

REPORT 5 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (A-14)
Guidelines for Mobile Medical Applications and Devices
(Reference Committee E)

EXECUTIVE SUMMARY

Objective. To examine key trends and findings relevant to the developing field of mHealth apps, and how these realities impact the feasibility of our AMA taking a leadership or convening role in this arena.

Methods. English-language reports were selected from a PubMed and Google Scholar search from 2007 to April 1, 2014 using the search terms “medical,” “mobile,” or “health” in combination with the text term “app*,” as well as “mobile health,” or “mHealth.” Additional articles were identified by manual review of the references cited in these publications. Further information was obtained from the Internet sites of the Food and Drug Administration, Federal Communications Commission and IMS Health.

Results. Thousands of mobile health (mHealth) apps have been developed for personal use on smartphones and other personal electronic products. Many of these apps provide direct medical advice or instructions, and a smaller proportion can be used to convert smartphones, tablets, etc., into medical devices. A limited number of these mHealth apps have been formally evaluated as a mobile medical app for their ability to accomplish their intended purpose. A large percentage of available mHealth apps are lacking in overall quality and only limited advice is available to help guide selection of those that may be more useful or reliable. However, emerging evidence suggests that well-designed mHealth apps can make a significant difference in clinical care. Accordingly, many questions remain about how clinicians should respond to patient inquiries about the use of mHealth apps, recommend their use, or prescribe mHealth apps or “medical devices” created by the interface of apps with a smartphone or other electronic platform.

Conclusion. In order to improve health outcomes and provide value, systematic evaluation and information on mHealth app functionality, limitations, data integrity, security and privacy is needed from a neutral trusted source. Additional important considerations include the extent to which apps support clinical decision-making in a user friendly fashion, interoperability with other patient care and technology platforms existing in offices, clinics, and hospitals, and the need for peer-review systems, supporting statements of evidence, or certification standards to maintain the quality and credibility of health-focused apps. Given the complexity and sheer volume of mHealth apps and their rapid evolution, our AMA should continue to engage with relevant stakeholders to identify guiding principles for promoting a vibrant, useful and trustworthy mHealth app market, and to identify appropriate opportunities for AMA involvement.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 5-A-14

Subject: Guidelines for Mobile Medical Applications and Devices

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Referred to: Reference Committee E
(Jay A. Gregory, MD, Chair)

1 INTRODUCTION

2
3 Policy D-480.975, “Guidelines for Mobile Medical Applications and Devices,” directs our
4 American Medical Association (AMA) to prepare a report on the appropriate indications,
5 guidelines and certification processes necessary to ensure the efficacy and safety of mobile medical
6 applications and devices developed for smartphones and other personal electronic devices that may
7 be used by physicians, allied health professionals, caregivers and patients.

8
9 The rapid rate of technological change in the past decade has led to the proliferation of new
10 terminology and vocabulary that can both clarify or lead to confusion as phrases are coined with
11 limited consensus over meaning and scope. This is true of the current evolving vernacular in the
12 arena of technology and health care. The following terms capture current distinctions and working
13 definitions for mobile applications and devices that are integral to the framework of this report:

14
15 Mobile applications (mobile apps). A software application that can be run on a mobile product such
16 as a mobile phone, smartphone, or tablet (with or without wireless connectivity) or a web-based
17 software application run on a server, but meant to be used through a mobile product (such as a
18 smartphone).

19
20 Health apps (also referred to as mobile health or mHealth apps). A mobile app that delivers health-
21 related services using a mobile phone, smartphone or tablet. This covers a wide spectrum of
22 functions to support health and fitness, as well as disease management.

23
24 Medical apps. A mobile app that meets the definition of a device in the Federal Food, Drug, and
25 Cosmetic Act is considered by the Food and Drug Administration (FDA) to be a medical device,
26 subject to risk-based oversight and regulation (see below). A mobile medical app could be
27 considered a regulated subset of mHealth apps.

28
29 *Current Guidance and Activity*

30
31 The FDA released guidance for industry on mobile medical apps in September 2013.¹ Essential
32 elements of this guidance are discussed below. While the FDA will provide oversight on a limited
33 subset of mHealth apps that are also medical apps, most mHealth apps are not medical apps. As a
34 result, there remains an ongoing deliberation among federal agencies and major stakeholders in

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1 evaluating and/or establishing the appropriate processes, principles, and entities to assist physicians
2 and patients in understanding the value and reliability of mHealth apps that are not medical apps.

3 The regulation of mobile health itself is a subset of the much broader array of health information
4 technology (HIT). In addition to the guidance on mobile medical apps, the FDA was required to
5 develop a broader report on HIT. This draft report, developed in consultation with the Office of the
6 National Coordinator for Health Information Technology and the Federal Communications
7 Commission, proposes a strategy and recommendations to develop an appropriate, risk-based
8 regulatory framework for health information technology, including mobile medical applications.
9 The strategy is intended to “promote innovation, protect patient safety, and avoid regulatory
10 duplications.” The draft report (named the FDASIA Health IT Report) was released in April 2014.²
11 Some of its recommendations and conclusions are relevant to mobile medical apps and also are
12 briefly highlighted below.

13
14 Thousands of mHealth apps have been developed for personal use on smartphones and other
15 personal electronic products. Many of these apps provide direct medical advice or instructions, and
16 a smaller proportion can be used to convert smartphones, tablets, etc., into medical devices. A
17 limited number of these mHealth apps have been formally evaluated for their ability to accomplish
18 their intended purpose. Therefore, many questions remain about how clinicians should respond to
19 patient inquiries about the use of mHealth apps, and whether to recommend or prescribe mHealth
20 apps.

21
22 Relevant AMA policy related to mobile medical apps encourages physicians to become familiar
23 with and capitalize on opportunities to use technology to ensure patient safety in prescribing
24 medications and medical devices (Policy H-450.949). Additionally, the regulation of medical
25 devices should be accomplished in a manner that does not interfere with the patient-physician
26 relationship nor impose regulatory burdens that discourage creativity and innovation in advancing
27 medical device technology (Policy H-480.996). Manufacturers are ultimately responsible for
28 conducting the necessary testing, research and clinical investigation to establish the safety and
29 efficacy of medical devices requiring FDA approval (Policy H-480.972).

30
31 Accordingly, this report examines key trends and findings relevant to the developing field of
32 mHealth apps, and how these realities impact the feasibility of our AMA taking a leadership or
33 convening role in this arena.

34 35 METHODS

36
37 English-language reports were selected from a PubMed and Google Scholar search from 2007 to
38 April 1, 2014 using the search terms “medical,” “mobile,” or “health” in combination with the text
39 term “app*,” as well as “mobile health,” or “mHealth.” Additional articles were identified by
40 manual review of the references cited in these publications. Further information was obtained from
41 the Internet sites of the FDA, FCC, and IMS Health.

42 43 OVERVIEW OF MOBILE HEALTH APPS

44
45 mHealth apps are a solution that leverages the ubiquity of mobile devices to promote access to
46 health care, improve patient self-management, enable electronic interactions between patients and
47 their physicians, and potentially reduce healthcare costs. mHealth apps are one of the fastest
48 growing market spaces with mHealth app revenue expected to grow from \$4.5 billion in 2013 to
49 \$27 billion in 2017.³

50

1 Most mHealth apps are designed to assist individuals in their own health and wellness
2 management. Others are targeted to healthcare providers as tools to improve and facilitate the
3 delivery of patient care. Some mHealth apps are designed for doctors themselves to access drug
4 and treatment decision information. With respect to more direct patient care involvement, mHealth
5 apps (a subset of which are devices) are currently involved in a broad array of clinical functions
6 including, for example: 1) applications that use advanced algorithms, logic and/or artificial
7 intelligence to simulate and/or replicate the decision-making process and guidance of expert
8 clinicians; 2) self-monitoring devices created by attaching hardware peripherals to smartphones; 3)
9 remote collection of clinical data; and 4) electronic delivery of clinical advice and motivational
10 messaging to patients.

11 RELEVANT TRENDS AND ATTITUDES

12
13
14 *Smart Phones and mHealth apps.* As of May 2013, more than 90% of U.S. adults owned a cell
15 phone of some kind and 56% owned a smartphone, a 21% increase since 2011.⁴ Higher income
16 adults and those under age 35 years comprise the largest proportional ownership categories. Fifty-
17 two per cent of smart phone owners have looked up health information on their smart phone, and
18 19% have at least one app on their smart phone specifically to track and manage a health-related
19 parameter.⁵ mHealth apps are the third fastest growing app category for both iOS (Apple) and
20 Android (Google) phones and tablets. As of June 2013, more than 43,000 unique iOS mHealth
21 apps existed based on a search for apps with “health and fitness” or “medical” attributes.⁶ With
22 duplication, an estimated 97,000 mHealth applications are available for download across major app
23 stores.⁷

24
25 *Early Adopters.* Among those who already use or plan to use mHealth apps to track their health and
26 fitness, 70% use the app daily. Sixty percent have not shared their progress, achievements or
27 discoveries with their physician, some because they had not thought about it and others because
28 they believed they would “not be taken seriously.”⁸ On the other hand, one-third of these early
29 adopters indicated they “would be more likely to use mHealth apps to track their health and fitness
30 if their physicians actually recommended it.”

31
32 *Physicians.* More than 30% of physicians own a tablet, and more than half of them employ them at
33 the point of care.⁹ The Department of Veterans Affairs (VA) is implementing the Mobile Health
34 Provider Program intended to leverage the power of mobile technology and transform the way their
35 clinicians and patients interact.¹⁰ A recent poll conducted by QuantiaMD to better understand
36 physician perspectives on prescribing mHealth apps found that 37% of physicians have
37 recommended such an app to their patients.¹¹ A similar percentage is largely unaware of what
38 mHealth apps are available or in the marketplace. Forty-two percent of physicians will not
39 prescribe them because of lack of regulatory oversight or evidence of safety and effectiveness; 21%
40 said they would never recommend them.¹¹

41
42 Approximately 40% of physicians believe that mobile health technologies have the capacity to
43 reduce the number of office visits, and 88% of physicians would like their patients to monitor
44 health at home. Physicians are not alone, with some 78% of consumers expressing an interest in
45 mobile health solutions.⁵ Among consumers with cell phones, some demographics—Latinos,
46 African Americans, women and those between the ages of 18-49 years—are more likely to seek
47 health information online, as are caregivers, those who recently faced a medical crisis, and those
48 who experienced a recent significant change in their physical health.⁵

49
50 *Pharmaceutical Companies.* Pharmaceutical companies are using smartphone technology to
51 facilitate physician recruitment of patients for trials, enable patients to participate in clinical trials

1 regardless of their proximity to a treatment site, and for disease management programs by
2 combining a personalized action plan with digital coaching and wireless monitoring to measure the
3 impact of behavioral interventions.¹² In a related fashion, significant attention has been devoted to
4 facilitating treatment and promoting medication adherence. Hundreds of mHealth apps are intended
5 to improve medication adherence, but an understanding of their actual effectiveness is
6 incomplete.¹³

7 8 MEDICAL DEVICE APPROVAL

9
10 Current FDA regulations and guidance on medical devices are relevant to the development and
11 appropriate regulation of mHealth apps that, based on their intended use, meet the definition of a
12 device. Although many mHealth apps exist, and many may be medical devices, the FDA will
13 oversee only a small subset of the mHealth apps that are medical devices (mobile medical apps).
14 The FDA's regulation of software as a medical device is based on risk and functionality and not the
15 platform.

16
17 *Definition of Device.* Medical devices are defined as “an instrument, apparatus, implement,
18 machine, contrivance, implant, in vitro reagent, or other similar or related articles, including any
19 component part, or accessory,” that is “intended for use in the diagnosis of disease or other
20 conditions, or in the cure, mitigation, treatment, or prevention of disease in man,” or “intended to
21 affect the structure or any function of the body of man or animals.”

22
23 The FDA's Center for Devices and Radiological Health is responsible for regulating firms who
24 manufacture, repackage, relabel, and/or import medical devices sold in the United States. Medical
25 devices are classified as Class I, II, and III. Regulatory control increases from Class I to Class III.
26 Most Class I devices are exempt from Premarket Notification 510(k), most Class II devices require
27 Premarket Notification 510(k), and most Class III devices require Premarket Approval.¹⁴

28
29 Device classification depends on the intended use and indication for the device, as well as the level
30 of control necessary to ensure safety and effectiveness. Classification determines the specific
31 regulatory requirements. Basic requirements that manufacturers of medical devices distributed in
32 the United States must comply with are general controls including facility registration, device
33 listing, quality control systems (subject to FDA inspection), as well as labeling and reporting
34 requirements.¹⁴ Incidents in which a device may have caused or contributed to a death or serious
35 injury must be reported to the FDA under the Medical Device Reporting program. In addition,
36 certain malfunctions also must be reported.

37
38 The FDA has classified and described more than 1,700 distinct types of devices and organized
39 them into medical specialty “panels” such as cardiovascular devices or ear, nose, and throat
40 devices. For more information on device regulation and requirements one can consult the dedicated
41 FDA webpage on this topic.¹⁴ A description of medical device classification and a link to the
42 Product Classification Database is available at “[Classification of Medical Devices](#).”

43 44 FDA GUIDANCE ON MOBILE MEDICAL APPLICATIONS

45
46 The FDA released final guidance on mobile medical applications on September 24, 2013.¹ This
47 final guidance was preceded by a draft guidance issued August 2013, on Radio Frequency Wireless
48 Technology in Medical Devices. The use of wireless technology includes additional regulatory
49 review processes—in particular, the Federal Communications Commission which has a mandatory
50 certification process.

1
2 *Definition.* According to the FDA guidance, a mobile medical app is a mobile app that meets the
3 definition of device (above) and is intended to either: 1) be used as an accessory to a regulated
4 medical device; or 2) transform a mobile platform into a regulated medical device. The intended
5 use of a mobile app determines whether it meets the definition of a “device.”¹

6
7 FDA’s authority to regulate a particular mobile medical app stems from which medical device
8 classification (i.e., I, II, or III) the mobile app falls into, which depends upon the potential risk to
9 the user.⁹ As noted above, most mobile apps are not medical devices. However, as is the case with
10 traditional medical devices, certain mobile medical apps could pose potential risks to public health,
11 or the risks could be derived from the platform on which the app is run (e.g., attempting to interpret
12 radiologic images on a mobile device screen for the purpose of diagnosis). Therefore, the FDA
13 intends to apply its regulatory authority to only those mobile apps performing medical device
14 functions and whose functionality could pose a risk to patient safety if the app were not to function
15 as intended. The FDA intends to exercise “enforcement discretion,” for many other mobile medical
16 apps, meaning that even though they technically meet the definition of a medical device, they
17 possess such a low risk profile that regulation is not necessary to protect patient safety.

18
19 As noted in the guidance, selected examples^a of mobile apps that FDA does not consider to meet
20 the definition of medical device include:

- 21 • apps that provide access to medical textbooks, references
- 22 • apps that offer training materials for physicians
- 23 • apps intended for general patient education.

24
25 Some examples of mobile apps for which the FDA intends to exercise enforcement discretion
26 include:

- 27 • apps that provide periodic reminders or motivational guidance
- 28 • apps that allow patients to track and manually enter symptoms
- 29 • apps that use a checklist of common signs and symptoms to provide a list of possible
30 medical conditions with advice on when to consult a healthcare provider.

31
32 Some examples of mobile apps and accessories that are the focus of FDA’s regulatory oversight
33 include mobile apps that:

- 34 • use a sensor or lead connected to a mobile platform to measure and display heart rhythm
- 35 • create a stethoscope
- 36 • generate controlled tones for audiologic testing
- 37 • use an attachment to the mobile platform to measure blood oxygen saturation, alter the
38 function or setting of an infusion pump, or allow remote perinatal monitoring.

39
40 According to one analysis of the FDA’s medical device database, FDA has approved more than
41 100 mobile medical apps through 2013.¹⁵ A representative list of mobile medical applications
42 cleared by the FDA since 1997 is available.¹⁶

43
44 *FDASIA Health IT Report.* The draft FDASIA Health IT Report proposed three categories of health
45 IT (administrative, health management, medical device) and the creation of a public-private entity
46 termed the Health IT Safety Center. The Center would, among other things, establish a governance
47 structure for the creation of a sustained integrated health IT learning system.² This report also
48 directed the FDA to provide greater clarity on several aspects of medical device regulation

^a A more complete list of examples in each category is available in the FDA guidance.⁹

1 involving health information technology including: 1) the distinction between wellness and
2 disease-related claims; 2) medical device accessories; 3) medical device clinical decision support
3 software; 4) medical device software modules; and 5) mobile medical apps. Among these aspects,
4 mobile medical apps may directly intersect with clinical decision support software. Also relevant to
5 Policy D-480.975, key priority areas for the Health IT Safety Center include the development of
6 quality management principles and standards and best practices, including promoting
7 interoperability and electronic information sharing between health IT products and across
8 organizational boundaries.

9
10 *Development of Mobile Medical Apps.* The relevance of the FDA guidance for business
11 development of mobile medical apps can be illustrated by two high profile examples.¹⁷ In February,
12 Biosense Technologies Private Ltd. (based in India) unveiled uChek, a mobile application and
13 companion kit that allows individuals to use their phone cameras to read subtle color differences on
14 urine test strips. Biosense maintained that uChek could potentially inform an individual's risk for
15 more than 25 medical conditions, including diabetes and hepatitis. This mobile app clearly meets
16 the definition of a medical device, and within one month of marketing the device in the United
17 States, the company was notified by the FDA that it needed to seek clearance to market its product.
18 On the other hand, recognizing the need to pursue FDA approval before marketing its device,
19 Scanadu (a mobile technology company based in California) raised more than \$1.5 million through
20 the crowdfunding site Indiegogo to support the device application process for its Scout monitor
21 device. The Scout monitor connects wirelessly to a smartphone and is capable of measuring blood
22 pressure, temperature, heart activity, and other vital signs.¹⁷

23 24 AN UNREGULATED MARKET

25
26 A major challenge faced by the mobile health market is the quality of mHealth apps and whether
27 their use helps patients or physicians achieve the intended purpose.

28
29 The most comprehensive analysis of mHealth apps currently available was conducted by the IMS
30 Institute for Healthcare Informatics.⁶ IMS conducted an extensive review of the more than 23,000
31 iTunes Store mHealth apps. Approximately 70% of these apps were intended for consumers and
32 the remainder for health care professionals. IMS was able to evaluate the health apps based on their
33 ability to inform, provide instruction, and provide reminders or alerts, capture user-entered data,
34 graphically display data, offer clinical guidance, or enable communication with healthcare
35 providers or other patients via social networks. Most efforts in app development have been in the
36 overall wellness category, do little more than provide information, and do not target populations
37 accounting for the greatest contribution to healthcare expenditures, namely older patients with
38 multiple chronic diseases. Fewer than half the apps which provide information also provide
39 instruction, and less than one-third of apps that provide information also track or capture user data.
40 IMS scored the apps based on a proprietary system using twenty-five functional criteria with a
41 maximum possible score of 100. More than 90% of the apps scored at or below 40.

42
43 An analysis of 1,500 mHealth apps for purchase by the New England Center for Investigative
44 Reporting found that "both the iTunes and Google Play stores are riddled with health apps that
45 experts say do not work and in some cases could even endanger consumers."¹⁸ One in five made
46 claims to treat or cure medical problems using light, sound, or vibrations emitted from the cell
47 phone for conditions such as acne, seasonal affective disorder, insomnia, and chronic pain. Even
48 high-profile vendors like Epocrates have recently come under scrutiny. Their popular Bugs &
49 Drugs App, specifically designed to assist physicians in identifying the best antimicrobial choice
50 for specific pathogens, has been criticized for significant content errors.¹⁹

1 Apps capable of running medical calculations to gauge the severity of a disease or condition, risk
2 stratify, or estimate the likelihood of having a certain condition appear to be more reliable.²⁰ Also
3 as might be expected, apps for complex medical disorders often fail to measure up. An evaluation
4 of HIV/STD-related apps identified nearly 2000 apps in Apple iTunes and Android Google Play
5 stores. Only 6 of these apps covered all major prevention areas by providing disease information
6 and information on testing or resources, condom use, and safe sex practices.²¹

7
8 A systematic review of hundreds of apps focusing on cancer and available for general use by the
9 public from iPhone, Android, Nokia, and Blackberry platforms found evidence was lacking to
10 support their effectiveness in promoting behavior change, monitoring symptoms and physiological
11 indicators of disease, or providing real time supportive interventions, conveniently and at low
12 cost.²²

13
14 Another systematic review identified more than 100 apps for asthma self-management, nearly half
15 of which provided specific tools.²³ No apps combined reliable, comprehensive information about
16 asthma with supportive tools for self-management. Nearly half the time, apps made unequivocal
17 recommendations about strategies for asthma control or prophylaxis that were unsupported by
18 current evidence-based guidelines.

19
20 The ability to record, analyze, share and obtain feedback on self-monitored blood glucose levels
21 would seem to be a potentially valuable aid in the management of diabetes. Analysis of apps
22 available from the Apple App store identified more than 400 diabetes related apps. Most of these
23 did not conform to evidence-based recommendations or addressed only a narrow subset of
24 generally recommended target behaviors.²⁴

25
26 Based on these types of reviews, a large percentage of available mHealth apps are lacking in
27 overall quality, and only limited advice is available to help guide selection of those that may be
28 more reliable in providing useful guidance and assistance in medical decision-making.

29 *Efficacy in Clinical Practice*

30 Asthma

31
32 A systematic review of clinical trials that evaluated the effect of a mobile-phone-based asthma self-
33 management intervention compared with traditional paper-based asthma self-management found
34 insufficient evidence to recommend use of the mobile medical app platform to improve asthma
35 control.²⁵

36 Diabetes

37
38 One of the more advanced mobile medical apps for condition management and remote monitoring
39 approved by the FDA is the WellDoc Diabetes Management system, a software-based patient-
40 coaching and provider clinical decision support system.²⁶ This multimodal tool enables patients to
41 wirelessly upload blood glucose readings and other diabetes-related information, and receive real-
42 time feedback via a health care provider, caregiver or WellDoc research team. In a 1-year cluster-
43 randomized clinical trial, the intervention group's A1c decreased by 1.9% compared with 0.7% in
44 the usual care group. The initial randomized clinical trial of this app demonstrated improvements in
45 outcomes for A1c values, diet, medication adherence, and exercise compared with usual care.²⁷

46
47
48 Use of another diabetes app, the DiabetesManager® sponsored by AT&T and Health Care Service
49 Corporation, demonstrated a decrease in hospital admissions and emergency room utilization in
50 Medicaid participants when comparing their data 90 days before the pilot trial to 90 days after

1 enrollment. Participants demonstrated high adoption, sustained engagement and high levels of
2 satisfaction.²⁸

3 Weight Loss

4 Several randomized controlled trials have been conducted of mHealth apps designed to promote
5 weight loss. Apps were designed to provide information about meal replacement options, deliver
6 reminders or motivational messages at various intervals, and combine self-monitoring of diet,
7 weight, and activity with feedback to and/or from practitioners. Significant improvements were
8 observed in 8 out of 10 studies.²⁹

9
10 These cited examples represent only a limited sampling of published evidence. However, evidence
11 is emerging that the use of well-designed mHealth apps can make a significant difference in
12 clinical care.

13 14 CERTIFICATION AND STANDARDS

15
16 A need exists for some process to aid the marketplace in sorting through the vast majority of
17 mobile applications that will not be subject to FDA approval. Some kind of private certification or
18 at least a reputable and trusted evaluation platform for mHealth apps could spur app developers to
19 produce better, more secure products and provide guidance for consumers.^b What, if any, role
20 might be played by a public/private Health IT Safety Center, as described in the FDASIA Health IT
21 report, is uncertain.

22
23 There have been limited efforts to address the problems described above. Happtique, a commercial
24 health app storefront established a certification program that recently certified 16 apps after a
25 technical and content review following published guidelines. However, the program was suspended
26 after questions were raised about flaws in the technical review of 3 of the 16 certified apps. The
27 IMS analysis noted above offered its top ratings of mHealth apps for healthy lifestyles, finding a
28 healthcare professional or facility, self-diagnosing certain conditions, filling prescriptions, and
29 promoting medication adherence.⁶ Additionally, IMS identified top mHealth apps for diabetes,
30 mental health and behavioral disorders, chronic musculoskeletal pain, oncology, and central
31 nervous system disorders such as epilepsy.

32
33 Aetna launched CarePass, a wellness app that pulls data from 20-plus free consumer wellness apps,
34 downloads those that are wanted and tracks health improvement progress.³⁰ CarePass allows
35 individuals who download multiple apps to display data from those apps in a single normalized
36 dashboard, rather than having to view the data in silos.

37
38 iMedicalApps is an independent online medical publication written by a team of physicians and
39 medical students who provide commentary and reviews of mobile medical technology and
40 applications.³¹ Reviews and commentary are based on the physicians' and students' own
41 experiences in hospital and clinic settings. Content control is managed by the medical professionals
42 running the site. According to the iMedicalApps website, their publication receives more than
43 400,000 views monthly.

44

^b While the FCC currently has a certification process for wireless products, a private certification for mHealth apps would include an evaluation of a broader scope of factors relevant to physicians, patients and those interested in health promotion.

1 Among other efforts to bring clarity to the field, the Johns Hopkins School of Public Health has
2 developed a program to grade mobile health evidence based on literature reviews, and Continua
3 Health Alliance is developing a certification program for the interoperability of medical devices.
4 Finally, the Scripps Translational Science Institute has established a digital health program to
5 conduct clinical studies of select mHealth apps.

6 SUMMARY AND CONCLUSION

7
8 Health care reform—with new delivery and payment models—is likely to place increasing
9 emphasis on wellness and self-care as physicians apply themselves to delivering high quality care
10 in the most cost-effective manner, and as incentives for consumers to take accountability for their
11 own health proliferate. According to Ernst and Young, “mobile technology that enables remote
12 monitoring of patients and provides patients with rapid access to clinicians...is expected to play a
13 key role.” In a recent Healthcare IT Trends report from AT&T, a shift from stand-alone
14 “unsponsored” apps to meaningful “sponsored” mHealth app solutions supported by insurance
15 companies, healthcare providers, employers, or other institutions will result in higher patient
16 adoption and engagement. In order to improve health outcomes and provide value, systematic
17 evaluation and information on mHealth app functionality, limitations, data integrity, security and
18 privacy is needed from a neutral trusted source. Furthermore, additional important considerations
19 include the:

- 20
- 21 • extent to which apps support clinical decision-making in a user friendly fashion
- 22
- 23 • interoperability of mHealth and mobile medical apps with other patient care and
24 technology platforms existing in offices, clinics, and hospitals
- 25
- 26 • need for peer-review systems, supporting statements of evidence, or certification standards
27 to maintain the quality and credibility of health-focused apps. As with any other clinical
28 intervention, as evidence of clinical usefulness is developed, findings should be published
29 in peer-reviewed journals and be reproducible.
- 30

31 Given the complexity and sheer volume of mHealth apps, and in light of the rapidly evolving
32 policy and market considerations, our AMA should continue to engage with relevant stakeholders
33 to identify guiding principles for promoting a vibrant, useful and trustworthy mHealth app market,
34 and to identify appropriate opportunities for AMA involvement.

35 RECOMMENDATIONS

36
37
38 The Council on Science and Public Health recommends that the following statements be adopted
39 and the remainder of the report be filed.

- 40
- 41 1. That our American Medical Association (AMA) monitor market developments in mobile
42 health (mhealth), including the development and uptake of mHealth apps, in order to
43 identify developing consensus that provides opportunities for AMA involvement.
44 (Directive to Take Action)
- 45
- 46 2. That our AMA continue to engage with stakeholders to identify relevant guiding principles
47 to promote a vibrant, useful and trustworthy mHealth market. (Directive to Take Action)
- 48
- 49 3. That our AMA make an effort to educate physicians on mHealth apps that can be used to
50 facilitate patient communication, advice, and clinical decision support, as well as resources

1 that can assist physicians in becoming familiar with mHealth apps that are clinically useful
2 and evidence-based. (Directive to Take Action)

3

4 4. That Policy D-480.975, "Guidelines for Mobile Medical Applications and Devices," be
5 rescinded. (Rescind HOD Policy)

Fiscal Note: \$5,000

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