MHAFF\_CONS\_MHAFF\_R1\_D1\_2018JAN



**HL7 Consumer Mobile Health Application
Functional Framework, Release 1 (PI ID: 1182)**

January 2018

**HL7 STU Ballot**

**Sponsored by:
Mobile Health Work Group
Electronic Health Records Work Group**

Copyright © 2017-2018 Health Level Seven International ® ALL RIGHTS RESERVED. The reproduction of this material in any form is strictly forbidden without the written permission of the publisher. HL7 and Health Level Seven are registered trademarks of Health Level Seven International. Reg. U.S. Pat & TM Off**.**

Use of this material is governed by HL7's [IP Compliance Policy](http://www.hl7.org/legal/ippolicy.cfm?ref=nav).

**IMPORTANT NOTES:**

HL7 licenses its standards and select IP free of charge. **If you did not acquire a free license from HL7 for this document,** you are not authorized to access or make any use of it. To obtain a free license, please visit http://www.HL7.org/implement/standards/index.cfm.

**If you are the individual that obtained the license for this HL7 Standard, specification or other freely licensed work (in each and every instance "Specified Material")**, the following describes the permitted uses of the Material.

**A. HL7 INDIVIDUAL, STUDENT AND HEALTH PROFESSIONAL MEMBERS,** who register and agree to the terms of HL7’s license, are authorized, without additional charge, to read, and to use Specified Material to develop and sell products and services that implement, but do not directly incorporate, the Specified Material in whole or in part without paying license fees to HL7.

INDIVIDUAL, STUDENT AND HEALTH PROFESSIONAL MEMBERS wishing to incorporate additional items of Special Material in whole or part, into products and services, or to enjoy additional authorizations granted to HL7 ORGANIZATIONAL MEMBERS as noted below, must become ORGANIZATIONAL MEMBERS of HL7.

**B. HL7 ORGANIZATION MEMBERS,** who register and agree to the terms of HL7's License, are authorized, without additional charge, on a perpetual (except as provided for in the full license terms governing the Material), non-exclusive and worldwide basis, the right to (a) download, copy (for internal purposes only) and share this Material with your employees and consultants for study purposes, and (b) utilize the Material for the purpose of developing, making, having made, using, marketing, importing, offering to sell or license, and selling or licensing, and to otherwise distribute, Compliant Products, in all cases subject to the conditions set forth in this Agreement and any relevant patent and other intellectual property rights of third parties (which may include members of HL7). No other license, sublicense, or other rights of any kind are granted under this Agreement.

**C. NON-MEMBERS,** who register and agree to the terms of HL7’s IP policy for Specified Material, are authorized, without additional charge, to read and use the Specified Material for evaluating whether to implement, or in implementing, the Specified Material, and to use Specified Material to develop and sell products and services that implement, but do not directly incorporate, the Specified Material in whole or in part.

NON-MEMBERS wishing to incorporate additional items of Specified Material in whole or part, into products and services, or to enjoy the additional authorizations granted to HL7 ORGANIZATIONAL MEMBERS, as noted above, must become ORGANIZATIONAL MEMBERS of HL7.

Please see http://www.HL7.org/legal/ippolicy.cfm for the full license terms governing the Material.

**Ownership. Licensee agrees and acknowledges that HL7 owns all right, title, and interest, in and to the Materials. Licensee shall take no action contrary to, or inconsistent with, the foregoing.**

**Licensee agrees and acknowledges that HL7 may not own all right, title, and interest, in and to the Materials and that the Materials may contain and/or reference intellectual property owned by third parties (“Third Party IP”). Acceptance of these License Terms does not grant Licensee any rights with respect to Third Party IP. Licensee alone is responsible for identifying and obtaining any necessary licenses or authorizations to utilize Third Party IP in connection with the Materials or otherwise. Any actions, claims or suits brought by a third party resulting from a breach of any Third Party IP right by the Licensee remains the Licensee’s liability.**

Following is a non-exhaustive list of third-party terminologies that may require a separate license:

| **Terminology** | **Owner/Contact** |
| --- | --- |
| Current Procedures Terminology (CPT) code set | American Medical Associationhttps://www.ama-assn.org/practice-management/apply-cpt-license |
| SNOMED CT | SNOMED International http://www.snomed.org/snomed-ct/get-snomed-ct or info@ihtsdo.org |
| Logical Observation Identifiers Names & Codes (LOINC) | Regenstrief Institute |
| International Classification of Diseases (ICD) codes | World Health Organization (WHO) |
| NUCC Health Care Provider Taxonomy code set | American Medical Association. Please see www.nucc.org. AMA licensing contact: 312-464-5022 (AMA IP services) |

Contents

[1 Introduction 5](#_Toc500920519)

[1.1 Acknowledgements 5](#_Toc500920520)

[1.2 Background 5](#_Toc500920521)

[1.3 Intended Audience 5](#_Toc500920522)

[1.4 How to Use this Guide 6](#_Toc500920523)

[2 Overview 7](#_Toc500920524)

[2.1 Goals 7](#_Toc500920525)

[2.2 Scope 8](#_Toc500920704)

[2.2.1 In Scope 8](#_Toc500920705)

[2.2.2 Out of Scope 8](#_Toc500920710)

[2.3 Conformance Design Principles 9](#_Toc500920711)

[2.4 Exemplary Use Cases 9](#_Toc500920712)

[2.4.1 Use Case A: Simple, Standalone 10](#_Toc500920713)

[2.4.2 Use Case B: Device-Connected Wellness App 11](#_Toc500920714)

[2.4.3 Use Case C: EHR-Integrated Disease Management App 13](#_Toc500920715)

[2.4.4 Risk factors 14](#_Toc500920716)

[2.4.5 Summary of Major Differences in Use Case Scenarios 15](#_Toc500920717)

[2.5 Environmental Scan 15](#_Toc500920718)

[3 Conformance Criteria, Resources, and Implementation Guidance 16](#_Toc500920719)

[3.1 General Considerations 16](#_Toc500920720)

[3.2 Product Development and Support 17](#_Toc500920723)

[3.2.1 Regulatory Considerations 17](#_Toc500920730)

[3.2.2 Product Risk Assessment and Mitigation 20](#_Toc500920731)

[3.2.3 Usability/Accessibility Assessment 22](#_Toc500920732)

[3.2.4 Customer/Technical Support 23](#_Toc500920733)

[3.3 Download and Install App 24](#_Toc500920734)

[3.3.1 Product Information 24](#_Toc500920735)

[3.3.2 Launch App and Establish User Account 26](#_Toc500920736)

[3.4 Use App 27](#_Toc500920737)

[3.4.1 Authentication 27](#_Toc500920738)

[3.4.2 User Authorizations (Consent) for Data Collection and Use 28](#_Toc500920739)

[3.4.3 Pairing or Syncing User Accounts with Devices and Data Repositories 29](#_Toc500920740)

[3.4.4 Security for Data at Rest 30](#_Toc500920741)

[3.4.5 Security for Data In Transit 31](#_Toc500920742)

[3.4.6 Data Authenticity, Provenance, and Associated Metadata 31](#_Toc500920743)

[3.4.7 Data Exchange and Interoperability 32](#_Toc500920744)

[3.4.8 Notifications and Alerts 33](#_Toc500920745)

[3.4.9 Product Upgrades 36](#_Toc500920746)

[3.4.10 Audit 37](#_Toc500920747)

[3.5 App Service Termination 37](#_Toc500920748)

[3.5.1 App and Data Removal 38](#_Toc500920749)

[3.5.2 Permitted Uses of Data Post Account Closure 39](#_Toc500920750)

[3.6 Nonfunctional Requirements: Conditions and Agreements 39](#_Toc500920751)

[3.6.1 Conformance 39](#_Toc500920752)

[3.6.2 Related Regulations and Standards 40](#_Toc500920753)

[3.6.3 Implementation Guidance 40](#_Toc500920754)

[4 Definitions (Glossary) 41](#_Toc500920755)

[5 Implementation 44](#_Toc500920756)

[5.1 Device- or OS-specific Considerations 44](#_Toc500920757)

[6 Appendices 45](#_Toc500920758)

[6.1 Reference Documents 45](#_Toc500920759)

[6.2 Version History/Change Log 48](#_Toc500920760)

[6.3 CMHAFF Labeling of App 48](#_Toc500920761)

[6.4 Relationship to Other Standards 51](#_Toc500920762)

# Introduction

## Acknowledgements

The consumer Mobile Health Application Functional Framework (cMHAFF) team acknowledges the members of the HL7 Mobile Health Workgroup, who developed this Standard for Trial Use. In addition, acknowledgements are due to the HL7 EHR Workgroup and the HL7 Security Workgroup, and the Community Based Health Services (CBHS) workgroups, which also provided valuable guidance. Many other mobile health initiatives in the European Union and USA influenced cMHAFF as well, as referenced throughout this specification.

## Background

As of 2015, there are thousands of consumer health applications (apps), which run on smartphones, watches, tablets, and other mobile devices, available for download from platform-specific application stores such as the Apple App Store (iOS) and Google Play (Android). Consumer acceptance and use of these apps is primarily based on recommendations—either personal recommendations through individual contacts or social media or app store ratings. While this information is important in understanding the relevance of an app to one’s life and the design and usability of an app, it is insufficient in communicating how an app secures and protects the personal information of its users. This poses a problem both for consumers and clinicians, who may be considering or prescribing use of an app to help track and improve health behaviors and conditions.

There is a great diversity in consumer health apps. Some are meant to be used for oneself, some help manage care for others, and some work best when an individual uses an app along with consultation from a health professional. Within section 2.4, three exemplary use cases of increasing complexity are introduced and serve to guide development of cMHAFF.

## Intended Audience

1. CMHAFF is primarily directed at **developers and vendors of mobile health apps for consumers**, to assist them in building and marketing apps that educate consumers and protect their privacy, security, data access, etc.
2. CMHAFF is also directed at organizations (such as test labs, certification bodies, professional societies, or organizations that provide app reviews and ratings) that will assess or endorse mobile apps for conformance to essential criteria.
3. CMHAFF can also be informative as a checklist (or “gold standard”) for prospective purchasers of mobile apps (e.g., consumers, or providers on behalf of consumers).
4. The beneficiaries of cMHAFF will primarily be consumers, due to improvements in apps and in a consumer’s increased understanding and trust.
5. Other beneficiaries may include those who receive information from consumer health apps, such as providers, caregivers, and researchers. Some provider organizations, such as the American Medical Association, have published principles[[1]](#footnote-1) to ensure accurate, effective, safe and secure mHealth apps.

## How to Use this Guide

The questions in this section help the intended audience (particularly mobile app developers and vendors) determine which conformance subsections of cMHAFF should be read. Each subsection of 3.x contains one or more conformance statements. Based on the characteristics of the app being developed, some of those subsections may be applicable and some may not. To assist developers understand which subsections of cMHAFF are relevant to their app, the following table is presented. The left column is a yes/no question, and the right column represents decisions whether or not to apply sections of cMHAFF, depending on the answer to that question.

|  |  |
| --- | --- |
| **QUESTIONS** | **DECISIONS BASED ON ANSWERS** |
| The following sections of cMHAFF should be reviewed by any Mobile App developer, no matter how simple the app.  | 3.2.x (Product Development), 3.4.9 (Product Upgrades), 3.3.x (Download and Install App) |
| Does the app handle patient-identifiable information? | YES – then cMHAFF sections 3.4.1 (authentication), 3.4.2 (authorization), 3.4.10 (audit), 3.5.1 (app and data removal), and 3.5.2 (permitted uses post closure) applyNO – then those sections from cMHAFF do not apply |
| Does the app store or transmit data outside the mobile device, e.g., the cloud or another HIT system? | YES – then cMHAFF 3.4.4 (security for data at rest), 3.4.5 (security in transit) and 3.4.6 (data authenticity and provenance) apply |
| Does the app connect to sensors or other types of devices that gather measurements of the patient’s condition? | YES – then cMHAFF 3.4.3 (pairing), 3.4.5 and 3.4.6 also apply |
| Does the app send alerts or notifications to the user? | YES – then cMHAFF 3.4.8 (notifications and alerts) applies |

**For this current January 2018 HL7 ballot, reviewers are asked to:**

1. **Make recommendations concerning conformance criteria, particularly the SHALL vs SHOULD vs MAY**
2. **Extend lists of resource references, including references to other normative and emerging standards**
3. **Review the framework for broad applicability and ability to be profiled in different countries.**

The intent of the Mobile Health Work Group is to use this feedback to improve the quality and relevance of the Framework so that it can be approved as a Standard for Trial Use (STU) in 2018.

Section 3 forms the core of the Framework. Each section addresses product information and technical concerns based on a given stage of the app lifecycle, through conformance criteria, supported by references to related regulations and standards. Implementation guidance is also included.

# Overview

## Goals

The primary goals of cMHAFF are to provide a standard against which a mobile app’s foundational characteristics -- including but not limited to security, privacy, data access, data export, and transparency/disclosure of conditions -- can be assessed. The framework is based on the lifecycle of an app, as experienced by an individual consumer, from first deciding to download an app, to determining what happens with consumer data after the app has been deleted from a smartphone. It is important to note that the Framework does *not* speak directly to the specific health or clinical functionality of an app, but can be extended to do so through the use of profiles (with constraints and/or extensions) developed on top of cMHAFF.

The decision to create a standard focused on a smaller set of criteria was made so that the standard is both developer-friendly and easy to update on a frequent basis. CMHAFF challenges market assumptions concerning safe and acceptable use of personal information, and may in some circumstances increase coding complexity and decrease the efficiency of data transmission. As such, there is no expectation that most consumer health apps will choose to follow this standard. Yet, for apps which conform, cMHAFF can potentially provide a path to assessments that can span a range including self-attestation, testing, endorsement[[2]](#footnote-2), and/or certification (voluntary or regulatory). CMHAFF is independent of the method of assessment, but aims to be suitable for use for types of assessments up to and including certification. Certified apps can promote their conformance, and as a consequence, consumers who use the apps, and providers who recommend them, can be more confident of an app’s rigor in enforcing basic security, its respect for the privacy of individuals, and the usefulness of data for improving and maintaining a better state of health.

1.
2.

|  |  |  |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

|  |  |  |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

## Scope

### In Scope

CMHAFF focuses specifically on **consumer** mobile apps than run on devices such as smartphones, tablets, and wearables. It is focused on the **general** capabilities, that can be thought of as “horizontal” features that are applicable to most or all apps, rather than to the specific health, clinical, or medical functionality of an app.

There is a broad range of apps that cMHAFF intends to cover, from simple self-contained standalone apps that a consumer can use for personal benefit, which do not exchange or store data outside the mobile device; to apps that share or store data externally (e.g., in the app provider’s cloud) but do not interact directly with provider systems; to systems that share and store data externally and interact with provider EHRs or organizations (in the USA, covered entities or business associates governed by HIPAA and/or FDA).

The intent is to lay a foundation, on top of which realm-specific and domain-specific “profiles” can be layered, that addresses an app’s:

* Product Information for consumers (e.g., App Store descriptions, product disclosures)
* Security
* Privacy
* Permission to use device features
* Data Access
* Data Sharing
* Terms of Use, Conditions
* Product Development, including risk management, user-centered design, compliance with applicable regulations, functions (product description), reliability, performance, scalability, safety, compatibility, and portability.
1.
2. 1. 1.

### Out of Scope

* “Professional” apps that may run on consumer devices, but are intended for healthcare workers, e.g., clinical decision support aids, which are not consumer-focused.
* Clinical or health app functionality (e.g., diabetes monitoring, exercise calculations). The Mobile Health workgroup does not have the subject matter expertise to define those types of criteria.
* General “device” security requirements, e.g., password or biometric locking of a phone. CMHAFF is an *application* functional framework intended for app developers, not a framework for the devices or platforms on which the apps run (e.g., cMHAFF is not directed to Apple, Google, Samsung…). However, risk management should identify dependencies or assumptions about the platforms that an app may rely on.
* General “infrastructure” requirements for consumers or healthcare organizations, such as the protection of networks via virus or malware protection, firewalls, etc., physical environmental security, since app developers have no control over such networks or environments. However, risk management should identify dependencies or assumptions about the supporting infrastructure that an app may rely on, and should identify threats and mitigate risks.
* Human resource policies and procedures of developers, healthcare organizations, or consumers, such as security awareness education, except inasmuch as they directly affect product development.

## Conformance Design Principles

Conformance Criteria in sections 3.x follow a lifecycle model in relation to a consumer’s use of a mobile health application, from first finding an app in an App Store to disuse and de-installation.

**CMHAFF Sections and Mobile App Life Cycle**



## Exemplary Use Cases

As noted in the Introduction, consumer mobile heath apps take many forms, and as such, conformance statements in section 3 of this standard must allow for variation based on multiple factors, including data sensitivity, the nature of conditions addressed by the app (e.g., wellness, chronic illness), and whether/how app data connect to other data sources.

In this section, three archetypal use cases are introduced. While most consumer mobile health apps will not precisely fit any of these models, the models are meant to demonstrate a continuum of issues which may be applied to any app. Use Case C is the most sophisticated and generates the most requirements. Its description includes examples of the risk factors that should be considered by developers and users.

Section 3 (Conformance Criteria) includes discussion of considerations as to how subsets of conformance criteria can be addressed in different manners, referencing the use cases in this section as a way to provide directional, rather than pinpoint, guidance.

### Use Case A: Simple, Standalone

A walking app collects data based on how far someone walks, using GPS technology. A consumer can view a history of walks taken and summary statistics related to distance walked and estimated calories burned. App developer is not a HIPAA-covered[[3]](#footnote-5) entity (CE) such as a healthcare provider, nor is the app sponsored by a CE (such as a hospital or physician).

 

|  |  |
| --- | --- |
|  | Simple |
| Medical Device App Categorization | Wellness |
| Data Device Categorization | None |
| PHI Data Storage | Smartphone |
| Data transmission by App | None |
| Importance of Data Integrity | Low |
| (USA) HIPAA covered? | No |

### Use Case B: Device-Connected Wellness App

A weight management app helps consumers to systematically collect weight information, food consumption information and exercise information. Weight can be entered manually, or a consumer can link a wireless scale to the app so that weight is automatically collected when using the scale. Food consumption is entered manually, and a tool estimates calories consumed based on the consumer’s input. Exercise information may be entered manually, or collected automatically through integration with a smart watch. The app analyzes all the data and offers warnings and advice (e.g., patient’s unhealthy combination of weight and exercise levels lead to recommendations for diet and exercise changes): these make it potentially a medical device and candidate for government regulation, though not at this time.[[4]](#footnote-6) The app has an ability to download weight, activity, and food consumption information to PHRs through a published API. In the US Realm, the App developer is not a HIPAA entity, but app can be white-labeled by HIPAA entities, such as a clinic offering a PHR to its patients through a portal.

 

|  |  |
| --- | --- |
|  | Device Integrated |
| Medical Device App Categorization | wellness |
| Data Device Categorization | regulated device |
| PHI Data Storage | smartphone/PHR |
| Data transmission by App | device-app-PHR |
| Importance of Data Integrity | mid |
| (USA) HIPAA covered? | no, but yes, if white-labeled |

### Use Case C: EHR-Integrated[[5]](#footnote-7) Disease Management App

A diabetes management app allows a consumer to collect blood sugar readings through a Bluetooth-enabled glucometer. A healthcare provider offers the app to enable the patient’s[[6]](#footnote-8) blood sugar to be captured through devices, rather than relying on manual entry by the patient, and to electronically transmit the readings to the patient’s physician, rather than using paper or FAX. Activity data are collected through an activity tracker, and a consumer can open the app to record meals and snacks to enable estimates of caloric consumption. Collected data is automatically “pushed” to a third-party cloud-based platform. The patient is aware of the cloud, though not familiar in detail with how data are protected in transit or storage. When a consumer views information in the app, which shows daily glucometer readings and related information, this information is “pulled” in but does not persist on the smartphone when the app is closed. It is also possible for the consumer to directly enter blood sugar readings (e.g., if Bluetooth connection is not working). From the cloud platform, consumer information is “pushed” to a provider’s Electronic Health Record (EHR), where it is accepted as Patient Generated Health Data (PGHD), according to the preferences of the patient and the policies of the provider. From the EHR, a physician can define logic to assess blood sugar readings such that the consumer is alerted through the app when a measurement is out of range or when a set number of high or low readings are noted within a prescribed period of time.

 

|  |  |
| --- | --- |
|  | EHR Integrated |
| Medical Device App Categorization | medical |
| Data Device Categorization | regulated device |
| PHI Data Storage | cloud/EHR |
| Data transmission by App | device-app-cloud-EHR |
| Importance of Data Integrity | high |
| (USA) HIPAA covered? | yes |

### Risk factors

For apps, especially those like Use Case C, there are several potential threats and vulnerabilities which should be assessed and mitigated, where necessary, by mHealth developers (see 3.2.2 Product Risk Assessment and Mitigation). While cMHAFF does not attempt to “do” the risk assessment for any particular mobile app, the following are *examples* of specific risk scenarios that may be applicable and point to cMHAFF criteria (🡺potential mitigations are listed in parentheses).

|  |  |
| --- | --- |
|  |  |

* Consumer loses their device. Confidential information is handled by the app, and there is risk of information disclosure (🡺encryption of data, automatic timeout/logoff)
* The device can be lost or damaged, impeding the consumer’s use of the app, thereby impacting their care, even if privacy is protected. (🡺information about backup of data, ability to restore to new device)
* The consumer, for convenience, may turn on “automatic login” (saved credentials, “remember me”), so the app may be accessed without re-authentication. (🡺 don’t offer such a feature if app handles PHI)
* The app is used and left open, where others could see it while the device is unlocked (🡺 automatic timeout/logoff)
* Measurements are not captured accurately or not transmitted accurately, and consumer takes action based on inaccurate measurements (🡺 quality management, disclosure of evidence)
* A data collection device paired with the mobile phone may in fact be for a different person (mis-association of data) (🡺 Pairing User Accounts)
* A third party cloud-based platform may have inadequate security measures of which the consumer is unaware. (🡺 disclosure of infrastructure security measures)
* Transmission between mobile app and cloud-based platform may have inadequate or unknown transmission security (🡺 encryption of data in transit)
* The consumer exchanges or discontinues their use of the mobile device without removing all data from the device or other locations to which the device transmitted data. (🡺App and Data Removal, Permitted Uses of Data Post Account Closure)
* The device is not on the person, is turned off, is silent, or is otherwise unable to get the consumer’s attention when the app issues an important alert. (🡺 disclosure of degree of liability re notifications)
* The healthcare provider to which the app communicates data has little or no control over the device characteristics, environment, or usage patterns, unlike enterprise IT where only approved/provisioned devices are used. (🡺 out of scope, not a developer issue, but should be documented in product risk assessment)

Some of these potential risks are motivators for the conformance criteria in cMHAFF. Where risks have both high likelihood and high impact, SHALL criteria are indicated.

### Summary of Major Differences in Use Case Scenarios

|  |  |  |  |
| --- | --- | --- | --- |
|  | Simple | Device Integrated | EHR Integrated |
| Medical Device App Categorization | Wellness | wellness or medical | medical |
| Device Data Collection | None | unregulated or regulated device | regulated device |
| PHI Data Storage | smartphone | smartphone/PHR | cloud/EHR |
| Data transmission by App | None | device-app-PHR | device-app-cloud-EHR |
| Importance of Data Integrity | Low | mid | high |
| (USA) HIPAA covered? | No | no, but yes, if white-labeled | yes |

## Environmental Scan

The documents mentioned below are not standards, but explain the state of the mobile health industry in the USA and Europe, and assist developers to understand which legislation is applicable to their apps.

* **Journal of Medical Internet Research: mHealth and Mobile Medical Apps: A Framework to Assess Risk and Promote Safer Use** <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4180335/>
* **HIMSS Interoperability Environmental Scan (to be published early 2018)** This was announced in the HIMSS **Call to Action** <http://www.himss.org/library/himss-call-action-achieve-nationwide-ubiquitous-secure-electronic-exchange-health-information>
* **ONC/Accenture Patient-Generated Health Data white paper** (draft). This addresses opportunities and challenges for patient-generated health data (PGHD) and their use by clinicians. Much PGHD could come from mobile devices. <https://www.healthit.gov/policy-researchers-implementers/patient-generated-health-data> Final version expected in 2017 or early 2018.
* **eHealth Action Plan 2012-2020.** <https://ec.europa.eu/digital-single-market/en/news/ehealth-action-plan-2012-2020-innovative-healthcare-21st-century>The European Commission's eHealth Action Plan 2012-2020 provides a roadmap to empower patients and healthcare workers, to link up devices and technologies, and to invest in research towards personalized medicine. Given the rapid uptake of tablets and smartphones, it also includes a special focus on mobile health**.**
* **Good Practice Guidelines on Health Apps and Smart Devices (Mobile Health or mHealth)**.

While this is written for France, and influenced many of the criteria in cMHAFF, it also contains an extensive literature search and references that serve as an environmental scan.
<https://www.has-sante.fr/portail/upload/docs/application/pdf/2017-03/dir1/good_practice_guidelines_on_health_apps_and_smart_devices_mobile_health_or_mhealth.pdf>

# Conformance Criteria, Resources, and Implementation Guidance

## General Considerations

Each section (3.2.x) is a category of criteria that follows a common format. First, there is a brief non-normative description of the category. Then there is a subsection containing a normative table of **conformance criteria**. Some criteria are applicable to all consumer health apps and other criteria are to be applied conditionally based on the functionality and scope of an app. For example, some apps do not transmit personal data to a source outside of the smartphone, while some integrate with external data sources; some apps integrate with medical and wellness devices, while others do not. Criteria are separated from “force”. That is, each criterion stated in a neutral way, and the optionality of addressing the criteria while claiming conformance to the standard, is in a separate column. The key words "MUST", "MUST NOT", "REQUIRED", "SHALL", "SHALL NOT", "SHOULD", "SHOULD NOT", "RECOMMENDED", "MAY", and "OPTIONAL" in this document are to be interpreted as described in Internet Engineering Task Force (IETF) RFC 2119. Force follows this convention:

SHALL The definition is an absolute requirement of the specification.

SHOULD This word, or the adjective "RECOMMENDED", mean that there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.

MAY This word, or the adjective "OPTIONAL", mean that an item is truly optional. One vendor may choose to include the item because a particular marketplace requires it or because the vendor feels that it enhances the product while another vendor may omit the same item. An implementation which does not include a particular option MUST be prepared to interoperate with another implementation which does include the option, though perhaps with reduced functionality. In the same vein an implementation which does include a particular option MUST be prepared to interoperate with another implementation which does not include the option (except, of course, for the feature the option provides.)

[IF] The stated force applies only when the clause in brackets is applicable to the product. When the clause does not apply, no conformance is expected.

Following the table of conformance criteria, there are two non-normative subsections that provide optional guidance:

* ***Related regulations and standards***: References to documents which can help an app developer or vendor are included. Regulations, standards and guidelines are cited here only if they are the direct source of a conformance criterion: otherwise, then they are listed in the Appendices (section 6.1, Reference Documents). To avoid redundant listings, any referenced document (with its URL) is only listed in the first relevant subsection: subsequent references are abbreviated and placed in footnotes. No regulations are cited as normative in cMHAFF, because they are realm-specific. NOTE: Legislation and regulations will vary between realms (locations) internationally and even within a country (e.g., states or provinces). Applicable regulations take precedence over cMHAFF when overlap or discrepancies exist. CMHAFF does not replace or override regulations of a realm.
* ***Implementation guidance***: Guidance for app developers is included. As applicable, the differential application of conformance criteria by type of app is discussed, referencing the exemplary use cases described in section 2.4.
1.
2.

## Product[[7]](#footnote-9) Development and Support

Prior to marketing a mobile app, the developer has a responsibility to ensure it meets Realm-specific rules and **regulations**. Although cMHAFF does not have guidelines for all aspects of the software product life cycle, cMHAFF still recommends that the product development life cycle, for new apps and for upgrades to apps, ensure that requirements for functionality, reliability, performance, scalability, safety, compatibility, portability, and maintainability have been addressed. The security and privacy of information used by the app needs to be considered throughout the development phases of the app. Functionality must support the intended use of the app for the target users and stakeholders. Thorough and iterative risk assessment and requirement analysis, testing, evidence collection, documentation, and configuration management ensures quality to satisfy the needs of the application’s various stakeholders[[8]](#footnote-10). Assessing the **usability** of the app helps ensure the app’s viability and adoption; testing must be population-relevant and demonstrate reasonable product usability (accessibility) by people with visual, auditory and motor disabilities within the intended target audience. Establishing a system of **customer support** enables product defects and usability issues to be surfaced in a systematic way and helps problems related to use of the app to be effectively resolved and the developer to continually deliver the intended use of the app.

* 1.
	2.
1.
2. 1.
	2.

### 3.2.1 Regulatory Considerations

This section is about the compliance of apps to applicable regulations for the domains (realms, locales, environments) in which they are intended to be used. CMHAFF is designed as a framework that can be further constrained (profiled) for these domains, and does not require conformance to any specific locale’s regulations.

#### Conformance

|  |  |  |
| --- | --- | --- |
| No. | Strength | Requirement |
| 1 | SHALL | Following Realm-specific regulatory rules, determine if the app needs regulatory approval before the app is used by the general public.  |
| 2 | SHALL [IF] | [App requires regulatory approval] Regulatory approval is obtained before app is made available to the general public. |
|  |  |  |

#### Related Regulations and Standards

The documents listed below are overviews of the regulatory landscape, rather than specific regulations governing mobile health apps. Specific references are listed either following the conformance tables, or in the Appendix.

* **USA Federal Trade Commission Mobile Health Apps Interactive Tool** for guidance as to which federal laws apply. <https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool> All USA mobile app developers should consult this tool, which includes determining if the app is a regulated “medical device” according to the U.S. Food and Drug Administration (FDA), and if so, obtaining necessary pre-market approval.
* **Commission Staff Working Document on the existing EU legal framework applicable to lifestyle and wellbeing apps.**

<https://ec.europa.eu/digital-single-market/en/news/commission-staff-working-document-existing-eu-legal-framework-applicable-lifestyle-and> This broad guidance for the European Union, analogous to the USA FTC document. It is complemented by country-specific guidelines. In the EU, some mHealth apps may fall under the definition of a medical device and therefore may have to comply with the safety and performance requirements of **Council** **Directive 93/42/EEC** concerning medical devices <https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en>.

#### Implementation Guidance

* Use Case A: In the US Realm, a walking app which encourages general wellness is not considered a medical device by the FDA. As such the FDA does not intend to regulate this type of app.
* Use Case B: In the US Realm, a weight management app is not considered a medical device by the FDA as long as it makes no claims to improve/cure a disease. How the app is described is important, and FDA guidance defining wellness vs. apps which aim to improve specific disease conditions should be referenced and reviewed before making a definitive decision as to its FDA classification.
* Use Case C: There are two distinctions regarding compliance issues for this app. For the data collection devices in this use case, a glucometer would be FDA regulated, while a general activity monitor, would not. Apps which collect and display disease information would not typically be regulated until the information is compiled or transformed and clinical decisions are made on the data. In this case, the app is capable of receiving alerts, but the logic behind the alerts are based on individualized settings through a rules engine which is integrated into an EHR. In this case, the locus of regulation is not clear, and as such counsel should be engaged in forming a definitive case as to what regulatory approvals might be needed.

For the European Union, the following diagram summarizes relevant guidance and regulations for Mobile Health. There are three principal EU regulatory areas impacting mHealth Apps:

* Medical devices, applying to higher medical risk apps only, including Regulation (EU) 2017/745 for medical devices in general and Regulation (EU) 2017/746 for in vitro diagnostic devices.
* Information protection, applying to all apps that store or transmit personal data – currently a group of three directives, that will largely be replaced by the General Data Protection Regulation on 25th May 2018, together with an expected mHealth-specific voluntary code.
* Consumer protection, including the right to fair treatment, products which meet acceptable standards, and right of redress if something goes wrong.

Shades of blue indicate directives and regulations. Red indicates voluntary codes/guidelines. Yellow indicates possible other actions with uncertain timing.



### 3.2.2 Product Risk Assessment and Mitigation

This category deals with process steps for those who are developing a new app, or an upgrade to an app, prior to its being deployed to consumers. Degrees of risk should be assessed and mitigated according to the intended use of the app. In general, risk management should manage security, privacy, safety, and other types of risks such as potential app failure scenarios, events that could lead to undesirable outcomes, probability and severity of risk, and mitigations or resolutions. One size does not fit all. For example, if apps handle sensitive personal information or give health interpretation or advice, higher degrees of risk are involved than for apps that do not collect personal information or do not interpret or advise. If some information identified during this step should be disclosed to consumers, that is stated in the “Informing Consumers/Users” section.

#### Conformance

|  |  |  |
| --- | --- | --- |
| No. | Strength | Requirement |
|  |  |  |
|  |  |  |
| 1 | SHALL | Create and document a product risk assessment and mitigation plan. Explicitly determine what risk must be addressed through software coding, hardware adaptions, policy, and what residual risk will be accepted by the entity responsible for the app. |
| 2 | SHALL | In development, follow secure coding practices using an established framework. |
| 3 | SHALL | In development, test for security flaws in the app using defined scripts which can be executed using automated methods and/or by human testers. |
| 4 | SHALL [IF] | [Personally Identifiable Information is collected] Rank risk assessment findings in terms of their potential effect on adequately securing an individual’s personally identifiable information (PII) including any protected health information (PHI), and also information used to access an EHR/PHR (e.g., logon credentials). |
| 5 | SHALL [IF] | [app transmits data to an EHR] Document failure rates, measurement error rates, software bugs, and hardware risks of all types. |
| 6 | SHOULD | Prior to product launch, complete User Acceptance Testing (UAT) by testers who are not part of the formal development team.  |
| 7 | SHOULD | Monitor and document conflicts or compatibility issues of the app with other apps, device features (e.g., camera), or connected devices. |
| 8 | SHOULD | Have measures to safeguard minors in accordance with applicable regulations.  |
| 9 | SHOULD[IF] | [app relies on external supporting infrastructure, (e.g., cloud-based servers) to operate] Document measures to ensure the availability of that infrastructure. |
| 10 | MAY | Provide documentation to show that the app publisher has adequate resources to continue to develop, maintain, and support the product (e.g., human resources, finances, IP rights, facilities, equipment, tools).  |

#### Related Regulations and Standards

While mobile computing environments may introduce some specific threats not present in non-mobile computing, the principles of risk management are the same across environments, so some standards and regulations are cited, even though they are not mobile-centric. Documents (listed alphabetically below) were sources of some cMHAFF criteria for risk assessment. Other useful references on risk assessment are listed in the Appendix. While some are realm-specific, they have much material that is applicable beyond their countries. Realms are listed in parentheses, if not explicit in the title.

* **Andalusian Complete list of recommendations on design, use and assessment of health Apps**http://www.calidadappsalud.com/en/listado-completo-recomendaciones-app-salud/
* **British Standards Institution Publically Available Specification (PAS) 277:2015 Health and wellness apps – Quality criteria across the life cycle – Code of practice** Recommendations and guidance throughout the app’s product development life cycle
* **French Good Practice Guidelines on Health Apps and Smart Devices (Mobile Health or mHealth)**. <https://www.has-sante.fr/portail/upload/docs/application/pdf/2017-03/dir1/good_practice_guidelines_on_health_apps_and_smart_devices_mobile_health_or_mhealth.pdf>
* **National Institute of Standards and Technology NISTIR 8144 Assessing Threats to Mobile Devices & Infrastructure, *The Mobile Threat Catalogue*** (USA)<https://nccoe.nist.gov/sites/default/files/library/mtc-nistir-8144-draft.pdf> (context and background information)
<https://pages.nist.gov/mobile-threat-catalogue/application.html#vulnerable-applications> (actual catalog of threats, specifically the “Vulnerable Application” category, which is the part of the threat catalog closest to cMHAFF)
* **Open Web Application Security Project (OWASP) Top 10 Mobile Security Risks:** <https://www.owasp.org/index.php/Mobile_Top_10_2016-Top_10> This is focused on app developers, so most of it is pertinent to cMHAFF, and for each risk, there are suggested mitigations.
* OWASP Secure Coding Practices Quick Reference Guide. <https://www.owasp.org/index.php/OWASP_Secure_Coding_Practices_-_Quick_Reference_Guide>. This provides resources for developers that can assist in implementing secure coding practices. It is recommended that developers adopt secure coding practices so that applications are developed with an emphasis on security vs having to apply security measures to protect the application.

#### Implementation Guidance

While later sections in this standard include specific security and privacy controls to be applied to Consumer Mobile Health Apps, all products addressing health issues, regardless of their type, must be subjected to an overall risk analysis. This risk analysis *may* uncover the need for additional security controls over-and-above the conformance statements included in this document. As such, a risk analysis provides an additional layer of considerations such that conformance statements are not misused as a simple checklist in which it is assumed all security risks have been addressed if an app is in compliance with the conformance statements in this standard. For an app/product, the risk analysis should be conducted for the target environment(s) where the app will actually be used by consumers. Because of the diversity of consumers, such a risk analysis is wider ranging and more challenging than a risk analysis for the development organization’s own environment.

### 3.2.3 Usability/Accessibility Assessment

This category is about the assessment of usability during the product development cycle, for the intended use by a target audience. Certain accessibility requirements (usability for users with specific disabilities) are recommended, but the list is not exhaustive. Other disabilities not mentioned (e.g., cognitive/learning disabilities) should be considered under the umbrella of conformance criterion #1.

#### Conformance

|  |  |  |
| --- | --- | --- |
| No. | Strength | Requirement |
| 1 | SHALL | Assess product against an industry-validated usability assessment tool, using subjects who are demographically-similar to intended users (target audience). |
| 2 | SHALL [IF] | [intended users include those with motor disabilities] Assess product for usability by people with motor disabilities.  |
| 3 | SHALL [IF] | [intended users include those with visual disabilities] Assess product for usability by visually-impaired people using a standard mobile screen reader. |
| 4 | SHALL [IF] | [intended users include those with auditory disabilities] Assess product for usability by people with auditory disabilities. |
| 5 | SHOULD | Assess product for usability by a sample of intended users. If geared towards a certain age segment or to people with a specific chronic health condition, or to persons with disabilities other than those specified above, usability testing subjects are drawn from these populations. |
| 6 | SHOULD | Create a written usability assessment plan, including known problems with product usability and mitigation plan. NOTE: for U.S. Realm when an app is sponsored by a HIPAA entity, the force of this criteria is elevated to “SHALL” with plan specifically addressing usability issues for people with visual and motor disabilities. |
| 7 | SHOULD | Follow design/style guide standards established by the platform provider(s) for the app, e.g., Android, iOS) |
| 8 | SHOULD | Avoid excessive data use by the app, minimizing it as much as possible warning users when high data usage occurs (e.g., downloads and updates).[[9]](#footnote-11) |
| 9 | SHOULD | Describe the use cases (business scenarios) and intended users for the App’s main functions[[10]](#footnote-12) |
| 10 | SHOULD | Permit flexibility (adaptation) to the user’s specific abilities, needs, or requirements |

#### Related Regulations and Standards

See Appendix: Reference Documents

#### Implementation Guidance

The timing of implementation of usability findings can be indicated in functional profiles based on the severity of findings. At a minimum a usability assessment plan includes information about the timeframe under which remediation will occur.

These conformance statements apply to any type of app addressed in this standard. However, specific usability measures and remediation plans will differ based on app functionality, intended users, and app platform, and as such this standard does not discuss specific controls; instead, it speaks to a development process which encourages inclusion and end user satisfaction.

### 3.2.4 Customer/Technical Support

This category is about disclosure of the level of customer support available. The specific mechanisms for support (e.g., phone, chat, email, FAQ, online help, etc.) are not prescribed by cMHAFF.

#### Conformance

|  |  |  |
| --- | --- | --- |
| No. | Strength | Requirement |
| 1 | SHALL | Information as to how to access customer support, and channels of support (e.g., voice, email, text, Twitter, etc.) is clearly stated within the app’s Terms of Use and as a feature accessible from within the app. |
| 2 | SHALL | Customer support may be accessed prior to establishing a user account (e.g., User can contact customer support with questions about the app’s Privacy Policy or Terms of Use before making a decision to actively use the app). |
| 3 | SHALL | Customer support is provided in the language(s) in which the app is published. |
| 4 | SHALL | Within the app’s Terms of Use, or in documentation available from within the app, any open source code library or code under copyright used to develop the app is given attribution. |
| 5 | SHALL[IF] | [Support request involves accessing, disclosing, or changing customer data] The identity of the customer, and the customer’s data access rights, must be verified before any disclosure or changing of customer data. |
| 6 | SHOULD | Customer support queries will receive responses which directly address a stated problem or issue within two business days. A simple acknowledgement that a query has been received, without additional action, is insufficient. |
| 7 | SHOULD | Provide app consumers with aggregated satisfaction ratings relevant to customer support terms and conditions as appropriate. |
| 8 | SHOULD | Provide a FAQ resource where users can find answers to common questions.[[11]](#footnote-13) |
| 9 | MAY | A comprehensive performance dashboard is publicly available and offer features for comparison with similar or competing apps |

#### Related Regulations and Standards

None: recommendations are solicited.

#### Implementation Guidance

None: recommendations are solicited.

## Download and Install App

Apps are frequently marketed and downloaded through platform-specific “App Stores.” Before an app can be housed within an app store, it must meet requirements set by the app store host. The app store is one primary source of product information for consumers to decide whether they want to install the app. In some realms, apps may also be obtained through an app registry.

### 3.3.1 Product Information

This category is about providing information about the product to consumers and also other parties (e.g., governments, consumer or provider organizations) who have interest in potential purchase, use, endorsement, or recommendation of apps. The experience of installing an app begins at an app store, and completes on a user device. See also the Conditions and Agreements section of this specification for guidance regarding Conditions and Agreements that usually appear as part of the app store experience. cMHAFF does not specify exactly how or where product information is conveyed, e.g., app store, web site, online help.

#### Conformance

|  |  |  |
| --- | --- | --- |
| No. | Strength | Requirement |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  | **GENERAL INFORMATION** |
| G1 | SHALL | 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. |
| G2 | SHALL | Screen shots of the app accurately depict the screens of the current version of the product. |
| G3 | SHOULD | Product information is provided *before* the app is used by the consumer, to help consumers decide whether the app is suitable.  |
| G4 | SHOULD | The app description clearly states the human languages the app supports.  |
| G5 | SHOULD | Provide information about accessibility characteristics in the app description and in contextual assistance sections of the app. |
| G6 | SHOULD | Provide information about the app publisher (persons/organizations) and provide mechanisms to communicate with the publishers |
| G7 | SHOULD | 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. |
|  |  | **PAYMENT** |
| P1 | SHALL | The payment amount for the app, if any, must be clearly noted according to app store rules. |
| P2 | SHALL | Apps which have required or optional payments after download must clearly state this in their app store description, along with the amount of payment required and the actions which result from such in-app payments (for example, payment of a certain amount results in an ad-free experience when using the app). The impact of *not* making payments must also be stated (e.g., limited functionality).  |
|  |  | **EVIDENCE/CREDENTIALS** |
| E1 | SHALL [IF] | [App provides health recommendations] Disclose the scientific degree of evidence and the types and dates of sources used (e.g., clinical practice guidelines and protocols, peer-reviewed articles, professionals and organizations with their credentials) that guided the app content. |
| E2 | SHALL [IF] | [there is human[[12]](#footnote-14) and/or automated interpretation of health-related content] The credentials of qualified health professionals are disclosed, and/or the algorithms and testing plans and reports are documented.[[13]](#footnote-15) |
| E3 | SHOULD | The app descriptions should identify the health professionals and credentials of those who worked on the app and/or at least the professional organization that made, reviewed, endorsed, or sponsored the app.  |
| E4 | SHOULD | Show the date of the last update to the app, and describe the changes from the previous release (e.g., revisions due to new scientific evidence). |
| E5 | MAY | The app description may also include data related to app reliability and validity tests or population research results. |
| E6 | SHOULD | Declare the degree of admission of liability (publisher’s acceptance or disclaimer of responsibility) regarding the selection and use of the app’s content.[[14]](#footnote-16)  |
|  |  | **LIMITATIONS AND WARNINGS** |
| L1 | SHALL [IF] | [App provides health recommendations] Disclose the potential risks to patient safety and their mitigations. |
| L2 | SHOULD[IF] | [App offers health advice] State that the use of the app does not replace the provider-patient relationship or the recommendation, opinion, or diagnosis of a health professional. |
| L3 | SHOULD | Document contraindications, potential risks and limitations of use. For example, environmental or patient conditions under which apps or connected devices may be unreliable (e.g., tattoos that impact optical sensors; avoid usage when pregnant; avoid usage outside a temperature range). |
| L4 | SHOULD | Warn users of updates caused by possible errors in functionality, in health-related information, or in any other sensitive data. |
| L5 | SHOULD[IF] | [App has collected personal health information] guarantee continuity of data use across different versions of the app.  |
|  |  | **TECHNICAL DETAILS** |
| T1 | SHALL [IF] | [user can enter personal health information into the app] Clearly disclose whether or not data validity checking is done, and document or reference the evidence for such validity checking |
| T2 | SHALL [IF] | [App collects or receives quantitative data] The precision (accuracy, granularity) of measurements (e.g., physical activity, physiological data from connected devices) is documented and justified as appropriate for the intended use of the App.  |
| T3 | SHALL [IF] | [personal health information are hosted] Backup and recovery procedures are documented and compliant with applicable regulatory requirements |
| T4 | SHALL [IF] | [personal health data are imported or exported] Functions for data import or export are documented, including the ability to convert to standard formats.  |

#### Related Regulations and Standards

See Appendix: Reference Documents

#### Implementation Guidance

None: recommendations are solicited.

### 3.3.2 Launch App and Establish User Account

This category is about the process of a consumer getting started with an app, potentially including establishing an account.

#### Conformance

|  |  |  |
| --- | --- | --- |
| No. | Strength | Requirement |
| 1 | SHALL | A user can review the app’s Terms of Use before personal data about the user is collected or used. |
| 2 | SHALL [IF] | [the app creates user accounts] User acceptance of the app’s Terms of Use is logged before a user account is authorized. (See section 3.4.10 for information about audit log record creation.) |
|  |  |  |
| 3 | SHALL [IF] | [user is a child and approval from parent or guardian is required by law] Require acknowledgement of age, or documented approval from parent or guardian.[[15]](#footnote-17) |
| 4 | SHALL [IF] | [User is allowed to use pre-existing account credentials from an Identity Provider (IDP) to access the app] Before a user chooses to use pre-existing account credentials to access the app,1. The user is informed about what attribute information will be used by the app associated with the pre-existing credentials;
2. The user is informed about what data is communicated back to the IDP at the time of account creation and at each subsequent user authentication.
 |
| 5 | SHOULD | For purposes of establishing an account, the minimum necessary amount of a user’s personally identifiable information (PII) is collected. E.g., the information is *necessary* to authenticate the user, provide customer support, or affect the app logic.  |
|  |  |  |

#### Related Regulations and Standards

See Appendix: Reference Documents

#### Implementation Guidance

* Use Case A: Knowing who the user is, in an absolute sense, is not needed as data is not being sent to any external data set. Primarily, account controls are in place to ensure the same person is using the app each time. For this walking app, possession of a smartphone may be sufficient to allow someone to use it without any additional need for authentication or need to set up a unique user ID and password to access the app.
* Use Case B: Knowing the user’s absolute identity is not needed but minimal account controls (e.g., user ID and password) should be established as the app will allow information to be sent to an existing data set, and these data sets will need some ability to be linked, in part showing evidence an individual has control over both the app data and a right to access the existing data set.
* Use Case C: requires more rigorous identity proofing as data will be both sent to an EHR and interactions initiated by a physician result in information being pushed to the app. Identity proofing can occur within the app itself, or in the use of pre-existing identity credentials (e.g., patient portal credentials for the entity controlling the EHR) to establish identity.

## Use App

### 3.4.1 Authentication

This category is about the system[[16]](#footnote-18) protecting against unauthorized access (e.g., by persons other than the consumer).

#### Conformance

The functionality of an app, its sponsorship, and linkages to external data sources all affect the security, privacy and data controls which are established to ensure safe and effective use. In this section, conformance criteria point to issues which can be addressed through a range of options, and as such implementers should consider not only the conformance criteria but the discussion regarding applicability to the exemplary use cases.

|  |  |  |
| --- | --- | --- |
| No. | Strength | Requirement |
| 1 | SHALL | The identity of an app user is authenticated prior to any access of PHI or PII. The method of authentication is communicated to the app user when an app account is established.  |
| 2 | SHALL | The app user is authorized to access a feature of the app before that feature or any associated PHI or PII is displayed. Authorization may be internal to the app or derived from an external source. |
| 3 | SHALL | At the request of an app user, the app terminates such that access to PHI or PII requires a new, successful authentication attempt. |
| 4 | SHALL [IF] | [Other external HIT system (e.g., EHR) is a system actor] Verify a subject’s association with their real-world identity, establishing that a subject is who they claim to be (identity proofing).  |
| 5 | SHALL [IF] | [EHR is a system actor][[17]](#footnote-19) The EHR authorizes an app user’s access to app features when these features are supported by data provided by or written to the EHR. |
| 6 | SHALL [IF] | [PII or PHI are displayed] The app terminates the app or makes PHI or PII invisible after a period of time of user inactivity as described in the app’s Terms of Use. This feature is sometimes called “inactivity timeout” “Session timeout” or “automatic logoff.” The determination to include this feature within an app is made as part of the overall risk analysis regarding the sensitivity of data provided by or through the app.  |
| 7 | SHALL [IF] | [Passwords are stored on the device] passwords are encrypted.  |
| 8 | SHALL [IF] | [Access to account exposes Protected Health Information (PHI) or PII] The user is given an option to utilize strong authentication methods (e.g., multi-factor authentication and/or biometrics) in addition to passwords. Before selection of this option, the mechanism for authentication is clearly described and/or demonstrated to the user. This capability may apply to an app itself, and also to the pairing of the app with a device.  |

#### Related Regulations and Standards

See Appendix: Reference Documents

#### Implementation Guidance

See section 3.3.2, Launch App and Establish User Account, for a discussion as to the selection and ongoing use of a user authentication mechanism.

* **API Task Force Final Report, May 12, 2016:** <https://www.healthit.gov/facas/sites/faca/files/HITJC_APITF_Recommendations.pdf>Specifically, Topic 8 recommends that identity proofing for apps be the same as for MU2-era patient portal sign-in and View/Download/Transmit.

### 3.4.2 User Authorizations (Consent) for Data Collection and Use

This category is about personal data collection and use, including access to device features, being understood and explicitly authorized (consented to) by the users of the app.

#### Conformance

|  |  |  |
| --- | --- | --- |
| No. | Strength | Requirement |
| 1 | SHALL | Smartphone functionality and data sources may only be used when essential to perform specific functions of the app. This includes, but is not limited to, the use of: location services, camera, microphone, accelerometer and other sensors, contact lists, calendars. |
| 2 | SHALL | Before using select smartphone functions and data sources for the first time, app users are asked for permission to use these services and data sources. Permissions for each function, data source and user tracking activity controlled by the app can be individually specified by the user.  |
| 3 | SHALL | Before exporting data from the smartphone, or from any device integrated with the smartphone, the app user is asked for permission to transmit the data with an explanation of what data is being transmitted, and to which recipients for what purposes (e.g., to servers of the App supplier, for backups, for big data analysis). Permission is requested before the first potential transmission of data. Permission is re-requested the first time any *additional* data elements are sent to an external data source when permission had previously been extended for a smaller set of data. Permission is *not* requested at every transmission, if the scope of exported data remains unchanged.  |
| 4 | SHALL [IF] | [app requests permission to use data generated by the app after it is de-identified] Account holder is informed of who would have access to the de-identified data and for what purpose. |
| 5 | SHALL [IF] | [app requests permission to use data generated by the app after it is de-identified] Account holder is informed of the possibility that de-identified data can potentially be re-identified and steps the app sponsor takes to prevent re-identification. |
| 6 | SHALL [IF] | [user gives permission for data generated by the app to be de-identified and used] Data de-identification, at minimum, follows realm-specific rules (e.g., HIPAA safe-harbor in USA). |
| 7 | SHALL [IF] | [in-app payments exist]. In-app payments are not triggered in such a way that can expose healthcare-related information to payment organizations. |
| 8 | SHALL [IF] | [app uses in-app advertising]. Potential use of PHI or PII to personalize advertisements from the app shall be disclosed to the user, who shall be given the opportunity to consent or decline.  |
| 9 | SHOULD | An app user can choose to permit some, but not all, requested data to be exported from a smartphone or associated device. The user is informed as to how the choice to limit data affects the functionality of the app. |
| 10 | SHOULD | [app user denies a permission requested by the app] The app user is informed of the consequence of not extending the permission and is given a second chance to extend a permission. |
| 11 | MAY | Share data with social networks, only after obtaining explicit user consent[[18]](#footnote-20) |

#### Related Regulations and Standards

None: recommendations are solicited.

#### Implementation Guidance

None: recommendations are solicited.

### 3.4.3 Pairing or Syncing User Accounts with Devices and Data Repositories

This category is about consumer verification of all devices to which they wish to pair or sync data.

#### Conformance

|  |  |  |
| --- | --- | --- |
| No. | Strength | Requirement |
| 1 | SHALL | User has authenticated identity to an app and has an active session before pairing an external device to an app account. |
| 2 | SHALL | Before a device is paired with an app to collect information about a specific individual, the app displays a screen which asks the user to confirm that the device will collect information about a specific, named person. The person may be the account holder or a proxy subject of the account holder. |
| 3 | SHALL | The person who pairs a device with an individual in context of use of a specific app can un-pair the device and individual through an app utility. |
| 4 | SHALL | Before a device is paired with an app to collect information about a specific individual, the app states what data will be collected by the device and how the device data is used. This statement may include a link to an informational page which provides details about data collection and use. |
| 5 | SHALL [IF] | [Data for more than one person can be collected by the app/device pair] The app asks the account holder to confirm the person for whom data will be collected by the device before data is collected and transmitted. |
| 6 | MAY | Offer an option to sync data across multiple devices, with user’s consent (e.g., same app data synchronized across smartphone and tablet devices)[[19]](#footnote-21) |

#### Related Regulations and Standards

None: recommendations are solicited.

#### Implementation Guidance

None: recommendations are solicited.

### 3.4.4 Security for Data at Rest

This category is about providing assurance that the consumer’s stored data is secure, regardless of whether it is stored on the consumer’s devices or elsewhere (e.g., in cloud-based servers for an app).

#### Conformance

|  |  |  |
| --- | --- | --- |
| No. | Strength | Requirement |
| 1 | SHALL | PHI and PII stored on a smartphone is stored as encrypted values. |
| 2 | SHALL | PHI and PII stored by the mobile app on any external server is stored as encrypted values  |
| 3 | SHALL | Unless PHI and PII has been transmitted to a data set maintained by a Health Plan or Health Provider, the account holder can delete information collected through the app, including data generated by a device associated with the app. |
| 4 | SHOULD | Improve and/or upgrade encryption cipher and suites to match evolving best practices.  |

#### Related Regulations and Standards

See References in Appendix, particularly FDA Cybersecurity Guidelines.

#### Implementation Guidance

Encryption paradigms should follow contemporary practices as the strength of an encryption method may degrade over time as computational methods for breaking encryption continue to evolve. Changes may be implemented as scheduled patches or release updates, but if the new best practices were defined because hacker evolution has exposed new product vulnerabilities, then the update should be done ASAP.

### 3.4.5 Security for Data In Transit

This category is about providing assurance that consumer data is secure when it is moved between the consumer’s device(s) and other locations.

#### Conformance

|  |  |  |
| --- | --- | --- |
| No. | Strength | Requirement |
| 1 | SHALL | PHI and PII transmitted between an app and an external data source, including data generated through a device associated with the app, are transmitted as encrypted values. |
|  |  |  |

#### Related Regulations and Standards

None: recommendations are solicited.

#### Implementation Guidance

None: recommendations are solicited.

### 3.4.6 Data Authenticity, Provenance, and Associated Metadata

This category is about the attribution of sources of data (provenance) and assurance of data authenticity.

#### Conformance

|  |  |  |
| --- | --- | --- |
| No. | Strength | Requirement |
| 1 | SHALL | Apps conform to Best Practices for Data Authenticity, Provenance, and Associated Metadata  |
| 2 | SHALL[IF} | [App itself originates data <see ISO 21089 definition of “originate”>] Customer has review option which includes the option to irreversibly destroy, reject or discard data. |
| 3 | SHALL[IF} | [App itself only receives data as a “pass through” and cannot store data] Customer has a review option to display the data prior to executing the pass-through which includes the option to irreversibly stop and block the pass-through. |
| 4 | SHOULD[IF] | [App itself receives data and stores it] Customer has a review option that permits only appending data and/or free text comments to received data as author while preserving the original received data intact with original provenance. User may comment that data are erroneous, but does not have the option to delete the original data.  |

#### Related Regulations and Standards

The following are examples of standards for data provenance. Even though they are specific to the FHIR and CDA standards respectively, the principles and data elements -- for recording entities and processes involved in producing or delivering a resource (data) – may be applicable.

* **FHIR Provenance Resource** <http://www.hl7.org/FHIR/provenance.html>
* **HL7 CDA® R2 Implementation Guide: Data Provenance, Release 1 - US Realm** <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=420>
* **ISO 21089 Health Informatics – Trusted End-to-End Information Flows.** <https://www.iso.org/standard/35645.html>Offers a guide to trusted end-to-end information flow for health(care) records and to the key trace points and audit events in the electronic entity/act record lifecycle (from point of record origination to each ultimate point of record access/use).

#### Implementation Guidance

None: recommendations are solicited.

### 3.4.7  Data Exchange and Interoperability

This category applies only if an app exchanges data with other devices, health apps, and/or HIT systems. If so, there are applicable standards for data format, vocabulary, and transport, to increase interoperability and ease of connection.

#### Conformance

|  |  |  |
| --- | --- | --- |
| No. | Strength | Requirement |
| 1 | SHALL[IF] | [App exchanges discrete clinical data] Use standard terminologies (e.g., SNOMED CT, LOINC…) |
| 2 | SHALL[IF] | [App exchanges discrete clinical data] Use standard format/content, e.g., HL7 FHIR, SMART on FHIR, HL7 Consolidated CDA, Detailed Clinical Models (HL7 CIMI), etc.  |
| 3 | SHOULD[IF] | [App exchanges discrete clinical data with devices] Use standard format/content, e.g., IEEE 11073 |
| 4 | SHOULD[IF] | [App exchanges unstructured data] Use standard or commonly accepted formats, e.g., HL7 CDA, PDF |
| 5 | SHOULD[IF] | [App collects personal health information] allow data to be imported or exported from the app.[[20]](#footnote-22)  |

#### Related Regulations and Standards

* **Direct Project Applicability Statement for Secure Health Transport** <https://www.healthit.gov/policy-researchers-implementers/direct-project>
* **HL7 Consolidated CDA**
* **HL7 FHIR STU.** <http://www.hl7.org/FHIR/index.html>
* **SMART ON FHIR.** <https://smarthealthit.org/>
* <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=379>
* **IEEE 10073 Personal Health Data Standards** <https://standards.ieee.org/develop/wg/PHD.html>
* **“MedMij” information Exchange standards for Personal Health Environment** <https://www.medmij.nl>(Netherlands)Includes HL7 Detailed Clinical Models (DCM), which provide context for discrete clinical data (e.g., systolic blood pressure); the standard is being used in the Netherlands.

#### Implementation Guidance

None: recommendations are solicited.

### 3.4.8 Notifications and Alerts

This category is about notifications and alerts, which may be used to inform consumers of important situations that they should know about. This includes, but is not limited to, information about the app itself (e.g., important updates) or about the health information that the app handles (e.g., the specific consumer’s personal health data warrants special attention).

#### Conformance

|  |  |  |
| --- | --- | --- |
| No. | Strength | Requirement |
| 1 | SHALL  | Opt-in consent is required by the account holder before receiving notifications and alerts from an app. |
| 2 | SHALL | To consent to receiving a notification or alert from an app, the account holder is informed of both the content and channel (SMS, push notification, email, etc.) of the notification or alert. |
| 3 | SHALL | An account holder can change consent decisions about notifications and alerts through settings available on the device on which the app was downloaded. |
| 4 | SHALL | Notifications and alerts contain the least amount of information necessary for the recipient of the alert to take a focused action. |
| 5 | SHALL [IF] | [app alerts notify user of conditions such as “abnormal” or “exceptional” or “out of range”] Document or reference the sources (evidence base) of the formulas/algorithms upon which such alerts and notifications are based.  |
| 6 | SHOULD | As permitted by the account holder and agreed to by recipients, notifications and alerts may be sent to the account holder and/or to another person or entity. |
| 7 | SHOULD | Provide alerts to notify the user of potential faults that could cause inconvenience or harm to the user, e.g., low battery alerts.  |
| 8 | SHOULD | Notify the user in case of external interruptions or delays (e.g., loss of network connection, database problem, lengthy operation) |

#### Related Regulations and Standards

See platform-specific guidelines.

#### Implementation Guidance

In the realm of alerts and notifications, the following table proposed suggested standardized (generic) terms in the left column, with mappings to the leading two platforms in the middle columns, and comments in the right column. The platform-specific definitions have been derived from web sources, with preference given to information from the creators of the platforms (Apple, Google). Note: the mapping cannot be made an exact 1:1. In some cases, the platform-specific term may be more precise (e.g., subtypes) than the generic term, but we do not require a generic equivalent for every platform-specific term. In other cases, there may be substantial similarity of concepts across platforms, but not identical behavior, and certainly not identical appearance.

Despite the proposed granularity of these terms, that does not mean that there need to be separate cMHAFF conformance requirements for each type, but at least the opportunity is there if the need arises. In particular, there may be different conformance requirements for “alerts” vs other types of notifications.

| Suggested “standardized” (generic) term for cMHAFF | Apple (iOS) equivalent | Google (Android OS) equivalent | Comments**[[21]](#footnote-23)** |
| --- | --- | --- | --- |
| **Message**Any computer to computer or computer-to-human interface, whether via visual, aural, haptic, olfactory, taste, or neural mediums. However, when discussing interoperability, the focus is on computer-to-computer[[22]](#footnote-24) messaging. Note that the messages can be transmitted within the same physical computer, but between different software (e.g., APIs).  | Generally refers to messages within specific types of apps, like email, text, IM, Facebook… | Generally used to refer to messages from one device (or server) to another. | Message, or Messaging, can describe cMHAFF’s overarching term for the data packages that are sent by apps. While we consider notifications and alerts as special types of messages, the specific term “message” is used a lot for messages within apps, but not generally used when describing alerts and notifications. We in HL7 also have the HIT-specific legacy of structured “messaging” formats that include healthcare content and sometimes PHI (e.g., HL7 v2 message).  |
| **Notification**A device-specific message communicated to a user to inform them of device or app activities that are deemed important to the user. Some types of notifications require a response from the user, while others do not.  | Notification – generic term to cover many types of notifications.  | Notification – generic term to cover many types of notifications. | Generic term that has subtypes. While HIT also has “notifications” that may delivered to an app, not just to a human user, let’s stick with the common consumer-based definition |
| **Alert**A type of Notification that is communicated to a user and requires a response before the user can proceed with activity on the device. For example, it may take the form of a “modal” pop-up dialog that must be dismissed by clicking OK or taking some other action.  | Alert | Alert Dialog, aka Dialog Notification | These messages will always be seen by the user, except if the device is turned off or the user does not look at the device at all (nothing is guaranteed). In general, these are considered more “serious” than other types of notifications. Local or other policy make have more stringent rules for anything deemed an “alert” vs a “notification.”  |
| **Persistent Notification**A device-specific message communicated to a user to inform them of device or app activities and remain displayed on the device. These remain persistent until the user deletes them or takes an action that changes their status (e.g., checks text messages, checks email) | Notifications (in Notification Center)Badge (on individual app icons) | Status NotificationStatus Notifications can appear outside the app window and can be used to attract the user back to the app.  | Android has more than one type of notification. While HIT also has “notifications” that may delivered to an app, not just to a human user, let’s stick with the common consumer-based definition |
| **Temporary Notification**A subtype of Notification that does not remain displayed on the screen more than a short time period.  | Banner“Lock screen notifications” look like banners but appear on the lock screen. Do they vanish like regular banners that aren’t on the lock screen? I don’t think so.  | ToastToasts appear within the app window, not outside of it | Since these messages fade after a short time, it is very possible that they will not be seen at all. In Android, Toasts appear within the app window (not outside the app). In iOS, they can appear outside the app.  |
| **Emergency Notification**A notification from an external source, such as the government, communicating important information about your area (e.g., emergency, disaster, weather…) | iPhone provides options for two types of Government Alerts, “AMBER Alerts” and “Emergency Alerts.”  | Four types: presidential notifications, imminent extreme notifications, imminent severe alert and AMBER alert. You can turn off every alert except for the presidential alert. | These are outside the scope of an app, are not written by MH app developers, but can be configured to display on the device. They are mentioned so that we don’t use the same terms for something else.  |

**Hierarchy**

* **Message** (overarching term)
	+ **Content Message** (e.g., HL7 v2, C-CDA payload, FHIR resource) – out of the scope of this set of definitions. Probably need a better term for this.
	+ **Notification** (overarching term)
		- **Alert** (**requires** user action, whereas all other types of notifications do not require it, though they may allow it)
		- Persistent notification
		- Temporary notification
		- **Emergency Notification** (government, outside app control)

### 3.4.9 Product Upgrades

This category is about the process of updates (upgrades) to apps, as required to be current: e.g., new features, new health information, new technology, security, etc.

#### Conformance

|  |  |  |
| --- | --- | --- |
| No. | Strength | Requirement |
| 1 | SHALL | The app respects operating system level permissions concerning automatic product updates. |
| 2 | SHALL [IF] | [an updated version of the app includes updated terms of use] Updated Terms of Use are presented to the account holder for acceptance before an updated version of an app may be used. Significant changes to terms and conditions are highlighted, and a link to the full set of updated Terms of Use is available. |
| 3 | SHALL [IF] | [automatic app updates are not enabled] The app prompts the user to the availability of a new version of the app when a new version is available.  |
| 4 | SHALL [IF] | [account holder elects to not install a new version of an app] The consequences of not installing the new version of the app, including information about support limitations for the older version of the app, are presented to the account holder. |
| 5 | SHALL [IF] | [new version of app increases what information is exposed by alerts] The user must consent to the information being exposed, and the changes to the exposed information must be clearly highlighted when they make that consent.  |

#### Related Regulations and Standards

None: recommendations are solicited.

#### Implementation Guidance

None: recommendations are solicited.

### 3.4.10 Audit

This category is about auditing, which is a mechanism for user and system accountability. Important events, such as logins and access to particular functions and data, are recorded and can be used to detect instances of non-compliant behavior and to facilitate detection of improper creation, access, modification, and deletion of personal health information.

#### Conformance

|  |  |  |
| --- | --- | --- |
| No. | Strength | Requirement |
| 1 | SHALL[IF] | [User authentication is required to access app] User authentication attempts, both successful and unsuccessful, generate an audit record. |
| 2 | SHALL | User permissions to access, or the revocation of access, regarding smartphone/tablet device capabilities for use by the app (e.g., use of camera, location services) generate an audit record. |
| 3 | SHALL[IF] | [App uses external devices or data sources for data collection] Pairing a device or data repository external to the app, which supplies data used by the app, generates an audit record. |
| 4 | SHALL[IF] | [App allows for the export of data to a data repository external to the app] Any export of data from the app generates an audit record. |

#### Related Regulations and Standards

* **Integrating the Healthcare Enterprise (IHE) Audit Trail and Node Authentication (ATNA) Integration Profile.** <https://www.ihe.net/Technical_Frameworks/#IT> This IHE profile references the **Internet Engineering Task Force (IETF) RFC 3881 Audit Record standard** <http://www.rfc-base.org/rfc-3881.html>
* **HL7 EHR Records Management and Evidentiary Support Functional Model, Release 1 (RMES)** <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=86>Provides functions in an EHR system that can help an organization maintain a legal record for business and disclosure purposes

#### Implementation Guidance

Every consumer mobile health app needs an audit strategy, which includes what data will be generated for audit, who will be able to access audit records, the location where audit data is stored, the length of time audit information will be stored, and any ability to delete audit data. Audit for security events is highly dependent on the nature of the app itself; audit requirements will differ significantly based on app sponsorship (e.g., sponsor is a HIPAA entity or a commercial non-covered entity), the need for user authentication, and if data generated through an app is accessible by consumers, clinicians, or both.

## App Service Termination

Health apps may be used indefinitely or for a finite period of time. Disuse may happen when a health condition improves, a new health habit is established, when motivation to use the app wanes, or when the user determines a different app better meets their needs. Procedures for how data continues to be retained and used after account closure must be clear and understandable and give the app user options for relocation of their data to a new data repository.

### 3.5.1 App and Data Removal

This category is about the process of terminating use of an app and removing it from a device.

#### Conformance

|  |  |  |
| --- | --- | --- |
| No. | Strength | Requirement |
| 1 | SHALL | An app Account Holder can remove an app from a smartphone at any time. |
| 2 | SHALL | An app Account Holder is informed of the consequences of removing the app (e.g., loss of locally-stored data) from a smartphone and given an opportunity to confirm the removal of the app before the app is removed. |
| 3 | SHALL | An app Account Holder can close an associated account or data store associated with the app. |
| 4 | SHALL | An app Account Holder is informed of the consequences of deleting the account and is given an opportunity to confirm closing the account before it is closed. |
| 5 | SHALL | After deleting an account associated with an app, the Account Holder is informed of what data associated with the account persists, and the Account Holder’s rights in terms of access and deletion of that data. The user should be informed that data that was part of the account may have been transmitted to other systems, outside of the account itself, and may persist. For example, suppose the user collects device data in an app, and transmits that data to an EHR which stores it as PGHD. Deleting the account will not delete the data that is now in the EHR. |
| 6 | SHOULD | Before closing an app account, the account holder can download data generated by the account holder or a proxy subject of the account holder to a data set under the full control of the account holder (data portability). |
| 7 | SHALL [IF] | [the device permits remote or external access to device data] Any PHI or PII stored on a device can be wiped remotely by the account holder without deleting the account which is related to the wiped data. |
| 8 | SHOULD | Clear criteria are set and communicated to the user regarding the deletion of data, including automatic deletion if the user has not used the app for a specified period.  |

#### Related Regulations and Standards

* **European Union Privacy Code of Conduct on Mobile Health apps**
<https://ec.europa.eu/digital-single-market/en/privacy-code-conduct-mobile-health-apps>

#### Implementation Guidance

Data download should be in a standard or at least nonproprietary format (e.g., CSV, XML, JSON) that can be manipulated by off-the-shelf tooling. The format should be selected appropriate to the data being downloaded.

### 3.5.2 Permitted Uses of Data Post Account Closure

This category is about what is done with consumers’ data if they close their account (terminate use of the app).

#### Conformance

|  |  |  |
| --- | --- | --- |
| No. | Strength | Requirement |
| 1 | SHALL | Data associated with a closed app account is not released to any new persons or entities. This includes data which has been de-identified. |
| 2 | SHALL | Offer the consumer the option to decide what to do with their data (keep, delete, etc.). |

#### Related Regulations and Standards

None: recommendations are solicited.

#### Implementation Guidance

None: recommendations are solicited.

## Nonfunctional Requirements: Conditions and Agreements

This section of cMHAFF deals with nonfunctional, and usually nontechnical, aspects of mobile health apps. While not traditionally in scope for HIT standards oriented at large or small enterprise organizations, it is a very important and distinctive characteristic of apps targeted at consumers. Since one goal of cMHAFF is consumer protection, including their privacy and security, guidance in the area of “Conditions and Agreements” (CnA) is offered. CnA is not a formal or legal term, but an umbrella under which can be grouped various expressions of conditions that consumers to which are asked to agree before they start using a mobile health app. These may be called “Terms and Conditions,” “Terms of Use,” “Terms of Service,” “End User License Agreement (EULA),” and similar concepts. Typically, CnA are displayed and consumers are asked to click buttons to agree to terms, when they interact with “App Stores” (a generic term including wherever a consumer downloads a mobile health app). In addition to what the consumer agrees to, CnA may also commit the app supplier to certain behaviors or restrictions. While cMHAFF does not prescribe what these CnA must include, it provides guidance as to items that are important to disclose. In that respect, there is some precedent in the ONC 2015 Edition Certification, which contains disclosure and transparency requirements for EHR developers, e.g., about pricing and services that are not included in the base software.

### 3.6.1 Conformance

|  |  |  |
| --- | --- | --- |
| No. | Strength | Requirement |
| 1 | SHALL | Before download, a user can easily access the app’s Terms of Use. This may be accomplished through a link in the app description in the relevant app store.  |
| 2 | SHALL | Before download, a use can easily access the app’s Privacy Policy. This may be accomplished through a link in the app description in the app store. |
| 3 | SHALL [IF] | [rewards are given for app participation] Clearly disclose all conditions and time limitations governing rewards. These include but are not limited to: how activity is tracked; how promptly rewards are fulfilled; whether rewards can expire or be withdrawn; whether and how rewards can be transferred to another person; whether rewards can be accumulated into larger rewards; etc.  |
| 4 | SHOULD | The consumer should indicate that they acknowledge and understand the app functionality |
| 5 | SHALL [IF] | [app includes in-app payments] The app description shall disclose what is included as base functionality without payment, and what functionality would require additional payment. |
| 6 | SHALL [IF] | [App permits in-app payments] The benefits for paying for a service or feature are clearly stated in a manner which allows an account holder to make an informed decision about making or declining an in-app payment. |
| 7 | SHALL [IF] | [App access is by subscription] The requirements for cancelling a subscription are clearly stated in the CnA.  |
| 8 | SHALL [IF] | [App requires an additional charge to upgrade] The upgrade charges, the amount of advance warning for upgrades, and the length of support for the old version (if not upgraded) are clearly stated in the CnA.  |
| 9 | SHOULD | Disclose the use of advertising mechanisms, distinguish advertisements from app content, and provide ways to deactivate or skip advertisements.[[23]](#footnote-25)  |
| 10 | SHOULD | Provide a means for a user to access the app’s Privacy Policy at any time during the usage of the app.  |

### 3.6.2 Related Regulations and Standards

* **Federal Trade Commission: How to Make Disclosures in Digital Advertising, March 2013** [*https://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-staff-revises-online-advertising-disclosure-guidelines/130312dotcomdisclosures.pdf*](https://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-staff-revises-online-advertising-disclosure-guidelines/130312dotcomdisclosures.pdf)(USA). Explains how to make disclosures clear and conspicuous to avoid deception, and takes into account the expanding use of smartphones.

### 3.6.3 Implementation Guidance

None. Recommendations are solicited.

# Definitions (Glossary)

Philosophically, the MH group favors using terms that are commonly accepted in the consumer mobile space, in preference to terms that are used only in the EHR space, because of the target user for these devices, who are consumers rather than clinicians. However, where terms are used differently in EHR vs consumer spaces, we take note of that, and acknowledge the various uses. This does not purport to be an exhaustive set of mobile health definitions, but terms are included only to provide clarity within cMHAFF. See **British Standards Institution Publically Available Specification (PAS) 277:2015 Health and wellness apps. Quality criteria across the life cycle. Code of practice** (<https://shop.bsigroup.com/forms/PASs/PAS-2772015/>) which has a good set of Terms and Definitions (section 3). Definitions below that are taken from PAS277 are labeled (PAS).

|  |  |
| --- | --- |
| **Term** | **Definition** |
| Alert | A type of message that conveys information that is important enough to require a user response.  |
| App | A software application that can be executed (run) on a computing platform, and is typically a small application run or accessed on mobile devices. (PAS) Apps provide a specific set of functions which, by definition, do not include the running of the computer itself. In the context of cMHAFF, an app is the program that is downloaded to run on the user’s device. It may be supported by additional infrastructure (such as cloud-based resources) for processing, storage, etc.  |
| App store | A type of digital distribution platform for computer software, often in a mobile context. Also known as “app marketplace.” |
| Assessment | In the context of cMHAFF, “assessment” is a broad term to describe evaluations of a consumer mobile health app based on the cMHAFF criteria. Assessment methods may range from self-attestation by an app publisher, through higher levels of rigor including testing, endorsement by a third party, and/or certification by an accredited body (with or without regulatory mandates). CMHAFF does not prescribe which method(s) should be used.  |
| Caregiver | A caregiver is typically an unpaid or paid member of a person's social network who helps them with their health needs, often to address impairments related to old age, disability, a disease, or a mental disorder. For cMHAFF purposes, a caregiver *may* use a health app to help a person other than him/herself.  |
| Consumer | A person who purchases goods or services for personal use. Specifically for cMHAFF, the consumer is the acquirer of the mobile app.  |
| Consumer mobile health app | An app intended to be used by a consumer (who may or may not be a “patient”) rather than by a health professional. According to the US FDA:[[24]](#footnote-26) “Mobile apps are software programs that run on smartphones and other mobile communication devices. They can also be accessories that attach to a smartphone or other mobile communication devices, or a combination of accessories and software. Mobile *medical* apps are medical devices that are mobile apps, meet the definition of a medical device and are an accessory to a regulated medical device or transform a mobile platform into a regulated medical device. Consumers can use both mobile medical apps and mobile apps to manage their own health and wellness, such as to monitor their caloric intake for healthy weight maintenance.”  |
| Detailed Clinical Model | A Detailed Clinical Model (DCM) is an information model of a discrete set of precise clinical knowledge which can be used in a variety of contexts.(<http://wiki.hl7.org/index.php?title=Detailed_Clinical_Models>) |
| Developer (app) | The person(s) or group(s) that technically developed (programmed) the app, which may be the same or different from the app Publisher or Sponsor.  |
|  |  |
| Directive (EU) | A directive is a legal act of the European Union which requires member states to achieve a particular result without dictating the means of achieving that result. It can be distinguished from **regulations** which are self-executing and do not require any implementing measures. |
| EHR | Electronic Health Record. An electronic version of a patient’s health/medical history, that is maintained by the **provider** over time, and may include all of the key administrative clinical data relevant to that person’ care under a particular provider, including demographics, progress notes, problems, medications, etc. |
| FDA | Food and Drug Administration (FDA), a USA governmental agency whose regulations include medical devices |
| Health and wellness app | An app that contributes to any aspect of the physical, mental or social wellbeing of the user or any other subject of care or wellbeing (PAS) |
| HIPAA | Health Insurance Portability and Accountability Act is United States legislation (from 1996) that provides data privacy and security provisions for safeguarding medical information. |
| Medical app | See Consumer mobile health app definition for distinction between “health” apps and “medical” apps.  |
| Mobile platform | Commercial or open computing platforms, with or without wireless connectivity, that are hand held in nature (PAS) Typically this includes smartphones, tablets, and wearables such as smart watches.  |
| Notification | A general term for messages that convey information to a user. Alerts are a subset of Notifications: non-alert notifications convey information but do not require a user response. |
| Pairing | Pairing is establishing a trusted connection between two devices, e.g., a measurement device such as a fitness tracker paired to a mobile phone. This is similar to how headsets or car audio systems are paired via Bluetooth to a mobile phone.  |
| Personal data | Any information relating to an identified or identifiablenatural person (PAS) |
| PGHD | Patient-Generated Health Data. Health-related data created, recorded, or gathered by or from patients (or family members or other caregivers) to help address a health concern. PGHD are distinct from data generated in clinical settings and through encounters with providers in two important ways: Patients, not providers, are primarily responsible for capturing or recording these data. Patients decide how to share or distribute these data to health care providers and others. |
| PHR | Personal Health Record, also known in some locales as a “Personal Health Environment,” is an electronic application used by **patients** to maintain and manage their own health information, and access to the information, in a private, secure, and confidential environment. |
| Publisher (app) | Individual or organization who is responsible for making the app available to users (PAS) |
| Sponsor (app) | Individual or entity who organizes and is committed to the development or use of an app, e.g., a healthcare organization that sponsors an app for use by its patients, or an employer that sponsors an app for use by its employees.  |
| Subject of care or wellbeing | Person whose care or wellbeing is being supported by use of the app (PAS) |
| Syncing | Syncing (synchronizing) is updating one or more devices to contain the same information, such as versions of an app, or data used by an app. This is similar to how a phone, tablet, and watch could share the same contact list. |
| User | Person who is directly using the app interfaceNOTE 1 This may be the subject of care or wellbeing directly, or an individual assisting (as proxy for) the subject of care or wellbeing. An app may have one or more subjects of care or wellbeing interacting with the same device, either under the same subject of care or wellbeing account or using individual subject of care or wellbeing accounts. Each user may have one or more proxy users, either under the same user account or individual user accounts. (PAS) |

# Implementation

## Device- or OS-specific Considerations

In general, the vast majority of mobile phones use Android (from Google) or iOS (from Apple) operating systems (platforms).[[25]](#footnote-27) Other mobile platforms do not have significant enough market share to require specific references in cMHAFF. However, as a general principle, *if* an app is developed for any specific platforms, developers should follow all manufacturer-provided guidance for their platform, in addition to cMHAFF. The references listed here are only a small sample related to alerts and notifications.

* <https://developer.apple.com/library/ios/documentation/UserExperience/Conceptual/MobileHIG/NotificationCenter.html> -- This Apple guidance uses “Notifications” as a general term, encompassing two delivery mechanisms: **local** notifications (delivered on same device as app) and **remote (“push”)** notifications sent to all devices that have the app installed. They also then talk about supporting “as many as possible of the following notification types.”
	1. Banner – translucent, disappears after a few seconds, offers users the ability to tap the banner to switch to the sending app
	2. Alert – requires user interaction to dismiss
	3. Badge – small red oval that displays the number of pending notification items for an app
	4. Sound – something that can accompany any of the above three types.

Even though Apple also speaks of local and remote as “types” of notifications, we can think of that as a distinction along a “delivery location” axis, whereas banner/alert/badge/sound are along a “user experience or style” axis.

* <http://code.tutsplus.com/tutorials/android-sdk-using-alerts-toasts-and-notifications--mobile-1949>
* <https://blog.udemy.com/android-notification-examples/>

# Appendices

## Reference Documents

| **Document** | **Relevance to cMHAFF** |
| --- | --- |
| **Americans with Disabilities Act, Website Accessibility Under Title II of the ADA** <https://www.ada.gov/pcatoolkit/chap5toolkit.htm> | Usability |
| **Andalusian Complete list of recommendations on design, use and assessment of health Apps**http://www.calidadappsalud.com/en/listado-completo-recomendaciones-app-salud/ | Risk Assessment and Mitigation, Usability, Product Information, Launch App, Conditions and Agreements |
| **British Standards Institution PAS 277:2015 Health and wellness apps – Quality criteria across the life cycle – Code of practice Recommendations and guidance throughout the app’s product development life cycle** [https://shop.bsigroup.com/upload/271432/PAS%20277%20(2015)bookmarked.pdf](https://shop.bsigroup.com/upload/271432/PAS%20277%20%282015%29bookmarked.pdf) | Product Development and Support |
| **Cross-Device Tracking Considerations** <https://www.ftc.gov/system/files/documents/public_events/630761/cross-device_tracking_workshop_deck.pptx> | Authorization for Data Collection and Use |
| **EU Draft Code of Conduct on privacy for mobile health applications.** <https://ec.europa.eu/digital-single-market/en/privacy-code-conduct-mobile-health-apps> | Authorization for Data Collection and Use |
| **EU Directive on Consumer Rights** <http://ec.europa.eu/consumers/consumer_rights/rights-contracts/directive/index_en.htm> | Product Information, Conditions and Agreements |
| **EU General Data Protection Regulation (GDPR) , Data Privacy laws across EU** <https://www.eugdpr.org/the-regulation.html> | Regulatory Considerations, Authorization for Data Collection and Use |
| **EU Privacy Code of Conduct on Mobile Health Apps.** <https://ec.europa.eu/digital-single-market/en/privacy-code-conduct-mobile-health-apps> | Regulatory Considerations |
| **EU Unfair Commercial Practices Directive** <http://ec.europa.eu/consumers/consumer_rights/unfair-trade/index_en.htm> | Product Information |
| **Federal Trade Commission Mobile Health Apps Interactive Tool** (to help USA developers know which federal laws apply)<https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool>  | Regulatory Considerations |
|  |  |
|  |  |
|  |  |
| **French Haute Autorite de Sante: Good Practice Guidelines on Health Apps and Smart Devices (Mobile Health or mHealth).**<https://www.has-sante.fr/portail/upload/docs/application/pdf/2017-03/dir1/good_practice_guidelines_on_health_apps_and_smart_devices_mobile_health_or_mhealth.pdf> | General, Regulatory Considerations, Risk Assessment and Mitigation, Usability, Customer Support, Product Information, Pairing or Syncing, Data Exchange |
| **German Assessment Criteria for health-related apps.** <https://appcheck.de/kriterienkatalog> | Risk Assessment and Mitigation |
| **HITRUST Alliance Risk Analysis Guide** <https://hitrustalliance.net/documents/csf_rmf_related/RiskAnalysisGuide.pdf>This is targeted to for health care organizations, but describes a framework that could also benefit developers of mobile health apps | Risk Assessment and Mitigation |
| **HL7 Security Workgroup and CBHS workgroups** have provided “cookbooks” containing guidance on how to assess security and privacy risks and mitigate them. While they are intended for risk assessment of a standard or specification, rather than a product, they are still helpful resources. <http://wiki.hl7.org/index.php?title=Cookbook_for_Security_Considerations><http://wiki.hl7.org/index.php?title=HL7_Standards_Privacy_Assessment_Project> | Risk Assessment and Mitigation |
| **International Standards Organization (ISO) 14971:2007, Medical devices - Application of risk management to medical devices**. <https://webstore.ansi.org/RecordDetail.aspx?sku=ISO+14971%3a2007>  | Risk Assessment and Mitigation |
| **International Standards Organization (ISO) 21089 Health Informatics – Trusted End-to-End Information Flows.** <https://www.iso.org/standard/35645.html> | Data Authenticity and Provenance, Audit |
| **NHS Connecting for Health: Clinical Risk Management: its Application in the Manufacture of Health IT Systems - Implementation Guidance** (United Kingdom)[http://webarchive.nationalarchives.gov.uk/+/http://www.isb.nhs.uk/documents/isb-0129/amd-39-2012/0129392012impguid.pdf](http://webarchive.nationalarchives.gov.uk/%2B/http%3A//www.isb.nhs.uk/documents/isb-0129/amd-39-2012/0129392012impguid.pdf) | Risk Assessment and Mitigation |
| National Institute of Standards and Technology NISTIR 8144 Assessing Threats to Mobile Devices & Infrastructure, The Mobile Threat Catalogue (USA)https://nccoe.nist.gov/sites/default/files/library/mtc-nistir-8144-draft.pdf (context and background information) https://pages.nist.gov/mobile-threat-catalogue/application.html#vulnerable-applications (actual catalog of threats)  | Risk Assessment and Mitigation |
| National Institute for Standards and Technology (NIST), Cybersecurity Framework, <http://www.nist.gov/cyberframework/> | Risk Assessment and Mitigation |
| **National Institute for Standards and Technology (NIST), Special Publication 800-163, Vetting the Security of Mobile Applications,** <http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-163.pdf>This is intended to help organizations “vet” mobile apps that they acquire, but is also intended to help app developers understand potential software vulnerabilities. | Risk Assessment and Mitigation |
| **NIST: UNDERSTANDING THE MAJOR UPDATE TO NIST SP 800-63: DIGITAL IDENTITY GUIDELINES, August 2017,** <http://csrc.nist.gov/publications/nistbul/itlbul2017-08.pdf> | User Authentication |
| **NIST: Measuring Strength of Identity Proofing, December 16, 2015,** <https://www.nist.gov/sites/default/files/nstic-strength-identity-proofing-discussion-draft.pdf> | User Authentication |
| **NIST SP 800-122, Guide to Protecting the Confidentiality of Personally Identifiable Information (PII) (April 2010),** <https://doi.org/10.6028/NIST.SP.800-122>, for the US realm.  | Launch App and Establish User Account |
| **Office of Civil Rights (OCR):** **Health App Use Scenarios & HIPAA**, Guidance to USA Health App developers regarding HIPAA applicability<http://hipaaqsportal.hhs.gov/>**)**  | Regulatory Considerations |
| ONC API Task Force Final Report, <https://www.healthit.gov/facas/sites/faca/files/HITJC_APITF_Recommendations.pdf>  | General, Authentication, Authorization |
| ONC Model Privacy Notice (updated December, 2016) <https://www.healthit.gov/sites/default/files/2016_model_privacy_notice.pdf>  | Authorization for Data Collection and Use |
| **Open Web Application Security Project (OWASP) Top 10 Mobile Security Risks:** <https://www.owasp.org/index.php/Mobile_Top_10_2016-Top_10> | Risk Assessment and Mitigation, Authentication, Authorization, Security for Data at Rest, Security for Data in Transit |
| **U.S. Department of Health and Human Services, Usability Guidelines,** <http://guidelines.usability.gov/> | Usability |
| **US Department of Health and Human Services (HHS) Summary of the HIPAA Privacy Rule,** <https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/> which includes a definition of PHI (also known as “individually identifiable health information”) for the US realm. | Launch App and Establish User Account |
| **U.S. Federal Trade Commission, Children’s Online Privacy Protection Rule (COPPA),** <https://www.ftc.gov/tips-advice/business-center/guidance/complying-coppa-frequently-asked-questions> for the US realm. National Institute of Standards and Technology, Electronic Authentication Guideline, NIST 800-63-2. | Launch App and Establish User Account |
| U.S. Food and Drug Administration. Applying Human Factors and Usability Engineering to Medical Devices. February, 2016. <https://www.fda.gov/downloads/MedicalDevices/.../UCM259760.pdf>  | Usability |
| **U.S. Food and Drug Administration: Web page of guidance on Mobile Medical Applications,** <http://www.fda.gov/medicaldevices/digitalhealth/mobilemedicalapplications/default.htm>and more specific guidance on medical devices, published February 9, 2015 <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf> | Regulatory Considerations  |
| **U.S. Food and Drug Administration (FDA) – FDASIA Health IT Report.** <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf> | Risk Assessment and Mitigation |
| **U.S. Food and Drug Administration (FDA) Cybersecurity Guidance.** <https://www.fda.gov/MedicalDevices/DigitalHealth/ucm373213.htm> | Risk Assessment and Mitigation |
| **U.S. Food and Drug Administration (FDA) Digital Health Innovation Action Plan,** <https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/UCM568735.pdf>Indicates where FDA will and will not focus its regulations of mobile health apps.  | Regulatory Considerations |
| **User Agent Accessibility Guidelines (UAAG) Overview,** <https://www.w3.org/WAI/intro/uaag.php>Mobile Accessibility is covered in existing **W3C WAI accessibility standards/guidelines**…there are not separate guidelines for mobile accessibility. <https://www.w3.org/WAI/mobile/> | Usability |
| **W3C Mobile Usability**, <http://www.w3.org/WAI/mobile/> | Usability |
| **Web Content Accessibility Guidelines (WCAG) 2.0**, <https://www.w3.org/TR/WCAG20/> | Usability |

## Version History/Change Log

Because the initial ballot for cMHAFF was a comment-only ballot, the changes have been very substantial and have not been formally tracked.

## CMHAFF Labeling of App

It is possible that cMHAFF can assist both consumers (purchasers, users) of MH apps, as well as assessment organizations, through a “Label” that summarizes the major facts about the product. Well known examples (shown below) include Nutrition Facts labels and OTC Drug Facts labels required by governmental agencies. For cMHAFF, each “topic” (the sections of conformance criteria) would be represented by an entry, for example a table. We envision an easy-to-understand combination of graphical symbols and colors (red = bad/fail, yellow = middle/partial, green = good/present, gray = not applicable). The label’s information would be provided by a combination of self-attestation (by the app provider) verified by a third party (e.g., assessment or certification body), and possibly supplemented by third party testing (e.g., technical requirements for interoperability, security, etc.).

To be understandable, the Label should present cMHAFF categories in consumer-friendly language, not the developer-centric terms used for the cMHAFF categories.

 

**Proposed cMHAFF Information Label for an App**

The “Ind” column is an indicator (score) for the category, summarized by a color and a graphical symbol (green/up arrow = pass, red/down arrow=fail, yellow/side arrow=middle/partial). For “not applicable, cells are shaded gray and **…** is proposed as a graphical symbol.

**SIMPLIFIED cMHAFF LABEL (LUMPING OF CATEGORIES)**

|  |  |  |
| --- | --- | --- |
| **App Name:** |  | **Publisher:** |
| **Category** | **Ind** | **Other Contents (examples)[[26]](#footnote-28)** |
| 1. **Product Information**
 | **⇩** | Missing information on authors of app and evidence for app claims  |
| 1. **Starting an Account**
 | **⇧** |  |
| 1. **Security and Trust**
 | **⬄** |  |
| 1. **Exchanging or Sharing Data**
 | **…** | App does not share data |
| 1. **Ongoing Support and Updates**
 | **⬄** |  |
| 1. **Notifications and Alerts**
 | **⇧** |  |
| 1. **Ending Use of the App**
 | **⇩** | Does not ask user about keeping or deleting data.  |
| 1. **Product Development Process**
 | **⇧** | “Follows all applicable laws recommended by FTC Mobile Health Tool” |

Other icons, as alternatives to up/down arrows, include  or  The goal is to be internationally recognizable unlike letters, the meaning of which may be locale-specific.

**Notes on Categories and Potential Assessment Methods**

The category name is listed first (followed by the corresponding cMHAFF section names in parentheses). Then there is a consumer-friendly explanation of what that section includes, and finally a recommended means of assessment.

Principles of assessment:

* Green = all SHALL and SHALL [IF] statements met (where the [IF] conditions apply), plus some “subset of SHOULD criteria” (to be determined: may be some specific set of criteria, or some percentage).
* Yellow = Not all of the “subset of SHOULD criteria” were met. (This is the fuzziest area. It is “clean” if *all* SHOULD criteria are required for green, but that may be too tough)
* Red = one or more SHALL or applicable SHALL [IF] statements were not met
* Notes on how measured (self-attestation, test, inspection, etc.).
1. **Product Information**Do you have enough information to make decisions about downloading, purchasing, and using the app?
Inspection of Product Information for consumers (typically app store description). Typically, this Product Information will contain answers to the other categories on the Label, but the Label provides a high-level summary.
2. **Starting an Account (Launch App and Establish Account, Conditions and Agreements)**
	1. Starting Use of an App: How do you start using the app?
	Inspection of app registration and startup
	2. Conditions and Agreements**:** What are you asked to agree to?
	Inspection that all required conditions and agreements are present
3. **Security and Trust (includes Authentication, Authorization, Security for Data at Rest, Security for Data in Transit, Data Authenticity/Provenance, Audit)**
	1. Authentication: Protecting you from unauthorized access to the app or unwanted of your device’s features.
	Inspection of authentication and use of services
	2. Authorization and Consent: Getting your permission to gather data from you and use it
	Inspection of SHALL consent features
	3. Security for Data at Rest: Protecting your saved data
	Self-attestation: documentation of encryption methods for storage
	4. Security for Data in Transit: Protecting your data as it moves
	Self-attestation: documentation of encryption methods for transit
	5. Data Authenticity/Provenance: Ensuring your data is authentic
	Test???
	6. Audit: Recording how your app is used and who accessed it
	Inspection of audit trail SHALLs
4. **Exchanging or Sharing Data (includes Data Exchange/Interoperability, Pairing or Syncing)**
	1. Data Exchange/Interoperability: Sharing your data with others
	Test tools???
	2. Pairing or Syncing with Devices/Repositories: Connecting to your other devices
	Inspection of SHALL connection (pairing, syncing)
5. **Ongoing Support and Updates (includes Customer Support, Product Upgrades)**
	1. Customer Support: What support (if any) is offered, during what times, and how timely can you expected responses to be?
	Self-attestation: customer support policies are described
	2. Product Upgrades**:** Keeping up with app changes
	Self-attestation
6. **Notifications and Alerts**Notifying you when something important happens
Self-attestation: documentation of notifications and alerts
7. **Ending Use of the App (includes App and Data Removal, Permitted Uses of Data Post Closure)**What happens when you decide to stop using the app?
Self-attestation (difficult to test)
What can happen to your data after you stop?
Self-attestation (difficult to test)
8. **Product Development Process (includes Regulatory Considerations, Risk Assessment/Mitigation, Usability/Accessibility Assessment)**
How does the app comply with applicable laws? How carefully did the app consider risks and minimize their impact appropriately? How did the app consider ease of use for its intended users, including those with disabilities?
Self-attestation: app owner lists the regulations that were followed, risk assessment approach is documented, usability assessment is documented

## Relationship to Other Standards

* The HL7 EHR System Functional Model and the HL7 PHR System Functional Model, and their profiles, provided inspiration for cMHAFF. While cMHAFF is not intended for EHRs and PHRs, it is similar in that it is a broad general framework that can be constrained or extended (profiled) to focus on specific realms or types of apps.
* Several European standards and guidelines for mHealth apps were analyzed and mapped to cMHAFF categories. These are included in Section 6.1, References.
1. <https://www.ama-assn.org/ama-adopts-principles-promote-safe-effective-mhealth-applications> [↑](#footnote-ref-1)
2. See ONC API Task Force Final Report, <https://www.healthit.gov/facas/sites/faca/files/HITJC_APITF_Recommendations.pdf>, Topic 3 Endorsement/Certification of Apps, page 17. “The Task Force discussed the pros and cons of consumer protection benefits of an app certification process; however, ultimately, we favor a secondary market in app endorsements. In such a market, various kinds of organizations (EHR vendors; security experts; consumer advocacy groups; clinical professional societies; provider organizations) can "endorse" a given app through a distributed, publicly visible process, without centralized regulatory oversight.” [↑](#footnote-ref-2)
3. HIPAA is US-realm-specific, for example purposes only. [↑](#footnote-ref-5)
4. For US Realm, FDA is the regulating agency. See <https://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf>. Section V.A says that the following type of app IS within FDA oversight: “Mobile apps that become a regulated medical device (software) by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations. These types of mobile medical apps are similar to or perform the same function as those types of software devices that have been previously cleared or approved. ”
Appendix B, which contains a list of apps that MAY meet the definition of medical device, for which FDA intends to exercise enforcement discretion. Examples include “Mobile apps that are intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health or wellness…” [↑](#footnote-ref-6)
5. “EHR-Integrated” in this example means that the app is designed and developed as part of the EHR application and offered by a provider, i.e., it is not standalone or independent of an EHR. “EHR+” includes provider software, e.g., administrative systems, beyond the scope of an EHR. Note that even if the consumer sends data to an EHR, and the EHR accepts the data, that does not in itself make the app developer a business associate of the covered entity (source: Office of Civil Right Health App Use Scenarios and HIPAA) [↑](#footnote-ref-7)
6. The “consumer” and the “patient” are the same person in this example. From the EHR’s perspective, the record is a patient record. [↑](#footnote-ref-8)
7. Note on terms: “Product” is used interchangeably with “App” in cMHAFF conformance statements. Also, “product” is not intended to imply that it is sold commercially: an App is the “work product” of someone developing software for consumer health. Similarly “Publisher” is used to mean the person or organization that supplies the app to the consumer, typically via an App Store. It could also be called “owner” and is not necessarily the same as the “developer” of the app. [↑](#footnote-ref-9)
8. See IEC 62304 standard, Medical Device Software, Software Life Cycle. [↑](#footnote-ref-10)
9. See Andalusian Complete list of recommendations on design, use and assessment of health Apps [↑](#footnote-ref-11)
10. See French Good Practice Guidelines of Health Apps and Smart Devices [↑](#footnote-ref-12)
11. See French Good Practice Guidelines [↑](#footnote-ref-13)
12. Example: qualified cardiologists credential required for ECG/EKG interpretation service [↑](#footnote-ref-14)
13. Many criteria are from French Good Practice Guidelines [↑](#footnote-ref-15)
14. From Andalusian Recommendations. Example: a disclaimer regarding the app being used outside the intended purpose, e.g., for a heart rate monitor publisher is not liable for harm incurred if the user were to continue activity when exceeding the peak heart rate. Or in an app intended for adult medication management, disclaimer of responsibility if used with children. [↑](#footnote-ref-16)
15. From Andalusian recommendations [↑](#footnote-ref-17)
16. “System” includes the app itself (on the device) as well as its supporting infrastructure (e.g., cloud-based or other services provided outside the device) [↑](#footnote-ref-18)
17. This means that the EHR is connected to the mobile app, such that the EHR is part of the overall system with which the consumer interacts. [↑](#footnote-ref-19)
18. From French Good Practice Guidelines [↑](#footnote-ref-20)
19. From French Good Practice Guidelines [↑](#footnote-ref-21)
20. See French Good Practice Guidelines [↑](#footnote-ref-22)
21. Also include discussion of where the same terms are used with different meanings in clinical/EHR space [↑](#footnote-ref-23)
22. “Computer” is broadly defined to encompass smart mobile devices such as phones and tablets, as well as PCs, servers, and all other computing machinery. [↑](#footnote-ref-24)
23. See Andalusian recommendations [↑](#footnote-ref-25)
24. <https://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/default.htm> [↑](#footnote-ref-26)
25. <https://www.idc.com/promo/smartphone-market-share/os> In 2017 Q1, Android had 85.0% of unit sales, iOS 14.7%, Windows 0.1%, and other platforms 0.1%. [↑](#footnote-ref-27)
26. For self-attestation, this column may be provided by App Owner as needed to explain product briefly, e.g., reasons why category is not applicable. For testing and inspection items, notes are added by tester/inspector. For certification, **all** items would have to be certified for accuracy by a third party certifying body. [↑](#footnote-ref-28)