

**M4 Portfolio Assignment: Regulatory Applicability of Health Software** for  
Specialized Graduate Certificate in Health Informatics  
Concentration: Digital Health

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### Briefly introduce your digital/virtual health solution

The iCare HOME2 Tonometer is a digital/virtual health solution for remote diagnosis and monitoring of intraocular (IOP) eye pressure in glaucoma patients. The device is a handheld “rebound” tonometer requiring no topical anesthesia, and allows a patient to measure IOP sitting, standing, or supine. The digital/virtual components of the device include real-time transmission of IOP data via Bluetooth or USB cable to a smart phone mobile application “iCare PATIENT2”, a cloud database “iCare CLINIC”, and a desktop application the “iCare EXPORT” (iCare, 2023).

### List any app features that may require regulatory oversight and compliance

- 1. Individually identifiable health information** is transmitted and received by the mobile app “iCare PATIENT2”, the “iCare CLINIC” cloud database, and the “iCare EXPORT” desk application.
  - ☐ **HIPAA rules apply:** 45 CFR Part 160 and 45 CFR Part 164.
  - ☐ Identifiable health information includes but is not limited to name, geographic IDs, IP address, and URLs (HHS.gov, 2022).
- 2. All apps transmit information in electronic form**, are ONC certified health IT devices, and exchange data with **more than 2 unaffiliated parties**.
  - ☐ These features are subject to **Information Blocking Regulations**.
  - ☐ The manufacturer, iCare USA Inc., notes in their Apple Store privacy policy that a patient’s **personal information may be shared** with the following unaffiliated parties (icare-world, 2021):
    - ☐ *nonaffiliated service providers*
    - ☐ *regulatory authorities*
    - ☐ *our auditors and legal advisors*
    - ☐ *relevant industry self-regulatory bodies; and*
    - ☐ *others, where permitted by law.*
  - ☐ “Unaffiliated partes” could also be a health system, provider, EHRs, a 3<sup>rd</sup> party app such as Apple Health & Fitness, or a health insurance payer who may need the information to approve payment of the device (Savage et al, 2020).
- 3. A prescription is required to utilize the iCare HOME2 and access the digital health applications** (myeyes.net, 2023).
  - ☐ The prescription requirement is subject to **HIPAA rules**.

**4.** The FTC act states an app “**can’t be deceptive about how you will handle or distribute users PHI and personally identifiable data.**” The act also notes that you need to “**openly disclose this information to all consumers** (FTC, 2022).”

o The iCare devices are subject to the FTC act: there is a statement hidden within the “App Privacy” section of the iCare PATIENT2 mobile app store page that is **NOT openly disclosed or transparent to the consumer** (Apple Store Preview, 2023).”

o If you open the “privacy policy” link it goes into detail (icare-world, 2021):

- *“Personal data is collected by our apps”*
- *“We store personal information about you on computer systems operated by our service providers.”*
- *“Intraocular pressure measurements are stored and shared with external parties”*
- *“Free-text messages exchanged between you and a professional health care provider you have voluntarily provided are stored and shared.”*
  - It is **not transparent to the consumer** that their personal information and health data is shared with unaffiliated parties.
  - It goes on to state: *“Your information may only be transferred to another country for processing as permitted and in compliance with applicable law.”*

**5.** These applications collect, receive, and maintain identifiable health information for consumers as stated above. They also allow users to upload data from outside sources and are capable of syncing with other health apps on a mobile device or computer.

o The **FTC Health Breach Notification Rule** applies.

**6.** All apps can be utilized for collecting and transmitting IOP measurements in pediatric glaucoma patients (Flemmons et al, 2011).

o **Children’s Online Privacy Protection Rule (COPPA)** will apply.

### **Summarize how you would ensure appropriate regulatory compliance**

**HIPAA rules and Information Blocking:** to ensure HIPAA and Information blocking compliance, the provider and healthcare facility should immediately present the patient with a privacy policy (HHS.gov, 2023). This can be done during initial authorization of the patient’s smart phone app using a standard such as “OAuth” that has been widely adopted by mHealth applications as well as SMART on FHIR. Doing this allows the patient to consent to their personal information being

shared with all necessary parties involved in their care including unaffiliated 3<sup>rd</sup> parties such as healthcare payors or application vendors (Sayeed et al, 2021).

**FTC act:** as mentioned above, data and privacy practices are hidden at the bottom of the app store page in a “hyperlinked disclosure”. This violates the FTC standard for not being open and transparent about privacy practices. To rectify this situation, the FTC recommends the links *“should be prominent, near the claim it is qualifying, easily noticeable, and lead directly to the qualifying information (FTC, 2000).”* Information should be moved to the top of the page in addition to enhancing the font size and graphics to demonstrate the importance, relevance, and transparency of the disclosed information. The same process should be followed for all device web pages and user guides to ensure full regulatory compliance.

**FTC Health Breach Notification Rule:** the app store privacy policy states *“if any suspected data security incident occurs, we will notify you (icare-world, 2021).”* To ensure compliance we would need to enforce the FTC’s “breach timeline” and notify the following 3 groups within 60 days of discovery: impacted individuals, the FTC, and the Media of the US state or territory impacted (McKeon, 2023).

**COPPA:** the iCare app privacy policy for children and minors states they *“do not collect or store information for any individual under age 18 unless consented by parent or guardian (icare-world, 2021).”* For COPPA compliance, the policy should be visible on all product pages. A parental consent form needs to be utilized by the healthcare facility for collecting the child’s IOP measures and confirming the child’s information will not be sent to any unaffiliated 3<sup>rd</sup> party. Furthermore, we will need to give parents full access to all app devices to review and transmit the child’s personal information (Federal Trade Commission, 2023).

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