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3 Title: Use Plain Language in Written Consent Forms
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5 Introduced by: Laura Carravallah, MD, for the Genesee County Delegation
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7 Original Author: Rachel Santay
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9 Referred to: Reference Committee E
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11 House Action: **APPROVED AS AMENDED**
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14 Whereas, the 2003 National Assessment of Adult Literacy, the first and only national assessment of
15 adult literacy in the United States, found that more than a third of United States adults had basic, or below
16 basic, health literacy skills, meaning they may struggle to give two reasons why someone with certain
17 symptoms might have a certain test, even when they used information from a clearly written, accurate
18 pamphlet¹, and
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20 Whereas, only 12 percent had proficient health literacy, and the majority of adults, 53 percent, had
21 intermediate literacy skills, meaning they would be able to read instructions on a prescription label, and
22 determine what time they could take medication^{2,3}, and
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24 Whereas, health literacy was found to increase with additional education, but “44 percent of high
25 school graduates and 12 percent of college graduates had below basic or basic health literacy”², and 51
26 percent of adults 65 or older had below basic or basic health literacy skills, compared to 31-35 percent of
27 those under 65², and
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29 Whereas, more recent studies have shown that the average reading level of written research consent
30 forms and discharge summaries are a 10th grade level or greater^{4,5,6}, and invasive procedure consent forms,
31 used in daily clinical practice, had a 15th grade reading level⁷, and
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33 Whereas, this disconnect between reading level and health literacy of patients and the
34 inappropriately high reading level of consent forms has been present for decades⁸, and
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36 Whereas, the American Medical Association’s (AMA) Code of Ethics states that patients “have the
37 right to receive information and ask questions about recommended treatments so that they can make well-
38 considered decisions about care,” and physicians have the responsibility to assess their ability to understand
39 relevant medical information when obtaining informed consent⁹, and “the patient’s right of self-decision can
40 be effectively exercised only if the patient possesses enough information to enable an informed choice,”¹⁰
41 and
42

43 Whereas, the disparity between the reading level of consent forms and their intended audience
44 constitutes a breach in informed consent, given that patients often hesitate to say they do not understand
45 what providers tell them, feel uncomfortable asking for more of a provider’s time, and there is often a gap
46 between patients’ perception of their understanding and their actual understanding of their medical
47 situation^{11,12,13,14,15}, and
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49 Whereas, the Centers for Disease Control and Prevention (CDC) and National Institutes of Health
50 (NIH) endorse the use of plain language in written documents, defined as “grammatically correct language
51 that includes complete sentence structure and accurate word usage”¹⁶ and described by guidelines in the
52 Federal Plain Writing Act of 2010¹⁷, in order to promote understanding of health information by all patients,
53 regardless of literacy level^{18,19}, and

54 Whereas, current AMA policy on health literacy (Health Literacy H-160.931), recommends that “all
55 healthcare institutions adopt a health literacy policy with the primary goal of enhancing provider
56 communication and educational approaches to the patient visit,”²⁰ and
57

58 Whereas, despite these CDC and NIH endorsements of plain language use in health care, and its
59 support in AMA policy, plain language has not been universally implemented²¹; therefore be it
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61 RESOLVED: That the Michigan State Medical Society supports the American Medical Association
62 policy number Health Literacy H-160.931 and Readability of Medical Notice of Privacy Practices H-190.958.
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WAYS AND MEANS COMMITTEE FISCAL NOTE: \$1,000.00 as this is new MSMS policy.

Relevant MSMS Policy: None

Relevant AMA Policy:

Health Literacy H-160.931

Our AMA:

- (1) recognizes that limited patient literacy is a barrier to effective medical diagnosis and treatment;
- (2) encourages the development of literacy appropriate, culturally diverse health-related patient education materials for distribution in the outpatient and inpatient setting;
- (3) will work with members of the Federation and other relevant medical and nonmedical organizations to make the health care community aware that approximately one fourth of the adult population has limited literacy and difficulty understanding both oral and written health care information;
- (4) encourages the development of undergraduate, graduate, and continuing medical education programs that train physicians to communicate with patients who have limited literacy skills;
- (5) encourages all third party payers to compensate physicians for formal patient education programs directed at individuals with limited literacy skills;
- (6) encourages the US Department of Education to include questions regarding health status, health behaviors, and difficulties communicating with health care professionals in all future National Assessment of Adult Literacy studies;
- (7) encourages the allocation of federal and private funds for research on health literacy;
- (8) recommends all healthcare institutions adopt a health literacy policy with the primary goal of enhancing provider communication and educational approaches to the patient visit;
- (9) recommends all healthcare and pharmaceutical institutions adopt the USP prescription standards and provide prescription instructions in the patient's preferred language when available and appropriate; and
- (10) encourages the development of low-cost community- and health system resources, support state legislation and consider annual initiatives focused on improving health literacy.

Readability of Medical Notices of Privacy Practices H-190.958

Our American Medical Association continues to support physician efforts to provide Notices of Privacy Practices at an appropriate reading level and in a language appropriate to the patient population served; and will make available on its Web site a link to the US Department of Health and Human Services Health Resources and Services Administration document, Plain Language Principles and Thesaurus for Making HIPAA Privacy Notices More Readable.

¹ https://publichealth.gwu.edu/departments/healthpolicy/CHPR/downloads/LowHealthLiteracyReport10_4_07.pdf

² <https://health.gov/communication/literacy/issuebrief/>

³ <https://nces.ed.gov/pubsearch/pubsinfo.asp?pubid=2006483>

⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5915809>

⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5351029>

⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5245984>

⁷ <https://ascpt.onlinelibrary.wiley.com/doi/pdf/10.1111/cts.12364>

⁸ <https://www.ncbi.nlm.nih.gov/pubmed/11651140>

⁹ <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/code-of-medical-ethics-chapter-2.pdf> 10

¹⁰ <https://journalofethics.ama-assn.org/article/ama-code-medical-ethics-opinions-informing-patients/2012-07>

¹¹ https://muse.jhu.edu/article/206208/pdf?casa_token=kzpOmYgeLSEAAAAA:5C9Zf1azR20H uYXkl40s7XQuhSmbE8YyDtnzA_g2KY-OB-YuK2_z5oyoX4pEN5Ew-XveYqJK

¹² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3086818/>

¹³ <http://spectrum.diabetesjournals.org/content/23/4/220>

¹⁴ <https://www.nytimes.com/2009/04/02/health/02chen.html>

¹⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3836871>

¹⁶ <https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/clear-communication/plain-language>

¹⁷ <https://www.plainlanguage.gov/guidelines/>

¹⁸ <https://www.cdc.gov/healthliteracy/developmaterials/plainlanguage.html>

¹⁹ https://www.cdc.gov/healthliteracy/pdf/Simply_Put.pdf

²⁰ <https://policysearch.ama-assn.org/policyfinder/detail/health%20literacy?uri=%2FAMADoc%2FHOD.xml-0-746.xml>

²¹ <https://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit /healthlittoolkit2.html>