ISMS BOARD ACTION
04/05/2019

RESOLUTION 01.2019-11 (A-19), DIRECT-TO-CONSUMER GENETIC TESTS CHOICE

Adopted Resolution 01.2019-11 (A-19), as amended:

RESOLVED, that the Illinois State Medical Society (ISMS) reaffirm that direct-to-consumer genetic testing results are not clinically validated unless performed by CLIA-approved labs; and be it further

RESOLVED, that the ISMS endorse the American Medical Association (AMA) ~~(6)~~, Federal Trade Commission (FTC), Federal Drug Administration (FDA), and Centers for Disease Control (CDC) recommendations ~~(7,8)~~ establishing clear policies for data-sharing, educating participants about the risks and benefits of genetic studies by each genetic testing company~~, see details footnote*~~; and be it further

RESOLVED, that the ISMS regard research using consumer genome data derived from saliva, cheek swab, or other human tissue samples as research on human subjects requiring consents in compliance with the Health and Human Services (HHS) Office for Human Research Protection (OHRP) ~~(9)~~. An "opt in" option is recommended to allow more consumer choice in the consent process; and be it further

RESOLVED, that ISMS request the AMA to regard research using consumer genome data derived from saliva, cheek swab, or other human tissue samples as research on human subjects requiring consents in compliance with the Health and Human Services (HHS) Office for Human Research Protection (OHRP) ~~(9)~~. An "opt in" option is recommended to allow more consumer choice in the consent process; and be it further

RESOLVED, that ISMS work with Chicago Medical Society (CMS) and the AMA to provide amendments to the AMA Patient Privacy and Confidentiality Statement, H-315.983, to align with current research and privacy infringement findings since the ISMS BOT review in 2012. The proposed amendments ~~are~~ in the following sections of this AMA policy ~~in footnote **~~<u>are:</u>

1. Our AMA affirms the following key principles that should be consistently implemented to evaluate any proposal regarding patient privacy and the confidentiality of medical information: (a) That there exists a basic right of patients to privacy of their medical information and records, and that this right should be explicitly acknowledged; (b) That patients' privacy should be honored unless waived by the patient in a meaningful way or in rare instances when strong countervailing interests in public health or safety justify invasions of

patient privacy or breaches of confidentiality, and then only when such invasions or breaches are subject to stringent safeguards enforced by appropriate standards of accountability; (c) That patients' privacy should be honored in the context of gathering and disclosing information for clinical research and quality improvement activities, and that any necessary departures from the preferred practices of obtaining patients' informed consent and of de-identifying all data be strictly controlled; (d) That any information disclosed should be limited to that information, portion of the medical record, or abstract necessary to fulfill the immediate and specific purpose of disclosure; and (e) That the Health Insurance Portability and Accountability Act of 1996 (HIPAA) be the minimal standard for protecting clinician-patient privilege, regardless of where care is received, while working with the Department of Health and Human Services (HHS) to stop the transfer of birthdates and state of residence by genetic testing companies and their affiliates, unless there is explicit user approval, to prevent re-identification of the test user by way of surname inference methods.

2. Our AMA affirms: (a) that physicians and medical students who are patients are entitled to the same right to privacy and confidentiality of personal medical information and medical records as other patients, (b) that when patients exercise their right to keep their personal medical histories confidential, such action should not be regarded as fraudulent or inappropriate concealment, and (c) that physicians and medical students should not be required to report any aspects of their patients' medical history to governmental agencies or other entities, beyond that which would be required by law.

3. Employers and insurers should be barred from unconsented access to identifiable medical information lest knowledge of sensitive facts form the basis of adverse decisions against individuals. (a) Release forms that authorize access should be explicit about to whom access is being granted and for what purpose, and should be as narrowly tailored as possible. (b) Patients, physicians, and medical students should be educated about the consequences of signing overly-broad consent forms. (c) Employers and insurers should adopt explicit and public policies to assure the security and confidentiality of patients' medical information. (d) A patient's ability to join or a physician's participation in an insurance plan should not be contingent on signing a broad and indefinite consent for release and disclosure.

4. Whenever possible, medical records should be de-identified for purposes of use in connection with utilization review, panel credentialing, quality assurance, and peer review.

5. The fundamental values and duties that guide the safekeeping of medical information should remain constant in this era of computerization. Whether they are in computerized or paper form, it is critical that medical information be accurate, secure, and free from unauthorized access and improper use.

6. Our AMA recommends that the confidentiality of data collected by race and ethnicity as part of the medical record, be maintained.

7. Genetic information should be kept confidential and should not be disclosed to third parties without the explicit informed consent of the tested individual. Our AMA regards studies using consumer genome data derived from saliva, cheek swab, or other human tissue samples as research on human subjects requiring consents in compliance with the HHS Office for Human Research Protections (OHRP). An "opt in" option is recommended to allow more consumer choice in the consent process.

8. When breaches of confidentiality are compelled by concerns for public health and safety, those breaches must be as narrow in scope and content as possible, must contain the least identifiable and sensitive information possible, and must be disclosed to the fewest possible to achieve the necessary end.

9. Law enforcement agencies requesting private medical information should be given access to such information only through a court order. This court order for disclosure should be granted only if the law enforcement entity has shown, by clear and convincing evidence, that the information sought is necessary to a legitimate law enforcement inquiry; that the needs of the law enforcement authority cannot be satisfied by non-identifiable health information or by any other information; and that the law enforcement need for the information outweighs the privacy interest of the individual to whom the information pertains. These records should be subject to stringent security measures.

10. Our AMA must guard against the imposition of unduly restrictive barriers to patient records that would impede or prevent access to data needed for medical or public health research or quality improvement and accreditation activities. Whenever possible, de-identified data should be used for these purposes. In those contexts where personal identification is essential for the collation of data, review of identifiable data should not take place without an institutional review board (IRB) approved justification for the retention of identifiers and the consent of the patient. In those cases where obtaining patient consent for disclosure is impracticable, our AMA endorses the oversight and accountability provided by an IRB.

11. Marketing and commercial uses of identifiable patients' medical information may violate principles of informed consent and patient confidentiality. Patients divulge information to their physicians only for purposes of diagnosis and treatment. If other uses are to be made of the information, patients must first give their uncoerced permission after being fully informed about the purpose of such disclosures

12. Our AMA, in collaboration with other professional organizations, patient advocacy groups and the public health community, should continue its advocacy for privacy and confidentiality regulations, including: (a) The establishment of rules allocating liability for disclosure of identifiable patient medical information between physicians and the health plans of which they are a part, and securing appropriate physicians' control over the disposition of information from their patients' medical records. (b) The establishment of rules to prevent disclosure of identifiable patient medical information for commercial and marketing purposes; and (c) The establishment of penalties for negligent or deliberate breach of confidentiality or violation of patient privacy rights.

13. Our AMA will pursue an aggressive agenda to educate patients, the public, physicians and policymakers at all levels of government about concerns and complexities of patient privacy and confidentiality in the variety of contexts mentioned.

14. Disclosure of personally identifiable patient information to public health physicians and departments is appropriate for the purpose of addressing public health emergencies or to comply with laws regarding public health reporting for the purpose of disease surveillance.

15. In the event of the sale or discontinuation of a medical practice, patients should be notified whenever possible and asked for authorization to transfer the medical record to a new physician or care provider. Only de-identified and/or aggregate data should be used for "business decisions," including sales, mergers, and similar business transactions when ownership or control of medical records changes hands.

16. The most appropriate jurisdiction for considering physician breaches of patient confidentiality is the relevant state medical practice act. Knowing and intentional breaches of patient confidentiality, particularly under false pretenses, for malicious harm, or for monetary gain, represents a violation of the professional practice of medicine.

17. Our AMA Board of Trustees will actively monitor and support legislation at the federal level that will afford patients protection against discrimination on the basis of genetic testing. The AMA will work with Congress and HHS to modify the Genetic Information Nondiscrimination Act of 2008 (GINA), which bans genome-based policy and hiring decisions by health insurance companies and employers, by adding Long-Term Care, Life Insurance, and Disability Insurance to the Act to prevent applicant rejection based on their genetic make up.

18. Our AMA supports privacy standards that would require pharmacies to obtain a prior written and signed consent from patients to use their personal data for marketing purposes.

a. Our AMA supports privacy standards that would prohibit pharmaceutical companies, biotechnology companies, universities, and all other entities with financial ties to the genetic testing company from sharing identified information with other parties without the consent of the user. An exception would be made when requested by law enforcement authorities or when keeping the information would seriously threaten their health or that of others. If a data security breach occurs with the Direct-To –Consumer genetic company or its collaborators, then the company has the responsibility to inform all users of the breach and the impact of the unprotected private data on those individuals;

19. Our AMA supports privacy standards that require pharmacies and drug store chains to disclose the source of financial support for drug mailings or phone calls.

20. Our AMA supports privacy standards that would prohibit pharmacies from using prescription refill reminders or disease management programs as an opportunity for marketing purposes.

21. Our AMA will draft model state legislation requiring consent of all parties to the recording of a physician-patient conversation; and be it further

RESOLVED, that ISMS work with CMS and the AMA to amend the AMA policy D-480.987: Direct-to-Consumer Marketing and Availability of Genetic Testing by inserting “genetic” or “genetic testing” ~~as suggested see footnote ***~~, serving to update this policy; and be it further

RESOLVED, that ISMS request the AMA to work with ~~HIPAA~~ the Department of Health and Human Services or other relevant parties to modify the rules to prevent genetic testing entities from transferring the date of birth and state of residence to third parties which may result in the re-identification of the user based on surname inference ~~(4)~~; and be it further

RESOLVED, that ISMS ~~work with CMS to~~ lobby the Illinois state legislature and request the AMA to work with Congress and HHS to extend the consumer protections of the Genetic Information Non-Discrimination Act (GINA) of 2008 by adding long-term care, disability insurance, and life insurance to the Act modeled after other states' laws, such as California ~~(10)~~.