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.
INTRODUCTION

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

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

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

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

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

Current Guidance and Activity

The FDA released guidance for industry on mobile medical apps in September 2013.1 Essential elements of this guidance are discussed below. While the FDA will provide oversight on a limited subset of mHealth apps that are also medical apps, most mHealth apps are not medical apps. As a result, there remains an ongoing deliberation among federal agencies and major stakeholders in
evaluating and/or establishing the appropriate processes, principles, and entities to assist physicians and patients in understanding the value and reliability of mHealth apps that are not medical apps.

The regulation of mobile health itself is a subset of the much broader array of health information technology (HIT). In addition to the guidance on mobile medical apps, the FDA was required to develop a broader report on HIT. This draft report, developed in consultation with the Office of the National Coordinator for Health Information Technology and the Federal Communications Commission, proposes a strategy and recommendations to develop an appropriate, risk-based regulatory framework for health information technology, including mobile medical applications. The strategy is intended to “promote innovation, protect patient safety, and avoid regulatory duplications.” The draft report (named the FDASIA Health IT Report) was released in April 2014. Some of its recommendations and conclusions are relevant to mobile medical apps and also are briefly highlighted below.

Thousands of 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 for their ability to accomplish their intended purpose. Therefore, many questions remain about how clinicians should respond to patient inquiries about the use of mHealth apps, and whether to recommend or prescribe mHealth apps.

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

Accordingly, this report examines 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 FDA, FCC, and IMS Health.

OVERVIEW OF MOBILE HEALTH APPS

mHealth apps are a solution that leverages the ubiquity of mobile devices to promote access to health care, improve patient self-management, enable electronic interactions between patients and their physicians, and potentially reduce healthcare costs. mHealth apps are one of the fastest growing market spaces with mHealth app revenue expected to grow from $4.5 billion in 2013 to $27 billion in 2017.
Most mHealth apps are designed to assist individuals in their own health and wellness management. Others are targeted to healthcare providers as tools to improve and facilitate the delivery of patient care. Some mHealth apps are designed for doctors themselves to access drug and treatment decision information. With respect to more direct patient care involvement, mHealth apps (a subset of which are devices) are currently involved in a broad array of clinical functions including, for example: 1) applications that use advanced algorithms, logic and/or artificial intelligence to simulate and/or replicate the decision-making process and guidance of expert clinicians; 2) self-monitoring devices created by attaching hardware peripherals to smartphones; 3) remote collection of clinical data; and 4) electronic delivery of clinical advice and motivational messaging to patients.

RELEVANT TRENDS AND ATTITUDES

Smart Phones and mHealth apps. As of May 2013, more than 90% of U.S. adults owned a cell phone of some kind and 56% owned a smartphone, a 21% increase since 2011. Higher income adults and those under age 35 years comprise the largest proportional ownership categories. Fifty-two per cent of smart phone owners have looked up health information on their smart phone, and 19% have at least one app on their smart phone specifically to track and manage a health-related parameter. mHealth apps are the third fastest growing app category for both iOS (Apple) and Android (Google) phones and tablets. As of June 2013, more than 43,000 unique iOS mHealth apps existed based on a search for apps with “health and fitness” or “medical” attributes. With duplication, an estimated 97,000 mHealth applications are available for download across major app stores.

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

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

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

Pharmaceutical Companies. Pharmaceutical companies are using smartphone technology to facilitate physician recruitment of patients for trials, enable patients to participate in clinical trials
regardless of their proximity to a treatment site, and for disease management programs by combining a personalized action plan with digital coaching and wireless monitoring to measure the impact of behavioral interventions. In a related fashion, significant attention has been devoted to facilitating treatment and promoting medication adherence. Hundreds of mHealth apps are intended to improve medication adherence, but an understanding of their actual effectiveness is incomplete.

MEDICAL DEVICE APPROVAL

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

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

The FDA’s Center for Devices and Radiological Health is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States. Medical devices are classified as Class I, II, and III. Regulatory control increases from Class I to Class III. Most Class I devices are exempt from Premarket Notification 510(k), most Class II devices require Premarket Notification 510(k), and most Class III devices require Premarket Approval. Device classification depends on the intended use and indication for the device, as well as the level of control necessary to ensure safety and effectiveness. Classification determines the specific regulatory requirements. Basic requirements that manufacturers of medical devices distributed in the United States must comply with are general controls including facility registration, device listing, quality control systems (subject to FDA inspection), as well as labeling and reporting requirements. Incidents in which a device may have caused or contributed to a death or serious injury must be reported to the FDA under the Medical Device Reporting program. In addition, certain malfunctions also must be reported.

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

FDA GUIDANCE ON MOBILE MEDICAL APPLICATIONS

The FDA released final guidance on mobile medical applications on September 24, 2013. This final guidance was preceded by a draft guidance issued August 2013, on Radio Frequency Wireless Technology in Medical Devices. The use of wireless technology includes additional regulatory review processes—particularly, the Federal Communications Commission which has a mandatory certification process.
Definition. According to the FDA guidance, a mobile medical app is a mobile app that meets the definition of device (above) and is intended to either: 1) be used as an accessory to a regulated medical device; or 2) transform a mobile platform into a regulated medical device. The intended use of a mobile app determines whether it meets the definition of a “device.”

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

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

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

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

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

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

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

According to one analysis of the FDA’s medical device database, FDA has approved more than 100 mobile medical apps through 2013. A representative list of mobile medical applications cleared by the FDA since 1997 is available.

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

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

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

**AN UNREGULATED MARKET**

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

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

An analysis of 1,500 mHealth apps for purchase by the New England Center for Investigative
Reporting found that “both the iTunes and Google Play stores are riddled with health apps that
experts say do not work and in some cases could even endanger consumers.” One in five made
claims to treat or cure medical problems using light, sound, or vibrations emitted from the cell
phone for conditions such as acne, seasonal affective disorder, insomnia, and chronic pain. Even
high-profile vendors like Epocrates have recently come under scrutiny. Their popular Bugs &
Drugs App, specifically designed to assist physicians in identifying the best antimicrobial choice
for specific pathogens, has been criticized for significant content errors.
Apps capable of running medical calculations to gauge the severity of a disease or condition, risk stratify, or estimate the likelihood of having a certain condition appear to be more reliable.\textsuperscript{20} Also as might be expected, apps for complex medical disorders often fail to measure up. An evaluation of HIV/STD-related apps identified nearly 2000 apps in Apple iTunes and Android Google Play stores. Only 6 of these apps covered all major prevention areas by providing disease information and information on testing or resources, condom use, and safe sex practices.\textsuperscript{21}

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

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

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

Based on these types of reviews, 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 reliable in providing useful guidance and assistance in medical decision-making.

\textbf{Efficacy in Clinical Practice}

\textbf{Asthma}

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

\textbf{Diabetes}

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

Use of another diabetes app, the DiabetesManager\textsuperscript{\textregistered} sponsored by AT&T and Health Care Service Corporation, demonstrated a decrease in hospital admissions and emergency room utilization in Medicaid participants when comparing their data 90 days before the pilot trial to 90 days after
enrollment. Participants demonstrated high adoption, sustained engagement and high levels of satisfaction.28

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

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

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

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

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

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

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

SUMMARY AND CONCLUSION

Health care reform—wi th new delivery and payment models—is likely to place increasing emphasis on wellness and self-care as physicians apply themselves to delivering high quality care in the most cost-effective manner, and as incentives for consumers to take accountability for their own health proliferate. According to Ernst and Young, “mobile technology that enables remote monitoring of patients and provides patients with rapid access to clinicians…is expected to play a key role.” In a recent Healthcare IT Trends report from AT&T, a shift from stand-alone “unsponsored” apps to meaningful “sponsored” mHealth app solutions supported by insurance companies, healthcare providers, employers, or other institutions will result in higher patient adoption and engagement. 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. Furthermore, additional important considerations include the:

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

Given the complexity and sheer volume of mHealth apps, and in light of the rapidly evolving policy and market considerations, 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.

RECOMMENDATIONS

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

1. That our American Medical Association (AMA) monitor market developments in mobile health (mhealth), including the development and uptake of mHealth apps, in order to identify developing consensus that provides opportunities for AMA involvement. (Directive to Take Action)

2. That our AMA continue to engage with stakeholders to identify relevant guiding principles to promote a vibrant, useful and trustworthy mHealth market. (Directive to Take Action)

3. That our AMA make an effort to educate physicians on mHealth apps that can be used to facilitate patient communication, advice, and clinical decision support, as well as resources
that can assist physicians in becoming familiar with mHealth apps that are clinically useful and evidence-based. (Directive to Take Action)

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

Fiscal Note: $5,000
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