

App Gaps and Challenges: Mobile Health WG Perspective



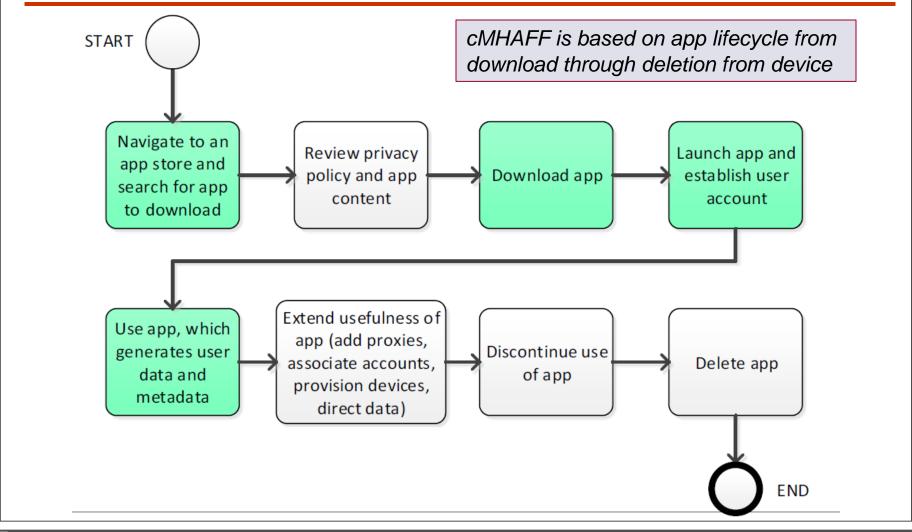
Mobile Health
September 2016
Working Group Meeting



Why this Panel Discussion?

- Rapid proliferation of Mobile Health (MH) apps
- Both HHS and HL7 have identified:
 - Risks or dangers needing mitigation
 - Confusion or unawareness in consumers
 - Gaps in regs/standards/guidance for entities not covered by HIPAA (NCEs), e.g., MH apps
- What could regulations, standards, guidelines, endorsements, testing or certification be based on?
- Overlap/synergy with Consumer Mobile Health Functional Framework (cMHAFF)

Mobile App Lifecycle



cMHAFF and API Task Force Scope

HHS NCE Report includes aspects from all sectors

cMHAFF

API Task Force

Both

Provider/EHR perspective Constrained MU3 focus

- Recommendations re regulatory oversight
- App registration (deployment)
- App endorsements and experience sharing via secondary market
- Model Privacy Notice
- Model Authorization Form
- Ability of provider, patient, and app to restrict access
- Auditing and accounting of disclosures in EHR
- Identity-proofing

Consumer device connected to EHR via API

- · Read-access to EHR
- · Assess applicable regulations
- Communication of app's privacy policies and practices
- · Usability and Accessibility
- · Patient/User authorization (consent)
- · Auditing of access
- · User authentication
- App authorization
- Security for data at rest (for EHR, already covered in certification)
- · Security for data in transit

Consumer/device perspective
Use Case: Simple Standalone App
Use Case: Device-connected wellness app
Broad focus

- · Write-access to EHR
- · Product risk assessment and mitigation
- Product usability
- Customer Support
- Download and install App
- Launch App and establish user account
- Authorization for use of smartphone services
- · Pairing user accounts w. devices/repositories
- Data authenticity and provenance
- · In-app payments
- · Notifications and alerts
- · Product upgrades
- Reward and incentives
- · App testing and certification to standards
- Auditing on consumer device (note: "accounting of disclosures" not covered)
- App and data removal
- · Permitted uses of data post closure

Addressing USA National Gaps

- Opportune time for HL7/cMHAFF to consider
 - ONC Report: Gaps in Oversight of Non-Covered Entities (MH apps, social media, PHRs)
 - HIT Joint Committees API Task Force
 - > FTC, OCR, HIPAA, FDA... direct or indirect guidance
 - ONC PHR Model Privacy Notice: applicable to MH?
 - MH platform-specific guidelines (e.g., new for iOS)
- Balance benefit vs burden; innovation vs chaos
- Comment-only cMHAFF ballot gives leeway for broad changes to meet emerging needs

Next Steps and Collaboration

- HL7
 - Mobile Health WG
 - Possible involvement from other WGs, e.g.,
 - Security WG
 - EHR WG
 - Community Based Collaborative Care
- Other private sector MH initiatives?
- Federal Government
 - What HHS/ONC initiatives are planned?
 - Plans of other agencies or organizations?