease or other emergency situation

• Guidance explaining when a covered entity may disclose PHI (such as the name or other identifying information about individuals) to first responders without their HIPAA authorization

• Guidance on how health care providers can share information with the CDC, family members of patients, and others, to help address the COVID-19 emergency.
FDA Activities

- Guidance offering flexibility around clinical trial policies, including the possibility of virtual and phone visits for trial participants.
- Easing enforcement on “limited” modifications to the labeling claims of connected devices and clinical decision support software during pandemic.
- Giving states authority to authorize COVID diagnostic tests in their own states and said private labs can develop and use tests prior to FDA approval.
COVID-19 Regulatory Policy Updates

FCC Activities
FCC Activities

• Wireline Competition Bureau has temporarily waived the gift rules to enable service providers to offer, and Rural Health Care and E-Rate program participants to solicit and accept, improved connections or additional equipment for telemedicine

• COVID-19 Telehealth Program to distribute the $200 million (from Phase 3 bill) to providers who need assistance purchasing IT and internet, as well as paying for new technology to engage patients.
COVID-19 Regulatory Policy
Updates

CDC Activities
CDC Activities

National Healthcare Safety Network (NHSN) released Patient Impact and Hospital Capacity Module within NHSN’s Patient Safety Component.

• Enables hospitals to report daily counts of patients with suspected and confirmed COVID-19 and current use and availability of beds and ventilators.
• NHSN will let state and local health departments gain immediate access to the COVID-19 data for hospitals in their jurisdictions.
  • Data submitted to NHSN will be used by CDC’s response and by the HHS’ COVID-19 tracking system.
Trends & Outlook
April 2, 2020
Things to Watch on the Policy Front

- Section 3224 on HIPAA Data Sharing during emergencies
- Direct-to-Consumer Testing
- ONC and CMS Interoperability Rules
  - OMB just concluded review of the OIG Info Blocking Penalty Proposed Rule
- COVID-19 Case Reporting, Tracking, and Tracing
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This webinar series is designed to share informatics responses and discuss informatics challenges to the COVID-19 pandemic:

- The series will highlight how the informatics community is addressing this global pandemic from all angles.
- Panelists will share their informatics experience in specific domains, including the challenges and solutions that they have developed and implemented within their institutions.
Several additional webinars are being planned to highlight members of AMIA and the informatics community.

- Next Webinar: April 7 @ 10am
- Managing the Global COVID-19 Pandemic with Health Informatics – Successes and Challenges
  - The session will include officials in China and Vietnam, and a view from the situation in Singapore, Korea, and Hong Kong.
  - [https://attendee.gotowebinar.com/register/8801360088856055051](https://attendee.gotowebinar.com/register/8801360088856055051)