ACTIONS ON OMSS RESOLUTIONS

1. Emeritus Membership Category
   Introduced by the OMSS Governing Council

OMSS Action: Resolution 1 referred for report back at the 2018 Interim Meeting.

RESOLVED, That our Organized Medical Staff Section (OMSS) direct the OMSS Governing Council to pursue amendment of the AMA Bylaws and OMSS Internal Operating Procedures as necessary to establish a new category of Section membership as follows:

Emeritus members of the Organized Medical Staff Section

1. Membership criteria -- An emeritus member must:
   a. Be an active member of the AMA;
   b. Have previously been an OMSS representative; and
   c. Be retired from medical practice and no longer in a position to represent a medical staff in the OMSS.

2. Membership rights -- An emeritus member shall have the right to speak and debate, but shall not have the right to introduce business, make motions, vote, or run for election to the OMSS Governing Council.

3. Certification -- The Governing Council shall establish a process, which shall be codified in the Internal Operating Procedures, for certifying emeritus members.

2. Health Care Workplace Ergonomics
   Introduced by the OMSS Governing Council

OMSS Action: Resolution 2 adopted as amended and transmitted to the AMA House of Delegates for consideration at the 2018 Annual Meeting:

RESOLVED, That our American Medical Association: (1) support research on reducing physician and staff ergonomic injuries in the health care workplace, including but not limited to studying medical instrument and work station design and development; and (2) work with resident training programs, hospitals and other interested parties to help integrate evidence-based ergonomics programs with other types of wellness programs for physicians and medical staffs (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for legislation that would: (1) appropriate an adequate percentage of research dollars to National Institutes of Health (NIH), NIH Institutes, National Science Foundation (NSF), The National Institute for Occupational Safety and Health (NIOSH), and National Academy of Medicine for basic and advanced research of health care workplace ergonomics; and (2) require that such research be focused on practicing physicians, with practicing physicians as Principal Investigators. (Directive to Take Action)

HOD Action: Resolution 434 adopted.
3. Discrimination Against Physicians By Patients
Introduced by the OMSS Governing Council

OMSS Action: Resolution 3 adopted as amended and transmitted to the AMA House of Delegates for consideration at the 2018 Annual Meeting:

RESOLVED, That our American Medical Association study (1) the prevalence, reasons for and impact of physician reassignment based upon patients’ requests and expectations; (2) how hospitals and other health care systems accommodate such patient requests, including but not limited to formal policies or procedures on handling patient bias; and (3) the legal, ethical, and practical implications that physicians and health care systems must consider when accommodating or refusing such reassignment requests. (Directive to Take Action)

HOD Action: Resolution 018 adopted as amended:

RESOLVED, That our American Medical Association study (1) the prevalence, reasons for, and impact of physician, resident/fellow and medical student reassignment based upon patients’ requests; (2) hospitals’ and other health care systems’ policies or procedures for handling patient bias; and (3) the legal, ethical, and practical implications of accommodating or refusing such reassignment requests. (Directive to Take Action)

4. Preservation of the Physician-Patient Relationship
Introduced by Robert Tortolani, MD

OMSS Action: Resolution 4 not adopted.

RESOLVED, That our American Medical Association make the preservation of the patient-physician relationship an essential goal, through an ongoing effort to bring this important issue before our membership, educational efforts of multiple Sections of our AMA, as well as any appropriate advocacy efforts. (Directive to Take Action)

5. Medical Suicide
Introduced by Nestor Ramirez, MD

OMSS Action: The following resolution was adopted in lieu of Resolution 5 and transmitted to the AMA House of Delegates for consideration at the 2018 Annual Meeting:

STUDY OF MEDICAL STUDENT, RESIDENT, AND PHYSICIAN SUICIDE

RESOLVED, That our American Medical Association conduct a study to accurately quantify the actual incidence of medical student, resident, and physician suicide, and report back with recommendations for action. (Directive to Take Action)

HOD Action: Resolution 019 adopted.
6. Hospital Closures
Introduced by Ohio State Medical Association OMSS

OMSS Action: The following resolution was adopted in lieu of Resolution 6 and transmitted to the AMA House of Delegates for consideration at the 2018 Annual Meeting:

HOSPITAL CLOSURES AND PHYSICIAN CREDENTIALING

RESOLVED, That our American Medical Association work with appropriate stakeholders, such as the AMA Organized Medical Staff Section and National Association Medical Staff Services (NAMSS), to produce an AMA credentialing repository that would allow hospitals and other organizations that credential physicians to access verified credentialing information for physicians who were on staff at a hospital, or one of its departments, at the time of closure, and report back at the 2018 Interim Meeting. (Directive to Take Action)

HOD Action: Resolution 716 referred with report back at Interim 2018.

7. Basic Practice Professional Standards of Physician Employment
Introduced by Indiana State Medical Association OMSS

OMSS Action: The following resolution was adopted in lieu of Resolution 7:

BASIC PRACTICE PROFESSIONAL STANDARDS OF PHYSICIAN EMPLOYMENT

RESOLVED, That the OMSS Delegate be instructed to seek referral of Resolution 702, Basic Practice Professional Standards of Physician Employment.

HOD Action: Resolution 702 referred.

8. “Good Samaritan” Law Application to Teaching Physicians
Introduced by Massachusetts Medical Society OMSS

OMSS Action: Resolution 8 referred for report back at the 2019 Annual Meeting.

RESOLVED, That our American Medical Association advocate at the national level to implement a “Good Samaritan Law” type waiver of liability on behalf of physicians who render opinions at clinical conferences and receive no remuneration (Directive to Take Action); and be it further

RESOLVED, That our AMA further define that a “bag lunch and parking voucher” do not represent “remuneration as a physician for medical care” (New HOD Policy); and be it further

RESOLVED, That our AMA work with state medical societies to advocate for the adoption of a waiver of liability to be enacted on the state level until national legislation is achieved. (Directive to Take Action)
9. Impact of the High Capital Cost of Hospital EHRs on the Medical Staff
Introduced by Massachusetts Medical Society OMSS

OMSS Action: The following resolution was adopted in lieu of Resolution 9 and transmitted to the AMA House of Delegates for consideration at the 2018 Annual Meeting:

RESOLVED, That our American Medical Association study the long-term economic impact for physicians and hospitals of EHR system procurement, including but not limited to their impact on downsizing of medical staffs and its effect on physician recruitment and retention. (Directive to Take Action)

HOD Action: Resolution 717 adopted.

10. Improving Health Care Proxy Use
Introduced by Massachusetts Medical Society OMSS

OMSS Action: Resolution 10 referred for report back at the 2019 Annual Meeting.

RESOLVED, That our American Medical Association work with relevant stakeholders, including medical staffs, to find ways to encourage completion of Health Care Proxies through various venues, such as providing a Health Care Proxy form when renewing a motor vehicle license, or when enrolling in Medicare and various other government enrollment and registration opportunities (Directive to Take Action); and be it further

RESOLVED, That our AMA work with the government regulatory and legislative entities, including Congress to explore the feasibility of creating a national Health Care Proxy registry, available to physicians, other providers, and appropriate entities, with 24/7 secure access (Directive to Take Action); and be it further

RESOLVED, That our AMA work to distribute information to medical staffs and other invested parties to stress the importance for the public to complete Health Care Proxy documents (Directive to Take Action); and be it further

RESOLVED, That our AMA work with state medical and national medical societies to advocate for establishing state wide registries that will ultimately feed into a national registry until federal legislation is achieved. (Directive to Take Action)

11. The Obligatory Nature and Enduring Purpose of the Self-Governed Organized Medical Staff
Introduced by the OMSS Governing Council

OMSS Action: Resolution 11 adopted and transmitted to the AMA House of Delegates for consideration at the 2018 Annual Meeting.

RESOLVED, That our American Medical Association amend Policy H-225.942 by addition to read as follows:

Our AMA adopts and will distribute the following Medical Staff Rights and Responsibilities:

Preamble

The organized medical staff, hospital governing body and administration are all integral to the provision of quality care, providing a safe environment for patients, staff and visitors, and working continuously to improve patient care and outcomes. They operate in distinct, highly expert fields to fulfill common goals, and are each responsible for carrying out primary responsibilities that cannot be delegated.

The organized medical staff consists of practicing physicians who not only have medical expertise but also possess a specialized knowledge that can be acquired only through daily experiences at
the frontline of patient care. These personal interactions between medical staff physicians and their patients give rise to a heightened and incomparable accountability to patients that is not shared by hospital administrators or members of the governing body. This unparalleled accountability requires that physicians remain answerable first and foremost to their patients.

Medical staff self-governance is vital in protecting the ability of physicians to act in their patients’ best interest. Only within the confines of the principles and processes of self-governance can physicians ultimately ensure that all treatment decisions remain insulated from interference motivated by commercial or other interests that may threaten high-quality patient care.

From this fundamental understanding flow the following Medical Staff Rights and Responsibilities...

HOD Action: Resolution 717 adopted as amended:

RESOLVED, That our American Medical Association amend Policy H-225.942 by addition to read as follows:

Our AMA adopts and will distribute the following Medical Staff Rights and Responsibilities:

Preamble

The organized medical staff, hospital governing body and administration are all integral to the provision of quality care, providing a safe environment for patients, staff and visitors, and working continuously to improve patient care and outcomes. They operate in distinct, highly expert fields to fulfill common goals, and are each responsible for carrying out primary responsibilities that cannot be delegated.

The organized medical staff consists of practicing physicians who not only have medical expertise but also possess a specialized knowledge that can be acquired only through daily experiences at the frontline of patient care. These personal interactions between medical staff physicians and their patients lead to an accountability distinct from that of other stakeholders in the hospital. This accountability requires that physicians remain answerable first and foremost to their patients.

Medical staff self-governance is vital in protecting the ability of physicians to act in their patients’ best interest. Only within the confines of the principles and processes of self-governance can physicians ultimately ensure that all treatment decisions remain insulated from interference motivated by commercial or other interests that may threaten high-quality patient care.

From this fundamental understanding flow the following Medical Staff Rights and Responsibilities...
The following reports were presented by David Welsh, MD, Chair:

House of Delegates Resolutions & Reports

Refer to annotated House of Delegates reference committee reports for final adopted language:

1. Council on Ethical and Judicial Affairs Report 2 - Mergers of Secular and Religiously Affiliated Health Care Institutions
   OMSS Action: OMSS Delegate instructed to support the intent of CEJA Report 2.

2. Resolution 106 - Prohibit Retrospective ER Coverage Denial
   OMSS Action: OMSS Delegate instructed to support the intent of Resolution 106.

3. Resolution 112 - Enabling Attending Physicians to Waive the Three-Midnight Rule for Patients Receiving Care within Downside Risk Sharing Accountable Care Organizations and Advance Bundled Payments Care Improvement Programs
   OMSS Action: OMSS Delegate instructed to support the intent of Resolution 012.

4. Board of Trustees Report 17 - Evaluating Actions by Pharmacy Benefit Manager and Payer Policies on Patient
   OMSS Action: OMSS Delegate instructed to support the intent of BOT Report 17.
   HOD Action: Board of Trustees Report 17 adopted as amended and the remainder of the report filed.

5. Resolution 207 - Quality Improvement Requirements
   OMSS Action: OMSS Delegate instructed to support the intent of Resolution 207.
   HOD Action: Policy H-450.947 reaffirmed in lieu of Resolution 207.

6. Resolution 215 - Regulation of Hospital Advertising
   OMSS Action: OMSS Delegate instructed to support the intent of Resolution 215.

7. Resolution 223 - Treating Opioid Use Disorder in Hospitals
   Resolution 239 - Treating Opioid Use Disorder in Hospitals
   OMSS Action: OMSS Delegate instructed to support the intent of Resolution 223 and Resolution 239.
   HOD Action: Resolution 223 adopted as amended in lieu of Resolution 239 with addition of a third Resolve.
8. **Resolution 310 - U.S. Institutions with Restricted Medical Licensure**

   OMSS Action: OMSS Delegate instructed to seek referral of Resolution 310.

   HOD Action: Resolution 310 was withdrawn and not considered.

9. **Resolution 420 - Mandatory Influenza Vaccination Policies for Healthcare Workers**

   OMSS Action: OMSS Delegate instructed to oppose the intent of Resolution 420.

   HOD Action: Resolution 420 not adopted.

10. **Resolution 425 - Hospital Food Labeling**

    OMSS Action: OMSS Delegate instructed to support the intent of Resolution 425.

    HOD Action: Resolution 425 adopted as amended.


    OMSS Action: OMSS Delegate instructed to support the intent of CSAPH Report 2 and seek amendment by addition as follows:

    15. Our AMA advocates for a transparent process that allows for individual physicians to report emerging drug shortages.


12. **Resolution 701 - Employed Physicians Bill of Rights**

    OMSS Action: OMSS Delegate instructed to seek referral of Resolution 701.

    HOD Action: Resolution 701 referred.

13. **Resolution 703 - Economic Credentialing**

    OMSS Action: OMSS Delegate instructed to seek reaffirmation of AMA Policy H-180.963 in lieu of Resolution 703.

    HOD Action: Policy H-180.963 reaffirmed in lieu of Resolution 703.

14. **Council on Medical Service Report 2 - Improving Affordability in the Health Insurance Exchanges**

    OMSS Action: OMSS Delegate instructed to seek referral of CMS Report 2.


15. **Resolution 015 - Human Trafficking/Slavery Awareness**

    OMSS Action: OMSS Delegate instructed to support the intent of Resolution 015.

    HOD Action: Resolution 015 adopted as amended.
16. Resolution 232 - Recording Law Reform

OMSS Action: OMSS Delegate instructed to support the intent of Resolution 232.

HOD Action: Resolution 232 adopted.

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**Governing Council Report B: Proposal to End the Federal Certification of EHRs Program**

**OMSS Action:** Recommendation in Report B adopted and the remainder of the report filed.

At its 2017 Annual Meeting, the OMSS Assembly referred Resolution 14, “Proposal to End the Federal Certification of EHRs Program,” to the Governing Council for report. Resolution 14, which was introduced by the Massachusetts Medical Society OMSS, asked the AMA to:

1. advocate to the appropriate governing bodies and Federal Representatives to end all legal constraints and financial inducements arising from the use or non-use of the Office of National Coordinator (ONC) Certified EHR Technology;

2. encourage Federal Legislators to introduce legislation to end the ONC’s EHR certification program, and ask the President of the United States to immediately request that such legislation be introduced;

3. request the ONC to define HIT standards that can be freely used by HIT vendors/innovators to exchange medical information between EHRs and other HIT tools;

4. request the ONC maintain a public website where physicians, innovators, and vendors can assess the ability of their EHR to exchange information with other EHRs in accordance with the ONC’s recommended standards; and

Testimony on Resolution 14 was mixed. While many agreed that electronic health record (EHR) technology is lacking, there was disagreement about the value of EHR certification—whether by the Office of the National Coordinator for Health Information Technology (ONC) or other entities. It was also suggested that many aspects of Resolution 14 are already addressed by existing AMA policy and ongoing AMA activities.

**DISCUSSION**

**Legal constraints and financial inducements of ONC Certified EHR Technology**

Resolution 14 asks that the AMA advocate for ending all legal constraints and financial inducements arising from the use or non-use of ONC Certified EHR Technology. Existing AMA policy already supports removing penalties for non-compliance and providing inflation-adjusted funds to cover all costs of implementation and maintenance of EMR systems (AMA Policy H-478.991). Additionally, AMA Policy D-478.972, EHR Interoperability, further supports this general principle by advocating for the AMA to “seek exemptions from...penalties due to the lack of interoperability or decertified EHRs...”

**Legislation to end ONC’s EHR certification program**

Resolution 14 also seeks to address the lack of Health Information Technology (HIT) vendor transparency and accountability by asking that the AMA encourage federal legislators to introduce legislation to end the ONC’s EHR certification program. While we support the sponsors’ intent, we note that this particular resolve clause addresses complex EHR certification requirements that continue to evolve in today’s rapidly changing regulatory environment.

For example, the 21st Century Cures Act enacted by Congress in December 2016 established the Health Information Technology Advisory Committee (HITAC) to provide recommendations to ONC on policies, standards, implementation specifications, and certification criteria relating to the implementation of a local and national HIT infrastructure that advances the electronic access, exchange, and use of health information. More recently, it was announced that Carolyn Peterson, MD, a longtime patient advocate and a past president of the AMA, will co-chair HITAC. The Committee kicked off its first meeting in January, and ONC officials have announced they will soon release a proposed rule that will address HIT certification and interoperability enhancements. We will await the release of this proposed rule and report back to the Assembly as appropriate.
Additionally, the AMA remains committed to improving interoperability with the recent launch of the Integrated Health Model Initiative, which will develop a framework for the industry to collect, organize, and share health data. The AMA anticipates working with agency officials to ensure Integrated Health Model Initiative efforts and ONC goals are mutually reinforcing with aims similar to the HIT technology goals stemming from the 21st Century Cures Act.

**Interoperability and the use of HIT standards by vendors/innovators**

Lastly, Resolution 14 asks that the AMA advocate for ONC to define HIT standards that can be freely used by HIT vendors/innovators to exchange medical information between EHRs and other HIT tools—and that the ONC maintain a public website where physicians, innovators, and vendors can assess the ability of their EHR to exchange information with other EHRs in accordance with the ONC’s recommended standards. The AMA is not only invested in helping facilitate the connections between physicians, innovators, HIT vendors, lawmakers, and other stakeholders, but is also thoroughly involved in a number of initiatives and partnerships that focus on EHR usability and interoperability.

For example, through its partnership with MATTER, the AMA hosts the *AMA Interaction Studio at MATTER*, which serves as a unique technological test bed for optimizing new products in multiple simulated medical settings. Other AMA initiatives and partnerships include:

- Development of a scoring dashboard, in partnership with MedStar Health's National Center for Human Factors in Healthcare, to increase transparency of EHR vendor usability testing against best practices.
- SMART Initiative, created by Boston Children's Hospital and Harvard Medical School, which is designed to ensure EHR systems work better for physicians and patients. A key component of this effort is the development of a flexible information infrastructure that allows for free, open development of plug and play applications to increase interoperability among health care technologies, including EHRs, in a more cost-effective way.
- AMA Physician Innovation Network, a pilot online platform designed to connect physicians with entrepreneurs, including those who focus on improving the use and interoperability of EHRs. The Network will also help to introduce the physician voice into the development of digital health products and to improve usability and impact when they come to market.

A list of all current AMA efforts and partnerships in this area, including more detailed information on the above initiatives, can be found on the AMA’s website: [ama-assn.org/delivering-care/digital-health-your-practice](http://ama-assn.org/delivering-care/digital-health-your-practice).

**RECOMMENDATION**

In view of rapid, continuous changes in the current regulatory environment, as well as the ongoing AMA advocacy efforts described above, the Governing Council recommends that the following be adopted in lieu of Resolution 14-A-17 and the remainder of the report be filed:

That the OMSS Governing Council monitor the development, implementation, and oversight of Certified EHR Technology and update the Assembly as appropriate. (Directive to Take Action)

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**Governing Council Report C: Supporting an Appeals Process for Out of Network Patient Referrals**

**OMSS Action:** Recommendation in Report C adopted and the remainder of the report filed.

At its 2017 Annual Meeting, the OMSS Assembly referred Resolution 12 “Supporting an Appeals Process for Out of Network Patient Referrals,” to the Governing Council for report. Resolution 12, which was introduced by the Massachusetts Medical Society OMSS, asked the AMA to:

1. advocate for a transparent process within Alternative Payment Models and Medicare Advantage to protect physicians who seek to provide optimal and timely care for patients from punitive consequences for patient referrals; and

2. advocate by developing legislation that requires health care organizations to have an appeals and grievance process, to protect providers, who advocate for both facility and provider referrals that address patient specific conditions with the appropriate and available health care resource and skill; and
(3) support protecting the patient’s freedom to choose a physician and a health care delivery system, in order to preserve the patient-physician relationship.

DISCUSSION

Resolution 12 asks the AMA to focus its advocacy efforts on addressing the adverse impact that alternative payment model (APM) incentives may have on a physician’s ability to deliver high quality patient care. While we support the intent of this resolution, we note that existing AMA policy already directs current AMA advocacy efforts in this important area. In particular, the following policy excerpts, which by no means constitute a comprehensive listing, address the issues raised by the sponsors of Resolution 12:

- “Our AMA supports…the freedom of choice of physicians to refer their patients to the physician practice or hospital that they think is most able to provide the best medical care when appropriate care is not available within a limited network of providers.” (H-160.901)
- “Our AMA supports the following principles...2. Individuals should have freedom of choice of physician and/or system of health care delivery...” (H-373.998)
- "Our AMA encourages the Centers for Medicare & Medicaid Services (CMS) to ensure that Medicare Alternative Payment Models (APMs) do not require physicians to assume responsibility for costs they cannot control because such a requirement could potentially create an ethical conflict of interest…and will advocate to CMS that any review process of alternative payment models proposed by stakeholders be completed in a timely manner, include an administratively simple appeals process and access to an ombudsman." (H-390.840)
- “Our AMA recognizes that the physician is best suited to assume a leadership role in transitioning to alternative payment models (APMs) and supports APM goals that…provide flexibility to physicians to deliver the care their patients need; promote physician-led, team-based care coordination that is collaborative and patient-centered… provide adequate and predictable resources to support the services physician practices need to deliver to patients, and should include mechanisms for regularly updating the amounts of payment to ensure they continue to be adequate to support the costs of high-quality care for patients…limit physician accountability to aspects of spending and quality that they can reasonably influence...” (H-385.913)

The AMA is dedicated to protecting patient choice, quality of care and the freedom of choice of physicians to refer their patients to the physician practice or hospital that will provide the best medical care. In fact, the AMA was the first to sponsor research on the impact of new payment models on individual physician practices. The 2015 study, conducted in partnership with the RAND Corporation, assessed many of the concerns raised by Resolution 12. Its findings continue to support current AMA efforts to improve the effectiveness of APMs and address physicians’ concerns about the operational details of these payment models.

Further, the AMA’s efforts to improve current and future APMs and help physician practices succeed in these new payment models remain ongoing. For example, in a September 11, 2017, letter to CMS Administrator Seema Verma, the AMA highlighted the importance of developing innovative care delivery models and payment models to give consumers multiple good choices for care delivery, rather than a choice between the current system and one APM:

“In many cases, higher-quality care will be less expensive. However, for some patients, better outcomes can only be achieved with additional services or more intensive services that will involve higher costs, at least in the short run. We support testing of models in which physicians have the ability to deliver more or different services to patients...”

As physician payment continues to move towards pay-for-value, the AMA remains committed to ensuring that those at the forefront of care–patients and physicians–have practical payment models that are flexible, innovative, and help to improve outcomes. We note that the AMA has also developed a number of tools and resources to help

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1 [https://www.rand.org/pubs/research_reports/RR869.html](https://www.rand.org/pubs/research_reports/RR869.html)
specialty societies and other physician organizations develop, refine, and implement APMs that give physicians more resources and greater flexibility to deliver appropriate care to their patients than they have today. 3

RECOMMENDATION

In view of the existing AMA policy and ongoing AMA efforts described above, the Governing Council recommends that Resolution 12-A-17 not be adopted, and that the remainder of this report be filed.


OMSS Action: Recommendations in Report D adopted and the remainder of the report filed.

HOD Action: Resolution 526 adopted.

At its 2017 Annual Meeting, the OMSS Assembly referred Resolution 6, “Implications of Direct Access Testing,” to the Governing Council for report. Resolution 6, which was introduced by Lee Ansel, MD, asked the AMA to:

1. in alliance with other interested parties, foundations and agencies, investigate the consequence of allowing the public to get whatever lab tests, from nearly any lab they may choose, and for whatever reason they may wish, without a physician’s order, including but not limited to cost, access, risk, insurance, oversight and regulation; and

2. report back to the House of Delegates by the 2018 Annual Meeting the results of its investigation into the adverse effects of allowing the public to get whatever lab tests, from nearly any lab they may choose, and for whatever reason they may wish, without a physician’s order.

While testimony generally supported the intent of Resolution 6, many expressed a number of concerns related to direct access testing that were not addressed by the resolution, including any legal implications, issues related to quality, and patient education. As such, Resolution 6 was referred for report to allow for further clarification of these and other ambiguities.

BACKGROUND

Over the past decade, the number of individuals that have shown a greater involvement in decisions affecting their healthcare has increased. As policies that enable this involvement continue being implemented, individuals now have more control over their personal health than ever before. Today, our patients have the option to purchase over-the-counter test kits that allow them to collect a sample and mail it to a laboratory that performs the test, or in some cases, they are able to conduct the test themselves in their own homes.

Direct-to-consumer (DTC) laboratory testing, also referred to as direct access testing, allows individuals to initiate their own laboratory tests without an order from, or consultation with, a physician or other health care provider. Instead, DTC laboratory testing places the clinical laboratory professional in a direct provider relationship with patients. Today, a wide variety of tests are available to consumers that may be used to either monitor an existing health condition, identify a previously unknown medical disorder, or provide data regarding personal health characteristics.

In the United States, DTC laboratory testing is regulated at both the federal and state level. At the federal level, the Food and Drug Administration (FDA) is responsible for ensuring that the medical claims made by DTC laboratory testing companies are true before the test is marketed to consumers, while The Federal Trade Commission (FTC) safeguards against any deceptive marketing practices and false claims. To ensure the accuracy and reliability of test results, the Centers for Medicare & Medicaid Services (CMS) regulates all laboratory tests performed on humans in the United States through the Clinical Laboratory Improvement Amendments (CLIA).

All facilities, including DTC laboratory testing facilities, that meet the definition of “laboratory” under CLIA must obtain an appropriate CLIA certificate prior to conducting patient testing—regardless of whether they file Medicare

3 To access these tools and resources, including letters and testimonies from the AMA’s latest advocacy efforts in this area, please visit https://bit.ly/2DPHDWC.
claims for their tests. These certificates must be maintained and CLIA laboratory procedures must be followed throughout all phases of testing.

Although CMS enforces regulatory requirements for analytical validity under CLIA, it does not have the authority to enforce requirements for the clinical validity of DTC laboratory tests. In addition, some companies that offer DTC laboratory testing are not required to be CLIA certified. A 2006 Government Accountability Office (GAO) investigative study found that a number of testing facilities were claiming exemption from regulatory oversight by asserting that they provide "health information," not diagnostic test results. Other DTC laboratory testing companies may not meet the definition of "laboratory" because the companies serve only as a mailing service and do not perform testing, or because the companies simply provide an interpretation service to clarify results from a CLIA-certified laboratory.

At the state level, the availability of DTC laboratory testing and the range of tests offered vary according to each state’s laboratory laws. A majority of states define the practice of medicine as diagnosing, treating, or advising on patient symptoms or disease—and under this definition, states have not historically viewed DTC medical testing as the unauthorized practice of medicine, so long as the companies do not provide results analysis or medical advice. Currently, approximately 37 states and the District of Columbia allow for patient direct authorization of laboratory testing in some shape or form. And only a small number of states—including Connecticut, Georgia, Hawaii, Idaho, Kentucky, New Hampshire, Pennsylvania, Rhode Island, and Tennessee—explicitly require the order of a physician or other licensed health care professional to perform any type medical testing.

DISCUSSION

Concerns on the use of DTC laboratory testing vary with the purpose of the test, the quality of laboratory testing, and the business model of the company offering the test. For instance, DTC laboratory tests—such as those that check cholesterol levels, cancer predisposition, and DNA for paternity identification—if conducted by properly certified laboratories through companies that provide for licensed physicians or other credentialed professionals to explain the results to patients, may raise little to no red flags. But laboratory companies that are not properly certified due to gaps in federal and state oversight could potentially perform tests of questionable clinical value that ultimately put patients at risk for harm.

Low-quality and inappropriately-performed DTC laboratory tests may lead to poor patient outcomes if a patient misinterprets test results and ultimately decides to base healthcare decisions on this misinterpretation. While there is a lack of scientific evidence that patients have in fact relied on DTC test results to their detriment, the grave impact that this may have on patient health should this occur is not lost. Existing AMA policy addresses this important patient safety concern by recognizing that diagnostic laboratory testing should only be performed by those individuals who possess appropriate clinical education and training, under the supervision of licensed physicians, and further, seeks to limit laboratory test ordering and interpretation of test results solely to licensed physicians and licensed dentists (AMA Policy D-35.999).

We recognize that allowing patients direct access to medical laboratory testing is a subject of some controversy. Patient safety concerns related to low-value DTC laboratory testing include patient anxiety over results, self-misdiagnosis, and the risks of downstream interventions based on false-positive testing. However, direct patient access to certain fully-proven laboratory tests that help patients keep track of certain measures (e.g., lipid panel or profile to check cholesterol levels) may allow for improvements in monitoring specific diseases.

State and federal guidance and regulations that effectively close gaps in the oversight of DTC laboratory testing must be developed in order to minimize the harms and maximize the benefits of DTC laboratory testing—a market that is expected to grow past $350 million by 2020. Further, it is vital that patients not only receive complete, accurate, and balanced information that describe the benefits, risks, and limitations of DTC laboratory tests, but also continue being educated on the importance of consulting with a physician to select the appropriate tests and interpret all results.

RECOMMENDATION

The Governing Council recommends that the following be adopted in lieu of Resolution 6-A-17, and that the remainder of the report be filed:

That our American Medical Association: (1) advocate for vigilant oversight of direct-to-consumer (DTC) laboratory testing by relevant state and federal agencies; and (2) encourage physicians to educate their patients about the limitations of DTC laboratory tests, as well as the risks associated with interpreting DTC test results without input from a physician. (Directive to Take Action)

Governing Council Report E: Uncompensated and Burdensome Medical Record Requests

OMSS Action: Recommendation in Report E adopted and the remainder of the report filed.

At its 2017 Annual Meeting, the OMSS Assembly referred Resolution 9, “Uncompensated and Burdensome Medical Record Requests,” to the Governing Council for report. Resolution 9, which was introduced by Chris Bush, MD, asked the AMA to:

“work with health insurance entities to amend their policies regarding physician office chart review to state that whenever possible, vendors should be provided for on-site reviews, and in cases where it is not possible, physician practices should be fairly compensated for use of staff time and resources with a fee schedule similar to that which is used when providing records for legal purposes.”

DISCUSSION

Resolution 9 suggests that Medicare and other public and private health insurance entities requesting patient records for risk management stratification, utilization, or quality review purposes should reimburse physician practices for the cost of producing and copying medical records. Consistent with existing AMA policy in strong support of this concept (AMA Policies H-335.980, H-315.992, and H-285.943), the AMA has already added this goal to its regulatory relief agenda, which puts it among the most pressing concerns on which the AMA seeks to engage the Administration.

AMA advocacy efforts in this area remain ongoing. For example, in a September 11, 2017, letter to CMS Administrator Seema Verma, the AMA highlighted the burdens associated with routine demands for medical records from physician practices to support risk adjustment scores:

“Plans generally provide no compensation for staff time required to pull records and make copies. Physicians frequently complain that charts are demanded for large numbers of patients and that the same practices are repeatedly subject to these demands, often for the same patients. Medicare Advantage plans frequently subcontract the chart audits to third parties so the medical practice has no idea which plan is making these demands, and misleading statements are made that the audits are required by CMS when they are not.”

The letter further stressed that “[p]hysicians need a single transparent, consistent, and fair review process to reduce administrative burden,” and the AMA made a number of related principle recommendations to CMS, including that Recovery Audit Contractors (RACs) be required to reimburse physicians for medical records, and that record request limits be retained to ensure audits are not overly burdensome to physicians.

12 AMA policies cited in this report are reproduced in full in the Appendix.
The AMA has also met with CMS on a monthly basis to discuss developing a framework to eliminate fraud and abuse while not negatively impacting physicians with burdensome and unnecessary requirements. Although positive steps have been taken as a result of AMA advocacy efforts, including the possibility that CMS will take immediate action to clarify contractor function and scope of authority, the AMA continues to push for more changes that will reduce physicians’ audit and other review-related administrative burdens.

RECOMMENDATION

In view of the existing AMA policy and ongoing AMA advocacy efforts described above, the Governing Council recommends that Resolution 9-A-17 not be adopted, and that the remainder of the report be filed.

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Report AA: Board of Trustees Report 35-A-18: Model Hospital Medical Staff Bylaws

OMSS Action: The recommendation in Report AA adopted as amended. OMSS Delegate instructed to support the intent of the recommendations of CEJA Report 1-A-17; and:

RESOLVED, That our OMSS Governing Council review BOT Report 35-A-18 and present to OMSS at I-18 specific ways to strengthen our AMA's efforts to improve the accessibility and usability of, and to proactively disseminate, the content contained in the AMA Physicians Guide to Medical Staff Organization Bylaws.

HOD Action: The recommendation in Board of Trustees Report 35 adopted and the remainder of the Report filed.

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HOD Action: The recommendation in Board of Trustees Report 25 adopted as amended, and the remainder of the report filed.

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HOD Action: Board of Trustees Report 31 referred.


HOD Action: Board of Trustees Report 19 adopted as amended and the remainder of the report filed.