DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

The Assistant Secretary for Planning and Evaluation
Washington, D.C. 20201

AUG 13 2001

Brooke Dickson
Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, D.C. 20503

Dear Ms. Dickson:

We appreciate the opportunity to provide comments from the Department of Health and Human Services on the OMB Proposed Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies. The Guidelines have been developed to implement the requirements imposed on OMB by Section 515 of Public Law 106 -554, a followup to the Shelby Amendment enacted earlier. We also appreciate your briefing to the HHS Data Council on August 8 on the proposed guidelines.

HHS has a long tradition and commitment to ensuring the quality and objectivity of the information we develop and disseminate. In support of agency missions, HHS develops and disseminates a wide variety of information, including the results of scientific research, statistical information, regulatory information, and programmatic and consumer information. The very missions of several HHS divisions are knowledge and information-oriented, and quality assurance mechanisms are interwoven with the development and dissemination of information for a variety of purposes and audiences.

Our consolidated HHS comments are enclosed. In general, HHS supports and encourages the OMB approach of allowing each agency to develop its own guidelines appropriate to its mission and unique information dissemination activities and audiences. In addition to general comments, suggestions are provided relating to scope and definition, procedures, and potential implementation issues.

We would be pleased to answer any questions or provide additional information.

Sincerely,

James Scanlon for
William F. Raub, Ph.D.
Cochairperson
HHS Data Council

Enclosure

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

COMMENTS ON PROPOSED OMB GUIDELINES FOR ENSURING THE QUALITY OF INFORMATION DISSEMINATED BY FEDERAL AGENCIES

General Comments

Current Information Quality Efforts

It would be desirable for the OMB guidance to state that information developed by federal agencies is already subject to high standards of quality, objectivity, utility and integrity. In particular, statistical, accounting, scientific and much other information developed by HHS agencies often sets the national or international standard for such information. This is true for many agencies, and it should be recognized.

Applicability to Scientific Research

There are some fundamental tensions between the very nature of science and the positions taken by these guidelines. Research seeks to generate new information. Sometimes that process results in over-turning established information or existing "facts." This is not to say that the original information or facts were incorrect or misleading; it is to say that our understanding of scientific facts is mutable as we learn more through research. We must allow for the process of knowledge development and evolution of ideas if we expect to foster scientific advances. Similarly, we must allow for the dissemination of the facts as we currently know them. Everyone benefits when the public is familiar with research findings. It would be most unfortunate if our resources were diverted from ongoing research efforts to time-intensive efforts to deal with challenges.

Further, the specific call for "independent analysis of the underlying data" of scientific research information ignores rigorous quality control efforts already in place and puts at risk important resources that would be brought to bear in conducting the re-analysis of the data. There are many quality control measures embedded in the scientific process to ensure that the information generated is of the highest quality. Grant applications submitted to HHS research agencies such as NIH undergo rigorous scientific review. Scientific journals do not publish articles until they have gone through a similar peer review process.

There is a tension inherent in biomedical research between releasing information in a timely fashion and waiting for the peer review process to result in a published article. For example, sometimes the NIH or another HHS agency provides "late breaking news" to the public on research findings prior to publication in scientific journals and prior to peer review by the journals. However, when it does so, there is an internal review process to ensure that information disseminated to the public summarizes the facts as we currently know them. We believe that these processes, and many other formal quality review systems now in use, are not reflected in the guidelines and fear that activities defined in the guidelines will be at odds with these respected and successful processes.

Scope and Definitions

The definition of "information" included in the proposed guidelines is very broad, and OMB correctly notes the great variety of information types involved under these guidelines. The terms quality, objectivity, utility, and integrity are problematic in that they lack specificity and there is often considerable subjectivity in making these judgements. Given the different perspectives, interests and values of people and the various connotations of words and other factors, people can disagree about the quality, objectivity, utility and integrity of any information product. The more controversial the topic, interests at stake, and lack of undisputed fact, the more likely the chance of disagreement. Accordingly, it is important that the OMB guidelines emphasize a good process foundation for ensuring quality, not on opinions of quality. For example, government-wide guidelines should place the burden of proof on the "affected person" to show evidence of the lack of quality versus placing the burden on the federal agency.

These provisions should be applied specifically to written, electronic, or audiovisual forms, not oral forms (the provision isn't clear).

Each of the key terms in the guidelines would benefit from clear, operational definition that can be applied across Federal agencies.

As currently defined, "information" includes opinion. It is unclear why opinion is commingled with fact. Opinions are not considered factual data. It would be misleading and counterproductive to include opinion as subject to the kinds of standards applied to more strictly factual information. Opinion should not be included in the definition of information for purposes of provability or correction. We recommend eliminating "opinion" from the definition of information.

There is a fundamental tension between information generated under the auspices of the Paperwork Reduction Act (PRA) and all information. This needs to be clarified before publication so that comments can focus on the "information" targeted. For example, there are activities under PRA that are not intended to generate information for public consumption, such as SF 398. SF 398 is a form that is used by all individuals applying for PHS funding. While the NIH uses some elements that applicants submit on the completed 398 form (i.e., abstracts), there is nothing in the 398 form itself that looks like information as this term was used throughout the draft guidance. It would be extremely helpful to clarify what is meant by information—what this guidance seeks to address. It would be most helpful if some activities or types of information were excluded from the definition of information.

It may be preferable to return to the original language in the PRA to define the scope of information for these guidelines. If "information" in the proposed guidance were limited to data generated under the PRA, then there would be less confusion about scope of this guidance and implications of this rule. We would suggest being very clear about what PRA covered and did not cover (i.e., the 398 form).

Concerns were raised about the issue of bias as currently treated in the guidelines. The current draft does not provide clear guidance about this complex issue.

The requirement (also in "Definitions") that agencies identify the source of disseminated information so that the public can assess its objectivity could be a problem in certain types of publications or other communications that do not take a formal, scholarly approach (e.g., materials produced for patients or for people with low reading ability). Putting such information in the material itself should be optional, but agencies should be able to produce the sources upon request.

The statute (5152A) refers only to information "disseminated by the agency." The guidance should limit itself to this, because the Department is not in a position to control information disseminated by others. This definition would exclude articles published by grantees, for example.

"Quality" should be the umbrella term for the attributes of accuracy, objectivity, utility, and integrity. In the section prior to the definitions, OMB seems to be using "quality" and "accuracy" interchangeably.

The background and proposed guidelines themselves seem to conflate "information" and "data." At the very least, the guidelines should make a clear distinction between communication activities and data analysis and dissemination. Most agencies have a major communications function and this should be specifically recognized. The quality of communication products is distinct from the accuracy of statistical data or other types of data about individuals.

Agency Processes

The guidelines now require that the "... agency should respond in written form to the complainant." A written response may not always be the most appropriate or efficient form of response, and this should be left to the agencies. Consequently, we suggest that the guidelines require an "appropriate response" to requests for corrections or complaints, rather than a written response in particular. For example, the appropriate form of response to an e-mail complaint could well be an e-mail. " The guidelines should be revised to read:

> The agency should respond to complaints in a manner appropriate to the nature and extent of the complaint. Examples of appropriate response measures include personal contact via letter or phone, an email, form letter, an errata, a press release or other measure that addresses the complaint. Agency specific guidelines should determine when written responses are necessary.

It is suggested that a boilerplate be developed for the annual report back to OMB

Affected Persons

Neither the statute nor the OMB guideline defines "affected persons" with respect to this requirement. Consequently it is unclear whether this applies to only individuals for which the federal government possesses personally-identified information which the individual could refute the accuracy of, or it pertains to a much broader class of affected "entities" or "parties." The OMB guidance preamble implies it may be the broader class. If so, this opens the agencies to challenges associated with information disseminations that may have some direct or indirect affect on a wide array of entities such as private sector companies, associations, unions, etc. In either event, the OMB guidance needs to define affected persons so that there is appropriate scope in agency guidelines and procedures.

Similarly, will individuals be able to request correction of information only pertaining to themselves or about any information that they perceive does not comply with the guidelines? Is it the intent of the statute to allow individuals to dispute substantive points in information not about themselves as individuals but created and disseminated by the government about matters of science or policy? OMB should use whatever latitude it has to make the distinction clear, as noted above, between data about individuals or organizations and information, opinion, etc.

Audience

Concerns were raised about the concept of "utility for the public." From the perspective of many agencies, there is no single public and there is no single utility. Informational materials are produced with a particular audience or audiences in mind. There are multiple public groups who may take very different positions on the usefulness of any particular document disseminated by HHS agencies. The public may represent a random sample of the U.S. population. It may represent activists who rally around a specific disease or issue, such as the use of animals in research. A research report that summarizes the utility of the rhesus macaque model for specific types of research might be extremely helpful (that is, useful) for scientists working in these areas but anathema to animal rights groups. Who is the intended public? Who will adjudicate when different "publics" have different views? It should be recognized that "utility" of information has to be judged in light of the intended audience, but individuals from other audiences clearly have access to information disseminated by HHS. Thus, we don't necessarily expect consensus with respect to evaluations of the utility of our documents.

All information cannot be "useful to all users of the information." A demonstrated general usefulness of the information should suffice.

V1A -- change "useful" to "intended users" of the information. Messages need to be tailored to particular audiences.

Information Dissemination Exigencies

Issues may arise in disseminating information about emerging or urgent developments when insufficient information is available to meet the normal quality standards but nevertheless, it is in the public interest to disseminate the information. Any government-wide model or standard needs to consider and provide for this need.

Government Role

It should be made clear in the guidelines that agencies are responsible for the quality of content of information which they develop, but that for information products developed by others but disseminated by an agency, the agency is only responsible for accurate conveyance. Thus papers included in an agency-sponsored document should be reproduced accurately (and appropriate for inclusion), but quality of content is the responsibility of the authors.

The draft guidelines pose a particular problem for the National Library of Medicine if, in fact, the guidelines apply to NLM's traditional library functions (as well as the bibliographic, full text, and molecular biology data bases it produces). The traditional library function—making available materials produced by other sources, some of them ancient, in fact—surely was not meant to be included under these draft guidelines.

Many agencies distribute information created by individuals or organizations other than themselves. The agency may be acting in a publishing rather than editorial capacity. Requiring agencies to "attest to the quality of the information" which includes opinion, seems very problematic. Will the agency then be in a position of attesting to the quality of the opinion?

Agency Implementation

The guidelines should make clear that correction mechanisms already exist for individuals under the Privacy Act, and thus the guidelines correctly exclude responses under that Act or FOIA from the process being developed now.

Rather than identifying each agency's CIO as its ombudsman, OMB should leave this choice to the agencies. CIOs may be the appropriate choice in some instances, but in other instances a science office or communications office may make much more sense to monitor compliance and evaluate the appropriateness of quality assurance mechanisms for agencies with a wide variety of missions and mandates. Responsibility for the actual substance of the activity should more properly be shared with agency communications officials and content area specialists. The usefulness and clarity of the information can only be judged in relation to the users' own requirements, which vary by audience. A knowledge of both content and communications is essential. Similarly, the CIO typically does not have content expertise in terms of attesting to the quality or integrity of the information being disseminated. Agencies should be given the opportunity and the impetus to examine the need and their response. Indeed, the relationship

between the content and technical aspects of information management in light of the Internet in particular is an unresolved issue in many agencies.

Existing Federal statistical information systems can be a source of guidance in crafting definitions and procedural guidance.

Consideration needs to be given to the impact on timeliness of any new standards and procedures.

There is some concern that the guidelines could make it possible for special interest groups or advocates to lodge trivial complaints in order to draw larger public and political attention toward their own favorite products or procedures, e.g., people for or against a specific complementary or alternative medicine (CAM) to complain about its inclusion or lack of inclusion in patient information materials produced and disseminated by the NIH. Addressing frivolous complaints could tie up agency resources. The grounds for complaints or a threshold for formal action on a complaint should be better defined, and some recognition of challengers' responsibilities would be useful.

Government-wide vs Individual Agency Guidelines

Because of the diversity of programs and types of information included in the scope of the guidelines, **most HHS components support the concept of flexibility to develop Agency-level guidelines rather than one set of guidelines across all agencies and programs.** The argument in favor of consistency across all agencies is that otherwise, standards will vary (and this would be confusing to the public). The argument in favor of the approach OMB has taken is that agencies currently have quality control processes in place. Taken in balance, the difficulty of arriving at a single set of guidelines across the Federal Government probably outweighs the benefits of such consistency.

HHS recognizes that there is tremendous diversity in information products across the federal government and providing agencies flexibility in addressing their unique information products under this requirement is beneficial. However, the lack of any government-wide guidance in this area is likely to lead to a wide range of interpretation, dissimilarity, and consequent confusion by the public. While we strongly support the requirement for individual agencies to develop and implement guidelines specific to their information dissemination activities, this does not preclude OMB from issuing guidelines in certain common areas or a model guideline that could serve as a baseline for the entire federal government. Such a model would be particularly useful in avoiding unintended and unnecessary diversity and inconsistencies in approaches and standards that would likely emerge even for the same types of information dissemination products. Moreover, it would avoid the necessity of all Departments and independent agencies developing their own guidelines in common areas.

Specifically, the OMB guidance could identify various levels or categories of information and some suggested quality approaches appropriate for each. The importance, sensitivity, and impact of various information products vary widely and should not necessarily be held to the same standards or a public perception of the same standard. If this were the unintended outcome, agencies will be inundated with complaints on information dissemination products that are not, by their nature, of the same quality rigor as scientific peer-reviewed research, for example. Therefore the OMB guidance should go further in identifying some generic levels or categories of information dissemination products but allow for agency-specific extensions as may be necessary.

Additional Comments

II 2-- Eliminate phrase "and documenting for users" -- this goes considerably beyond the statute. Intent is covered by #3.

For example, grant-giving agencies have peer review processes, and agencies performing intramural research have processes for reviewing initial project and peer review processes at publication. Data releases usually have a quality-control mechanism built in by the contractor and by staff.