cMHAFF Scope and Goals

- Provide a framework for assessment of the **common foundations** of mobile health apps
  - Product Information (disclosures/transparency)
  - Security
  - Privacy/consent/authorization
  - Risk assessment/analysis
  - Data access privileges
  - Data exchange/sharing
  - Usability & Accessibility
- Assessment could include attestation, endorsement, testing, voluntary or regulatory-driven certification
- Out of scope: specific clinical content or functionality
Why cMHAFF? What’s the Need?

- **Target Audience:** mobile health app developers needing guidance on building apps
- **Beneficiaries:** consumers, providers, caregivers
- **Consumers** need protection, transparency and assurance regarding mobile apps. Some examples:
  - What does the app **do**? What **evidence** supports it?
  - What **security** protections exist behind that “cloud?”
  - Who can the app **share** data with?
  - What does the app **know** about me (location, microphone, camera, contacts, etc.), and what can it **do** on my device?
  - Can I **access** my app data like I can under HIPAA?
cMHAFF January’18 Ballot Results

- **Passed!**
  - 48 Affirmative (30 needed to pass)
  - 0 Negative
  - 57 Abstain

- 79 specific comments
  - 3 NEG (UPDATE: All withdrawn)
  - 76 A-S, A-Q, or A-C
  - **All** comments RESOLVED
Types of Ballot Comments

- Clarify ambiguous or confusing wording
- Consolidate similar criteria or moving to different section
- Recommend changes to conformance strength (e.g., SHOULD to SHALL or vice-versa)
- Recommend more specificity (e.g., data elements)
- Remove burdensome or un-actionable items
- Question about audience (developers vs consumers)
- Recommend more precise definition of app categories
Changes Since September’17

- Incorporation of remaining ballot comment dispositions
- Proposed Consumer Information Label
- Expanded Glossary
- Expanded and reorganized References
- U.K. PAS277 Guidelines (recommended in Sept’17 WGM)
- EU Regulatory Landscape Overview
- End-to-End Review
cMHAFF Exemplar Use Cases

<table>
<thead>
<tr>
<th></th>
<th>Simple</th>
<th>Device Integrated</th>
<th>EHR Integrated</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA App Categorization</td>
<td>wellness</td>
<td>wellness</td>
<td>medical</td>
</tr>
<tr>
<td>Device Data Collection</td>
<td>none</td>
<td>unregulated device</td>
<td>FDA regulated device</td>
</tr>
<tr>
<td>PHI Data Storage</td>
<td>smartphone</td>
<td>smartphone/PHR</td>
<td>cloud/EHR</td>
</tr>
<tr>
<td>Data transmission by</td>
<td>none</td>
<td>device-app-PHR</td>
<td>device-app-cloud-EHR</td>
</tr>
<tr>
<td>App</td>
<td>low</td>
<td>mid</td>
<td>high</td>
</tr>
<tr>
<td>HIPAA covered?</td>
<td>no</td>
<td>no, but yes, if white-labeled</td>
<td>yes</td>
</tr>
</tbody>
</table>
cMHAFF Sections and App Life Cycle

App Development and Support
✓ Regulatory Considerations ✓ Risk Assessment and Mitigation
✓ Usability Assessment ✓ Customer Support

Consumer Use of App

Product Information → Launch app, establish account → Authentication → Authorization/consent for data collection/use

Data exchange/interop → Data provenance/authenticity → Security for data at rest & in transit → Pairing or syncing with user devices

Notifications and Alerts → Product Upgrades → Audit → App and Data Removal
Criteria Example: General Product Info

<table>
<thead>
<tr>
<th>No.</th>
<th>Strength</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>G1</td>
<td>SHALL</td>
<td>The description of an app includes the main functionality, the intended use, the intended (target) audience, and potential use of the user’s personal data by the app.</td>
</tr>
<tr>
<td>G2</td>
<td>SHALL</td>
<td>Screen shots of the app accurately depict the screens of the current version of the product.</td>
</tr>
<tr>
<td>G3</td>
<td>SHALL</td>
<td>Product information is provided before the app is used by the consumer, to help consumers decide whether the app is suitable.</td>
</tr>
<tr>
<td>G4</td>
<td>SHOULD</td>
<td>The app description clearly states the human languages the app supports.</td>
</tr>
<tr>
<td>G5</td>
<td>SHOULD</td>
<td>Provide information about accessibility characteristics in the app description and in contextual assistance sections of the app.</td>
</tr>
<tr>
<td>G6</td>
<td>SHOULD</td>
<td>Provide information about the app publisher (persons/organizations) and provide mechanisms to communicate with the publishers</td>
</tr>
<tr>
<td>G7</td>
<td>SHOULD</td>
<td>Provide disclosure about sources of funding and possible conflicts of interest for the app (e.g., app use could incent user to buy products or services from app publisher.</td>
</tr>
</tbody>
</table>
Informing Consumers

Disclosures
Evidence
Limitations
Contents
Sample of U.S. Policies & Guidelines Assessed

- Health Insurance Portability and Accountability Act
- FDA Playbook on Medical Device Cybersecurity
- NIST Special Publication: 1800-1
- FTC Cross-Device Tracking Considerations
- FTC Guidance for mHealth Developers
Sample of European Guidelines Assessed

- French mHealth Good Practice Guidelines
- German Mobile Health Assessment Criteria
- Andalusian App Recommendations
- U.K. PAS277 Quality Criteria
- Finland PHR Cert Criteria
- Other EU initiatives
CMHAFF Next Steps

- CMHAFF to Normative PSS (TSC Approved 10/1/2018!)
- CMHAFF Web Guide
- CMHAFF Piloting
  - Ongoing 3 Participants (US, Netherlands)
  - US Hospital, Dutch Hospital, Non-profit Care Giver, App Developer
- CMHAFF Marketing
CMHAFF Web Guide

- Development of a web-based guide for accessing the CMHAFF standard.

- Increased transparency and visibility for the CMHAFF standard.

- Provides ability to more easily cross-reference associated regulations and region-specific guidelines.

- Tooling for piloting of CMHAFF Standard.
CMHAFF Pilots

- Children’s Health Fund
- Universitair Medisch Centrum Groningen
- Children's Hospital of Philadelphia (CHOP)
- CMHAFF Health App Certifier
CMHAFF Policy Guidance & Collaborations

- Review of GDPR constraints
- Submission of CMHAFF related comments to the ONC Interoperability Standards Advisory
- Meeting with the University of Arkansas Medical Sciences
CMHAFF Domains

Functional Requirements
- Usability & Accessibility
- Download & Installation Considerations
- App Launch & Registration
- App Use & Operation
- Consent for Data Collection
- Account Synchronization
- Security for Data at Rest
- Security for Data in Transit
- Data Authenticity, Provenance, and Associated Metadata

Non-Functional Requirements
- Data Exchange and Interoperability
- Product Upgrades
- Audit
- App and Data Removal
- Permitted Uses of Data Post Account Closure

Product Risk Assessment & Mitigation
- Regulatory Considerations
- Product Information
- Conditions and Agreements
- Use/Availability De-identified Data to third party entities
CMHAFF Scoring Mechanism

- **Goal**
  - Need to be able to derive a method for determining the level of compliance/conformance/quality
  - Need to identify which sections/measures carry greater weight than others
  - Need to create a score that is rigorous, meaningful, reliable, and actionable
Weighting per Domain

- How to effectively weight each domain per its impact/emphasis on scoring?
- How does security for data at rest compare to product information in terms of importance?
- Should specific conformance statements be weighed heavier than others?
Scoring per conformance level

- **Scoring SHALL**
  - Fully meets the criteria = 6
  - Partially meets the criteria = 3
  - Barely meets the criteria = 1
  - Does not meet the criteria = 0

- **Scoring SHOULD**
  - Fully meets the criteria = 2
  - Partially meets the criteria = 1
  - Barely meets the criteria = 0
  - Does not meet the criteria = 0

- **Scoring MAY**
  - Fully meets the criteria = 2
  - Partially meets the criteria = 0
  - Barely meets the criteria = 0
  - Does not meet the criteria = 0
The CMHAFF Web Guide is Live!

Check out our first draft of the CMHAFF web guide and pilot site at:
https://cmhaff.healtheservice.com
cMHAFF Invitation: Join us!

- It’s a major opportunity in an exploding space: get in on the ground floor!
- Action is under way around the world – people are ready!
- Passed January 2018 STU ballot: on its way to Normative!
- Help HL7 collaborate well with the public and private sectors
- Stay connected via HL7 Mobile Health listserv
- Find us [Mobile Health Confluence](#)
Project and Contact Info

- cMHAFF meetings are Thursdays at 3pm Eastern
  - Web Meeting
    - Free Conference Link: https://join.freeconferencecall.com/mhealth
  - Phone (515) 604-9930, passcode 836039
  - Project Leads: Nathan Botts, Frank Ploeg, Gora Datta, Matthew Graham

- Join us to publish and start using cMHAFF!