

REPORT 6 OF THE COUNCIL ON MEDICAL SERVICE (I-16)
Integration of Mobile Health Applications and Devices into Practice
(Reference Committee J)

EXECUTIVE SUMMARY

Digital health, including the utilization of mobile health applications (mHealth apps) and devices, has the potential to be integrated into everyday practice in order to promote improved patient health outcomes, support care coordination and improve communication. The Council initiated this report to address the need to balance these innovations with appropriate industry standards for mHealth apps and US Food and Drug Administration (FDA) regulation of mobile medical devices. For those mHealth apps and mobile medical devices that are subject to FDA review and approval, FDA resources need to be sufficient to respond to the number of mHealth products under its jurisdiction.

While some mobile apps and devices are subject to FDA regulation, others are not, and do not undergo rigorous evaluation before deployment for general use, which raises quality and patient safety concerns. However, without ensuring that there is strong and sufficient evidence that provides clinical validation to mHealth apps and associated devices, trackers and sensors, the Council recognizes that physicians will not fully integrate mHealth apps into their practices. More investment is needed in expanding the evidence base necessary to show the accuracy, effectiveness, safety and security of mHealth apps.

The Council proposes principles to guide health plan coverage and payment decisions, employer wellness program inclusions and flexible spending account eligibility determinations concerning mHealth apps and associated devices, in order to protect the patient-physician relationship, support care delivery that is patient-centered, promote care coordination and facilitate team-based communication. Overall, coverage of and payment for mHealth apps and associated devices should be contingent upon a clinical evidence base to support their use in order to ensure app safety and effectiveness. In addition, interoperability between a patient's mobile technology and electronic health records will be an asset, as physicians must be able to meaningfully use the volumes of data mHealth apps and devices create. It is also essential for mHealth apps to follow evidence-based practice guidelines, to the degree they are available, to ensure patient safety, quality of care and positive health outcomes. National medical specialty societies have a key role in developing guidelines for the integration of mHealth apps and associated devices into care delivery.

Patient privacy and data security need to be a priority in digital health, because mobile apps and devices can be subject to privacy and data breaches. Patients must also be aware of the level at which their information and data is protected by mHealth apps. Overall, mHealth apps and associated devices, trackers and sensors need to abide by applicable laws addressing the privacy and security of patients' medical information. If physicians are unsure of whether mHealth apps meet Health Insurance Portability and Accountability Act's standards, they should consult with qualified legal counsel and inquire about any applicable state privacy and security laws. Given the lack of regulation of mHealth apps, regardless of whether an mHealth device is encrypted, physicians should alert patients to the potential privacy and security risks of any mHealth apps that he or she prescribes or recommends, and document the patient's understanding of such risks. Questions remain regarding liability risks to physicians who use, recommend or prescribe mHealth apps. Accordingly, the Council believes that the AMA should assess the potential liability risks to physicians for using, recommending, or prescribing mHealth apps, including risk under federal and state medical liability, privacy, and security laws.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 6-I-16

Subject: Integration of Mobile Health Applications and Devices into Practice

Presented by: Peter S. Lund, MD, Chair

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 The use of digital and mobile health technologies and tools is increasing among patients and
2 physicians, with the potential to play a significant role in new payment and care delivery models.
3 The evolution of digital and mobile health technologies, including mobile applications (apps) and
4 devices, impacts all three strategic focus areas of the American Medical Association (AMA):
5 improving health outcomes, creating the medical school of the future, and creating thriving
6 physician practices. This Council-initiated report provides background on the number, use,
7 effectiveness and safety of mobile health applications (mHealth apps) and medical devices;
8 outlines relevant regulatory and legislative activity; provides a snapshot of the current coverage and
9 payment environment for mobile health apps and devices; summarizes relevant AMA policy and
10 advocacy; and presents policy recommendations.

11 BACKGROUND

12
13
14 Mobile health apps and medical devices are continuously being introduced into the marketplace to
15 assist patients in managing their health and wellness, with some having the capacity to support the
16 ability of physicians to monitor the health status and indicators of patients. Mobile health apps that
17 facilitate chronic disease management and patient engagement have the potential to serve as tools
18 to manage the care of patients with comorbidities, as well as patients who incur high health care
19 costs. There are distinct definitions that can be applied to the range of mobile apps and devices
20 available for use by patients and physicians:

- 21
22 • Mobile applications (mobile apps): A software application that can be run on a mobile
23 product such as a mobile phone, smartphone, or tablet (with or without wireless
24 connectivity) or a web-based software application run on a server, but meant to be used
25 through a mobile product (such as a smartphone).
26
- 27 • Mobile health applications (also referred to as mobile health or mHealth apps): A mobile
28 app that delivers health-related services using a mobile phone, smartphone or tablet. These
29 apps cover a wide spectrum of functions to support health and fitness, as well as disease
30 management.
31
- 32 • Mobile medical device applications: A mobile app that meets the definition of a device in
33 the Federal Food, Drug, and Cosmetic Act is considered by the US Food and Drug
34 Administration (FDA) to be a medical device, subject to risk-based oversight and
35 regulation. A mobile medical device app could be considered a regulated subset of
36 mHealth apps.

1 Approximately two-thirds of Americans own smartphones, including 27 percent of individuals 65
 2 and older and half of those with incomes under \$30,000 per year¹—populations that may be key
 3 targets for mobile health interventions. In addition, an increasing number of patients are taking
 4 advantage of mHealth apps, as well as wearable sensor technologies to allow for real-time
 5 monitoring and tracking of important health information.

6
 7 There are more than 165,000 mHealth apps available to consumers. The number of mHealth apps
 8 available in the marketplace has been increasing at a significant rate—from 2013 to 2015, the
 9 number of mHealth apps on the iOS platform rose from 43,689 to 90,088—a 106 percent increase.²
 10 While patient-facing health apps may track personal fitness and nutrition, provide medication
 11 reminders, provide health-related information and display personal health records, physicians and
 12 other health care providers can use mobile health apps to track patient vital signs and other health
 13 indicators, and as diagnostic tools. Two-thirds of consumer mHealth apps are focused on wellness
 14 (e.g., fitness, diet, nutrition and lifestyle), with approximately one-quarter of mHealth apps
 15 targeting disease and treatment management.²

16
 17 Mobile health apps vary greatly in their functionality, accuracy, safety and effectiveness. Most
 18 mHealth apps have limited functionality, with many solely providing information without
 19 additional capabilities. In fact, providing information is the most common capability of mHealth
 20 apps. On the other hand, most apps lack the ability to communicate or connect with the systems of
 21 physicians and other health care providers. While the percentage of mHealth apps with the capacity
 22 to output user data increased between 2013 and 2015, the ability of mHealth apps to communicate
 23 externally, including with patients’ treating physicians, remained the same. Approximately 10
 24 percent of mHealth apps have the ability to connect to a device, which not only include fitness
 25 apps, but also disease management apps that monitor blood pressure and blood glucose levels.²

26
 27 The Commonwealth Fund conducted a search of the iOS and Android app stores for patient-facing
 28 health apps for a broad set of medical conditions. Notably, upon evaluating the 1,046 apps related
 29 to health care that were patient-facing based on criteria related to patient engagement, quality and
 30 safety, 43 percent of iOS apps and 27 percent of Android apps appeared to be useful.³ Although the
 31 Commonwealth Fund evaluated the health apps selected for this study for quality and safety, the
 32 Council notes that its evaluation process was limited to analyses under its purview, and additional
 33 efforts by industry to develop standards addressing the quality and safety of mHealth apps are
 34 needed moving forward. Overall, while recent studies show promise in using mHealth apps for
 35 patient engagement and treatment adherence, studies have also raised concerns regarding mHealth
 36 app content and accuracy, which can pose threats to the health and safety of patients.^{2,4,5,6} The
 37 nature of threats to patient safety differ based on what mHealth apps and associated devices
 38 measure. For example, while apps that measure steps taken or calories consumed would be
 39 considered to be lower-risk in nature, mHealth apps that are inaccurate in their blood pressure and
 40 blood sugar readings, miscalculate insulin doses or misdiagnose skin cancer raise significant and
 41 serious patient safety concerns.

42
 43 **REGULATORY AND LEGISLATIVE ACTIVITY**

44
 45 The Council notes that most mHealth apps available to consumers have not received clearance or
 46 approval by the FDA. In 2015, the FDA released guidance on mobile medical applications for
 47 industry and FDA staff.⁷ The guidance reiterated that the focus of FDA oversight of mobile health
 48 apps is on those meeting the statutory definition of a medical device; either are intended to be used
 49 as an accessory to a regulated medical device, or convert a mobile platform into a regulated
 50 medical device; and pose a risk to patient safety if they do not function as intended. Accordingly,
 51 the FDA regulates mobile health apps that use a mobile platform’s built-in features (light,

1 vibrations, camera, etc.) to perform medical device functions. In addition, the FDA regulates
2 mobile health apps that control the operation or function of an implantable or body worn medical
3 device. Finally, the FDA regulates mobile health apps that are used in active patient monitoring.⁸
4

5 The FDA has stated that it intends to exercise enforcement discretion for a subset of mobile health
6 apps that meet the definition of a medical device, but pose a low risk to the consumer. Therefore,
7 for these apps, the FDA's current guidance provides it does not intend to enforce requirements of
8 the Federal Food, Drug, and Cosmetic Act for this subset of mobile health apps that are medical
9 devices at this time. For example, mobile apps that fall into this category include those that assist
10 patients in managing their disease or conditions without providing specific treatment or treatment
11 suggestions, or provide patients with tools to organize and track their health information. In
12 addition, there are mobile health apps that are not considered medical devices, so the FDA does not
13 regulate them.
14

15 There is a noteworthy gap in ensuring the quality, safety, accuracy, effectiveness, and security of
16 mHealth apps, in part, due to the FDA's decision to exercise enforcement discretion with regard to
17 a broad category of medical devices apps coupled with the proliferation of mobile health apps that
18 do not meet the definition of medical device and, by law, are not subject to the FDA's jurisdiction.
19 As a result, several entities, including PatientView, Wellocracy and IMS Health's Appscript, are
20 moving forward with efforts to rate, evaluate and/or certify health apps.
21

22 In addition, the Federal Trade Commission (FTC), in cooperation with the FDA, the US
23 Department of Health and Human Services' Office for Civil Rights and Office of National
24 Coordinator for Health Information Technology (ONC), has developed the Mobile Health Apps
25 Interactive Tool to assist health app developers in ascertaining which federal laws apply to the
26 health app(s) they are developing, ranging from the Health Insurance Portability and
27 Accountability Act (HIPAA) to the FTC's Health Breach Notification Rule.⁹ In addition, the FTC
28 has offered best practices for mobile health app developers to build privacy and security into their
29 apps, as well as comply with the FTC Act, which prohibits deceptive or unfair acts or practices in
30 or affecting commerce, including those relating to privacy and data security, and those involving
31 false or misleading claims about apps' safety or performance.¹⁰
32

33 In addition to supporting health information technology (health IT) policy, ONC is charged with
34 establishing the certification and testing criteria for health IT products required by Centers for
35 Medicare & Medicaid Services (CMS) reporting programs. These programs, including the
36 electronic health records (EHR) incentive, or "Meaningful Use" program, require eligible
37 physicians to adopt and use health IT specifically designed to accommodate CMS objectives and
38 measures. While some base-level EHR functionality requirements can benefit physicians and
39 patients, CMS places additional requirements on the use of those functions – influencing the design
40 of the software. With the release of ONC's 2015 Edition Health IT Certification requirements, by
41 2018 many physicians participating in CMS reporting programs must use EHRs that include
42 application programming interfaces (API). These APIs will allow an app to access patient
43 information stored in the EHR.
44

45 Addressing health information privacy, the HIPAA Privacy, Security and Breach Notification
46 Rules apply only to covered entities, which include health plans, health care clearinghouses, and
47 health care providers, and their business associates. HIPAA generally does not apply to mHealth
48 apps, even if they handle or store an individual's health information. As such, mHealth apps are not
49 required to protect the privacy and security of an individual's health information in the same way
50 that a physician must because mHealth apps are not directly subject to HIPAA regulations.

1 Although HIPAA does not directly apply to mHealth apps, the HIPAA Security Rule sets out a
2 framework for safeguarding the content of transfers of protected health information. HIPAA
3 requires covered entities to consider encryption as an appropriate method of safeguarding protected
4 health information (PHI) and to encrypt electronic PHI if such a practice is considered a
5 “reasonable and appropriate” method of safeguarding PHI from environmental security threats.
6 Encryption offers the additional benefit of alleviating the physician from breach notification in the
7 event of impermissible use or disclosure. If the covered entity does not deem encryption to be a
8 reasonable and appropriate method of safeguarding PHI, then it must document the reasons for its
9 decision and adopt an equivalent alternative method for protecting PHI as necessary.

10
11 Legislation has been introduced in Congress in an effort to modify the FDA’s regulatory authority
12 and role in this space. Representative Marsha Blackburn (R-TX) introduced H.R. 2396, the
13 Sensible Oversight for Technology which Advances Regulatory Efficiency Act or the SOFTWARE
14 Act. An amended version of the legislation was passed by the US House of Representatives as part
15 of the 21st Century Cures Act. The SOFTWARE Act provides new statutory definitions and
16 categories of apps that would exempt health software from FDA regulation, including as a medical
17 device, with the exception of software that provides patient-specific recommendations and poses a
18 significant risk to patient safety. In addition, Senator Michael Bennet (D-CO) has introduced S.
19 1101, the Medical Electronic Data Technology Enhancement for Consumers’ Health Act or the
20 MEDTECH Act, which would exempt additional medical device software and mobile medical
21 devices from FDA regulation, and provide limitations on the software that would be regulated by
22 the FDA to protect patients.

23 24 COVERAGE AND PAYMENT OF MOBILE HEALTH APPS AND MEDICAL DEVICES

25
26 As payment models evolve, with payments to physicians and other health care entities being tied to
27 outcomes, digital and mobile health technologies are being increasingly used to manage patient
28 populations, improve patient access and engagement, and potentially control costs. Due to the wide
29 range of mHealth apps in the marketplace, the level of integration of applications into practice is
30 based on several factors, including whether or not the app and/or associated device are FDA-
31 cleared or approved; the demonstrated health benefit of the app and/or associated device; the
32 strength of research and data supporting the use of the health app and/or associated device; the
33 interoperability with EHR systems; outreach to physicians and patients; and patient and physician
34 out-of-pocket costs.

35
36 Typically, medical devices are covered by health insurance, conditioned on their FDA clearance
37 and approval, which can limit patient out-of-pocket costs. However, as most mHealth apps
38 currently will not be subject to clearance or approval by the FDA, the Council notes that health
39 insurance coverage of mHealth apps is likely to be an underutilized avenue to limit patient cost
40 exposure in this area in the near term. However, other financial incentives exist to spur patient
41 uptake of mHealth apps and associated devices, including eligibility for flexible spending account
42 (FSA) reimbursement and use in employee wellness programs, which could lead to a reduction in
43 employee health insurance premiums. Without mechanisms to limit patient cost exposure, patient
44 uptake of many mHealth apps and associated devices, trackers and sensors will depend on their
45 prices. This will be especially critical for low-income and elderly individuals, who could
46 potentially benefit from these digital health interventions.

47
48 There is a wide variation of how mobile apps are priced; pricing can include the initial purchase
49 price, in-app purchases and annual subscription costs. In addition, the functionality of some mobile
50 apps are dependent upon the purchase of an associated device, sensor or tracker. Increasingly,
51 sensors and trackers are increasingly built into the mobile device itself. One-third of apps studied

1 by IMS Institute for Healthcare Informatics in 2015 required a paid sensor for operation. More than
 2 90 percent of mHealth apps are available to consumers at no cost.² The Council notes that mHealth
 3 app costs can be hidden due to in-app techniques for purchasing and advertising. For those apps
 4 that have a cost, the average price of an mHealth app doubled from \$1 to \$2 between 2013 and
 5 2015. In this time period, there was also a four percent decrease in the percentage of mHealth apps
 6 costing less than \$3 and an increase in the cost for apps over \$10. A significant proportion of the
 7 most expensive mHealth apps available, the cost of which all exceed \$150, target therapeutic areas,
 8 including for autism and augmentative and alternative communication.²

9
 10 More than a third of US physicians have recommended an mHealth app to patients.² A noteworthy
 11 barrier to physician adoption of mHealth apps is the lack of evidence demonstrating the
 12 effectiveness, safety, and security of mHealth apps. In addition, within the fee-for-service payment
 13 environment, there are insufficient pathways to incentivize physicians and other providers to
 14 implement systems that use mobile apps and devices. Notably, the integration of mobile
 15 applications and devices into practice is directly related to the ability of physicians to analyze and
 16 interpret their data. Overall, payment mechanisms are necessary for physicians to allocate their
 17 time to provide services including, but not limited to, the review, analysis and follow-up of
 18 synthesized mHealth app data.

19
 20 **RELEVANT AMA POLICY AND ACTIVITIES**

21
 22 Policy H-480.946 outlines principles to guide the appropriate coverage of and payment for
 23 telemedicine services, encourages additional research to develop a stronger evidence base for
 24 telemedicine and supports pilot programs and demonstration projects to enable coverage of
 25 telemedicine services and address how telemedicine can be integrated into new payment and
 26 delivery models. Policy H-480.974 states that the AMA will work with CMS and other payers to
 27 develop and test appropriate payment mechanisms for telemedicine through demonstration projects
 28 aimed at evaluating the effect of care delivered by physicians using telemedicine-related
 29 technology on costs, quality, and the patient-physician relationship. The policy also encourages
 30 development of a code change application for Current Procedural Terminology (CPT) codes or
 31 modifiers for telemedical services, to be submitted pursuant to CPT processes.

32
 33 Addressing mobile applications and devices specifically, Policy D-480.972 states that our AMA
 34 will monitor market developments in mHealth, including the development and uptake of mHealth
 35 apps, in order to identify developing consensus that provides opportunities for AMA involvement.
 36 The policy also states that our AMA will continue to engage with stakeholders to identify relevant
 37 guiding principles to promote a vibrant, useful and trustworthy mHealth market. Important for the
 38 integration of mHealth apps in medical practice, the policy states that our AMA will make an effort
 39 to educate physicians on mHealth apps that can be used to facilitate patient communication, advice,
 40 and clinical decision support, as well as resources that can assist physicians in becoming familiar
 41 with mHealth apps that are clinically useful and evidence-based. Finally, the policy states that our
 42 AMA will develop and publically disseminate a list of best practices guiding the development and
 43 use of mobile medical applications.

44
 45 Policy H-450.949 encourages physicians to become familiar with and capitalize on opportunities to
 46 use technology to ensure patient safety in prescribing medications and medical devices. Policy
 47 H-480.972 stresses that manufacturers are ultimately responsible for conducting the necessary
 48 testing, research and clinical investigation to establish the safety and efficacy of medical devices
 49 requiring FDA approval.

1 The AMA has been engaged in legislative and regulatory advocacy concerning mHealth apps and
2 coverage of telemedicine services, including remote patient monitoring. Federal and state advocacy
3 efforts have been focused on streamlining and updating regulatory oversight and expanding private
4 and public payer coverage. In addition, the AMA submitted comments for the record to the
5 Subcommittee on Commerce, Manufacturing and Trade of the House Energy and Commerce
6 Committee addressing health care apps.
7

8 The AMA also has hosted regular meetings with national medical specialty societies to encourage
9 the development of objectives and initiatives to support digital medicine adoption, including the
10 use of telemedicine and mobile medical apps. The AMA is a member of Health Level Seven
11 International (HL7), a not-for-profit, standards developing organization accredited by the American
12 National Standards Institute (ANSI), with its current Fast Healthcare Interoperability Resources
13 (FHIR) standard being recognized as having the capacity to facilitate interoperability in the
14 mHealth space. The AMA is working with others to develop an industry collaborative representing
15 diverse stakeholder perspectives whose objective is to develop guidance for the mHealth
16 community that focuses on issues of importance to physicians and their patients, to be used in the
17 development and evaluation of digital health tools. This activity and forthcoming guidance will
18 fulfill the intent of Policy D-480.972, which calls for the AMA to develop and publically
19 disseminate a list of best practices guiding the development and use of mobile medical
20 applications.
21

22 The AMA is a founding partner of Health2047, an integrated health care innovation company that
23 is working to develop and make available system-level solutions that enhance care delivery and
24 practice of medicine. One of the purposes of Health2047 is to catalyze collaboration across a
25 network of partners including technology firms, product companies, physicians and payers to drive
26 rapid and responsive change that makes new solutions possible. Health2047 incorporates physician
27 perspectives to inform every step – from the design process, to testing prototypes, early access to
28 solutions, and the ability to submit ideas of their own – so that health technology solutions work
29 well in the practice setting and benefit physicians and patients.
30

31 Another partnership includes the AMA at MATTER, an effort to support ideation and collaboration
32 with hundreds of entrepreneurs to ensure the physician perspective is included in the development
33 of new tools and innovative solutions from the outset, and includes an interaction studio so
34 entrepreneurs are able to test their solutions in a simulated clinical and non-clinical environment
35 and collaborate with physicians virtually. Since the partnership was established in 2015, hundreds
36 of physicians have visited MATTER or offered insight and feedback to entrepreneurs working on
37 early stage technologies and solutions. Additionally, the AMA at MATTER partnership has
38 brought physicians and entrepreneurs together for a variety of educational workshops, interactive
39 simulations, and collaboration events focused on optimizing health care.
40

41 Furthermore, since 2014, the AMA has been an active participant and board member of the
42 Substitutable Medical Applications & Reusable Technology Platforms project. This initiative with
43 Boston Children's Hospital and Harvard University's Medical School is working to use a mobile
44 app infrastructure to improve existing EHR technology and enhance interoperability. The project
45 also promotes the development and use of mobile health apps with the goal of making such
46 applications widely available to practicing physicians and patients.
47

48 The AMA conducted a survey of 1,300 physicians during the summer of 2016, which focused on
49 physicians' understanding digital health and their attitudes regarding adoption. The survey covered
50 a broad range of digital health tools, including telemedicine and telehealth, mobile health apps,
51 wearables and remote patient monitoring technologies. The purpose of the survey was to obtain a

1 summary view of physicians' thoughts regarding digital health, to understand what motivates them
 2 to want to use various emerging digital tools, and what their requirements are for successfully
 3 integrating them into patient care and their practices. The survey results and report were released at
 4 the end of September, and can be accessed at [http://www.ama-](http://www.ama-assn.org/ama/pub/news/news/2016/2016-09-26-digital-health-innovation.page)
 5 [assn.org/ama/pub/news/news/2016/2016-09-26-digital-health-innovation.page](http://www.ama-assn.org/ama/pub/news/news/2016/2016-09-26-digital-health-innovation.page). Survey results show
 6 that in order to spur physician adoption of digital health technologies, including mobile health
 7 apps, physicians require such tools to fit within their existing systems and practices, including
 8 being linked to and working within their EHRs. The survey found that physicians need experts to
 9 ensure the data privacy and security of such tools. Results also indicated that physicians need
 10 digital health tools to be covered by liability insurance and linked to appropriate physician
 11 payment. In addition, as part of its work to bridge and increase interactions between physicians and
 12 digital health stakeholders, the AMA has plans to pilot the AMA Physician Innovation Network,
 13 which will connect physicians and health technology entrepreneurs and industry for interaction and
 14 feedback. The AMA continues to monitor the evolution of the digital health sector.

15

16 DISCUSSION

17

18 The Council believes that digital health, including the utilization of mobile health apps and devices,
 19 has the potential to be integrated into everyday practice in order to promote improved patient health
 20 outcomes, support care coordination and improve communication. The Council believes that,
 21 moving forward, there needs to be a balance between innovation and appropriate industry standards
 22 for mHealth apps and FDA regulation of mobile medical devices. For those mHealth apps and
 23 mobile medical devices that are subject to FDA review and approval, FDA resources need to be
 24 sufficient to respond to the number of mHealth products under its jurisdiction. Policy H-100.980
 25 supports a strong and adequately funded FDA to ensure that safe and effective medical products are
 26 made available to the American public as efficiently as possible.

27

28 While some mobile apps and devices are subject to FDA regulation, others are not, and do not
 29 undergo rigorous evaluation before deployment for general use, which raises quality and patient
 30 safety concerns. However, without ensuring that there is strong and sufficient evidence that
 31 provides clinical validation to mHealth apps and associated devices, trackers and sensors, the
 32 Council recognizes that physicians will not fully integrate mHealth apps into their practices. In
 33 addition, health insurers will not be as likely to consider payment for interventions stemming from
 34 mHealth apps, and employers will not be as likely to incorporate mHealth apps in their wellness
 35 programs. As such, the Council believes more investment is needed in expanding the evidence base
 36 necessary to show the accuracy, effectiveness, safety and security of mHealth apps, and believes
 37 that research should also focus on showing the impact of mHealth apps on costs, practice
 38 efficiencies and improvement in outcomes to facilitate mHealth app uptake and integration in
 39 alternative payment models. Overall, coverage of and payment for mHealth apps and associated
 40 devices should be contingent upon a clinical evidence base to support their use in order to ensure
 41 app safety and effectiveness.

42

43 It is also essential for mHealth apps to follow evidence-based practice guidelines, to the degree
 44 they are available, to ensure patient safety, quality of care and positive health outcomes. The
 45 Council believes that national medical specialty societies have a key role in developing guidelines
 46 for the integration of mHealth apps and associated devices into care delivery.

47

48 Other obstacles to the acceptance and widespread utilization of mHealth technologies include the
 49 current drivers of physician payment, as well as health insurance coverage and other mechanisms
 50 to limit patient cost exposure or provide financial incentives to patients. While the shift to
 51 alternative payment models is propelling the increased use of digital and mobile health tools, the

1 lack of insurance payment for related services remains an obstacle. Health insurance payment for
 2 mobile apps and associated devices has the potential to serve as a pathway to assist patients and
 3 physicians in monitoring patient health indicators, as well as improve medication and treatment
 4 adherence. For any mHealth app or device that facilitates the delivery of any telemedicine service,
 5 the Council stresses that Policy H-480.946, which guides the appropriate coverage of and payment
 6 for telemedicine services, must be followed. In addition, the Council believes that additional
 7 principles are necessary to guide health plan coverage and payment decisions, employer wellness
 8 program inclusions and FSA eligibility determinations concerning mHealth apps and associated
 9 devices, in order to protect the patient-physician relationship, support care delivery that is patient-
 10 centered, promote care coordination and facilitate team-based communication.

11
 12 The Council believes that prescriptive requirements on the use of EHRs have negatively affected
 13 the usability of these tools. Many health information technology (health IT) developers are forced
 14 to prioritize the design of their products to meet ONC and CMS demands, contributing to physician
 15 dissatisfaction and burnout. The Council is concerned that, while new certification requirements
 16 can improve data access for physicians and patients through the use of APIs and apps, many
 17 developers will limit software functionality to that of federal requirements. This, coupled with
 18 continued interoperability issues, may detract from app uptake, and could taint the rapidly maturing
 19 mHealth industry. The Council believes that CMS, ONC, and other federal agencies must
 20 acknowledge the history of EHR development, the unintended consequences of the Meaningful
 21 Use program, and allow new payment models and user demand to shape health IT functionality
 22 going forward. Furthermore, mHealth app developers should strive to incorporate physician and
 23 patient input early in the development of their products and allocate resources to ensure design
 24 reflects user needs.

25
 26 The Council recognizes that physicians can contribute to increases in patient retention rates for
 27 mHealth apps. Before prescribing any mHealth app or associated device, the usability of data from
 28 mobile apps and devices will remain a priority for physicians and their patients, as the success of
 29 mHealth apps in the long term will depend on the level and quality of connectivity between
 30 patients, apps and devices, and physicians and other health care providers. Overall, interoperability
 31 between a patient's mobile technology and EHRs will be an asset, as physicians must be able to
 32 meaningfully use the volumes of data mHealth apps and devices create. As such, EHRs must have
 33 the capacity to download and synthesize data from such mobile technologies. In addition, there
 34 must be mechanisms for physician payment to allow for the review, analysis and follow-up of
 35 synthesized mHealth app data.

36
 37 Patient privacy and data security need to be a priority in the digital health space, as mobile apps
 38 and devices can be subject to privacy and data breaches. Accordingly, the Council recommends
 39 that mHealth apps and associated devices, trackers and sensors must abide by applicable laws
 40 addressing the privacy and security of patients' medical information. In addition, physicians should
 41 consider whether the mHealth apps they wish to use offer encryption, and whether the level of
 42 encryption satisfies HIPAA's standards. Mobile health app developers may not readily disclose
 43 whether their apps are encrypted, and the level of encryption may be unclear. If the physician is
 44 unsure of whether the mHealth app meets HIPAA's standards, he or she should consult with
 45 qualified legal counsel; the physician should also inquire about any applicable state privacy and
 46 security laws. Given the lack of regulation of mHealth apps, regardless of whether an mHealth
 47 device is encrypted, physicians should alert patients to the potential privacy and security risks of
 48 any mHealth apps that he or she prescribes or recommends, and document the patient's
 49 understanding of such risks. The Council recognizes that questions remain regarding liability risks
 50 to physicians who use, recommend or prescribe mHealth apps. As such, the Council believes that
 51 the AMA should assess the potential liability risks to physicians for using, recommending, or

1 prescribing mHealth apps, including risk under federal and state medical liability, privacy, and
2 security laws.

3
4 Patients must also be aware of the level at which their information and data are protected by
5 mHealth apps. For apps that collect, store and/or transmit protected health information, the Council
6 believes that a standard privacy notice should be provided to patients. To the extent a physician, as
7 a HIPAA-covered entity, incorporates an app into his or her practice, HIPAA is implicated and
8 physicians should revisit their HIPAA Notice of Privacy Practices to ensure apps are appropriately
9 addressed and secured. Overall, there is a need for the mobile app industry and other relevant
10 stakeholders to conduct industry-wide outreach and provide necessary educational materials to
11 patients to promote increased awareness of the varying levels of privacy and security of their data
12 in mHealth apps, and how their information and data can potentially be collected and used.

13 14 RECOMMENDATIONS

15
16 The Council on Medical Service recommends that the following be adopted and the remainder of
17 the report be filed:

- 18
19 1. That our American Medical Association (AMA) reaffirm Policy H-480.946, which outlines
20 principles to guide the appropriate coverage of and payment for telemedicine services.
21 (Reaffirm HOD Policy)
22
- 23 2. That our AMA reaffirm Policy H-100.980, which supports a strong and adequately funded US
24 Food and Drug Administration to ensure that safe and effective medical products are made
25 available to the American public as efficiently as possible. (Reaffirm HOD Policy)
26
- 27 3. That our AMA support the establishment of coverage, payment and financial incentive
28 mechanisms to support the use of mobile health applications (mHealth apps) and associated
29 devices, trackers and sensors by patients, physicians and other providers that:
30
 - 31 a) support the establishment or continuation of a valid patient-physician relationship;
 - 32 b) have a high-quality clinical evidence base to support their use in order to ensure mHealth
33 app safety and effectiveness;
 - 34 c) follow evidence-based practice guidelines, especially those developed and produced by
35 national medical specialty societies and based on systematic reviews, to ensure patient
36 safety, quality of care and positive health outcomes;
 - 37 d) support care delivery that is patient-centered, promotes care coordination and facilitates
38 team-based communication;
 - 39 e) support data portability and interoperability in order to promote care coordination through
40 medical home and accountable care models;
 - 41 f) abide by state licensure laws and state medical practice laws and requirements in the state
42 in which the patient receives services facilitated by the app;
 - 43 g) require that physicians and other health practitioners delivering services through the app be
44 licensed in the state where the patient receives services, or be providing these services as
45 otherwise authorized by that state's medical board; and
 - 46 h) ensure that the delivery of any services via the app be consistent with state scope of
47 practice laws. (New HOD Policy)
48
- 49 4. That our AMA support that mHealth apps and associated devices, trackers and sensors must
50 abide by applicable laws addressing the privacy and security of patients' medical information.
51 (New HOD Policy)

- 1 5. That our AMA encourage the mobile app industry and other relevant stakeholders to conduct
2 industry-wide outreach and provide necessary educational materials to patients to promote
3 increased awareness of the varying levels of privacy and security of their information and data
4 afforded by mHealth apps, and how their information and data can potentially be collected and
5 used. (New HOD Policy)
6
- 7 6. That our AMA encourage the mHealth app community to work with the AMA, national
8 medical specialty societies, and other interested physician groups to develop app transparency
9 principles, including the provision of a standard privacy notice to patients if apps collect, store
10 and/or transmit protected health information. (New HOD Policy)
11
- 12 7. That our AMA encourage physicians to consult with qualified legal counsel if unsure of
13 whether an mHealth app meets Health Insurance Portability and Accountability Act standards
14 and also inquire about any applicable state privacy and security laws. (New HOD Policy)
15
- 16 8. That our AMA encourage physicians to alert patients to the potential privacy and security risks
17 of any mHealth apps that he or she prescribes or recommends, and document the patient's
18 understanding of such risks. (New HOD Policy)
19
- 20 9. That our AMA assess the potential liability risks to physicians for using, recommending, or
21 prescribing mHealth apps, including risk under federal and state medical liability, privacy, and
22 security laws. (Directive to Take Action)
23
- 24 10. That our AMA assess the feasibility of state and federal legislation, as well as other innovative
25 alternatives, in an effort to mitigate the physician's potential risk of liability from the use or
26 recommendation of mHealth apps. (Directive to Take Action)
27
- 28 11. That our AMA support further development of research and evidence regarding the impact that
29 mHealth apps have on quality, costs, patient safety and patient privacy. (New HOD Policy)
30
- 31 12. That our AMA encourage national medical specialty societies to develop guidelines for the
32 integration of mHealth apps and associated devices into care delivery. (New HOD Policy)

Fiscal Note: Less than \$5,000.

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