

Summary of Presentation by Mark Hochhauser
(appearing via conference call)
GLB Interagency Meeting on the ANPR on Privacy Notices
January 29, 2004
Federal Trade Commission

Participant:

Mark Hochhauser is a readability consultant from Minnesota.

Comments:

Mr. Hochhauser has analyzed a number of GLB financial privacy notices and medical privacy notices under the Health Insurance Portability and Accountability Act (HIPAA). He described readability standards generally and stated that a readability standard at the junior high level is generally recommended. For financial privacy notices, however, Mr. Hochhauser believes that a 12th grade reading level was probably more attainable. Readability factors include shorter, simpler sentences, for example, using 14 words per sentence and 149 syllables for every 100 words. Even if a notice meets a threshold reading level, or readability score, this does not necessarily indicate that everyone will understand a particular notice. Format and font sizes also have an impact on consumer comprehension. Also, research has not shown that simpler language alone has demonstrably improved comprehension. Information overload may be an issue.

Mr. Hochhauser recommended consumer testing of notices by using representative groups of consumers from around the country to review several different notice formats. Internet and telephone surveys are unreliable because consumers will typically tell surveyors what they think the surveyor wants to hear. Mr. Hochhauser proposed using qualitative testing which can include one-on-one testing or focus groups, as well as quantitative testing, where readability testing can play a role. He added it was important to get consumers involved in the writing and editing of proposed notices. He cautioned that readability alone does not equal comprehension. One way to measure comprehension is to have consumers paraphrase what they have read.

Mr. Hochhauser articulated some general principles companies (and agencies) should consider in drafting privacy notices:

- 1) Use plain language techniques. Sentence length should be limited (e.g., 12-14 words per line) and jagged margins and white space should be used.
- 2) Layered approach may be helpful (e.g., HIPAA notice model).
- 3) Treat privacy notices as a product financial institutions are trying to sell.
- 4) Consumer testing is essential. Consumers should be involved in the writing process. To date financial institutions have overemphasized legal compliance.

Consumer education: Improvements to a privacy notice will not be enough to get consumers to read the new notices, given consumers' prior bad experiences. Improvements must be coupled with a consumer education campaign (e.g., television, news articles and other media). It will take a long time to change consumer behavior (as evidenced by the public service campaigns on seatbelts and smoking) and quick payoffs on privacy notice improvements are unlikely.

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Compliance vs Communication

Mark Hochhauser

Psychologist; consultant on document readability and writing style

2003 HIPAA privacy notices

In April 2003, patients in the US began receiving Health Insurance Portability and Accountability Act (HIPAA) privacy notices from their doctors, hospitals, clinics, pharmacies, and other "covered entities" that use their personal health information. HIPAA privacy notices were designed to inform patients of their privacy rights regarding their personal health information, and what they could do to limit the "use and disclosure" of that information.

As part of the HIPAA regulatory guidelines (Section 164.52(b)—Content of Notice), privacy notices were to be written in "plain language" (Final Privacy Rule Preamble, II. Section-By-Section Description of Rule Provisions, <http://www.hhs.gov/ocr/part2.html>).

They are not. The regulations tell writers that "A covered entity can satisfy the plain language requirement if it makes a reasonable effort to: organize materials to serve the needs of the reader; write short sentences in the active voice, using "you" and other pronouns; use common, everyday words in sentences; and divide materials into short sections." (p. 137, Final Privacy Rule Preamble). These modest requirements proved insufficient to get HIPAA writers to use plain language. The requirements were essentially ignored.

As part of my consulting work with the US Department of Health and Human Services, I downloaded and analyzed six privacy notices and 31 online privacy notices (www.privacyrights.org/ar/HIPAA-Readability.htm). I found them to be written at an average 2nd-4th year college-reading levels. Patients will have a very hard time understanding the notices. The typical writing style used too many words per sentence, too many complicated sentences, and too many uncommon words.

While federal guidelines require HIPAA notices to be written in plain language and offer some suggested guidelines about plain-language writing strategies, there are no penalties if organizations do not write their notices in plain language. Also, the regulations did not include any examples of materials actually written in plain language.

In the aftermath of HIPAA, companies are issuing bizarre press releases, touting that they are "HIPAA compliant"—even though their notices are virtually incomprehensible to the average reader. For these companies, being compliant means that they have appropriate measures in place to protect patients' health information, not that they've written plain-language privacy notices. So they are "compliant" and "non-compliant" at the same time.

The legal need to “comply”

An employee of a state agency dealing with HIPAA emailed me: “However, the language required by the law and regulation make it near impossible to comply with regulations and make this a readable document.” To that, a colleague in a federal agency dealing with HIPAA replied: “What a cop out”—seeing that argument simply as a rationale for not writing notices in plain-language.

The only language required verbatim in the notices is the all-capitalized header that must accompany all privacy notices:

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

“Comply with regulations” is the key phrase. When HIPAA rules first came out, various health associations had law firms write sample notices that the associations made available to their members. From the very beginning, notices were written to comply with federal regulations, not to communicate privacy rights to patients. Many of the notices looked or sounded alike, probably because the health-care organizations simply used (sometimes with only minor changes) the examples that their professional associations had developed.

But this was not the goal of HIPAA regulations. Each health-care organization was supposed to develop its own unique notices. That they did not is testimony to the complexity of HIPAA regulations. For example, they cover 187 single-spaced pages in the Federal Register: Standards for Privacy of Individually Identifiable Health Information; Final Rule (<http://www.hhs.gov/ocr/hipaa/privrule.txt>), and a further 168 pages in the Final Privacy Rule Preamble II: Section-by-section description of rule provisions (<http://www.hhs.gov/ocr/part2.html>). In addition, these 355 pages were only a small part of all HIPAA regulations which were developed in the Clinton Administration and changed by the Bush Administration. Health-care organizations clearly believed that to reduce the likelihood of being non-compliant and getting into trouble with the federal government, the safest thing to do was to use the language of their health-association law firms. If law firms approved the language, then it must be all right, even if it wasn't “plain language.”

Lawyers try to protect their clients from legal problems. It's not surprising, then, that the HIPAA notices, which are written with much legal input, tend to reflect legal language rather than patient language. Unfortunately, it may be almost impossible for most HIPAA

privacy notice writers to communicate in language that is both legally compliant and understandable to patients. I've had several HIPAA privacy notice writers tell me that “The lawyers made us use this language.” So legal input (and legal language) trumps plain language. It is interesting how much influence lawyers have over the content of materials written for consumers. Lawyers seem to be the final judge of what's acceptable or unacceptable, and no other employee in the organization seems to be able to override those judgments.

But this perspective of legal language over plain language is not unique to HIPAA. About two years ago, I also reviewed 61 Gramm-Leach-Bliley financial privacy notices that were supposed to inform consumers of their financial privacy rights. These notices were written at about a 3rd-4th year college reading level. They had too many complicated sentences and too many uncommon words (www.privacyrights.org/ar/GLB-Reading.htm). And so I was not surprised that both HIPAA notices and the financial privacy notices were unreadable, because the same emphasis of compliance over communication was at work in both settings. In fact, I do not believe that federal regulators can pass any law requiring consumer privacy notices to be written in ways that consumers can understand.

Reading vs understanding

In the spring of 2002, a US Food and Drug Administration speaker at a clinical trials conference said that the FDA was requiring clinical-trial consent forms (which may include HIPAA privacy information) to be written at a sixth-grade reading level, but was not able to offer any rationale for that requirement. Let me make some comments on that. First, I doubt that anyone in the federal bureaucracy can write a consent form at a sixth-grade reading level; anyone who recommends that kind of writing should be required to provide an example. Second, on the basis of Rudolf Flesch's Reading Ease Score, a consent form written at a sixth-grade level would have to average about 14 words per sentence and 139 syllables per 100 words. Since consent forms are a combination of both legal and medical jargon, writing to meet that criterion is virtually impossible. While some medical terms can be made simpler, they probably can't be made simple enough to reach a statistical sixth-grade reading level.

Behind such "write to the formula" recommendations is the assumption that if you write at a lower grade level more people will understand.

However, this assumption has not been borne out by the research studies.⁽¹⁻⁸⁾ These studies assessed the impact of re-writing consent forms, patient education materials and jury instructions from higher grade levels to lower grade levels. The results are mixed. Sometimes comprehension is better, sometimes it isn't. But subjects in many of these studies tended to be college-educated, among whom the impact of plain language might be less evident.

Writing at a sixth-grade level does not mean that materials can be understood by anyone with sixth-grade education—that's a common misconception. It does not take into account changes in psychological development and how thinking skills change from concrete to abstract during adolescence. Not everyone develops into an adult with good abstract thinking skills, so readers at any age may be concrete thinkers who simply will not be able to understand abstract information in HIPAA privacy notices, financial privacy notices, informed-consent forms, patient-rights documents, etc—regardless of the grade level at which they are written. Readability and understanding are not the same.

Less information = more understanding

Readability formulas do not measure information overload. (However, I find the total number of words, sentences, and syllables/word provided by some readability software to be very helpful in estimating the amount of information readers have to process.) With changes in technology since readability formulas were developed, many writers have suggested that our technologically advanced culture can give people more information than their brains can process and understand. Different writers use different terms—"information overload" (Alvin Toffler), "information fatigue syndrome" (David Lewis), "data smog" (David Shenk), "information anxiety" (Richard Wurman). These terms try to capture what happens when readers are confronted with more information than they can easily process.

Informed-consent forms are "cognitively complex." The FDA regulates clinical trials, and requires each consent form to contain eight basic elements of informed consent (purpose, risks, benefits, etc) and six "when appropriate" elements.⁹ Add to that five HIPAA elements, and recipients have to read and understand a consent form that includes 13-19 pieces of information (See Table #1 on next page).

Table #1: FDA Required Elements of Informed Consent

Eight basic elements

- A statement that the study involves research, an explanation of the research purposes and expected duration of the subject's participation, a description of procedures to be followed, and identification of experimental procedures.
- A description of any reasonably foreseeable risks or discomforts to the subject.
- A description of any benefits to the subject or to others which may reasonably be expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
- A statement describing the extent to which confidentiality of records identifying the subject will be maintained and noting the possibility that the FDA may inspect the records.
- For research involving more than minimal risk, an explanation as to whether any compensation and any medical treatment are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
- An explanation of who to contact for answers to pertinent questions about the research and research subjects' rights, and who to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Six additional elements of informed consent to be used when appropriate:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
- Anticipated circumstances under which the investigator may terminate the subject's participation without the subject's consent.
- Any additional costs to the subject that may result from participation in the research.
- The consequences of a subject's decision to withdraw from the research, and procedures for orderly termination of participation by the subject.
- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
- The approximate number of subjects involved in the study.

HIPAA-related elements of informed consent (still evolving)

- Use and disclosure of personal health information for research.
 - Use and disclosure of research information for treatment, payment, and facility administration.
 - Access to information relating to your participation in the study.
 - Right to decline/withdraw authorization.
 - Expiration of authorization
-

At this point, reading-grade levels are almost irrelevant. Instead of helping people make an informed decision, too much information often leads to increased stress, confusion, impaired judgment, helplessness, and paralysis through analysis.

Informed-consent forms and HIPAA—some suggested improvements

Because medical information about human subjects in clinical trials can be shared with drug companies, federal regulatory agencies, contract research organizations, insurance companies, and the like, clinical trial consent forms will have to include a HIPAA notice as part of the informed consent process. Moreover, because consent forms suffer from the same language problems as HIPAA notices, a summary might help readers understand these incredibly complicated materials.

Table #2 is an example an informed-consent summary that could give prospective subjects an overview of a clinical trial¹⁰. I have been told by some in the clinical trial industry that it's too

simple and doesn't include enough information. My response is that it's supposed to be simple. Would you rather have a subject read the summary or sign the consent form without reading it at all?

Too much information is an especially serious problem for older readers. President Clinton asked medical researchers to include more elderly subjects in clinical trials. But research shows some age-related declines in cognitive skills. These include short-term memory, long-term memory and reasoning—all beginning at about age 60-65. At the very time researchers are trying to recruit older subjects, those potential subjects will be starting to experience cognitive declines that may make it more difficult for them to understand the research-consent process!

And so it is with HIPAA. A large percentage of hospital patients are Medicare patients aged 65 and older. Many will be completely overwhelmed by the cognitive demands of trying to read and understand typical HIPAA privacy notices, especially those printed in tiny type.

Table #2: Informed Consent Summary

Questions

What's the purpose of this study?

What's the procedure?

What are the risks of being in this study?

What are the benefits of being in this study?

Can I choose alternative treatments with existing cancer drugs?

Is information about me kept confidential?

Who should I contact if I have any questions?

Is my participation voluntary?

Answers

This is an experiment to compare two cancer drugs for your bone cancer.

You'll get an experimental drug or standard treatment, blood tests, physical exams for 6 months.

Side effects—fever, weakness, loss of appetite. Your cancer might not get better.

You probably won't benefit. But your involvement may help others with bone cancer.

Yes. You can choose standard medical treatment instead.

Yes. Your name will not appear in any publications. We may share information with government agencies.

Dr. Smith at 555-123-4567 or Dr. Jones at 555-987-6543 for questions about your rights as a subject.

Yes. You may leave the study at any time without losing any benefits.

