E. Centers for Medicare & Medicaid Services

Draft Guidelines for Ensuring the Quality of Information Disseminated to the Public

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I. Agency Mission

The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program, providing health care security and choice for aged and disabled people in this country. Jointly with the State governments, CMS administers the Medicaid program and the State Children's Health Insurance Program (SCHIP). CMS is the largest purchaser of health care in the United States -- our programs account for more than one third of the dollars spent on health care in the U.S. economy. In 2001, CMS programs provided health care coverage for 70 million people -- nearly one out of every four Americans.

In administering the Medicare, Medicaid and SCHIP, CMS activities are performed with one thing in mind: a commitment to the people who rely upon our programs for access to and quality of the health care they need. CMS' mission, though complex in execution, is simply stated: We assure health care security for beneficiaries. And our vision is no less ambitious: In the stewardship of our programs, we lead the Nation's health care system toward improved health for all.

CMS could not accomplish its mission by working alone. We work in partnership with many other organizations and individuals: other Federal and State agencies, and Territorial and Tribal governments; private-sector contractors; health plans, practitioners, and health care facilities; professional organizations, academia, and advocacy groups; and beneficiaries and their families.

II. Scope and Applicability of Guidelines

The OMB Guidelines apply to official substantive information (endorsed or authorized by CMS) that is released on or after October 1, 2002. This section identifies the types of information

covered by the Guidelines, and also lists the types of information that are exempt.

A. Information Covered

Information that IS subject to the Information Quality Guidelines includes:

* statistics and information designed for public dissemination to help CMS program beneficiaries make informed choices

* statistical or actuarial information

* studies and summaries prepared for public dissemination to inform the public about the impact of CMS programs

* studies and summaries prepared for use in formulating broad program policy.

To correct information that is subject to the Information Quality Guidelines, please follow the procedure for correcting CMS information outlined in Section VI of this notice.

B. Information Not Covered

Information that is NOT subject to the Information Quality Guidelines includes:

* personal information maintained for purposes of enrollment or adjudicative decisions

* data used to verify and pay individual claims

* information pertaining to basic agency operations, such as the Chief Financial Officer's Report

* procedural and policy manuals

* management information that is produced primarily for internal use

* information of which dissemination is limited to CMS employees or agency contractors.

* opinions where the agency's presentation makes it clear that what is being offered is personal opinion rather than fact or the agency views

III. Types of Information Disseminated

Generally speaking, information released by CMS falls into one of two broad categories: Medicare consumer information, and program information and evaluation. Typically, CMS does not provide detailed consumer information about Medicaid or SCHIP because these functions are carried out by individual State governments.

A. Medicare consumer information

This information is designed to help people enrolled in Medicare make informed decisions

about the types of insurance and service providers they use. For example,

* *Medicare & You* is an annual handbook mailed to Medicare enrollees. The book provides basic benefit information, and also provides information about managed care plans and other types of health insurance available to enrollees.

* *Nursing Home Compare* is a web site containing information about long-term care facilities. In combination with other factors, this information can be used by people who are contemplating nursing home care for themselves or others, to decide which facility is best for them.

B. Program information and evaluation

This type of information is designed to help improve the performance of CMS programs. Examples include:

* *Program Information* which provides summary statistics describing use of CMS program services, the number of people using those services, expenditure for those services, etc. For example, CMS publishes an annual *Medicare and Medicaid Statistical Supplement* to the *Health Care Financing Review*.

* Statistical data sets which are claims-level, person-level, or provider-level data used for program evaluation, health services research, or policy development. For example, CMS prepares Standard Analytic Files (SAFs) extracting Medicare hospital inpatient claims that can be used by outside researchers who abide by a data use agreement. The agency also releases information from the Medicare Current Beneficiary Survey (MCBS), a survey of a random sample of Medicare enrollees that collects social, demographic, and economic information about those enrollees.

* *Research and evaluation reports* which focus on issues germane to CMS programs and policy. Typically, each innovation in CMS programs must be evaluated; often, such innovations are preceded by research performed by CMS staff or by outside researchers under contract to the agency. Many of these evaluations are released through *Reports to the Congress*.

* *Technical reports* which summarize specific aspects of CMS and its program activities. For example, each year CMS actuaries produce the data underlying the report of Medicare's trustees on the financial health of the program. Similarly, CMS' Chief Financial officer produces an annual report on the agency's operation.

* *Payment updates* which establish the amount Medicare will pay for particular services or for capitated care of beneficiaries. For example, each year the agency publishes a fee schedule update that determines payments for physician services.

IV. Types of Dissemination Methods

CMS uses four modes to disseminate information.

A. Internet

The agency maintains two web sites. One of them -- www.medicare.gov -- is devoted to

consumer information. It is intended for use by program beneficiaries, their families and caregivers, and their advocates. The second site -- www.cms.hhs.gov -- is designed to serve researchers, policymakers, and health care providers. The sites are cross-linked for ease of access.

B. Printed matter

CMS produces a wide variety of pamphlets, handbooks, and directories related to our programs. For example, CMS publishes the *Health Care Financing Review*, containing scholarly articles relevant to CMS programs as well as data highlights from those programs. In addition to the *Medicare & You* handbook described above, smaller leaflets are prepared to describe program eligibility, enrollment, and benefits.

C. Storage Media

Data from CMS operations are available in a variety of storage media upon request for use at non-CMS computing facilities. Aside from download files available through the Internet, this form of information dissemination is ad hoc in nature.

D. Telephone

CMS maintains a national toll-free telephone number, 1-800-MEDICARE, to process questions and provide information about the Medicare program.

E. Multi-media

CMS is engaged in an ongoing multimedia effort to provide information about the Medicare program to its enrollees. The National Medicare Education Program (NMEP) is unique among the agency's information products in that it is intentionally designed to incorporate Internet, printed, and telephone information seamlessly.

V. Agency Quality Assurance Policies, Standards and Processes

Information released by CMS is developed from reliable data sources using accepted methods for data collection and analysis, and is based on thoroughly reviewed analyses and models. The guidelines below describe procedures that CMS employs to assure the quality of its information products, including their utility, objectivity, integrity, transparency, and reproducibility.

A. Utility

Utility involves the usefulness of the information to its intended users. Utility is achieved by staying informed of information needs and developing new data, models, and information products where appropriate.

Based on internal analyses of information requirements, convening and attending conferences, working with advisory committees, and sponsoring outreach activities, CMS keeps abreast of information needs with respect to the analysis of CMS programs. To the extent possible, we base our analysis on CMS administrative data and surveys by other federal agencies or established survey organizations. When major needs for data related to CMS populations are

identified, CMS conducts special-purpose surveys to address these needs. CMS's ongoing publication series and other information products are reviewed to ensure that they remain relevant and address current information needs. Based on internal product reviews, consultation with users, and in response to changing needs and emphases, content of ongoing information products is changed, new products are introduced and others discontinued. CMS prepares special reports and topical studies that address emerging information needs stemming from proposed changes in the law and related policy debates. Where appropriate, contact information is available on each publication (and in some cases on each table of a publication) to allow feedback and questions by users.

New and revised information products are tested with focus groups of intended recipients. In many cases, the structure of the content itself is a collaborative process involving providers, consumers, academicians, and policy analysts.

B. Objectivity

Objectivity involves a focus on ensuring that information is accurate, reliable and unbiased and that information products are presented in an accurate, clear, complete and unbiased manner. Objectivity is achieved by using reliable data sources and sound analytical techniques, and carefully reviewing information products prepared by qualified people using proven methods.

Using reliable data sources. Much of the information disseminated by CMS is based on administrative data files. These files contain information used to manage CMS programs, including data to determine benefit entitlement, and to compute and pay benefits. CMS staff conduct ongoing reviews of claims information in CMS data systems to ensure its accuracy. CMS administrative data are also covered under CMS's Financial Management Systems and conform to the high standards of financial accountability demanded by these Systems. These financial management systems are mandated by the Office of Management and Budget and are designed to provide complete, reliable, consistent, timely and useful management information to enable agencies to carry out their fiduciary responsibilities.

CMS-sponsored surveys are conducted using methodologies that are consistent with generally accepted professional standards for all aspects of survey development, including sample frame development, statistical design of the survey sample, questionnaire design and testing, data collection, sampling and coverage errors, nonresponse analysis, imputation of missing data, weights and variance estimates. CMS surveys follow guidelines and policies set forth in the Paperwork Reduction Act and other regulations related to the conduct of government surveys. CMS also prepares information products using data produced or maintained by other federal agencies and established survey organizations. All such external survey and administrative data used by CMS are produced using generally accepted methodologies.

Where samples from administrative data files are employed for analysis, sound statistical methods are employed to develop samples. Staff involved in producing statistical publications are knowledgeable about the content, structure and limitations of the administrative data files and maintain working relations with staff who create, update and maintain these files.

Where administrative files are linked to surveys for analysis, sound procedures for extracting and linking data from external sources are employed, based on a thorough understanding of the relevant components of the data sources. Computer programs for sampling, extracting and linking external data files are developed and tested by technically qualified staff. Samples from administrative files are evaluated to ensure that samples are representative of the underlying administrative data files. Estimates prepared from external data sources are reviewed to ensure that the data extraction and linkage processes were implemented correctly.

Using sound analytic techniques. Analytical reports are prepared using a variety of analytical techniques. These techniques range from simple tabulations and descriptive summary statistics to multivariate statistical methods and econometric models. Analytical techniques are reviewed for their appropriateness to the data and the analysis being conducted and are clearly identified in reports. Actuarial estimates are subject to the standards of that profession and are certified by the Chief Actuary.

Preparing statistical data products. Estimates in statistical data products are prepared from representative random samples of CMS administrative data files and from reliable external data sources. Procedures for sampling from administrative files and linking external data files to administrative data files are prepared using accepted statistical methods.

Output is reviewed by knowledgeable staff within the originating component and across components as appropriate. Estimates are compared to prior year estimates and estimates from other sources to ensure consistency, reasonableness and reliability.

All data sources used in producing statistical data products are identified, either for the publication as a whole or for individual tables. Documentation includes specification of variables used, definitions of variables when appropriate, sampling errors and disclosure avoidance rules or techniques.

Preparing analytical reports and policy studies. Information contained in analytical reports and policy studies is based on estimates derived from reliable administrative data files and external data sources. Analysts apply sound statistical and analytical techniques and are knowledgeable about the data sources and models being used.

All data sources are identified. When analyses are based on simulation model projections, the assumptions used to produce the projections are also identified as well as the rationale for the assumptions used and the impact of using alternative assumptions.

All analytic reports and policy studies are reviewed by technically qualified staff to ensure that analysis is valid, complete, unbiased, objective and relevant. Analytic reports and policy studies that are considered to be more technically complex are also reviewed by subject matter experts outside of the originating component to provide additional perspective and expertise.

Establishing editorial review for accuracy and clarity of information in publications. All information products are edited and proofread before release to ensure clarity and coherence of the final report. Text is edited to ensure that the report is easy to read and grammatically correct, that thoughts and arguments flow logically, and that information is worded concisely and lucidly. Tables and charts are edited to ensure that they clearly and accurately illustrate and support points made in the text, and include concise but descriptive titles. Tables and charts clearly indicate the unit of measure and the universe being examined and all internal labels (column heads, row stubs, and panel headings) accurately describe the information they contain. All changes made to a manuscript during the editing process are checked by a proofreader and reviewed and approved by the author.

C. Integrity

Integrity refers to the security of information from unauthorized access or revision to ensure that the information is not compromised through corruption or falsification. CMS has in place rigorous controls to ensure the integrity of its administrative information.

CMS is highly protective of the confidentiality of information it holds through its policies and practices. CMS administers social insurance programs that -- directly or indirectly -- touch the lives of almost every American. CMS has in place programs and policies for securing CMS resources as required by the Government Information Security Reform Act (P.L.106-398, Title X, Subtitle G). These security procedures address all major components of information security.

CMS is subject to a number of statutory requirements that protect the sensitive information it gathers and maintains on individuals. Among these are:

- * Health Insurance Portability and Accountability Act of 1996
- * Privacy Act of 1974
- * Computer Security Act of 1987
- * Office of Management and Budget (OMB) Circulars A-123, A-127, and A-130
- * Government Information Security Reform Act
- * Federal Managers' Financial Integrity Act (FMFIA) of 1982

D. Transparency and Reproducibility

If an agency is responsible for disseminating "influential" information, guidelines for dissemination should include a high degree of transparency about data and methods to facilitate its reproducibility by qualified third parties. Information is considered influential if it will have a substantial impact on important public policies or important private sector decisions. Since much of CMS's consumer, statistical and analytical information products potentially have an impact on important public policies, CMS's information that is subject to section 515 should be highly transparent and capable of being reproduced by qualified persons.

CMS's guidelines call for identification and documentation of data sets used in producing estimates and projections, and for clear descriptions of the methods used. Many estimates and projections included in CMS information products are not directly reproducible by the public because the underlying data sets used to produce them are confidential. However, some statistical publications that are based on publicly available data and whose programs are made available on request are fully reproducible by the public. Further, some CMS data is available to people outside the agency through adherence to a data use agreement, provided that the use of the data is consistent with the appropriate systems of records notice. Where estimates and projections may not be easily reproduced by third parties due to the complexity and detail of the methods and data, greater emphasis is placed on periodic review by outside panels of technical experts.

CMS also achieves transparency through wide dissemination of its information. Many reports and other data products are available both as printed and electronic documents. New documents posted on our Web sites are section 508 compliant, making information available to an audience that includes persons who have a visual impairment and read online using assistive technology. (Older documents are being converted to meet section 508 standards.)

VI. Agency Administrative Complaint Procedures

A. Responsibility of the Complainant

To seek a correction under Section 515 of Public Law 106-554 of information disseminated by the agency, individuals should follow the procedures described below. A) A complaint or request for review and correction of information shall be in written hard copy or electronic form; B) it shall be sent to the agency by mail or electronic-mail(e-mail) at the address below; and C) it shall state that a request for correction of information is being submitted under Section 515 of Public Law 106-554. The complaint shall contain D) a detailed description of the specific material that needs to be corrected including where the material is located, i.e. the publication title, date, and publication number, if any, or the web site and web page address (url), or the speech title, presenter, date and place of delivery; and E) the specific reasons for believing the information; G) a description of how the person submitting the complaint is affected by the information error; and H) the name, mailing address, telephone number, e-mail address, and organizational affiliation, if any, of the individual making the complaint.

B. Responsibility of the Agency

Based on a review of the information provided, the agency will determine whether a correction is warranted and if, so what action to take. The agency will respond to the requestor by letter or e-mail. The agency's response will explain the findings of the review and the actions that the agency will take, if any. The response will consider the nature and timeliness of the information involved and such factors as the significance of the correction on the use of the information and the magnitude of the correction. The response will describe how the complainant may request reconsideration. The agency will respond to all requests for correction within 45 working days of receipt. If the request requires more than 45 working days to resolve, the agency will inform the complainant that more time is required and indicate the reason why and an estimated decision date.

C. Appeals

If the individual submitting the complaint does not agree with the agency's decision (including the corrective action, if any), the complainant may send a written hard copy or electronic request for reconsideration within 30 days of receipt of the agency's decision. The appeal shall state the reasons why the agency response is insufficient or inadequate. Complainants shall attach a copy of their original request and the agency response to it, clearly mark the appeal with the words, "Information Quality Appeal," and send the appeal to the specific agency appeals address.

The agency official who resolved the original complaint will not have responsibility for the appeal.

D. Contact

Complaints filed under this guideline should be mailed to:

Information Quality Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, MD 21244-1850

Alternatively, the complaint can be emailed to infoquality@cms.hhs.gov

Appeals filed under this guideline should be mailed or emailed to the same address, and should contain the word "appeal" on the envelope or in the subject line.

VII. Influential Scientific, Financial, and Statistical Information

The OMB Information Quality Guidelines require that "influential" scientific, financial, or statistical information in official Government documents must be based on data or studies that could be substantially reproduced if the original or supporting data were to be independently reanalyzed using the same methods. "Influential" means that CMS can reasonably determine that dissemination of the information will have a substantial impact on important public policies or important private sector decisions or will have important consequences for specific health practices, technologies, substances, produces, or firms. Examples of the types of information disseminated by CMS that have the potential to be influential include the annual reports of the Medicare Board of Trustees and annual publication of provider payment rates.

CMS is committed to applying rigorous scientific standards to ensure the accuracy and reliability of program evaluation results. The scientific/research, financial, and statistical community recognizes peer review as the primary means of quality control. CMS routinely seeks input from qualified peer reviewers, inside and outside the Federal government prior to dissemination of this type of information.

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