Diabetes on the Go:
A Study of 275 Diabetes Apps

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The public is increasingly accessing health information on the go. Fifty-six percent of all American adults own a smartphone.[2] Over half of these smartphone owners use their devices to get health information, and roughly one-fifth have health apps.[3] The growing use of mobile health applications, games, and social networks help children and adults alike gain control of disease management, maintain independence, build skills, and increase responsibility. Apps serve as a platform for structured communication between parties such as a caregiver and an elderly parent or a child and the school nurse. Apps provide a repository for data, including compliance with medication regimens, activity notes, and food logs that can be shared with a doctor to identify trends and troubleshoot health issues. Notifications and alerts can be tailored for each user, providing reminders and warnings. Data from health and fitness apps, games, and social networks can be used to promote both individual and population health.[4]

With the benefits, come great risks. Any scenario where personal information—especially health information—is collected, analyzed, or stored provides a plethora of privacy concerns. Individuals voluntarily input personal information into apps, but the way in which this data is used, aggregated, and shared can be problematic. An individual's information may be publicly visible, with or without the knowledge of the user, revealing identifying information. Personal health information readily available on apps can be and is used against individuals.

Researchers at the Institute for Science, Law and Technology and the Center for Diabetes Research and Policy (ISLAT/CDRP) at IIT Chicago-Kent College of Law undertook a project to understand the privacy and liability issues raised by health apps. As part of this ongoing project, ISLAT/CDRP researchers conducted a diabetes app study, which assessed 275 diabetes apps to determine their functions, privacy policies, and whether the apps claimed to be approved by the Food and Drug Administration (FDA).[5] ISLAT/CDRP researchers also reviewed the law and policies that govern the design and use of health and fitness apps.

ISLAT/CDRP Study of Diabetes Apps

An ISLAT/CDRP study analyzed 275 diabetes-specific apps in the Google Play Store (where people can purchase apps for Android phones).[6] Two hundred and two of these diabetes-specific apps were available for free in the Google Play Store.[7] Less than 10%—only 25 out of 275—diabetes-specific apps have privacy statements or link to privacy policies in the Google Play Store prior to downloading the app.[8] Seventy-six percent (19) of the apps with privacy policies acknowledge that the apps collect user data[9] and 40% (10) of those apps openly disclose that cookies are used for data collection purposes.[10] Only three privacy policies explicitly state that neither data nor user logs were tracked.[11] The privacy policies of these apps also state that information is only shared if a user selects a specific person to receive the information.[12] Five out of the 25 apps with privacy statements note that they do not collect information from children

under 13 years of age.[13] Although a great deal of consumer information is collected via mobile health apps, companies often do not disclose details about their collection practices.

Name, email address, date of birth, and health information represent some of the personal information collected by the apps examined. Health information could include blood glucose levels, blood pressure, and activity logs. Typically, the information is collected when a user registers for the app through an online account. Some apps claim to collect the personal information for "legitimate business purposes" of the application, while others store and analyze user data for other purposes.[14] Some app developers justify their data collection practices by noting that data collection is a means of improving and personalizing the apps' services. Only five privacy statements note that no personally identifiable information would be sold. [15]
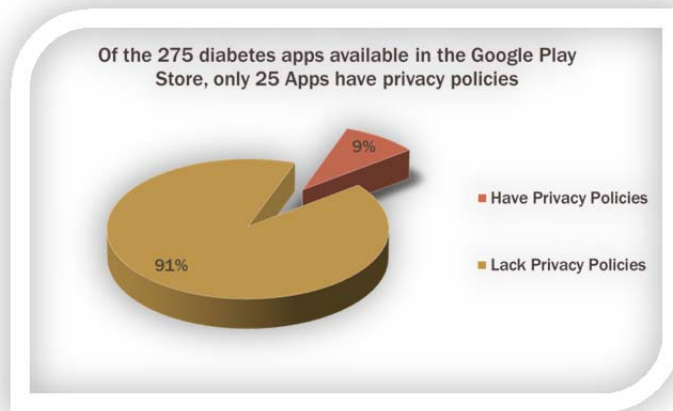

Figure1. Proportion of 275 diabetes apps with privacy policies.

Of the 25 out of 275 apps that have privacy policies, two apps share personal information only with the user's consent,[16] but 11 share data with unidentified third parties. Seven privacy policies mention that data may be used for advertisement purposes,[17] while only two privacy policies state that no personal information will be disclosed to third parties for advertisement purposes.[18] All of the privacy policies that acknowledge that personal information will be shared with third parties belong to apps that can be downloaded for free. Thus, free apps may pose a greater risk to the user's privacy than paid apps. The privacy statement of one diabetes forum app states that personal information may be disclosed to analytics and search engine providers or to research organizations when the user registers for a clinical trial.[19] The same app also provides non-personally identifiable information about users to pharmaceutical research organizations.[20] However, even non-personally identifiable information in the aggregate can be used to determine the identity of users.[21]

Only eight privacy policies state that the app uses electronic safeguards for data protection, either in the form of data encryption or storage of confidential information on secured servers. [22] Without security measures, such as data encryption, user information can easily be intercepted by hackers or identity thieves. Some privacy statements also contain information about the consumers' rights to protect their privacy. For instance, the user can request that certain information not be disclosed, the user can opt-out of cookies, or the user can opt-out of receiving marketing materials.

As part of the diabetes app analysis, ISLAT/CDRP researchers identified 119 educational apps and 89 apps with diabetes management features.[23] The educational apps provide a diverse range of resources, including access to diabetes-related articles and medical animations. Some educational apps have gamified components, utilizing flashcards and interactive quiz features to engage users. One app even provides special yoga instructions for individuals with diabetes.

Almost all of the diabetes management apps (98%) are designed to support diabetes self-management.[24] Diabetes management apps allow the user to monitor health-related parameters

such as blood glucose levels (98% of diabetes management apps), insulin doses (64% of diabetes management apps), and carbohydrate intake (59% of diabetes management apps). Thirty-four percent of the diabetes management apps have an alert function, which can remind users to take their medications or to attend scheduled medical appointments. Fifty percent of the diabetes management apps also include carbohydrate or insulin dose conversion functions. Although most of the apps with a conversion function provide insulin dose recommendations—arguably providing medical advice by guiding patients or caregivers towards decisions about medication administration—alarmingly, only a few of these apps have been thoroughly tested or are regulated by the FDA. ISLAT/CDRP researchers were only able to identify three FDA regulated diabetes apps in the Google Play Store: BlueStar Diabetes, Glooko and MyGlucoHealth.

Health-related personal information is collected by most of the diabetes management apps, yet only 21% of diabetes management app developers provide a privacy policy in the app's description in the Google Play Store or a link to a privacy policy hosted on another website. Consequently, people who purchased and downloaded diabetes-related apps may not understand the risks to their privacy. Such risks may include information about health, geolocation, and other information being shared with third parties. Those apps without encryption or other security measures place users' information—including detailed health information—in a vulnerable position. Once shared or stolen, this information could be used against individuals to limit opportunities, to discriminate against them based on disability, or to serve unwarranted, targeted, and potentially problematic advertisements.

Applicable Laws

Federal laws and regulations do not sufficiently protect consumers who use health apps. Federal and state laws have been implemented to safeguard health information through regulations implemented pursuant to the U.S. Health Insurance Portability and Accountability Act (HIPAA) and similar state laws. The HIPAA Privacy Rule is a collection of regulations that outline how health information should be protected.[25] However, health disclosures on health apps are not protected by these laws. The HIPAA Privacy Rule generally only covers health plans, health care clearinghouses, health care providers, and business associates.[26] There are some exceptions to the rule, such as protected health information used by public health agencies for public health purposes in certain circumstances.[27]

The Food and Drug Administration (FDA) regulates a small subset of medical apps, including those that serve as an accessory to a medical device and those that transform the mobile platform into a medical device.[28] But the majority of health apps will fall through the regulatory cracks. The FDA only gets involved if the app is considered to be a medical device.[29] Additionally, the Federal Trade Commission (FTC) attempts to protect consumers against fraud and misrepresentation, but has had little success in swaying industry to provide adequate self-regulation.[30] While there have been a few FTC complaints issued against mobile health app developers, many apps slide past the FTC's oversight or jurisdiction.[31] Current laws and regulations fall short of protecting the health information of mobile app users. Without adequate oversight and appropriate regulation, the risks go unaddressed.

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2. Aaron Smith, "Smartphone Ownership – 2013 Update," Pew Research Center-Pew Internet & American Life Project, at 2 (June 5, 2013), Pew Research Center-Pew Internet & American Life Project, at 2 (November 8, 2012), http://pewinternet.org/Reports/2013/Smartphone-Ownership-2013/Findings.aspx

3. Susannah Fox and Maeve Duggan, Pew Internet & American Life Project, "Mobile Health 2012," (November 8, 2012), at 2, http://www.pewinternet.org/~/media/Files/Reports/2012/PIP_MobileHealth2012.pdf

4. Renee Cocchi, "Can Phone Apps Really Help Patients With Compliance?" April 4, 2013, http://www.healthcarebusinesstech.com/can-phone-apps-really-help-patients-with-compliance/; Amy Dockser-Marcus, "Patients as Partners," *The Wall Street Journal*, April 16, 2012, http://online.wsj.com/article/SB10001424052702304692804577281463879153408.html; Brian Edwards, "UW Researchers Transform Smartphone Into Spirometer with Mobile App," *iMedical Apps*, September 25, 2012, http://www.imedicalapps.com/2012/09/researchers-smartphone-spirometer-mobile-app/; Milt Freudenheim, "More Using Electronics to Track Their Health," *The New York Times*, January 27, 2013, http://www.nytimes.com/2013/01/28/health/electronic-health-tracking-increasingly-common-researchers-say.html?ref=health&_r=5&; Timothy Hay, "The Rise of the 'Quantified Self' in Health Care," *The Wall Street Journal*, August 13, 2013, http://blogs.wsj.com/venturecapital/2013/08/13/the-rise-of-the-quantified-self-in-health-care/?curator=MediaREDEF&mod=WSJBlog; Hannah Hickey, "App Lets You Monitor Lung Health Using Only a Smartphone," University of Washington, September 18, 2012, http://www.washington.edu/news/2012/09/18/app-lets-you-monitor-lung-health-using-only-a-smartphone/; The Hospital for Sick Children, "myIBD," iTunes Preview, Apple App Store, July 30, 2011, https://itunes.apple.com/us/app/myibd/id444728980?mt=8; iHealthBeat, "More Doctors Starting To Prescribe Mobile Apps for Chronic Conditions," April 2, 2013, http://www.ihealthbeat.org/articles/2013/4/2/more-doctors-starting-to-prescribe-mobile-apps-for-chronic-conditions.aspx#; Lauren Neergaard, "Not 'Star Trek' Tricorder, But New Smartphone Tools May Help People Monitor Health," May 3, 2013, *The Philippine Star*, http://www.philstar.com/science-and-technology/2013/05/03/937830/not-star-trek-tricorder-new-smartphone-tools-may-help; Orpyx, "SurroSense Rx™ System," http://orpyx.com/pages/surrosense-rx; Orpyx, "SurroGait Rx™ System," http://orpyx.com/pages/surrogait-rx; Orpyx Medical Technologies Inc., "SurroSense Rx," iTunes Preview - Apple, June 12, 2013, https://itunes.apple.com/us/app/surrosense-rx/id589977546?mt=8; Molly Pace-Scrivener, "You, Me & IBD | Facebook App Plays Matchmaker," *C3N Project Blog*, February 29, 2012, http://c3nproject.org/blog/022912/you-me-ibd-facebook-app-plays-matchmaker; Patients Like Me, "Open Research Exchange," http://www.openresearchexchange.com/; PatientsLikeMe, "PatientsLikeMe Calls for Researcher Participation in New Open Research Exchange™ Platform," May 20, 2013, http://news.patientslikeme.com/press-release/patientslikeme-calls-researcher-participation-new-open-research-exchange-platform; Robert Wood Johnson Foundation, "Patients Like Me: Open Research Exchange," http://www.rwjf.org/en/grants/grantees/PatientsLikeMe.html; Robert Wood Johnson Foundation Pioneer Blog Team, "PatientsLikeMe Project Pioneers Use of Outcomes Data That Are Meaningful to Patients," *Pioneering Ideas Blog,* Robert Wood Johnson Foundation, February 25, 2013, http://www.rwjf.org/en/blogs/pioneering-ideas/2013/02/patientslikeme_proje.html; Eric Semling, "Daily Data App Portfolio Piece," http://ericsemling.com/daily-data-app; Emily Singer, "An App that Looks for Signs of Sickness," MIT Technology Review, June 21, 2011, http://www.technologyreview.com/news/424422/an-app-that-looks-for-signs-of-sickness/?mod=related; Ken Terry, "PatientsLikeMe Launches Open Research Exchange," *InformationWeek*, May 21, 2013, http://www.informationweek.com/healthcare/patient/patientslikeme-launches-open-research-ex/240155263; Ubiquitous Computing Lab, "SpiroSmart," University of Washington, September 16, 2012, http://ubicomplab.cs.washington.edu/wiki/SpiroSmart; Bruce Upbin, "PatientsLikeMe is Building A Self-Learning Healthcare System," *Forbes*, March 1, 2013, http://www.forbes.com/sites/bruceupbin/2013/03/01/building-a-self-learning-healthcare-system-paul-wicks-of-patientslikeme/; Neil Versel, "Wireless Shoe Insert Senses Foot Numbness That Can Lead to Diabetic Ulcers, Amputation," *MobiHealthNews*, July 16, 2012, http://mobihealthnews.com/17902/wireless-shoe-insert-senses-foot-numbness-that-can-lead-to-diabetic-ulcers-amputation/.

5. *See also* Michael Holloway, "Federal Agency Regulation of Mobile Medical Apps," Institute for Science, Law and Technology, conference report, (April 2014).

6. There is no universal accepted method to search for mobile health applications (apps). To identify diabetes-related apps, we entered the Google Play Store at https://play.google.com/store/apps and searched for the term

"diabetes" on January 3, 2013. A total of 275 apps were found. We focused on Android apps in our analysis. Each app in the Android store contains pictures of the app interface and a brief description of the app functions. Based on this description, we classified the apps into 6 categories: conversion function (carbohydrates and insulin), diabetes education, nutrition education and recipes, risk assessment, diabetes management, and other.

7   The majority of apps can be downloaded for free (73%). The remaining 7% cost between $0.99 and $39.99.

8   "Accu-Check360Mgmt. Description," *Google Play*, https://play.google.com/store/apps/details?id=com.roche.ac360mobile; "Privacy Policy," *BlueStar Diabetes*, https://www.bluestardiabetes.com/Portal/Guest/PrivacyPolicy.htm; "Terms and Conditions and Privacy Policy," *Care4Life*, https://www.care4life.com/mycare4life/Display/display.aspx?CurrentXsltId=9; "Policy, "Privacy Policy," *DSharp Mobile Diabetes Management*, http://dsharpdiabetes.com/privacy-policy/; "Diabetes Diary: Description," *Google Play*, https://play.google.com/store/apps/details?id=com.jeschuaschang.diabetesdiary, "Privacy Policy," *VCA Diabetes*, https://m.vcapetdiabetes.com/#privacy_policy/; "Privacy and Cookie Policy," *Diabetes.co.uk*, http://www.diabetes.co.uk/privacy html; "Diabetes HbA1c: Description," *Google Play*, https://play.google.com/store/apps/details?id=com.wiken.diabeteshba1c; "Privacy Policy," *Suderman Solutions*, http://sudermansolutions.com/Privacy.aspx; "Diabetes Manager: Description," *Google Play*, https://play.google.com/store/apps/details?id=com.bechmanns.diabetesmmol.manager; "Privacy," *Telcare*, http://www.telcare.com/privacy/; "Privacy Policy," *Diabetes Parent*, http://diabetesparent.se/policy/; "Privacy Policy," *Diabetic Connect*, http://www.diabeticconnect.com/privacy-policy; "Privacy Policy," *Publications International, Ltd.*, http://www.pilbooks.com/pilprivacy html; "Policies," *App-Buzz*, http://app-buzz.com/policies/; "Privacy," *DiaLog Privacy*, http://david-froehlich.de/android/diabetes/privacy/; "Datenschutzerklaerung," *Focus Magazin*, http://www.focus.de/magazin/digital/datenschutz/datenschutzerklaerung-datenschutzbestimmung-der-focus-magazin-verlag-gmbh-fmv_aid_880417 html; "Privacy Policy," *Glucose Buddy*, http://www.glucosebuddy.com/privacy_policy.; "HelpAround – Terms of Use," *HelpAround*, http://static.helparound.cc.s3.amazonaws.com/HelpAround_ToU_18feb2013.pdf ; "Our Commitment to Privacy," *Manage BGL*, http://www.managebgl.com/privacy.html.; "General Conditions of Use," *mySugr GmbH*, https://s3-eu-west-1.amazonaws.com/assets.mysugr.com/tos/US/2/en html; "Privacy Policy," *Medivo*, http://www.medivo.com/privacy-policy/.; "Privacy Policy," *Prognosis*, http://www.prognosisapp.com/privacy.php; "General Terms of Business," *Sinovo Ltd. & Co. KG*, http://www.sinovo.org/?id=144. Two additional apps claim to have privacy policies, but these policies could not be accessed via the links provided in the Google Play Store. *See* "Privacy Policy," *900 Diabetic Recipes*, http://www.mobifusion.com/; "Privacy Policy," *Diabetes Connect*, https://www.diabetesconnect.me/privacy_policy htm.

9   "Accu-Check360Mgmt. Description," *Google Play*, https://play.google.com/store/apps/details?id=com.roche.ac360mobile; "Privacy Policy," *BlueStar Diabetes*, https://www.bluestardiabetes.com/Portal/Guest/PrivacyPolicy.htm; "Terms and Conditions and Privacy Policy," *Care4Life*, https://www.care4life.com/mycare4life/Display/display.aspx?CurrentXsltId=9; "Policy; "Privacy Policy," *DSharp Mobile Diabetes Management*, http://dsharpdiabetes.com/privacy-policy/; "Privacy Policy," *VCA Diabetes*, https://m.vcapetdiabetes.com/#privacy_policy/; "Privacy and Cookie Policy," *Diabetes.co.uk*, http://www.diabetes.co.uk/privacy html; "Privacy Policy," *Suderman Solutions*, http://sudermansolutions.com/Privacy.aspx; "Privacy," *Telcare*, http://www.telcare.com/privacy/; "Privacy Policy," *Diabetes Parent*, http://diabetesparent.se/policy/; "Privacy Policy," *Diabetic Connect*, http://www.diabeticconnect.com/privacy-policy; "Privacy Policy," *Publications International, Ltd.*, http://www.pilbooks.com/pilprivacy.html; "Policies," *App-Buzz*, http://app-buzz.com/policies/; "Privacy Policy," *Glucose Buddy*, http://www.glucosebuddy.com/privacy_policy.; "HelpAround – Terms of Use," *HelpAround*, http://static.helparound.cc.s3.amazonaws.com/HelpAround_ToU_18feb2013.pdf ; "Our Commitment to Privacy," *Manage BGL*, http://www.managebgl.com/privacy.html.; "General Conditions of Use," *mySugr GmbH*, https://s3-eu-west-1.amazonaws.com/assets.mysugr.com/tos/US/2/en html; "Privacy Policy," *Medivo*, http://www.medivo.com/privacy-policy/.; "Privacy Policy," *Prognosis*, http://www.prognosisapp.com/privacy.php; "General Terms of Business," *Sinovo Ltd. & Co. KG*, http://www.sinovo.org/?id=144.

10   "Privacy Policy," *VCA Diabetes*, https://m.vcapetdiabetes.com/#privacy_policy/; "Privacy and Cookie Policy," *Diabetes.co.uk*, http://www.diabetes.co.uk/privacy html; "Privacy Policy," *Suderman Solutions*, http://sudermansolutions.com/Privacy.aspx; "Privacy," *Telcare*, http://www.telcare.com/privacy/; "Privacy Policy," *Diabetic Connect*, http://www.diabeticconnect.com/privacy-policy; "Privacy Policy," *Publications*

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International, Ltd.*, http://www.pilbooks.com/pilprivacy html; "Policies," *App-Buzz*, http://app-buzz.com/policies/; "Privacy Policy," *Glucose Buddy*, http://www.glucosebuddy.com/privacy_policy.; "Our Commitment to Privacy," *Manage BGL*, http://www managebgl.com/privacy html.; "Privacy Policy," *Medivo*, http://www.medivo.com/privacy-policy/.

[11] "Diabetes HbA1c: Description," *Google Play*, https://play.google.com/store/apps/details?id=com.wiken.diabeteshba1c; "Privacy," *DiaLog Privacy*, http://david-froehlich.de/android/diabetes/privacy/; "Diabetes Diary: Description," *Google Play*, https://play.google.com/store/apps/details?id=com.jeschuaschang.diabetesdiary.

[12] "Diabetes HbA1c: Description," *Google Play*, https://play.google.com/store/apps/details?id=com.wiken.diabeteshba1c; "Privacy," *DiaLog Privacy*, http://david-froehlich.de/android/diabetes/privacy/; "Diabetes Diary: Description," *Google Play*, https://play.google.com/store/apps/details?id=com.jeschuaschang.diabetesdiary.

[13] "Privacy Policy," *Medivo*, http://www.medivo.com/privacy-policy/; "Privacy Policy," *Glucose Buddy*, http://www.glucosebuddy.com/privacy_policy; "Our Commitment to Privacy," *Manage BGL*, http://www.managebgl.com/privacy html; "Policies," *App Buzz*, http://app-buzz.com/policies/; "Privacy Policy," *Diabetic Connect*, http://www.diabeticconnect.com/privacy-policy. (For *Diabetic Connect*, the privacy policy states that they don't collect information from children under 12).

[14] *See e.g.* "Privacy Policy," *Diabetic Connect*, http://www.diabeticconnect.com/privacy-policy.

[15] "Diabetes Manager: Description," *Google Play*, https://play.google.com/store/apps/details?id=com.bechmanns.diabetesmmol.manager; "Privacy Policy," *BlueStar Diabetes*, https://www.bluestardiabetes.com/Portal/Guest/PrivacyPolicy.htm; "Privacy Policy," *Publications International, Ltd.*, http://www.pilbooks.com/pilprivacy html; "Privacy Policy," *VCA Diabetes*, https://m.vcapetdiabetes.com/#privacy_policy/; "Terms & Conditions and Privacy Policy," *Care4Life*, https://www.care4life.com/mycare4life/Display/display.aspx?CurrentXsltId=9.

[16] "Privacy," *Telcare*, http://www.telcare.com/privacy/; "Privacy Policy," *Diabetic Connect*, http://www.diabeticconnect.com/privacy-policy.

[17] "Our Commitment to Privacy," *Manage BGL*, http://www managebgl.com/privacy html; "Privacy and Cookie Policy," *Diabetes.co.uk*, http://www.diabetes.co.uk/privacy html; "Privacy Policy," *Diabetic Connect*, http://www.diabeticconnect.com/privacy-policy; "Privacy Policy," *Glucose Buddy*, http://www.glucosebuddy.com/privacy_policy; "Privacy Policy," *Medivo*, http://www medivo.com/privacy-policy/; "Privacy Policy," *Prognosis*, http://www.prognosisapp.com/privacy.php; "Privacy Policy," *Diabetes eDiary*, https://m.vcapetdiabetes.com/#privacy_policy.

[18] "Diabetes Manager: Description," *Google Play*, https://play.google.com/store/apps/details?id=com.bechmanns.diabetesmmol.manager; "Privacy Policy," *Diabetes eDiary*, *My Diabetic Pet*, *VCA Animal Hospitals*, https://m.vcapetdiabetes.com/#privacy_policy; "Privacy Policy," *DSharp Mobile Diabetes Management*, http://dsharpdiabetes.com/privacy-policy/;

[19] "Privacy and Cookie Policy," *Diabetes.co.uk*, http://www.diabetes.co.uk/privacy.html.

[20] "Privacy and Cookie Policy," *Diabetes.co.uk*, http://www.diabetes.co.uk/privacy.html.

[21] "Privacy and Cookie Policy," *Diabetes.co.uk*, http://www.diabetes.co.uk/privacy.html.

[22] "Our Commitment to Privacy," *Manage BGL*, http://www managebgl.com/privacy html; "Privacy and Cookie Policy," *Diabetes.co.uk*, http://www.diabetes.co.uk/privacy html; "Privacy Policy," *Diabetic Connect*, http://www.diabeticconnect.com/privacy-policy; "Privacy Policy," *Glucose Buddy*, http://www.glucosebuddy.com/privacy_policy; "Privacy Policy," *Medivo*, http://www medivo.com/privacy-policy/; "Privacy Policy," *Suderman Solutions*, http://sudermansolutions.com/Privacy.aspx; "Privacy Policy," *VCA Diabetes*, https://m.vcapetdiabetes.com/#privacy_policy/; "Privacy Policy," DiaLog: Diabetes Logbook, http://david-froehlich.de/android/diabetes/privacy/.

[23] The third largest app category (15%) is nutrition education and recipes. Apps in this category offer recipes for individuals with diabetes, act as meal planners, and also provide the amount of carbohydrates in menus of popular fast food restaurants (Diabetes and Eating Out). Diabetes risk assessment apps represent another category. Around 4% of diabetes-related apps in the Google Play Store act as risk predictors for the development of type 2 diabetes based on questions about age, physical constitution and lifestyle. Diabetes forums, messengers, screen widgets, and translators were listed under the category "other."

[24] Some diabetes management apps are available for health care providers (Diabetes LogBook) or owners of pets with diabetes (Diabetes eDiary).

25 45 CFR 160; 45 CFR 164.

26 45 CFR 160.102; 45 CFR 160.104.

27 45 CFR 164.512(b).

28 *Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff*, Food and Drug Administration, Sept. 25, 2013, p. 7.

29 *Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff*, Food and Drug Administration, Sept. 25, 2013, p. 7. In a letter dated March 18, 2014, U.S. Senators Michael Bennet, Tom Harkin, Richard Burr, Orrin Hatch, Lamar Alexander, and Mark Warner sent a letter to FDA Commissioner Margaret Hamburg seeking additional clarification on the FDA Guidance on mobile medical applications, including additional information about how the risk-based approach will be implemented in practice. Additionally, the senators asked if legislation would help the FDA in their efforts to regulate mobile medical apps. Letter from Michael F. Bennet, Tom Harkin, Richard Burr, Orrin G. Hatch, Lamar Alexander, and Mark R. Warner, U.S. Senators, to Dr. Margaret Hamburg, Commissioner, Food and Drug Administration (Mar. 18, 2014).

30 *See e.g.* Katy Bachman, "FTC Chair Stuns Advertisers," *Adweek*, April 17, 2013, available at http://www.adweek.com/news/technology/ftc-chair-stuns-advertisers-148644.

31 For an example of one such enforcement action, *see* "FTC Approves Final Settlement Orders Against Marketers Who Claimed Their Mobile Apps Could Cure Acne," Federal Trade Commission (Oct. 25, 2011), available at http://www.ftc.gov/news-events/press-releases/2011/10/ftc-approves-final-settlement-orders-against-marketers-who. However, one commentator discussing the settlement found five other apps offering similar acne treatment that faced no FTC actions. *See* Brian Dolan, "US regulators remove two acne medical apps," *mobihealthnews.com*, Sept. 9, 2011, available at http://mobihealthnews.com/13123/us-regulators-remove-two-acne-medical-apps/.