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Submitted via email (Info.comments@hhs.gov)

Mr. James V. Scanlon
Director
Division of Data Policy
Office of the Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 440D
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Supplemental CRE Comments on HHS Data Quality Guidelines (including CDC/ATSDR, FDA, and NIH)

Dear Mr. Scanlon:

These comments are submitted on behalf of the Center for Regulatory Effectiveness (11 Dupont Circle, N.W., Suite 700, Washington, DC 20036, www.TheCRE.com), and they supplement the previous "generic" comments previously submitted by CRE to HHS and many other federal agencies.

1. Interim action: There will almost surely be instances where it is clear, either almost as soon as a correction request is received or at some later point before a formal agency response, that there are corrections or clarifications that should be made to an information dissemination product. However, at that point it might also be clear that agreeing on the necessary corrections or clarifications and substituting and disseminating the new information may require a period of months or more. Once it is clear that changes should be made, the original information should no longer be disseminated and news of a decision to revise should be disseminated. It is important that the guidelines specify that under such circumstances the agency will notify the public as soon as possible that it has been determined that corrections or clarifications should be made and therefore the initial information dissemination product is no longer valid, is no longer being disseminated, and is undergoing revision or has been permanently withdrawn. Withdrawal of the initial product should be done in a very transparent manner so that there is no confusion about whether the initial product is still viable.

Different agencies might want to accomplish this in different ways depending on the type of information and the manner in which it has been disseminated. What is essential is that there be notice to the public of the withdrawal and pending revisions commensurate with the original dissemination. For example, if a press release and/or fact sheet accompanied the original dissemination, a similar new release should inform the public that the product is in the process of being revised. In addition, all references and links to the initial product on the Internet/agency website should be disabled and a notice entered that the original product has been withdrawn and/or is being revised. The exact details of the methods that will be used to inform the public of the withdrawal and pending revision need not be contained in the guidelines; however, the guidelines should make clear that such measures will be taken as soon as possible after a decision has been made to revise the information.

In addition, since in some instances it might require a significant amount of time to reach a decision on a request for correction or clarification of an information dissemination product, the public should be notified when a request for correction has been received and is under review, even if there has been no decision on the petition. This could be done by adding a brief notation next to a website notice of the product or on the product itself, indicating that such a request has been received and the date of receipt. It would also be desirable if requests were publicly accessible via the Internet; thus, the notation could also be in the form of a link to the request. Such a notation would be made once the agency made an initial determination that the request for correction or clarification was valid and not likely to be summarily rejected as lacking sufficient basis.

2. "Utility": In general, little is said about "utility", and most of the emphasis is on other aspects of "quality". Higher standards of utility as well as other quality factors should apply to "influential" information. The guidelines should also state that when considering whether information maximizes "utility" for the intended users, due consideration will be given to evidence of Congressional intent regarding the purpose to be served by the information, what should be included in the information, and the manner in which it should be presented.

In addition, the concept of "utility" should encompass not only the usefulness of the information, but also whether it is being disseminated for the purpose of being used at that time. Agencies often disseminate "draft" or "preliminary" information for the purpose of public comment or external peer review. Usually, such drafts are accompanied by a disclaimer that the information is draft or preliminary, should not be quoted or cited, and does not represent the position of the agency. Yet, on occasion, such "drafts" are further disseminated and used by agency personnel as if they did in fact represent the position of the agency. The guidelines should state explicitly that "draft" or "preliminary" information does not meet acceptable standards of "utility" (particularly if it is "influential" information) and should not be disseminated and used by agency personnel in a manner indicating that it represents an agency position when in fact it does not. Information in draft or preliminary form should state prominently that it is such and that revisions are being considered (and that it is being disseminated in order to obtain comments and/or peer review, if applicable).

Finally, it should be a basic principle of "utility" that the agency should keep the public informed in a timely manner of agency determinations regarding "draft" or "preliminary"

information. Information that an agency is considering some action can, by itself, have impacts, even if the public is only notified that the action is under consideration or the information supporting the proposed action is "draft" or "preliminary". If the agency subsequently determines that the proposed action should be reconsidered, revised, deferred, or withdrawn, even if there is not a correction request which has been filed, the agency should promptly notify the public of any such action which affects the original draft or preliminary agency action.

Thank you for extending the public comment period and for considering these comments.

William G. Kelly, Jr.
CRE Western Representative