

REPORT 16 OF THE BOARD OF TRUSTEES (June 2021)  
Follow-up on Abnormal Medical Test Findings  
(Resolution 309-I-19)  
(Reference Committee D)

EXECUTIVE SUMMARY

**BACKGROUND.** Resolution 309-I-19, “Follow-up on Abnormal Medical Test Findings,” asked that our American Medical Association advocate for the adoption of evidence-based guidelines on the process for communication and follow-up of abnormal medical test findings to promote better patient outcomes and work with appropriate state and specialty medical societies to enhance opportunities for continuing education regarding professional guidelines and other clinical resources to enhance the process for communication and follow-up of abnormal medical test findings to promote better patient outcomes. However, there is currently no standardized definition for ‘abnormal medical test findings.’ Terminology can vary markedly around the degree of abnormality, required timeliness of the communication, and associated patient outcomes. Related definitions include “urgent, critical, acute, alert, emergent, abnormal, markedly or significantly abnormal, [and] clinically significant.

**DISCUSSION.** Notification preferences can evolve over time and include tradeoffs in terms of ease of use and degree of security. The ideal communication method may include an office visit, phone call, text, postal mail, email and/or the use of an online patient portal. Preferences may vary between patients and between different types of test results. Guidelines around notification should be flexible so that they can be tailored to meet various practice and patient needs. Overall, flexibility in approach to reporting abnormal and critical results is likely to continue to remain desirable. Flexibility is also needed to support communication policies that are standard practice in medicine such as brief embargo periods to enable care coordination, closing the referral loop, consultation, discussion of complex findings, care team planning, and/or other medically appropriate purposes. Such flexibility may be more readily accomplished by tailored clinical practice guidelines and local programs rather than broad mandates via additional regulation. Guidelines offered by medical specialty societies have the potential to help optimize appropriate notification frequency and response. Additional research is needed to develop best practices for communication of test results including via patient portals and apps.

**CONCLUSION.** While the AMA has extensive policy on medical test reporting and certainly agrees that reporting test results in a timely manner is an important patient safety issue, it is the role of national medical specialty societies to develop evidence-based guidelines on communicating with patients regarding abnormal test results. Communication requirements may vary by facility or jurisdiction and communication preferences may vary between patients and between different types of test results. As outlined in this report, there are existing tools and resources that physicians can leverage to facilitate communication with patients on abnormal and critical test findings. The report recommends that the AMA highlight relevant education regarding the communication and follow-up of abnormal and critical medical test findings and support the development of best practices and other clinical resources for communication of test results, including via patient portals and applications, and encourages additional research to ensure these innovative approaches and tools reach their potential to help advance patient care.

## REPORT OF THE BOARD OF TRUSTEES

B of T Report 16-JUN-21

Subject: Follow-up on Abnormal Medical Test Findings  
(Resolution 309-I-19)

Presented by: Russ Kridel, MD, Chair

Referred to: Reference Committee D

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### 1 INTRODUCTION

2  
3 Resolution 309-I-19, "Follow-up on Abnormal Medical Test Findings," which was introduced by  
4 the Georgia Delegation and referred by the House of Delegates, asked that:

5  
6 Our American Medical Association advocate for the adoption of evidence-based  
7 guidelines on the process for communication and follow-up of abnormal medical test  
8 findings to promote better patient outcomes; and

9  
10 Our AMA work with appropriate state and specialty medical societies to enhance  
11 opportunities for continuing education regarding professional guidelines and other  
12 clinical resources to enhance the process for communication and follow-up of  
13 abnormal medical test findings to promote better patient outcomes.

### 14 15 CURRENT AMA POLICY

16  
17 Existing AMA policy addresses medical test results and follow-up (see Appendix for full text).  
18 AMA Policy D-260.995, "Improvements to Reporting of Clinical Laboratory Results," encourages  
19 the usability and standardization of clinical laboratory reports including clearly identifiable  
20 diagnoses and test results. AMA Policy H-155.994, "Sharing of Diagnostic Findings," encourages  
21 providers to develop mechanisms for the sharing of diagnostic findings to avoid duplication of  
22 expensive diagnostic tests and procedures. AMA Policies H-478.979, "Quality Payment Program  
23 and the Immediate Availability of Results in Certified Electronic Health Record Technologies,"  
24 and D-478.979, "Promoting Internet-Based Electronic Health Records and Personal Health  
25 Records," address best practices for patient portals including education and sharing of medical test  
26 results. AMA Policy H-425.968, "Non-Physician Screening Tests," advocates for requiring  
27 consultation with a patient's primary care physician or usual source of care if a screening test  
28 shows a positive or otherwise abnormal test result.

### 29 30 BACKGROUND

31  
32 Medical testing is essential for providing quality health care. Testing services are frequently  
33 divided between the branches of laboratory medicine, anatomic pathology, and medical imaging.  
34 Other medical specialties also perform many additional forms of testing including mental health  
35 assessments, hearing and vision tests, sleep apnea tests, and neurocognitive tests. Test results are  
36 used for diagnostic and other medical decision-making purposes, with interpretation taking into  
37 account additional patient context.<sup>1</sup>

1 With approximately 14 billion clinical laboratory tests performed annually in the U.S.,<sup>2</sup> laboratory  
2 medicine is tightly integrated into nearly every physician's daily practice. Laboratory tests, and  
3 other test results including anatomic pathology and medical imaging, support clinical decision-  
4 making to assist the management of most human disorders. Tests also play an indispensable  
5 supportive role for models of evidence-based medicine and precision medicine.

### 6 7 *Defining abnormal and critical test results* 8

9 There is currently no standardized definition for 'abnormal medical test findings.' Terminology can  
10 vary markedly around the degree of abnormality, required timeliness of the communication, and  
11 associated patient outcomes. Related definitions include "urgent, critical, acute, alert, emergent,  
12 abnormal, markedly or significantly abnormal, [and] clinically significant."<sup>3</sup> An abnormal result is  
13 often understood in the context of a reference range, e.g., a value in the 95<sup>th</sup> percentile. However,  
14 reference ranges derived from population studies may not account for how patient characteristics  
15 such as age, sex, ethnicity, or specific conditions affect the likelihood of results being flagged as  
16 out-of-range. Reference ranges based on race are currently being reevaluated given concerns that  
17 race is a social and not biological construct. Given natural variation between individuals and testing  
18 variability, in many cases such results may not require changes in patient management or may be  
19 considered false positives.

20  
21 Interpretation of test results is also highly dependent on the overall clinical context, including  
22 working diagnosis, signs and symptoms, and a specific clinical question to be answered.<sup>4</sup> For  
23 example, when evaluating patients for adherence to prescribed opioids, levels of circulating opioid  
24 below a certain threshold or a negative result may be flagged as abnormal. On the other hand, when  
25 screening patients who have not been prescribed opioids, any positive result may instead be flagged  
26 as abnormal.<sup>5</sup> Accordingly, availability of other information about the patient can greatly enhance  
27 the clinical relevance of the test report and may be essential for optimal interpretation of results and  
28 patient care, including determining what findings may be considered abnormal for an individual  
29 patient.

30  
31 On the other hand, some test results require timely clinical evaluation because they are associated  
32 with life-threatening conditions (or imminent clinical deterioration), for which a clinical action is  
33 possible. Lundberg initially defined critical or "panic" values as "values which reflect  
34 pathophysiological derangements at such variance with normal as to be life threatening if therapy is  
35 not instituted immediately." His team also pioneered a system for communicating urgent results,  
36 including recognition, verification and finding a clinician who can take appropriate action.<sup>6-8</sup>

37  
38 The Joint Commission (TJC) has established a set of definitions that can inform institutional policy  
39 around reporting results. These include "critical test results" defined as "any result or finding that  
40 may be considered life threatening or that could result in severe morbidity and require urgent or  
41 emergent clinical attention." In contrast, "critical tests" have been defined as "tests that require  
42 rapid communication of results, whether normal, abnormal, or critical." Furthermore, "significant  
43 risk results" have been defined as "nonemergent, non-life-threatening results that need attention  
44 and follow-up action as soon as possible, but for which timing is not as crucial as critical results.  
45 They generate a mandatory notification in the electronic health record but are not required to be  
46 reported verbally."<sup>9-11</sup> Inclusion of these definitions within an institutional policy can help guide  
47 communication of test results, although the measures that are "critical" or "significant" must still  
48 be defined at the institutional level. Once defined, the requirement would then be to follow these  
49 locally adopted procedures including reporting timeframes.

## *Setting Thresholds for Critical Values*

Health systems may develop their own written procedures to manage critical results, including definitions, to whom results should be reported, and acceptable timing for reporting.<sup>11</sup> By design, each laboratory and health system may be responsible for setting its own critical values which may trigger different responses at different levels.<sup>7</sup> Some health systems seek alignment with critical values from reference laboratories to promote consistency in reporting, but physicians may also customize critical values for select tests and patient groups.<sup>12</sup>

There is a scarcity of outcomes-based data that examine optimal alert thresholds across diverse patient populations to help determine when clinical action should be taken.<sup>8,13</sup> In addition, variation in measurement between laboratories may also require that each laboratory director define critical ranges according to the assays and instrumentation currently in use. Currently, critical value thresholds are largely determined by consensus and expert opinions.<sup>14</sup> Movement towards evidence-based clinical decision limits (that empirically determine values for which a clinical action is most appropriate) will likely require long-term efforts to collect sufficient evidence, including from randomized controlled trials.

## DISCUSSION

### *National Academies of Science, Engineering and Medicine*

A lack of timely reporting of test results may have adverse impacts including patient harm when there is delay in access to appropriate treatment. The National Academies of Science, Engineering and Medicine (NASEM) released the report “Improving Diagnosis in Health Care” in 2015. This work highlights how patient safety and health care quality can be improved through a systems approach that centers on the diagnostic process. The report takes the patient’s viewpoint to define diagnostic error as “the failure to (a) establish an accurate and timely explanation of the patient’s health problem(s) or (b) communicate that explanation to the patient.” The report’s recommendations include facilitating more effective teamwork among health care professionals, partnering with patients to include increased engagement around the diagnostic process, and ensuring effective and timely communication of results. The scope of diagnostic errors in medicine has remained difficult to measure, though there is some evidence that most patients may be affected at least once during their lifetime.<sup>1</sup>

### *Clinical and Laboratory Standards Institute Guidelines*

Some effort has been made to standardize and harmonize critical results management both nationally and internationally taking into account the wide range of differences between laboratories.<sup>13</sup> For example, the Clinical and Laboratory Standards Institute (CLSI) has provided guidelines for laboratory directors and administrators for local policy development around “Management of Critical- and Significant-Risk Results.”<sup>15</sup> Nevertheless, there is often an explicit acknowledgement that “there should be some degree of flexibility for modification by each individual laboratory.”<sup>16</sup> There also remains a lack of consensus around policies for implementing critical laboratory values among national and international organizations.<sup>9</sup>

### *Medical Specialty Society Guidelines*

Guidelines are available to support reporting results from some types of imaging studies and tests. For example, the American College of Radiology (ACR) offers appropriateness criteria for communication of diagnostic imaging. These recommendations cover the importance of timely

reporting, the need for an interpreting physician to have access to previous tests and reports, when there may be a responsibility to communicate results directly to a patient, the method of non-routine communication between a laboratory and ordering physician (typically by phone or in person), patient access to results, and how to handle report discrepancies.<sup>4</sup> The ACR also provides more detailed guidance for reporting specific tests including mammography. This includes reporting systems with specific assessment categories such as BI-RADS® that are tied to management recommendations and risk level.<sup>17</sup>

In addition, international guidelines and consensus statements around communication of test results include those from the Royal College of Pathologists (RCP). The RCP recommends that laboratories should compile alert lists including high risk results, specify the mode of transmission and to whom results should be reported, develop systems to acknowledge and document receipt of test results, and have procedures to monitor outcomes.<sup>18</sup> There is an acknowledged need for additional consensus around definitions as well as outcomes-based evidence to identify alert thresholds where clinical action can help mitigate risk while minimizing false positives.<sup>13</sup>

#### *Regulation of Testing and Results Reporting*

Federal and state laws regulate laboratory testing, anatomic pathology, and imaging services. Clinical Laboratory Improvement Amendments (CLIA) of 1988 address laboratory testing performed on humans in the U.S. These laboratory standards include specifications for quality control, quality assurance, patient test management, and proficiency testing. There are now over 200,000 CLIA-certified laboratories.<sup>19</sup>

Regulatory bodies may also require critical results reporting on a timely basis. For example, under CLIA regulations, “The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.”<sup>20,21</sup> There is a requirement for the laboratory to have written policies and procedures around critical value reporting. Individual laboratories create their own lists for which analytes are to be included in the definition of a critical value, as well as the high and low values. Regulatory agencies do not include which tests and limits are included but instead leave these decisions to laboratory directors, including how contact and documentation of communication should be made.

Direct reporting of any significant abnormalities within imaging results was mandated under a recent state law. The “Patient Test Result Information Act” (Pennsylvania Act 112 of 2018) took effect in December of 2019. This law defined “significant abnormalities” as those that “would cause a reasonably prudent person to seek additional or follow-up medical care within three months.” The law requires reporting of results to the patient as well as to the ordering physician.<sup>22,23</sup> Data are needed to assess the impact of this type of requirement on patient outcomes.

#### *Accreditation of Testing and Results Reporting*

Critical results reporting has been identified as a National Patient Safety Goal by the College of American Pathologists (CAP). These goals include establishing laboratory procedures outlining “by whom and to whom” to report any critical results, as well as defining an acceptable delay between availability and the reporting of critical results. Notification burden including placing phone calls is likely to continue to shift away from laboratory personnel, in part due a shortage in laboratory professionals, towards automated notification systems.<sup>8</sup> TJC has a similar National Patient Safety Goal to provide “the responsible, licensed caregiver” a report of all critical results within the defined timeframe that was established by the laboratory.

The Mammography Quality Standards Act (MQSA) of 1992 requires mammography facilities across the nation to meet uniform quality standards where each facility must be accredited and certified. The FDA recognizes the ACR as a nationally approved accreditation body. At the state level, accreditation may also be provided by the Iowa Department of Public Health, Arkansas Department of Health, and Texas Department of State Health Services. Certification bodies for MQSA include the FDA, Iowa, Illinois and South Carolina.<sup>24</sup> MQSA addresses report generation and communication of screening findings. It also facilitates data collection for monitoring and improvement.

#### *Regulation of Interoperability and Information Blocking*

The 21<sup>st</sup> Century Cures Act of 2016 includes interoperability and “information blocking” provisions that mandate sharing of electronic health information. An ongoing concern has been that physicians may be required to release office notes and test results prior to physician review of the information with the patient. It is important to also note that once a patient opts to share electronic health records and other health data, for example with third-party vendors or smartphone applications (apps), the information may no longer be protected under certain federal or state privacy laws, e.g., the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Third-party access, including by payers and apps, may include a patient’s genetic test results and other sensitive information such as behavioral health, potentially compounding data privacy and security concerns. Payers are covered entities under HIPAA and the law includes provisions around the use of patient information for treatment, payment, and health care operations. However, HIPAA protections generally cover where data resides and not the data itself. For instance, covered entity to covered entity data exchange is regulated (e.g., physicians sending medical information to payers). Payers who receive or access information from entities not covered by HIPAA (e.g., app developers) can use the information to create discriminatory profiling—affecting patients’ access to care and coverage.

The AMA has advocated for additional clarity around these new regulations, in part due to their complexity, and has also requested an extension to prioritize COVID-19 response. The current compliance deadline or “applicability date” is April 5, 2021. The AMA has also developed educational resources<sup>25</sup> and continues to work with the federal government on implementation of these new regulations to reduce burden for physician compliance and to address privacy concerns and other impacts to patients.

#### *Programs, Policies, and Tools*

Policies defined at the local level can help address various aspects of reporting including the acceptable length of time between test completion and reporting critical test results, as well as outlining a procedure for how to effectively communicate the results. The Compass Hospital Improvement Innovation Network surveyed “best in class” performers for their “change package” called *Reducing Diagnostic Error Related to the Laboratory Testing Process*. This includes a focus on standardizing protocols for test reports and communicating patient test results, developing a communications plan to help close the loop, and reporting at a regular frequency.<sup>26</sup>

The Massachusetts Coalition for the Prevention of Medical Errors and the Massachusetts Hospital Association collaborated to develop practice recommendations emphasizing timely communication of critical test results. Their safe practice recommendations include addressing who should receive the results, the notification process, and what results require explicit time frames.<sup>27</sup> The American College of Obstetricians and Gynecologists released a committee opinion on tracking and reminder

1 systems to facilitate patient communication. This opinion outlines the design and implementation  
2 of a tracking and reminder system to help handle notification of test results.<sup>28</sup>

3  
4 The Office of the National Coordinator for Health Information Technology (ONC) offers Safety  
5 Assurance Factors for EHR Resilience (SAFER) Self-Assessment Guides to address safety  
6 concerns faced by health care organizations.<sup>29</sup> The SAFER guide on Test Results Reporting and  
7 Follow-Up includes a checklist and recommended practice worksheets with rationale and examples  
8 for how to implement. The self-assessment facilitates engagement of clinician leadership to reach  
9 consensus on priorities, resources and methods of ensuring that recommended practices for  
10 communication and management of diagnostic test result are in place.

11  
12 The ECRI Institute's Partnership for Health IT Patient Safety offers a toolkit called "Closing the  
13 Loop: Using Health IT to Mitigate Delayed, Missed, and Incorrect Diagnoses Related to Diagnostic  
14 Testing and Medication Changes."<sup>30</sup> Their recommendations include "to develop and apply IT  
15 solutions to communicate the right information (including data needed for interpretation), to the  
16 right people, at the right time, in the right format, using the right channel." This recommendation  
17 focuses on three domains: improving communication, tracking of loop closure, and linking  
18 acknowledgment to action taken.

19  
20 The Agency for Healthcare Research and Quality (AHRQ) has released a "Toolkit for Rapid-Cycle  
21 Patient Safety and Quality Improvement."<sup>31</sup> This toolkit uses the "Plan-Do-Study-Act (PDSA)  
22 Method for Practice Improvement" to survey the entire staff to highlight potential quality and  
23 safety issues that can be addressed to improve the reliability of the office testing process. The  
24 toolkit includes a patient engagement survey and handout to assess patient experiences. This  
25 approach can help offices to determine how often patients with abnormal results are not being  
26 monitored through follow-up and what the consequences may be. The tool also facilitates auditing  
27 medical records to examine whether patients were notified of results within the timeframe specified  
28 by the office policy and to plan for improvements and measure progress.

### 29 30 *Potential Impacts for Physicians and Patients*

31  
32 Notification preferences can evolve over time and include tradeoffs in terms of ease of use and  
33 degree of security.<sup>32,33</sup> The ideal communication method may include an office visit, phone call,  
34 text, postal mail, email and/or the use of an online patient portal. Preferences may vary between  
35 patients and between different types of test results. Guidelines around notification should be  
36 flexible so that they can be tailored to meet various practice and patient needs.

37  
38 Overall, flexibility in approach to reporting abnormal and critical results is likely to continue to  
39 remain desirable. Flexibility is also needed to support communication policies that are standard  
40 practice in medicine such as brief embargo periods to enable care coordination, closing the referral  
41 loop, consultation, discussion of complex findings, care team planning, and/or other medically  
42 appropriate purposes. Such flexibility may be more readily accomplished by tailored clinical  
43 practice guidelines and local programs rather than broad mandates via additional regulation. For  
44 example, MQSA has been associated with decreasing variability in mammography since enacted in  
45 1992, but in general such regulatory approaches may be considered complex and inflexible and  
46 may increase administrative burden. MQSA also does not cover newer screening technologies.<sup>1</sup>

47  
48 Online patient portals have the capacity to provide early access to test results in the absence of  
49 meaningful interpretation by a physician.<sup>34</sup> While patients should have timely access to their test  
50 results, providing such information without additional context or explanation at the appropriate

1 health literacy level may increase anxiety for some patients.<sup>35</sup> Patients may also encounter  
2 challenges accessing the results or require additional support.<sup>36</sup>

3  
4 Finally, systems reporting test results should be designed in a manner that minimizes unnecessary  
5 notification burden and avoids information overload and alert fatigue for physicians.<sup>37</sup> Guidelines  
6 offered by medical specialty societies have the potential to help optimize appropriate notification  
7 frequency and response. Additional research is needed to develop best practices for communication  
8 of test results including via patient portals and apps.

## 9 10 CONCLUSION

11  
12 This resolution asks the AMA to advocate for the adoption of evidence-based guidelines and  
13 enhance the availability of continuing education on the process for communication and follow-up  
14 of abnormal medical test findings to promote better patient outcomes. While the AMA has  
15 extensive policy on medical test reporting and certainly agrees that reporting test results in a timely  
16 manner is an important patient safety issue, it is the role of national medical specialty societies to  
17 develop evidence-based guidelines on communicating with patients regarding abnormal test results.  
18 Communication requirements may vary by facility or jurisdiction and communication preferences  
19 may vary between patients and between different types of test results. As outlined in this report,  
20 there are a number of existing tools and resources that physicians can leverage to facilitate  
21 communication with patients on abnormal and critical test findings.

## 22 23 RECOMMENDATIONS

24  
25 The Board of Trustees recommends that the language below be adopted in lieu of Resolution 309-I-  
26 19 and the remainder of this report be filed.

27  
28 Our American Medical Association encourages relevant national medical specialty societies to  
29 develop and disseminate evidence-based guidelines for communication and follow-up of  
30 abnormal and critical test results to promote better patient outcomes. (New HOD Policy)

31  
32 Our AMA will work with appropriate state and medical specialty societies to highlight relevant  
33 education regarding the communication and follow-up of abnormal and critical medical test  
34 findings to promote better patient outcomes. (Directive to Take Action)

35  
36 Our AMA supports the development of best practices and other clinical resources for  
37 communication of test results, including via patient portals and applications, and encourages  
38 additional research to ensure these innovative approaches and tools reach their potential to help  
39 advance patient care. (New HOD Policy)

Fiscal Note: Less than \$500

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## APPENDIX – Current AMA Policy

### D-260.995, “Improvements to Reporting of Clinical Laboratory Results”

1. Our AMA will: (a) make its involvement with the Office of the National Coordinator for Health Information Technology and its Health Information Technology Policy and Standards Committees a high priority; and (b) become involved in and/or provide input into policies involving electronic transmission of clinical laboratory results. 2. Our AMA will encourage the College of American Pathologists, Health Level 7, the National Institute for Standards and Technology, and the Agency for Healthcare Research and Quality to urgently address usability and standardization of laboratory report results for physicians and non-physician practitioners to ensure patient safety. 3. Our AMA will support the continued efforts of relevant national medical specialty societies, such as the American College of Radiology, the American Osteopathic College of Radiology and other like organizations whose members generate reports electronically to clarify terminology and work in consultation with physicians likely to be end users toward producing a standardized format with appropriate standard setting bodies for the presentation of radiology results, including clearly identifiable diagnoses and test results. 4. Our AMA will report back to the House of Delegates on progress with regard to medical record and reporting standardization.

### H-155.994, “Sharing of Diagnostic Findings”

The AMA (1) urges all physicians, when admitting patients to hospitals, to send pertinent abstracts of the patients' medical records, including histories and diagnostic procedures, so that the hospital physicians sharing in the care of those patients can practice more cost-effective and better medical care; (2) urges the hospital to return all information on in-hospital care to the attending physician upon patient discharge; and (3) encourages providers, working at the local level, to develop mechanisms for the sharing of diagnostic findings for a given patient in order to avoid duplication of expensive diagnostic tests and procedures.

### H-478.979, “Quality Payment Program and the Immediate Availability of Results in Certified Electronic Health Record Technologies”

Our AMA: (1) urges the Centers for Medicare & Medicaid Services, Office of the National Coordinator for Health Information Technology, and other agencies with jurisdiction to create guardrails around the “immediate” availability of medical test results, factoring in an allowance for physician judgement and discretion regarding the timing of release of certain results; and (2) encourages vendors to implement mechanisms that provide physicians the discretion to publish medical test results to a patient portal while ensuring patient access to such information in a reasonable timeframe.

### D-478.979, “Promoting Internet-Based Electronic Health Records and Personal Health Records”

Our American Medical Association will advocate for the Centers for Medicare & Medicaid Services (CMS) to evaluate the barriers and best practices for those physicians who elect to use a patient portal or interface to a personal health record (PHR) and will work with CMS to educate physicians about the barriers to PHR implementation, how to best minimize risks associated with PHR use and implementation, and best practices for physician use of a patient portal or interface to a PHR.

### H-425.968, “Non-Physician Screening Tests”

1. AMA policy is that any wellness program vendor providing non-physician ordered screenings should adhere to the following principles: a. Must disclose for whom a screening test is indicated on the basis of accepted evidence-based guidelines; b. Must inform patients of the potential benefits and risks of performing a test and of the implications of positive or negative screening test results before a test is performed; c. Must disclose the qualifications of any persons in contact with

the patient and of any persons interpreting the results of any screening test; d. Should use local physicians as medical directors or supervisors in the appropriate specialty with the requisite state licensure; e. Should send results of any screening to the individual patient and to the primary care physician or usual source of medical care, upon patient request; f. Should require a consultation with the patient's primary care physician or usual source of care if a screening test shows a positive or otherwise abnormal test result; g. If the test results are of a critical level or value, the patient should be contacted immediately and notified of the need for urgent or emergent medical evaluation. 2. Our AMA supports that physicians not be held liable for delayed or missed diagnoses indicated on wellness program vendor non-physician ordered screenings.

#### Code of Medical Ethics 2.1.5, "Reporting Clinical Test Results"

Patients should be able to be confident that they will receive the results of clinical tests in a timely fashion. Physicians have a corresponding obligation to be considerate of patient concerns and anxieties and ensure that patients receive test results within a reasonable time frame. When and how clinical test results are conveyed to patients can vary considerably in different practice environments and for different clinical tests. In some instances results are conveyed by the patient's treating physician, in others by other practice staff, or directly by the laboratory or other entity. To ensure that test results are communicated appropriately to patients, physicians should adopt, or advocate for, policies and procedures to ensure that: (a) The patient (or surrogate decision maker if the patient lacks decision-making capacity) is informed about when he or she can reasonably expect to learn the results of clinical tests and how those results will be conveyed. (b) The patient/surrogate is instructed what to do if he or she does not receive results in the expected time frame. (c) Test results are conveyed sensitively, in a way that is understandable to the patient/surrogate, and the patient/surrogate receives information needed to make well-considered decisions about medical treatment and give informed consent to future treatment. (d) Patient confidentiality is protected regardless of how clinical test results are conveyed. (e) The ordering physician is notified before the disclosure takes place and has access to the results as they will be conveyed to the patient/surrogate, if results are to be conveyed directly to the patient/surrogate by a third party.