REPORT 21 OF THE BOARD OF TRUSTEES (A-19)
Augmented Intelligence (AI) in Health Care
(Reference Committee B)

EXECUTIVE SUMMARY

At the 2018 Annual Meeting of the American Medical Association (AMA), the House of Delegates (HOD) adopted amended policy recommendations of Board of Trustees (BOT) Report 41, "Augmented Intelligence (AI) in Health Care," in lieu of Resolution 205-A-18, "Augmented Intelligence," introduced by the American Academy of Pediatrics. However, the HOD referred the following proposed additional recommendation to the report for a BOT Report at the 2019 Annual Meeting: "AI should be funded as an enhancement of the primary care medical home so that patients who really need AI can benefit from the technology and such that AI does not become a requirement that must be incorporated into the care of every patient." The referral was prompted in part due to testimony that the resolve was too narrowly focused and should address payment policy for health care AI. Since the resolve was referred, there has been significant federal and state legislative and regulatory activity related to health care AI, including the U.S. Food and Drug Administration's authorization of several AI-enabled software systems for clinical practice and the Centers for Medicare & Medicaid Services launch of an AI Health Outcomes Challenge in partnership with the American Academy of Family Physicians in order to incorporate AI in the implementation of both current and new payment and service delivery models. This underscores the benefit of developing AMA policy to address payment for AI systems without limits on medical specialty, practice setting, or payment model.

Existing health care AI policy provides that our AMA will "[p]romote development of thoughtfully designed, high-quality, clinically validated health care AI that is designed and evaluated in keeping with best practices in user-centered design, particularly for physicians and other members of the health care team; is transparent; conforms to leading standards for reproducibility; identifies and takes steps to address bias and avoids introducing or exacerbating health care disparities including when testing or deploying new AI tools on vulnerable populations; and safeguards patients' and other individuals' privacy interests and preserves the security and integrity of personal information. The policy also provides that the AMA will explore the legal implications of health care AI, such as issues of liability or intellectual property, and advocate for appropriate professional and governmental oversight for safe, effective, and equitable use of and access to health care AI." This report summarizes the need for additional AMA policy that is relevant to payment and use of health care AI; provides definitions of related terms; and addresses key issues that impact physician adoption of new health care technologies and delivery modalities, including clinical efficacy, usability and workflow integration, and liability. The recommendations build upon existing AMA policy and will enhance our AMA's continued engagement with a broad cross-section of stakeholders and policymakers to ensure that the perspective of physicians in various practice settings informs and influences the dialogue as this technology continues to develop.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 21-A-19

Subject: Augmented Intelligence (AI) in Health Care

Presented by: Jack Resneck, Jr., MD, Chair

Referred to: Reference Committee B
                (Charles Rothberg, MD, Chair)

1　At the 2018 Annual Meeting, our American Medical Association's (AMA) House of Delegates
2　(HOD) adopted Board of Trustees (BOT) Report (Report) 41-A-18, "Augmented Intelligence (AI)
3　in Health Care" policy recommendations as amended in lieu of Resolution 205-A-18, "Augmented
4　Intelligence," introduced by the American Academy of Pediatrics. However, the HOD referred the
5　following proposed additional recommendation to the report for a BOT Report at the 2019 Annual
6　Meeting.
7
8　　　AI should be funded as an enhancement of the primary care medical home so that patients who
9　　　really need AI can benefit from the technology and such that AI does not become a
10　　　requirement that must be incorporated into the care of every patient.
11
12　The reference committee heard overwhelmingly supportive testimony on BOT Report 41-A-18 and
13　mixed testimony on Resolution 205. The reference committee heard testimony that physicians must
14　provide a clear set of policy positions on health care AI to ensure the best interests of patients are
15　served. The reference committee noted that Resolution 205 intends to advance important goals of
16　health care AI such as ensuring it is part of workflow, that it is not mandated for use, and it
17　strengthens the medical home. The reference committee noted that BOT Report 41 captures those
18　goals and establishes policy that addresses additional important issues such as guarding against
19　bias, application to specialty care, and the legal implications of health care AI.
20
21　The reference committee heard further testimony that federal and state legislators and policymakers
22　are already developing laws and regulations on health care AI. The reference committee agreed
23　with testimony that physicians have a critical perspective and must engage now to ensure this
24　technology is developed in a way that improves patient outcomes, reduces administrative and
25　technological burdens, and contributes to physician professional satisfaction. The reference
26　committee heard testimony offering an amendment to safeguard patients' and individuals' privacy
27　interests. Finally, the reference committee recommended adoption of BOT Report 41 with
28　amendment in lieu of Resolution 205.
29
30　TERMINOLOGY[1]
31
32　The AMA's BOT Report 41-A-18 and the AMA's Council on Long Range Planning and
33　Development's (CLRPD) Primer on Artificial and Augmented Intelligence establish definitions
34　related to key AI systems, methods, and techniques. In this report on payment, it is essential to
35　specify systems that augment the work of clinicians do so by assisting the decision making or by
36　offering fully automated (autonomous) assistance. Furthermore, it is necessary to define and

1 differentiate between AI systems that utilize machine learning (ML) where there is either (1) a
2 continuous learner algorithm or (2) a locked learner algorithm. The foregoing approaches have
3 critical implications for risk, safety, regulation, liability, and, as a result, cost of integration into
4 clinical practice (whether in a health system or a physician practice).
5
6 *Augmented Intelligence and the Human – Machine Dyad*
7
8 Although AMA physician leaders considered using the term "artificial intelligence," ultimately
9 through the HOD process it was determined that the term augmented intelligence more accurately
10 reflects the purpose of such systems, whether assistive or fully autonomous, because they are
11 intended to coexist with human decision-making.[2] As we enter what many experts view as the
12 fourth industrial revolution, it is important to update terms to explicitly articulate the expectation
13 that rapidly evolving technologies should complement and extend the work of humans. And, the
14 AMA is not alone in this measured view of what current AI systems in health care are able to do
15 and what the expectations should be for the future development of such systems. The term
16 "augmented" intelligence has become the preferred term among key technology companies,[3] other
17 innovators, and physician AI experts. While one leading expert has advocated the use of the term
18 "dyadarity" to underscore the human-machine dyad, the rationale for the use of the term dyadarity
19 also points to the appropriateness of the use of the term "augmented intelligence:"
20
21   As we embed more and more machine learning in our clinical decision support and in our
22   clinical workflows (face to face [and] virtual care), we will discover far more interaction and
23   meshing between human and machine, physician and computer. The notion that the machine
24   will acquire absolute superiority over the human in decision-making implies that the output of
25   the machine will be strictly deterministic, as if it were just like the result of a serum sodium
26   level. . . . Incorporating […] highly variable and contextual human considerations into the
27   treatment plan really requires thoughtful and empathic discussion between doctor and patient.
28   The literature is now replete with references to various types of bias associated with how
29   machine learning is applied to different people in different contexts. Similarly, there are over
30   100 cognitive biases that have been well documented in human decision-making. What we will
31   really need as physicians is assistance in how to more systematically surface and expose the
32   biases of both the machine, also known as "thinking in silico" and the human "thinking in
33   carbon," in ways that allow the individual physician to manage, reconcile when possible, and
34   mitigate those biases. This will become more of a collaborative exercise and the notion of a
35   machine-superiority emerging after the "singularity is here" will begin to fade into a more
36   realistic "dyadarity" where all potential bias and ethical issues are made more transparent, but
37   ultimately the human will be responsible for making the decision.[4]
38
39 As noted in BOT Report 41-A-18, "combining machine learning software with the best human
40 clinician 'hardware' will permit delivery of care that outperforms what either can do alone."[5] Other
41 physicians have noted that "the applications of AI to 'augment' physicians is more realistic and
42 broader reaching than those that portend to replace existing health care services."[6] Other early
43 adopters of such systems note that "[t]he difference between artificial intelligence and augmented
44 intelligence may seem inconsequential to some; it could quite literally make a world of difference
45 when it comes to how we approach robotics in the decades to come ... [and] [i]t's businesses using
46 the technology to supplement rather than replace their employees that stand to benefit most from
47 the further development and refinement of this technology."[7] In sum, whether AI systems are
48 assistive (such as clinical decision support programs) or fully autonomous (such as software
49 programs that provide a definitive diagnostic decision), these rapidly evolving systems should
50 augment and scale the capabilities of physicians, the broader health care team, and patients in
51 achieving the quadruple aim in health care.[8]

1 *Machine Learning (ML): Continuous Learning System and "Locked" Model*
2
3 The term AI covers a range of methods, techniques, and systems. Common examples of AI systems
4 include, but are not limited to, natural language processing, computer vision, and ML. In health
5 care, as in other sectors, AI solutions may include a combination of these systems and methods.
6 ML presents some of the thornier regulatory and oversight challenges that implicate cost and
7 payment.
8
9 An AI system utilizing ML employs an algorithm programmed to learn from data referred to as
10 "training data."[9] The learner algorithm will then automatically adjust the ML model based on the
11 training data. In health care, it is important to know whether the learner algorithm is eventually
12 locked or whether the learner algorithm continues to learn once deployed into clinical practice. A
13 "continuous learning system" continues to update the model without human oversight as new data
14 is presented to the learner algorithm, whereas "locked learners" will not automatically update the
15 model with new data. There are both benefits and risks to continuous learning systems which may:
16
17   …more precisely calibrate suggestions to specific demographic or geographic areas over time,
18   taking into account [for example] that certain diagnoses are more common in that setting
19   and/or adjusting for local norms in the input data formatting or presentation. However, as
20   software changes, the rate and distribution of false-positives and false-negatives may also
21   change, potentially in ways that no longer have an acceptable benefit-risk profile. As such,
22   there are serious concerns about the risks and ethics of deploying a continuously learning
23   software system in the clinical setting.[10]
24
25 Current AI systems developed utilizing ML for clinical applications that have been authorized by
26 the U.S. Food and Drug Administration (FDA) involve a two-step process. First, the learner
27 algorithm remains "on" until the model, a software tool, has been developed with enough "training
28 data." The learner algorithm is then "locked" and model is not updated in real time. In short, "once
29 an AI system is developed utilizing a learning algorithm, it can be 'locked' and used without
30 automatic updates."[11] Why lock the learner algorithm? When AI systems are applied to patient
31 clinical care, it is necessary to allow developers (and regulators where the system is considered a
32 medical device) to undertake safety and clinical efficacy testing. However, reportedly, developers
33 may run a parallel AI system with a learner algorithm still "on" in order to assess quality and
34 identify enhancements. The developer will update the AI system which has a locked learner on a
35 periodic basis after validation for clinical efficacy and safety. This has been characterized by
36 certain innovators as "discontinuous learning."[12] In addition, it has been noted that if these regular
37 updates are not done, "locked models have the potential to degrade over time if inputs change
38 significantly."[13]
39
40 While there are significant benefits and needed health care transformations that AI systems using
41 ML promise to produce, careful consideration should be given to clinical applications of such
42 systems and the attendant quality and safety challenges. A group of British and U.S. experts has
43 proposed a general framework for identifying and addressing short-, medium-, and long-term
44 quality and safety issues vis-à-vis AI systems utilizing ML for clinical applications including
45 distributional shift, insensitivity to impact, black box decision-making, unsafe failure mode,
46 automation complacency, reinforcement of outmoded practice, self-fulfilling prediction, negative
47 side effects, reward hacking, unsafe exploration, and unscalable oversight.[14]
48 Furthermore, all AI systems are reliant upon data, but ML amplifies the risks associated with an
49 incomplete understanding or disclosure of data origin (often called provenance) and bias. Data
50 often can be incomplete and contain erroneous information[15] and all data is biased in some
51 manner.[16] It is imperative to disclose and provide means to address AI system bias in order to

1 avoid, among other unintended outcomes, exacerbating health disparities and other inequities.
2 Developers of AI systems used for clinical care should—as soon as there is a preliminary
3 validation of a clinically relevant bias or potential patient safety risk associated with any of the
4 recommendations emerging from an AI system—report the bias to the users of that software
5 (appropriate institutional notification should suffice for institutions with many users). Developers
6 of AI systems used in clinical care should be required to maintain an active intake process for
7 reports of such issues from end-users, and there should be transparency into those reporting and
8 quality assurance processes. Developers must have a process for continuous efficacy monitoring. In
9 addition, there should be transparency into key attributes of the population that was the source of
10 training data set while ensuring the protection of individual patient data and privacy interests. The
11 purpose of this transparency is to enhance the understanding of risk associated with applying an AI
12 system to individuals whose personal characteristics may diverge in significant ways from the
13 population in the training data set. Finally, there should be transparency and "traceability" of
14 training data.
15
16 USES AND APPLICATIONS OF AI SYSTEMS IN HEALTH CARE
17
18 A prerequisite to payment for AI systems involves identifying, at minimum, the intended use of the
19 AI system, whether it is assistive or fully autonomous, conditions required for successful
20 deployment, and the level of regulatory oversight required to ensure patient safety and the clinical
21 efficacy of the system. These factors, along with associated liability risk, impact costs and
22 sustainability. Broadly speaking, AI systems can be used in many areas of health care, including,
23 but not limited to: (1) research; (2) education and workforce professional development; (3) finance,
24 business processes, and health administration; (4) tools and services that improve medical practice,
25 e.g., cybersecurity; (5) population health and public health; (6) patient and caregiver engagement
26 and prevention; and (7) clinical care, e.g., clinical decision support or autonomous diagnostic
27 system. Furthermore, when used in the foregoing areas, AI systems can function to automate
28 repetitive and time-intensive tasks, improve communication and interactions, and enhance
29 decision-making which improve efficiency and accuracy.
30
31 *Key AI System Considerations, Standards Development and Ongoing Research*
32
33 While overall research on clinical applications of AI systems continues to grow rapidly, there is a
34 paucity of peer-reviewed publications of the results of head-to-head comparisons between
35 physicians and AI systems. The specialty areas where such research exists include: radiology,
36 neurology, pathology, dermatology, ophthalmology, gastroenterology, and cardiology.[17] There is
37 growing research in other areas such as oncology, but not necessarily comparative. Increased
38 funding and support for research into AI system applications in health care, particularly for specific
39 clinical applications, will remain a critical priority. However, research on AI system applications in
40 the areas of population health, patient engagement, and health administration will also produce
41 important findings of benefits and possible unintended consequences (such as inequitable impact).
42 Experts have also noted that the following areas of research remain a priority:
43
44 • Verification. Research into methods of guaranteeing that the AI systems meet established
45   specifications.
46 • Validation. Research into ensuring that the specifications, even if met, do not result in unwanted
47   behaviors and consequences.
48 • Security. Research on how to build systems that are increasingly difficult to tamper with –
49   internally or externally.
50 • Control. Research to ensure that AI systems can be interrupted (even with other AIs) if and
51   when something goes wrong, and restore normal function.[18]

1   Other priority areas include research into explicability (which is also referred to as explainability)
2   which is receiving significant focus by U.S. federal agencies and Congress. Widespread
3   deployment and scaling of advanced AI systems utilizing, for example, ML in health care has not
4   yet occurred. Conditions of deployment will require continued attention to assess safety, efficacy,
5   and fairness. And, while existing standards must be met, additional ones are needed to address
6   specific issues raised by AI and ML. For example, in February 2019, the British Standards
7   Institution (BSI) and the Association for the Advancement of Medical Instrumentation issued a
8   position paper with recommendations to support governance and regulation of AI and ML in health
9   care to specifically address: (1) level of autonomy; (2) changing outputs of algorithms;
10 (3) explicability; (4) transparency; and (5) quality of data outputs.[19] Federal agencies and Congress
11 are also prioritizing research and standards developments (as discussed below).
12
13 *Legal Requirements*
14
15 Depending on the intended use of an AI system, there are several legal requirements that
16 developers must adhere to when marketing AI-enabled software if commercializing for mass
17 distribution or when a health system designs, develops, and implements AI-enabled software
18 within their own health system.[20] AI systems with clinical applications that meet the existing
19 definition of medical device under the Food, Drug, and Cosmetic Act (FDCA) must comply with
20 the FDA requirements related to safety and efficacy. Some of these AI systems may be subject to
21 enforcement discretion because the FDA considers the risk of harm as it relates to a host of factors
22 including intended use and conditions of deployment for example, sufficiently low.
23
24 Even where AI systems are not subject to the FDCA, the development, marketing, and deployment
25 can be subject to a host of other federal and state laws. Some of the key laws include the:
26
27 • Health Insurance Portability and Accountability Act (HIPAA). HIPAA is meant to protect the
28   privacy and security of protected health information. Certain entities are required to provide
29   notifications of health information breaches. There are state laws that provide enhanced
30   protections. In addition, there are newly emerging international standards such as Europe's
31   General Data Protection Regulation (GDPR) that impact developers that reach global markets.
32 • Common Rule (Protection for Human Subject Research). Each federal agency that follows the
33   Common Rule has guidance on federally funded research involving human subjects.
34 • Federal Trade Commission Act (FTCA). The Federal Trade Commission (FTC) has the
35   authority to take action against developers of AI systems that engage in deceptive and unfair
36   trade practices. This is most relevant where the developer makes false and misleading health
37   claims, representations regarding the performance of an AI system, or claims that impact
38   consumer data security and privacy. The FTC also provides enforcement of the Health Breach
39   Notification Rule which applies to certain businesses that are required to provide notifications
40   consumers after a breach of personal health record information.
41
42 The above laws apply to AI systems with clinical uses (though the Common Rule will not always
43 be applicable). Developers, regulators, and standards setting bodies must identify dynamic and
44 useful mediums and methods to ensure physicians, medical staff, third-party payers, and patients
45 who rely on AI-enabled systems understand whether (or not) the developer has complied with the
46 relevant federal and state laws.
47
48 HEALTH CARE AI INVESTMENTS, ACQUISITIONS, AND PATENTS
49
50 The rapid growth in health care AI investments, acquisitions, and patents is expected to continue on
51 a steep upward trajectory. Analysts report that the AI health market investment is expected to reach

1   $6.6 billion by 2021, a 40 percent compound annual growth rate.[21] In addition, health care AI
2   startups have raised billions since 2013, which exceeds all other industries in AI deal activity.[22] A
3   harbinger of this interest involves one of the largest merger and acquisitions deals in health care AI.
4   Specifically, Flatiron Health was acquired by Roche Holdings for $1.9 billion largely due to the
5   curation of patient data by clinical experts that can be mined using AI systems employing ML.[23]
6   The rapid rise in patent applications involving AI in the health care field is also significant. There
7   were 79,936 patents filed in the United States between 2010 and 2018, with the plurality being in
8   the health field (32.6 percent).[24] Some of the patents are very broad or seek to patent the obvious
9   and, thus, may not ultimately be enforceable. However, such patents could create barriers to other
10 innovators and increase costs due to litigation. While support for AI in health care is based on the
11 promise of advancing the quadruple aim including lowering health care costs, manipulations of the
12 patent system may result in higher health care costs and perversely chill innovation.
13
14 CONGRESS, FEDERAL AGENCIES, WHITE HOUSE AND FEDERATION OF STATE
15   MEDICAL BOARDS (FSMB)
16
17 Since the HOD adopted the recommendation of BOT Report 41-A-18, federal and state
18 government activity has intensified rapidly. At the federal level, Congress and the Administration
19 are taking steps to advance the use of AI systems for national security purposes and to ensure U.S.
20 global economic competitiveness. The following summarizes the wide-range of actions from the
21 various congressional committees, federal agencies, the White House, and FSMB. However, this
22 BOT Report does not detail government activities[25] focused on data issues, which are broader—
23 although germane—in scope than AI. These issues could be addressed in a future board report.
24
25 *Congress*
26
27 Congressional interest in AI continues to grow, although both chambers are primarily in the fact
28 gathering and member education stages. In 2018, Representatives John Delaney (D-MD) and Pete
29 Olson (R-TX) launched the AI Caucus to "inform policymakers of the technological, economic and
30 social impacts of advances in AI and to ensure that rapid innovation in AI and related fields
31 benefits Americans as fully as possible." A number of congressional hearings concerning AI have
32 taken place.[26]
33
34 While a number of bills covering AI were introduced but not passed in the 115th Congress, [27] the
35 John S. McCain National Defense Authorization Act for Fiscal Year 2019 (H.R. 5515) became law
36 and had a provision regarding AI. Section 1051 of the law requires the establishment of the
37 National Security Commission on AI to provide recommendations to Congress and the President
38 via an annual report on AI. The law directs the Secretary of the U.S. Department of Defense
39 (DOD), no later than one year after the date of the enactment of law, to delineate a definition of the
40 term "artificial intelligence" for use within the DOD. However, the law provides that AI should
41 include:
42
43 •   Any artificial system that performs tasks under varying and unpredictable circumstances
44   without significant human oversight, or that can learn from experience and improve
45   performance when exposed to data sets.
46 •   An artificial system developed in computer software, physical hardware, or other context that
47   solves tasks requiring human-like perception, cognition, planning, learning, communication, or
48   physical action.
49 •   An artificial system designed to think or act like a human, including cognitive architectures and
50   neural networks.

1   • A set of techniques, including machine learning, that is designed to approximate a cognitive
2   task.
3   • An artificial system designed to act rationally, including an intelligent software agent or
4   embodied robot that achieves goals using perception, planning, reasoning, learning,
5   communicating, decision making, and acting.[28]
6
7   In September 2018, the U.S. House of Representatives Oversight and Government Reform
8   Subcommittee on Information Technology former Chairman Will Hurd (R-TX) and former
9   Ranking Member Robin Kelly (D-IL) released a white paper, titled "Rise of the Machines:
10 Artificial Intelligence and its Growing Impact on U.S. Policy." The white paper outlines three areas
11 of concern including: public safety, innovation, and investment in research and development.
12 Notably, the report contains a recommendation that the federal government should review existing
13 oversight of AI systems in order to assess whether it is sufficient to ensure public safety. Where
14 oversight is not adequate, the subcommittee recommended that Congress and the Administration
15 modernize oversight while not overregulating.
16
17 In February 2019, the House Energy and Commerce Committee Subcommittee on Consumer
18 Protection and Commerce scheduled a hearing on diversity in the technology industry. Though it
19 had to be rescheduled, the Committee Chairman Frank Pallone (D-NJ) and subcommittee
20 Chairwoman Jan Schakowsky (D-IL) issued a joint statement concerning AI systems and bias.
21 Specifically, they noted that a lack of diversity can affect the design of AI. And, the foregoing
22 could compound the risks of AI systems as the data used to train certain AI systems may amplify
23 bias and lead to discriminatory outcomes.
24
25 *White House*
26
27 In May 2018, the White House hosted a summit with business leaders, government officials, and
28 academics to identify how the U.S. government could increase AI research and prepare the U.S.
29 workforce for the disruptions that AI will bring. Officials from most cabinet-level agencies
30 participated including the HHS Deputy Secretary as well as the HHS Chief Technology Officer.
31 The health care AI panelists included representatives from CVS, Johnson & Johnson, Medtronic,
32 Quest Diagnostics, Google, IBM, and Verily, a subsidiary of Google. At the conclusion, the
33 Administration announced the establishment of an advisory committee comprised of federal
34 agencies and issued a report and memorandum.[29]
35
36 In February 2019, a Presidential Executive Order was issued launching the American AI Initiative.
37 The Initiative encompasses five key areas: (1) prioritization of investment by all federal agencies in
38 AI research and development (R&D); (2) requiring federal agencies to make federal data, models,
39 and computing resources more available to U.S.-based AI R&D experts, researchers, while
40 maintaining the safety, security, civil liberties, privacy, and confidentiality protections of
41 Americans; (3) establishing guidance for AI development and use across different types of
42 technology and industrial sectors and directing the National Institute of Standards and Technology
43 (NIST) to lead the development of appropriate technical standards for reliable, robust, trustworthy,
44 secure, portable, and interoperable AI systems; (4) requiring federal agencies to prioritize
45 fellowship and training programs to help U.S. workers gain AI-relevant skills through
46 apprenticeships, skills programs, fellowships, and education in computer science and other growing
47 Science, Technology, Engineering, and Math (STEM) fields; and (5) requiring federal agencies to
48 develop and implement an action plan to protect the advantage of the U.S. in AI and technology
49 critical to U.S. national and economic security interests against strategic competitors and foreign
50 adversaries.[30]

1   *Food and Drug Administration (FDA)*
2
3   In April 2018, the FDA authorized for market an "autonomous" AI system, IDx-DR, that detects
4   more than mild diabetic retinopathy. IDx-DR was not the first AI-enabled software that the FDA
5   has cleared or authorized for market under the existing FDA legal authorities designed to ensure
6   safety and efficacy; however, it is the first designated as fully autonomous, meaning that it provides
7   a diagnostic output and management recommendations without medical specialist interpretation.
8   IDx-DR is intended for use by primary care providers who may not have expertise of diabetic
9   retinopathy. A clinical staff member is able to upload the digital images of the patient's retinas to
10 the IDx-DR AI system. If the images are of sufficient quality, the system provides the medical
11 practice with one of two diagnostic results: (1) "more than mild diabetic retinopathy detected: refer
12 to an eye care professional" or (2) "negative for more than mild diabetic retinopathy; re-test in 12
13 months." If a positive result is detected, patients should be referred to a specialist for further
14 diagnostic and treatment evaluation.
15
16 The issue of levels of automation in the context of clinical care has become a central question from
17 both a regulatory perspective and for purposes of payment and coverage because a clinically
18 validated autonomous system is labeled by the FDA to perform a service without medical specialist
19 interpretation. The FDA did not identify specific criteria it used to designate the IDx-DR system as
20 autonomous; however, it did set precedent for autonomous AI by requiring a preregistered clinical
21 trial to establish safety, efficacy, and equity, as reflected by the three corresponding trial endpoints.
22 Narrowly defined, equity means that the AI is accurate and effective for all subgroups of the
23 intended population, including age groups, races and ethnicities, not just for one or a few. It
24 requires both design and validation of the AI to address potential bias and sources of bias. Thus,
25 equity is a component of both safety and efficacy. The FDA also established special controls for
26 the autonomous IDx-DR device including software documentation requirements, the requirement
27 for clinical data to evaluate image acquisition as part of the system, the requirement for human
28 factors validation, and the requirement for labeling to include instructions for obtaining quality
29 images and how performance is affected by users interacting with the system.
30
31 Also last year, the FDA permitted marketing of clinical decision support software that alerts
32 providers of a potential stroke in patients. The Viz.AI Contact application is intended for use by
33 neurovascular specialists and other professionals with similar training. The Viz.AI Contact
34 application analyzes CT images of the brain and sends a text notification to a neurovascular
35 specialist if a suspected large vessel blockage has been identified. The AI system automatically
36 notifies the specialist during the same time that the first-line provider is conducting a standard
37 review of the images, thereby involving the specialist sooner than the usual workflow in which a
38 radiologist reviews CT images and then notifies a neurovascular specialist. The specialist still
39 reviews the images on a clinical workstation. The application is limited to analysis of imaging data
40 and has not been authorized by the FDA as a replacement of a full patient evaluation or to be relied
41 upon solely to make or confirm a diagnosis.
42
43 Although AI system developers are able to utilize existing FDA regulatory pathways to secure
44 approval, or *de novo* authorization for AI systems, the FDA has indicated that the Agency's
45 alternative framework for oversight of software as a medical device (SaMD) could also serve as
46 potential pathway to market AI systems considered medical devices. Software that is intended for
47 use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or
48 prevention of disease, in humans meets the definition of medical device and is FDA regulated.
49 However, certain software that would have met this definition of medical device is no longer
50 subject to FDA oversight due to passage of the 21st Century Cures Act of 2016.

1   The FDA has two categories for software that qualifies as a medical device: SaMD and software in
2   a medical devices (SiMD). The FDA is dedicating a substantial amount of time to develop a new
3   voluntary SaMD oversight pathway for developers called the Precertification Program. The pre-
4   certification designation would be analogous to the Pre-Check program used by airline travelers.
5   Once initially vetted, a developer would go through a streamlined process. Simply stated, given the
6   rate of modifications to software and with the advent of software based on continuous learning
7   algorithms powered by deep learning and neural networks, the current oversight framework may be
8   strained by the volume of software and entrance of new software developers.
9
10   Early in 2019, the FDA issued an updated version of the proposed Precertification Program. The
11   FDA states that it contemplates that AI systems would be able to use the Precertification Program.
12   Throughout 2019, the FDA intends to pilot the Precertification Program in order to assess how the
13   program could maintain FDA standards for assuring safe and effective products, while still
14   achieving its aim of modernizing and streamlining the FDA's review of novel digital health
15   products. The FDA will test how the Precertification Program approach utilizing the streamlined *de*
16   *novo* authorization pathway compares to the traditional FDA submission pathway. The AMA
17   continues to provide comments and evaluate carefully the Precertification Program to assess
18   whether it will ensure the safety and efficacy of software, particularly AI-enabled software that
19   would be cleared, authorized, or approved through this pathway.
20
21   *Centers for Medicare & Medicaid Services (CMS)*
22
23   In November 2018, the CMS Center for Medicare & Medicaid Innovation (CMMI) announced a
24   cross-industry challenge competition to innovate how AI can be implemented in current and future
25   health care models dubbed the AI Health Outcomes Challenge. CMS noted it would seek
26   applications for AI and analytics that can boost clinical care and improve overall patient health.
27   The competition is open to technology vendors, clinicians, scientists, academics and patients who
28   are innovating their uses of AI for quality improvement. In February 2019, it was announced that
29   the challenge was being launched in partnership with the American Academy of Family
30   Physicians. Reportedly, CMS is "brainstorming how [the Agency] can incorporate AI in the
31   implementation of both our current and new payment and service delivery models."[31]
32
33   *National Institutes of Health (NIH)*
34
35   In July 2018, the NIH hosted a full-day public workshop titled Harnessing Artificial Intelligence
36   and Machine Learning to Advance Biomedical Research. Subsequently, the NIH established an AI
37   Working Group comprised of twelve members—drawn primarily from industry and universities.
38   The AI Work Group is co-chaired by an engineering director at Verily, and the NIH's Principal
39   Deputy Director. In December 2018 the AI Work Group provided an update as part of the Meeting
40   of the Advisory Committee to the NIH Director. The charge of the AI Work Group includes
41   making recommendations to address the following questions: (1) Are there opportunities for cross-
42   NIH effort in AI? How could these efforts reach broadly across biomedical topics and have positive
43   effects across many diverse fields? (2) How can NIH help build a bridge between the computer
44   science community and the biomedical community? (3) What can NIH do to facilitate training that
45   marries biomedical research with computer science? and (4) Identify the major ethical
46   considerations as they relate to biomedical research and using AI/ML/deep learning for health-
47   related research and care, and suggest ways that NIH can build these considerations into its AI-
48   related programs and activities.
49
50   The AI Work Group will offer interim recommendations in June 2019 and final recommendations
51   will be issued in December 2019. There are a range of additional NIH activities such as the NIH AI

Interest Group (AIIG) that is charged with facilitating communication among the scientists of NIH, FDA, universities and industries with interest in the development of AI systems to improve medical treatments. In August 2018, the NIH's National Institute of Biomedical Imaging and Bioengineering (NIBIB) hosted an Artificial Intelligence and Medical Imaging Workshop to discuss AI systems used for medical imaging and the challenges with regard to quality, reproducibility, and reliability of AI in medical imaging for clinical use. The meeting also sought to address how AI systems might improve the value of medical imaging and health care overall. In addition to ongoing NIH research, peer publications, and meetings, the Director of NIH also blogs concerning the research and evidence related to AI system applications to clinical care. In January 2019, for example, the Director posted a blog on Using Artificial Intelligence to Detect Cervical Cancer.

Federal Trade Commission (FTC)

In November 2018, the FTC held a two-day hearing on Algorithms, Artificial Intelligence, and Predictive Analytics. The hearing focused on: (1) the current and potential uses of these technologies; (2) the ethical and consumer protection issues that are associated with the use of these technologies; (3) how the competitive dynamics of firm and industry conduct are affected by the use of these technologies; and, (4) policy, innovation, and market considerations associated with the use of these technologies.

The developer of the IDx-DR program, a practicing physician, was invited by the FTC to provide testimony on the panel titled Understanding Algorithms, Artificial Intelligence, and Predictive Analytics Through Real World Applications. While he remarked that FDA has not set specific criteria for autonomous AI, the developer described proposed minimum criteria for autonomous AI and emphasized the need for rigorous FDA processes before deployment into clinical practice, including the three principles of safety, efficacy and equity. He also noted that AI developers with autonomous AI systems used for clinical applications must assume medical liability. The IDx-DR developer emphasized the importance of transparency; agreement on enforceable definitions; the minimum requirements for AI system validation, including human factors validation; requirements for addressing age, racial, and ethnic bias in the design; and validation of the AI system. He discussed the need for the highest-level reference standard based on patient outcomes, and aligned to the specialty preferred practice pattern, the importance of a pre-registered clinical trial reflecting the intended use, cybersecurity, training data stewardship, and other aspects unique to autonomous AI. The AMA filed comments which included the AMA policy on health care AI and expressing agreement that there is a need for: (1) clinical validation by regulators, (2) appropriate assignment of legal liability to developers for autonomous AI systems; and (3) transparency to support clinical decision-making.

Defense Advanced Research Projects Agency (DARPA)

In August 2016, DARPA launched the Explainable Artificial Intelligence (XAI) program. The program focuses on ML systems in order to: (1) produce more explainable models, while maintaining a high level of learning performance (prediction accuracy); and (2) enable human users to understand, appropriately trust, and effectively manage the emerging generation of artificially intelligent partners. In July 2018, DARPA launched the Artificial Intelligence Exploration (AIE) Program. And, then, in September 2018 the Agency announced a multi-year investment of more than $2 billion in new and existing programs called the "AI Next" campaign. Key areas of the campaign include automating critical DOD business processes, such as security clearance vetting or accrediting software systems for operational deployment; improving the robustness and reliability of AI systems; enhancing the security and resiliency of ML and AI technologies;

1   reducing power, data, and performance inefficiencies; and pioneering the next generation of AI
2   algorithms and applications, such as "explainability" and common sense reasoning.
3
4   *Federation of State Medical Boards*
5
6   In April 2018, the FSMB House of Delegates resolved to convene relevant stakeholders, subject
7   matter experts, including representatives from state medical boards, the AMA, and the American
8   Osteopathic Association to discuss AI and its potential impact on patient safety, decision-making
9   and regulation.[32] In November 2018, FSMB hosted AI in Health Care: The Role of Medical
10   Boards. The Summit was comprised of a cross-section of stakeholders including representatives
11   from the AMA and various state medical boards, FSMB leadership, staff, and industry. The
12   discussion centered on the regulatory environment in which health related AI technology is
13   deployed, the mission of state medical boards and approaches to AI regulation taken in other
14   jurisdictions, and the appropriate role and function of medical boards in the deployment of health
15   AI technology.
16
17   POLICY
18
19   The AMA's foundational Policy H-480.940, "Augmented Intelligence in Health Care," provides
20   that the perspective of practicing physicians should be included in the development, design,
21   validation, and implementation of health care AI. Furthermore, the policy provides that
22   thoughtfully designed, high-quality, clinically validated health care AI must be designed and
23   evaluated in keeping with best practices in user-centered design, particularly for physicians and
24   other members of the health care team; be transparent; conform to leading standards for
25   reproducibility; identify and take steps to address bias and avoid introducing or exacerbating health
26   care disparities including when testing or deploying new AI tools on vulnerable populations; and
27   safeguard patients' and other individuals' privacy interests and preserves the security and integrity
28   of personal information. The policy also provides that our AMA will address the legal implications
29   of health care AI, such as issues of liability or intellectual property, and advocate for appropriate
30   professional and governmental oversight for safe, effective, and equitable use of and access to
31   health care AI.
32
33   In addition, AMA policy concerning payment for digital medicine and integration of health
34   information technology are related to payment and use of AI systems in health care as the latter are
35   a subset of the former.
36
37   AMA Policy H-480.946, "Coverage of and Payment for Telemedicine," provides that payment and
38   coverage should only occur when delivered consistent with applicable regulatory and oversight
39   requirements designed to ensure patient safety and consistent with clinical practice guidelines
40   developed by national medical specialty societies and other evidence-based practice guidelines, to
41   ensure patient safety, quality of care and positive health outcomes. Furthermore, the policy
42   specifies appropriate disclosure, informed consent, and care coordination must be in place. The
43   policy also provides that digital modalities should comply with laws addressing privacy and
44   security of patients' medical information and urges physicians to verify that their medical liability
45   insurance policy covers use of such technologies. In this latter regard, it will be important that
46   physicians verify that AI system developers have taken steps to be legally responsible and
47   accountable for the AI system where there is a lack of transparency or the developer is providing or
48   marketing a fully autonomous AI system.
49
50   AMA policies (H-480.946 and H-480.940) outline the importance of: research to build the
51   evidence base for digital medicine; federally funded pilots to assess new delivery models, scaling,

1   quality, and payment; and physician organizations and national medical specialty societies in
2   particular in developing standards and clinical practice guidelines. The policies provide that
3   physician organizations should collaborate with other key stakeholders in the development of
4   technical standards for digital medicine, to the extent practicable, and to take the lead in the
5   development of clinical practice guidelines. AMA policy also provides support for research to
6   develop appropriate practice parameters to address the various applications of digital medicine
7   modalities and to guide quality assessment and liability issues.
8
9   In addition to outlining essential prerequisites to payment such as evidence of clinical usefulness,
10   compliance with state and federal legal requirements to ensure patient safety, and adherence to
11   clinical practice guidelines, AMA Policy H-480.974, "Evolving Impact of Telemedicine," provides
12   support for pathways to payment under existing payment and delivery models while also specifying
13   that the AMA will work with CMS and other payers to develop and test through demonstration
14   projects appropriate reimbursement mechanisms.
15
16   AMA also has policy concerning the acquisition and cost of health information technology. AMA
17   Policy D-478.990, "Clinical Information Technology Assistance," provides that the AMA will seek
18   a full refundable federal tax credit or equivalent financial mechanism to indemnify physician
19   practices for the cost of purchasing and implementing clinical information technology, including
20   electronic medical record systems, e-prescribing and other clinical information technology tools, in
21   compliance with applicable safe harbors. And, a related Policy D-478.996, "Information
22   Technology Standards and Cost," provides that our AMA will work with Congress and insurance
23   companies to appropriately align incentives as part of the development of a National Health
24   Information Infrastructure (NHII), so that the financial burden on physicians is not disproportionate
25   when they implement these technologies in their offices and to take into account the cost to
26   physicians at the office-based level; and to continue to advocate for and support initiatives that
27   minimize the financial burden to physician practices of adopting and maintaining electronic
28   medical records Finally, the policy provides that our AMA will advocate that physicians not be
29   financially penalized for certified EHR technology not meeting current standards.
30
31   DISCUSSION
32
33   The recommendation referred for report raises many of the same questions and concerns that
34   physicians across medical specialty and practice sites have expressed when adopting new digital
35   medicine modalities or when acquiring, implementing, and maintaining health information
36   technology, as discussed below. In addition, since the referral, payment and use of AI systems in
37   health care has rapidly taken on relevance as the FDA has authorized or cleared for use AI-enabled
38   systems for clinical practice, including, as detailed above, the first autonomous AI-system. And,
39   CMS in collaboration with the American Academy of Family Physicians has launched a challenge
40   competition to innovate how AI can be implemented in current and future health care payment and
41   delivery models.
42
43   AMA policies related to payment and coverage of digital medicine and acquisition of health
44   information technology are directly applicable to funding, payment, and access to AI systems for
45   health administration, population health, practice management, clinical care, and related use.
46   However, AI systems do raise additional issues. Also, these challenges (and potential benefits) may
47   impact physicians and their patients differently depending on the practice size, setting, and
48   specialty and these are germane.

1   *Advancing the Quadruple Aim for All Patients, Medical Specialties and Care Setting*
2
3   The referred recommendation would establish AMA policy to support funding for AI systems as an
4   "enhancement of the primary care medical home so that patients who really need AI can benefit
5   from the technology." While this should be one of the outcomes of payment and funding policy for
6   AI systems, it is not the only one. Instead, our AMA should support payment and funding for the
7   range of practice types and specialties where different AI system uses will advance the quadruple
8   aim. The quadruple aim seeks to advance simultaneously the improvement of the health of
9   populations, the enhancement of the patient experience of care, the reduction of the per capita cost
10   of health care, and the improvement the work life of health care clinicians and staff.[33]
11
12   In 2016, the AMA commissioned a survey of physicians from varied medical specialties and
13   practice settings in order to investigate their motivations, current usage, and expectations for
14   integrating digital medicine tools into their practice (Digital Health Study). The surveyed
15   physicians were optimistic that digital medicine tools would improve medical practice and patient
16   care. Surveyed physicians in larger practices tended to use digital medicine tools more. Key factors
17   relevant to increased adoption included practice size and setting which suggests economies of scale
18   and the ability of relatively larger practices to scale infrastructure may play a role in adoption.
19   More physicians reported adoption of telehealth visits than use of remote patient monitoring.
20   Physicians, however, have greater enthusiasm for the clinical benefit and work efficiencies of
21   remote patient monitoring and management systems. It is anticipated that this latter modality will
22   utilize increasingly advanced AI systems and methods. In addition, utilization of remote patient
23   monitoring is expected to increase as a result of Medicare expanded coverage of remote patient
24   monitoring for chronic conditions as of January 1, 2019.
25
26   In addition to needing credible evidence that a digital modality is clinically effective, surveyed
27   physicians ranked in order of importance the key issues that must be addressed to support their
28   adoption of these technologies including: (1) appropriate measures to address liability; (2) data
29   privacy/security assured by experts; (3) workflow integration with electronic health record systems;
30   and then, (4) coverage and payment. Similarly, our AMA policies specify that digital medicine
31   payment and integration are subject to: (1) appropriate regulatory oversight; (2) accountability by
32   technology developers for adverse events caused by such technologies; and (3) patient privacy and
33   security protections.
34
35   The foregoing underscores that AMA policy should address payment for AI systems without limits
36   on medical specialty, practice setting, or payment model. Furthermore, payment for such systems
37   should ensure key issues and considerations are addressed as with all digital medicine modalities
38   when incorporating these systems into practice, while also accounting for the additional risks that
39   AI systems may pose.
40
41   *Mandates, Penalties, Interference with Medical Practice, and Liability*
42
43   The referred also would have established AMA policy that AI systems should not be "a
44   requirement that must be incorporated into the care of every patient." If adopted, it would have
45   only partially addressed a range of long-standing physician concerns related to technology
46   mandates, penalties, and other similar requirements that interfere with the patient-physician
47   relationship and medical practice while exposing physicians to increased liability. When
48   technologies are well-designed and clinically validated and useful, mandates are not needed. Where
49   technologies are poorly designed, mandates and penalties have been used to drive adoption.
50   However, the approach to include mandates and penalties has stymied innovation and fueled
51   physician burnout. As a result, it is important that payment policies incentivize development of AI

systems that: (1) are informed by real-world workflow and human-centered design principles; (2) enable physicians and other health care stakeholders to prepare for and transition to changes in care delivery; (3) support effective communication and engagement among patients, physicians, and the health care team; (4) seamlessly integrate into the clinical and administrative workflow; and (5) enable frictionless end-user feedback to support iterative product improvement.

Furthermore, mandated use of AI systems for specific clinical uses or health administration raise concerns as to the validation and scaling of AI systems for a range of applications that remain a work in progress. As detailed in this report, there is an ongoing need for standards development and wide-spread adoption of such standards, regulatory modernization, research, and experience with varied deployment models. There are significant risks associated with AI systems that are not properly designed, developed, validated and deployed as previously detailed in BOT Report 41-A-18. In brief, AI systems utilizing ML present pronounced risk of bias. Physicians, health systems, developers, or regulators may not be in a position to understand the risks due to black-box systems due to design or for proprietary reasons. Thus, mandated or required uses of such systems should be disfavored and liability should be borne by the developer and/or the entity mandating use of such systems whether fully autonomous or assistive.

Building Evidence Base

The foregoing underscores that there is the need to build the evidence base for health care AI. Research should prioritize evaluation of AI systems that utilize ML in clinical practice to assess safety, efficacy, performance, equity, privacy, and security under varied conditions of deployment. Public and private funding and other resources should be prioritized to support research that expands the evidence base for applications of health care AI systems.

RECOMMENDATION

In light of these considerations, your Board of Trustees recommends that the following be adopted in lieu of the recommendation and the remainder of this report be filed:

Our AMA supports the use and payment of augmented intelligence (AI) systems that advance the quadruple aim. AI systems should enhance the patient experience of care and outcomes, improve population health, reduce overall costs for the health care system while increasing value, and support the professional satisfaction of physicians and the health care team. To that end our AMA will advocate that:

1. Oversight and regulation of health care AI systems must be based on risk of harm and benefit accounting for a host of factors, including but not limited to: intended and reasonably expected use(s); evidence of safety, efficacy, and equity including addressing bias; AI system methods; level of automation; transparency; and, conditions of deployment.

2. Payment and coverage for all health care AI systems must be conditioned on complying with all appropriate federal and state laws and regulations, including, but not limited to those governing patient safety, efficacy, equity, truthful claims, privacy, and security as well as state medical practice and licensure laws.

3. Payment and coverage for health care AI systems intended for clinical care must be conditioned on (a) clinical validation; (b) alignment with clinical decision-making that is familiar to physicians; and (c) clinical evidence.

4. Payment and coverage for health care AI systems must (a) be informed by real world workflow and human-centered design principles; (b) enable physicians to prepare for and transition to new care delivery models; (c) support effective communication and engagement between patients, physicians, and the health care team; (d) seamlessly integrate clinical, administrative, and population health management functions into workflow; and (e) seek end-user feedback to support iterative product improvement.

5. Payment and coverage policies must advance affordability and access to AI systems that are designed for small physician practices and patients and not limited to large practices and institutions. Government-conferred exclusivities and intellectual property laws are meant to foster innovation, but constitute interventions into the free market, and therefore, should be appropriately balanced with the need for competition, access, and affordability.

6. Physicians should not be penalized if they do not use AI systems while regulatory oversight, standards, clinical validation, clinical usefulness, and standards of care are in flux. Furthermore, our AMA opposes:
   a. Policies by payers, hospitals, health systems, or governmental entities that mandate use of health care AI systems as a condition of licensure, participation, payment, or coverage.
   b. The imposition of costs associated with acquisition, implementation, and maintenance of healthcare AI systems on physicians without sufficient payment.

7. Liability and incentives should be aligned so that the individual(s) or entity(ies) best positioned to know the AI system risks and best positioned to avert or mitigate harm do so through design, development, validation, and implementation. Our AMA will further advocate:
   a. Where a mandated use of AI systems prevents mitigation of risk and harm, the individual or entity issuing the mandate must be assigned all applicable liability.
   b. Developers of autonomous AI systems with clinical applications (screening, diagnosis, treatment) are in the best position to manage issues of liability arising directly from system failure or misdiagnosis and must accept this liability with measures such as maintaining appropriate medical liability insurance and in their agreements with users.
   c. Health care AI systems that are subject to non-disclosure agreements concerning flaws, malfunctions, or patient harm (referred to as gag clauses) must not be covered or paid and the party initiating or enforcing the gag clause assumes liability for any harm.

8. Our AMA, national medical specialty societies, and state medical associations—
   a. Identify areas of medical practice where AI systems would advance the quadruple aim;
   b. Leverage existing expertise to ensure clinical validation and clinical assessment of clinical applications of AI systems by medical experts;
   c. Outline new professional roles and capacities required to aid and guide health care AI systems; and
   d. Develop practice guidelines for clinical applications of AI systems.

9. There should be federal and state interagency collaboration with participation of the physician community and other stakeholders in order to advance the broader infrastructural capabilities and requirements necessary for AI solutions in health care to be sufficiently inclusive to benefit all patients, physicians, and other health care stakeholders. (New HOD Policy)

Fiscal Note: Less than $5000

REFERENCES

[1] In developing this BOT Report and the recommendations, the BOT received substantial input from the Council on Legislation, which considered input from a range of experts in health care AI systems including physician AI innovators involved in the design, development, validation, and deployment of health care AI systems.

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[4] Interview with John Mattison, MD, Assistant Medical Director and Chief Medical Information Office, Kaiser Permanente-Southern California Region and founding member of KP Innovation Fund and Board of Directors, March 1, 2019, and subsequent posts by John Mattison

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[11] Id.

[12] Id.

[13] Daniel, G., Silcox C., Sharma, I., Wright, M. Bennett. Current State and Near-term Priorities for AI Enable Diagnostic Support Software in Health Care, Duke Margolis Center for Health Policy (January 2019) Accessed February 20, 2019

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[15] Maddox TM, Rumsfeld JS, Payne PRO. Questions for Artificial Intelligence in Health Care. JAMA.2019;321(1):31–32. doi:10.1001/jama.2018.18932

[16] Knight, W. Forget Killer Robots—Bias is the Real AI Danger, MIT Technology Review, October 3, 2017 Accessed February 26, 2019

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[18] Russell, S. Dewey, D. Tegmark, M. Research Priorities for Robust and Beneficial AI, AAAI (2015) Accessed February 22, 2019

[19] The emergence of artificial intelligence and machine learning algorithms in health care: Recommendations to support governance and regulation BSI and AAMI (February 2019) Accessed February 22, 2019

[20] A future report addressing the practices, standards, and legal requirements followed by health systems designing, developing, validating, and deployment that may or may not be subject to oversight under the Food, Drug and Cosmetic Act may be needed.

[21] Artificial Intelligence: Healthcare's New Nervous System, Accenture Accessed February 20, 2019.

[22] The AI Industry Series: Top Health Care AI Trends to Watch, CB Insights Accessed on February 20, 2019

[23] Id.

[24] Columbus, L., Microsoft Leads the AI Patent Race Going into 2019, Forbes, January 6, 2019, Accessed on February 25, 2019 and see also graph of patents in various industries including health care over series of years.

[25] There has been significant government activity involving the work the National Institute of Standards and Technology (NIST) and certain operating and staffing divisions of the Department of Health and Human Services (HHS) including the Office of the National Coordinator for Health Information Technology (ONC), the Office of Civil Rights (OCR), and the Centers for Medicare and Medicaid Services (CMS) related to data uses and access.

[26] The U.S. House of Representatives, Oversight and Government Reform Committee Subcommittee on Information Technology has held a series of hearings captioned: Game Changer: Artificial Intelligence; Artificial Intelligence and Public Policy; and Artificial Intelligence and the Federal Government. The U.S. Senate Commerce Committee's Subcommittee on Space, Science and Competitiveness has also held a series of hearings including The Dawn of Artificial Intelligence (a broad overview of the state of AI and the policy implications and the effects on commerce), The Promise and Perils of Emerging Technologies for Cybersecurity (an exploration of the impact of emerging technologies, including AI, the internet of things, blockchain, and quantum computing on the future of cybersecurity), and The Digital Decision Making: The Building Blocks of Machine Learning and Artificial Intelligence (a review of the new and emerging role of AI in the nation's growing digital environment). Both the U.S. House of Representatives Energy and Commerce Committee and the U.S. Senate Committee on the Judiciary held hearings Facebook: Transparency and Use of Consumer Data and Facebook, Social Media Privacy, and Use and Abuse of Data, respectively. Facebook CEO and Chairman Mark Zuckerberg mentioned AI tools more than 30 times as a way to monitor and ban hate speech on the platform in the future. However, the Co-Chairs of the congressional AI Caucus subsequently released a statement that in part provided: "While AI can be utilized to help Facebook and other entities tackle problems on a massive scale, we also need to make sure that AI is implemented in an unbiased way. As the Co-Chairs of the AI Caucus, we believe that Facebook should provide more information to Congress on how they plan to use AI and what steps they are taking to make sure that AI is being used in an unbiased manner that also respects users' privacy." AI Caucus Co-Chairs: Facebook Should Clarify Plans to Use AI, Address Bias and Privacy Concerns, Congressional Artificial Intelligence Caucus Press Release, April 13, 2018 Accessed February 20, 2019.

[27] Other bills that were introduced, but not passed in the 115th Congress include: (1) H.R. 4829, the Artificial Intelligence Job Opportunities and Background Summary Act of 2018 (AI JOBS) Act of 2018 introduced by Rep. Darren Soto (D-FL) would direct Department of Labor to prepare report on Congress on AI and its impact on the workforce. Rep. Soto has reintroduced the AI JOBS Act of 2019 which is now H.R. 827 in the 116th Congress (2019-2020); (2) S. 2217/H.R. 4625, the Fundamentally Understanding the Usability and Realistic Evolution of Artificial Intelligence Act of 2017 (FUTURE of AI Act) introduced by Senators Maria Cantwell (D-WA) and Todd Young (R-IN) and Representative John Delaney, respectively, would have established the Federal Advisory Committee on the development and implementation of AI; (3) S. 3502, the Artificial Intelligence in Government Act introduced by Senators Gardner (R-CO), Schatz (D-HI), Portman (R-OH), and Harris (D- CA) would have promoted the use of AI by the federal government through increased executive agency coordination through an advisory board and development of a strategy for investing and deploying AI as part of the federal government.

[28] H.R. 5515, the John S. McCain National Defense Authorization Act for Fiscal Year 2019

[29] The advisory committee is the Select Committee under National Science and Technology Council's ("NSTC") and is tasked with "improv[ing] the coordination of federal efforts related to AI and ensur[ing] continued U.S. leadership in AI." As part of this effort, the Networking and Information Technology Research and Development Subcommittee (NITRD) and the new Select Committee were charged with updating "The National Artificial Intelligence Research and Development Strategic Plan" (the "Strategic Plan") that was created in 2016 in order to establish a set of objectives for federally-funded AI research. The ultimate goal of this federally-funded research is to "produce new AI knowledge and technologies that provide a range of positive benefits to society, while minimizing the negative impacts." The plan identifies seven priorities to achieve this goal: (1) Make long-term investments in AI research; (2) Develop effective

methods for human-AI collaboration; (3) Understand and address the ethical, legal, and societal implications of AI; (4)Ensure the safety and security of AI systems; (5) Develop shared public datasets and environments for AI training and testing; (6) Measure and evaluate AI technologies through standards and benchmarks; and, (7) Better understand the national AI research and development workforce needs.
[30] Executive Order on Maintaining American Leadership in Artificial Intelligence, February 11, 2019 Accessed February 20, 2019.
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APPENDIX: RELEVANT AMA POLICY

Policy H-480.940, "Augmented Intelligence in Health Care"
As a leader in American medicine, our AMA has a unique opportunity to ensure that the evolution of augmented intelligence (AI) in medicine benefits patients, physicians, and the health care community.
To that end our AMA will seek to:
1. Leverage its ongoing engagement in digital health and other priority areas for improving patient outcomes and physicians' professional satisfaction to help set priorities for health care AI.
2. Identify opportunities to integrate the perspective of practicing physicians into the development, design, validation, and implementation of health care AI.
3. Promote development of thoughtfully designed, high-quality, clinically validated health care AI that:
a. is designed and evaluated in keeping with best practices in user-centered design, particularly for physicians and other members of the health care team;
b. is transparent;
c. conforms to leading standards for reproducibility;
d. identifies and takes steps to address bias and avoids introducing or exacerbating health care disparities including when testing or deploying new AI tools on vulnerable populations; and
e. safeguards patients' and other individuals' privacy interests and preserves the security and integrity of personal information.
4. Encourage education for patients, physicians, medical students, other health care professionals, and health administrators to promote greater understanding of the promise and limitations of health care AI.
5. Explore the legal implications of health care AI, such as issues of liability or intellectual property, and advocate for appropriate professional and governmental oversight for safe, effective, and equitable use of and access to health care AI.

Policy H-480.946, "Coverage of and Payment for Telemedicine"
1. Our AMA believes that telemedicine services should be covered and paid for if they abide by the following principles:
a. A valid patient-physician relationship must be established before the provision of telemedicine services, through:
- A face-to-face examination, if a face-to-face encounter would otherwise be required in the provision of the same service not delivered via telemedicine; or
- A consultation with another physician who has an ongoing patient-physician relationship with the patient. The physician who has established a valid physician-patient relationship must agree to supervise the patient's care; or

- Meeting standards of establishing a patient-physician relationship included as part of evidence-based clinical practice guidelines on telemedicine developed by major medical specialty societies, such as those of radiology and pathology.
  Exceptions to the foregoing include on-call, cross coverage situations; emergency medical treatment; and other exceptions that become recognized as meeting or improving the standard of care. If a medical home does not exist, telemedicine providers should facilitate the identification of medical homes and treating physicians where in-person services can be delivered in coordination with the telemedicine services.
   b. Physicians and other health practitioners delivering telemedicine services must abide by state licensure laws and state medical practice laws and requirements in the state in which the patient receives services.
 c. Physicians and other health practitioners delivering telemedicine services must be licensed in the state where the patient receives services, or be providing these services as otherwise authorized by that state's medical board.
 d. Patients seeking care delivered via telemedicine must have a choice of provider, as required for all medical services.
 e. The delivery of telemedicine services must be consistent with state scope of practice laws.
 f. Patients receiving telemedicine services must have access to the licensure and board certification qualifications of the health care practitioners who are providing the care in advance of their visit.
 g. The standards and scope of telemedicine services should be consistent with related in-person services.
 h. The delivery of telemedicine services must follow evidence-based practice guidelines, to the degree they are available, to ensure patient safety, quality of care and positive health outcomes.
 i. The telemedicine service must be delivered in a transparent manner, to include but not be limited to, the identification of the patient and physician in advance of the delivery of the service, as well as patient cost-sharing responsibilities and any limitations in drugs that can be prescribed via telemedicine.
 j. The patient's medical history must be collected as part of the provision of any telemedicine service.
 k. The provision of telemedicine services must be properly documented and should include providing a visit summary to the patient.
 l. The provision of telemedicine services must include care coordination with the patient's medical home and/or existing treating physicians, which includes at a minimum identifying the patient's existing medical home and treating physicians and providing to the latter a copy of the medical record.
 m. Physicians, health professionals and entities that deliver telemedicine services must establish protocols for referrals for emergency services.

2. Our AMA believes that delivery of telemedicine services must abide by laws addressing the privacy and security of patients' medical information.
 3. Our AMA encourages additional research to develop a stronger evidence base for telemedicine.
 4. Our AMA supports additional pilot programs in the Medicare program to enable coverage of telemedicine services, including, but not limited to store-and-forward telemedicine.
 5. Our AMA supports demonstration projects under the auspices of the Center for Medicare and Medicaid Innovation to address how telemedicine can be integrated into new payment and delivery models.

 6. Our AMA encourages physicians to verify that their medical liability insurance policy covers telemedicine services, including telemedicine services provided across state lines if applicable, prior to the delivery of any telemedicine service.
 7. Our AMA encourages national medical specialty societies to leverage and potentially collaborate in the work of national telemedicine organizations, such as the American Telemedicine Association, in the area of telemedicine technical standards, to the extent practicable, and to take the lead in the development of telemedicine clinical practice guidelines.

Policy H-480.974, "Evolving Impact of Telemedicine"
Our AMA:
1. will evaluate relevant federal legislation related to telemedicine;
2. urges CMS, AHRQ, and other concerned entities involved in telemedicine to fund demonstration projects to evaluate the effect of care delivered by physicians using telemedicine-related technology on costs, quality, and the physician-patient relationship;

3. urges professional organizations that serve medical specialties involved in telemedicine to develop appropriate practice parameters to address the various applications of telemedicine and to guide quality assessment and liability issues related to telemedicine;
4. encourages professional organizations that serve medical specialties involved in telemedicine to develop appropriate educational resources for physicians for telemedicine practice;
5. encourages development of a code change application for CPT codes or modifiers for telemedical services, to be submitted pursuant to CPT processes;
6. will work with CMS and other payers to develop and test, through these demonstration projects, appropriate reimbursement mechanisms;
7. will develop a means of providing appropriate continuing medical education credit, acceptable toward the Physician's Recognition Award, for educational consultations using telemedicine;
8. will work with the Federation of State Medical Boards and the state and territorial licensing boards to develop licensure guidelines for telemedicine practiced across state boundaries; and
9. will leverage existing expert guidance on telemedicine by collaborating with the American Telemedicine Association (www.americantelemed.org) to develop physician and patient specific content on the use of telemedicine services--encrypted and unencrypted.

Policy D-478.990, "Clinical Information Technology Assistance"
 Our AMA will seek a full refundable federal tax credit or equivalent financial mechanism to indemnify physician practices for the cost of purchasing and implementing clinical information technology, including electronic medical record systems, e-prescribing and other clinical information technology tools, in compliance with applicable safe harbors.

Policy D-478.996, "Information Technology Standards and Costs"
 1. Our AMA will:
(a) encourage the setting of standards for health care information technology whereby the different products will be interoperable and able to retrieve and share data for the identified important functions while allowing the software companies to develop competitive systems;
(b) work with Congress and insurance companies to appropriately align incentives as part of the development of a National Health Information Infrastructure (NHII), so that the financial burden on physicians is not disproportionate when they implement these technologies in their offices;
(c) review the following issues when participating in or commenting on initiatives to create a NHII:
(i) cost to physicians at the office-based level;

(ii) security of electronic records; and
(iii) the standardization of electronic systems;
(d) continue to advocate for and support initiatives that minimize the financial burden to physician practices of adopting and maintaining electronic medical records; and
(e) continue its active involvement in efforts to define and promote standards that will facilitate the interoperability of health information technology systems.

2. Our AMA advocates that physicians:
(a) are offered flexibility related to the adoption and use of new certified Electronic Health Records (EHRs) versions or editions when there is not a sufficient choice of EHR products that meet the specified certification standards; and
(b) not be financially penalized for certified EHR technology not meeting current standards.

Policy D-480.970, "Access and Equity in Telemedicine Payments"
Our AMA will advocate that the Centers for Medicare & Medicaid Services pay for telemedicine services for patients who have problems accessing physician specialties that are in short supply in areas that are not federally determined shortage areas, if that area can show a shortage of those physician specialists.