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MEDICARE

Preliminary Strategies for Assessing Quality of Care

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The Honorable Fortney H. Stark
Chairman, Subcommittee on Health
Committee on Ways and Means
House of Representatives

Dear Mr. Chairman:

In response to your letter of March 3, 1986, we have examined Medicare's quality of care review systems, providing an informal briefing on our preliminary analyses in January, 1987. This report summarizes those analyses. As agreed to with your staff, our final report is scheduled to be completed in late 1987.

At issue is Medicare's ability to track what is happening to the quality of care as changes occur in methods of paying health care providers. Medicare reimburses physicians, other practitioners, and suppliers on a fee-for-service basis and, until recently, paid all facility-based providers on a cost basis. This has created incentives to overuse Medicare services. Accordingly, the medical review activities coordinated by the Health Care Financing Administration (HCFA), which is responsible for the Medicare program, have focused on ensuring that the program pays only for medical services that are necessary and appropriate.

The introduction of a payment system based on prospectively-determined fixed amounts for acute care hospitals, and the growth of prepaid health care programs (health maintenance organizations and competitive medical plans) created new incentives to increase efficiency by reducing unnecessary or inappropriate care. Unfortunately, incentives to increase efficiency in the delivery of health services may also lead to the withholding of some useful, needed services. Thus, Medicare payment reforms have increased the potential for quality of care problems—problems the Medicare review system should be capable of monitoring.

We believe optimal quality assurance requires a system of data collection, analysis, and feedback extending across the various components of the program being reviewed. Such a system was not anticipated in the development of the Medicare program. Our review indicates that developing effective methods to measure and monitor quality of care will

require the resolution of certain technical problems related to the availability of methods and information. It will require, in addition, consideration of the following set of general policy issues involving the basic intent and operation of quality assessment in the Medicare program.

First, the overall responsibility for assessing the quality of care provided across different care settings and for evaluating changes in levels of quality over time has not been assigned to any unit within HCFA. For example, the medical review activities conducted by peer review organizations (for most inpatient acute care) and by claims processors (for most ambulatory and posthospital care) are only loosely coordinated, and are overseen by two separate bureaus within HCFA.

Second, there is no in-place organizational structure for developing, coordinating or disseminating information about methods for assessing quality or their findings. For example, HCFA mandated in 1986 that all peer review organizations apply a generic quality of care screen to all cases selected for review. But the agency produced very little guidance on how to use the screen in a manner which would lead to consistent application or generalizable findings.

Third, in order to ensure that the best methods and medical judgment are incorporated into Medicare quality assurance activities, mechanisms for involving the medical community need to be structured more systematically. For example, there is no provision for on-going, formal input from clinical and health services researchers, from the range of medical professional societies, or from physicians and other providers who must deal with Medicare daily.

Fourth, HCFA's objective of developing better information about quality of care is in potential conflict with its objective of moving toward systems of prepaid health care which provide less information about patients than is currently available in the Medicare data system. For example, prepaid plans report no information to HCFA on patients' use of health services other than inpatient stays. The strategies presented in the report for improving Medicare quality assessment and assurance address these general issues.

You specifically requested that we consider options for short-term changes. We have identified four possible strategies: (1) adding uniformly-coded diagnostic data to Medicare part B (physician) data files as part of the new Medicare data system; (2) producing information on

the validity and effectiveness of current methods used to screen for possible quality of care problems and to profile provider performance; (3) evaluating reviews of the quality of care in Medicare capitated health care plans in order to provide comparative information on the effectiveness of methods for assessing quality, as well as on levels of quality across alternative delivery systems; and (4) using Medicare and Medicaid survey and certification inspection data to generate nationally-representative information on the needs of Medicare patients in subacute care settings and the quality of care provided.

In response to your request, we have also outlined three possible strategies for producing comprehensive quality of care information, strategies that would require a relatively longer timeframe: (1) taking steps to better integrate data collection and monitoring responsibilities of Medicare claims processors and Peer Review Organizations (PROs), the organizations primarily responsible for reviewing the appropriateness of Medicare services provided in hospitals; (2) developing options for incorporating valid, reliable medical record review methodologies into peer reviews; and (3) creating epidemiological data bases, drawn from the entire Medicare population or from specific subpopulations potentially at risk with respect to access or quality of health care.

We are continuing our analyses of the feasibility of specific recommendations addressing both the short and longer-term strategies. A final report will present them in greater detail, as well as any recommendations we may have.

Written comments on a draft of this report have been provided by the Department of Health and Human Services. The agency agrees or concurs in whole or in part with the appropriateness of all the short and longer-term strategies discussed in this report. However, HHS believes that the report does not sufficiently take into account the studies addressing quality of care issues underway at HCFA and asserts that these studies "form a comprehensive quality of care assessment program." We recognize the importance of the work being done by HCFA to examine quality of care issues, and we have referred to several of these projects in the report. We do not, however, agree that these studies can be viewed as a comprehensive quality assessment program. This is because of the absence of two essential components: an organizational structure for developing, coordinating and disseminating information about methods and procedures for assessing quality of care, and a mechanism for integrating the results of ongoing review activities.

HHS also makes a series of specific comments. The agency disagrees with our assessment of their efforts to assist Peer Review Organizations with new sampling procedures. In addition, HHS does not agree that their mechanisms for gaining input from the professional medical community are problematic. Technical points are also raised. The full text of HHS's comments, and our response, are presented in appendix III.

Copies of the report will be made available to the Department of Health and Human Services and any others who request them. If you have any questions or would like additional information, please call me at (202) 275-1854, or Dr. Lois-ellin Datta at (202) 275-1370.

Sincerely yours,

Eleanor Chelimsky
Director

Contents

Abbreviations

CMP	Competitive medical plan
HCFA	Health Care Financing Administration
HHS	Department of Health and Human Services
HMO	Health maintenance organization
HSQB	Health Standards and Quality Bureau, HCFA, HHS
MADRS	Medicare Automated Data Retrieval System
PRO	Utilization and Quality Control Peer Review Organization

Introduction

As Medicare reimbursement systems are reformed to contain costs and increase efficiency, methods for measuring and monitoring the quality of care delivered to beneficiaries should be reviewed. From the time Medicare began paying insurance claims in 1966 until recently, it reimbursed physicians and other practitioners on a fee-for-service basis and reimbursed facility-based providers on a cost basis. These methods of reimbursement encouraged the provision of all needed services, but also provided incentives to overuse medical services or to provide them inefficiently. Activities to prevent overuse of services and to protect beneficiaries from the risks of unnecessary medical care have focused primarily on the necessity and appropriateness of services. Recent efforts to contain program expenditures, however, have significantly altered the incentives for health care providers who participate in Medicare.

In 1983, a new reimbursement approach that limits Medicare hospital payments to prospectively determined fixed amounts created incentives to avoid unnecessary or inefficient care. Unfortunately, these same incentives may encourage the withholding of needed useful services. The negative effects of underserving the Medicare population could be substantial—not only in detrimental health effects for individual beneficiaries but also in monetary costs for additional care necessitated by poor initial treatment, administrative costs for investigating problems, and costs in terms of the diminished credibility of the Medicare program itself. If the program is to operate as a prudent purchaser of health care and if it is to protect the population it is designed to serve, it must know whether Medicare beneficiaries are receiving adequate care, which means that no unnecessary or harmful services are given, and also that no services needed to maintain and improve health are withheld.

Concerned about potential problems in the quality of care, the chairman of the Subcommittee on Health of the House Committee on Ways and Means asked us in March 1986 to examine options for short-term improvements in the measurement of quality of care in the Medicare program and to develop recommendations for long-term efforts regarding the program's assessment (the chairman's letter is in appendix I). In this report, we present our preliminary analyses and outline the issues that we are still reviewing. As agreed by the Subcommittee's office, a subsequent final report will discuss in more detail any recommendations we may have about assessing quality of care in the Medicare program.

Objectives, Scope, and Methodology

Objectives

In reviewing strategies for measuring and monitoring the quality of care Medicare beneficiaries receive, we had two basic objectives. First, we reviewed the activities of the Department of Health and Human Services (HHS) that are intended to provide information on the quality of Medicare services and assessed the types and usefulness of the information these activities generate. This was done in order to determine whether relatively short-term changes could allow the Health Care Financing Administration (HCFA), which administers the Medicare program, to produce better information using the Medicare data system as it is presently structured.

Second, we sought to provide a framework for considering broader, long-term issues related to the measurement and monitoring of the quality of care under various reimbursement arrangements. We wanted to examine the relationships between measurement and monitoring activities in the various components of the Medicare program and address the integration of these activities with research and evaluation.

Scope

We designed our project to address all the quality-related activities HCFA requires for all Medicare-covered services. This includes all activities HCFA or its contractors perform to ensure that the care provided to program beneficiaries meets professionally recognized standards as reflected in (1) the structure of care (physical plant and equipment, staffing, professional training, organization, use of technology, and the like); (2) the process of care (the provision of care itself, including among other things the diagnostic process, procedures, and therapies); and (3) health care outcomes (recovery rates, complications, mortality or morbidity rates, and so on). Our emphasis, however, was on the processes and outcomes rather than the structure of Medicare services.

Measurement and monitoring issues were considered in the context of both quality assessment and quality assurance. Quality assessment involves the application of measures of quality using either implicit or explicit criteria to the structure, process, or outcomes of care and the monitoring of levels of quality over time. Quality assurance extends the concept of assessment to include the formal and systematic organization

of activities designed to identify problems in the quality of medical care, determine solutions to them, monitor the effectiveness of the solutions, and institute additional change and monitoring where warranted.[1] The critical distinction between quality assessment and quality assurance is that the latter includes information feed-back and improvement, intended to assure enhanced levels of quality in the future.

Methodology

Current Assessment Activities

We conducted interviews, literature reviews, and a survey of Medicare contractors to determine what HHS, and in particular HCFA, is doing to assess the quality of care in Medicare services. We interviewed HCFA program officials and staff beginning in the summer of 1986, obtaining documentation throughout our work.

In addition, we conducted a series of interviews with professional staff of several Peer Review Organizations (PROs)[2] —organizations primarily responsible for reviewing the appropriateness and quality of Medicare services in hospitals—and with Medicare intermediaries and carriers, the contractors that review and process Medicare claims.

We examined information systems closely, reviewing technical literature, written descriptions, and other documentation related to the structure, organization, and quality (accuracy, validity, comparability, and interpretability) of HCFA's data files and information-reporting systems as they pertain to quality assessment and quality assurance. We formally requested descriptions and points of contact for additional information on HHS's research and evaluation activities that focus on the quality of care in Medicare services. We held meetings and interviews

[1]These definitions follow closely those developed by R. H. Brook and K. N. Lohr in "Efficacy, Effectiveness, Variations, and Quality: Boundary-crossing Research," Medical Care, 23:5 (May 1985), 711; A. Donabedian, Explorations in Quality Assessment and Monitoring, Volume 3, The Methods and Findings of Quality Assessment and Monitoring: An Illustrated Analysis (Ann Arbor, Mich.: Health Administration Press, 1985 pp 451-54; and F. Baker, "Quality Assurance and Program Evaluation," Evaluation and the Health Professions 6:2 (June 1983), 152-3.

[2]Throughout this report, we use "PRO" to refer to peer review organizations authorized under title XI of the Social Security Act. This definition includes medical peer review organizations that currently enter into contracts with HCFA for the review of the appropriateness or quality of Medicare services, as well as organizations that will be contracting to review the quality of care in health maintenance organizations (HMOS) and competitive medical plans (CMPS), although the latter organizations may not technically be called "PROs".

with key research and evaluation specialists, and HHS provided us with additional information as we requested it.

In our mail survey of all Medicare intermediaries and carriers we asked about the types of medical care reviews they perform in their capacity as Medicare contractors and about the types of information they generate and use in the course of their work. We used some of the information we obtained in preparing this report, but our analysis of the survey data is continuing; when it is complete, our findings will appear in our final report.

The Adequacy of Assessment and Its Improvement

Our methodology for assessing the adequacy of HCFA's activities consisted of a two-stage process of gathering information and synthesizing it. First, we prepared three detailed background papers summarizing (1) the legislative, administrative, organizational, and methodological issues underlying the review of quality of care in the Medicare program, (2) the range of "state-of-the-art" methodologies available for assessment and their applicability to the Medicare program, and (3) the current assessment activities of HCFA, intermediaries, carriers, and PROs, and the data they generate. The data sources for these three papers were literature reviews and interviews with HCFA's staff and contractors, which we supplemented by a series of interviews and written communications with health service researchers across the United States and in Canada, Europe, and Australia, and with private-sector health care cost-containment experts.

Second, we assembled a panel of nationally recognized experts on health care delivery, quality assessment, and evaluation. In addition to providing advice and information relating to their particular areas of expertise, the consultants, listed in appendix II, were asked to review and critique the three background papers and to draw from these materials (1) their perceptions of the basic issues in the assessment of quality that should be addressed and (2) specific proposals for useful and feasible improvements within the current constraints of the Medicare program. In January 1987, the panel members met for 1 1/2 days with our staff. In the structured sessions, the panel members first discussed a range of issues and concerns related to the purpose and scope of quality assessment and then helped us identify a set of short-term proposals to improve the collection and use of information, as well as long-term proposals for developing new types of information.

We used the expertise of the consultants to focus and clarify our analyses. We are in the process of examining the feasibility and costs of the panelists' proposals as well as other issues. The general issues and strategies presented in this report reflect our initial findings from our background papers, the information the panel provided us, and analyses conducted after the January meeting. Our final report will update and expand on the issues presented here and will present any recommendation that emerge from our continuing analyses.

Report Organization

The structure and operation of Medicare quality assessment activities are influenced by the types of services for which coverage is available and the decentralized administrative structure through which providers are reimbursed. Specific issues regarding quality assessment must be placed in the context of these broader concerns about the purpose and organization of the Medicare program as a whole. For that reason, we begin section 2 by summarizing the general issues that form the context for strategies for improving quality assessment in the Medicare program. We discuss short-term strategies in section 3; in section 4, we discuss long-term strategies—those that would either take longer to implement or require additional study, changes to the program's organization or procedures, or a major commitment of additional resources.

General Issues

Quality assessment and assurance activities can have a variety of goals and, therefore, different structural requirements for implementation and operation. For example, quality assessment can be designed primarily to improve medical practice by promoting the use of clinically effective treatments, procedures and therapies. Monitoring the processes and outcomes of medical care at the level of the provider/patient interaction is particularly important in this regard. Quality assessment can also be designed to help select "good" providers and physicians to participate in a health care program, or to help identify those that should be barred from participation. This type of assessment may be based on analyses of aggregate data that identify outliers, i.e. providers or physicians associated with potentially aberrant patterns of patient care, or from detailed examinations of the care actually provided, or both.

Finally, quality reviews can be designed to provide program monitoring and quality control information—that is, data on patterns and trends in the processes and outcomes of care over time, or data signaling unusual events that may require immediate attention. Consistent and comprehensive aggregate data on the type or distribution of quality problems is crucial for evaluating both the effectiveness of the quality review process itself and the effects of program changes on program outcomes, such as the effect of changing payment systems on the quality of medical care provided to program beneficiaries.

Just as the goals of quality assessment vary, so there is no standard definition of "quality of care" that allows health care providers, purchasers, or payers to decide how to combine the different dimensions or aspects of quality in an overall assessment of a health care program. Different assessment approaches provide different types of information: structural measures indicate whether the resources necessary to provide high-quality care are available; process measures indicate whether care reflects sound medical practice; outcome measures indicate whether the results of care are good, bad, or indifferent.[3] The development of quality assessment efforts in the Medicare program therefore involves not only technical problems related to the availability of information or methods for producing valid measures of the quality of care, but also policy issues related to the basic intent and operation of quality assessment programs.

[3]See, for example, A. Donabedian, Explorations in Quality Assessment and Monitoring, vol.1, The Definition of Quality and Its Assessment (Ann Arbor, Mich.: Health Administration Press,) 1980, and G. T. Hammons, R. H. Brook, and J. P. Newhouse, Selected Alternatives for Paying Physicians Under the Medicare Program (Santa Monica, Calif.: The Rand Corporation, 1986).

Below, we outline four issues related to (1) the scope of quality assessment in the Medicare program, (2) the organization of efforts to produce information and advance the level of knowledge regarding quality assessment techniques, (3) the role of the professional medical community in Medicare quality assessment, and (4) the consistency of HCFA's objectives as they affect the collection of information. These issues provide the general context for our discussion of strategies for improvement.

The Scope of Quality Assessment

HCFA's overall responsibilities for assessing and assuring the quality of care are authorized by law and specified in regulations. The Social Security Act states that no Medicare payment may be made for items or services that are determined to be "substantially in excess of the needs of individuals or to be of a quality which fails to meet professionally recognized standards of health care."[4] The coordination of quality review is assigned to HCFA, but the responsibility for assessing the quality of care across care settings and for evaluating changes in levels of quality over time has not been clearly assigned to any unit within HCFA.

Three types of organizations review the use of medical services covered by Medicare: PROs, part A intermediaries, and part B carriers. Under the Social Security Act, the Secretary of HHS is authorized to enter into contracts with PROs to review all or some of the professional activities of physicians and other institutional and noninstitutional providers of health care services and items for which payment is made (in whole or in part) under Medicare. This law assigns PROs the responsibility of ensuring that (1) Medicare pays only for "reasonable" and "necessary" services eligible for coverage under the Medicare statute, (2) the quality of these services meets professionally recognized standards of health care, and (3) the items and services that are consistent with the provision of appropriate medical care could not be effectively provided more economically on an outpatient basis or in an inpatient facility of a different type. The law does not define "reasonable," "necessary," or "appropriate," but clearly leaves their interpretation to HHS and the medical community.

Under the regulations governing the first set of contracts with PROs, these organizations were required to review only inpatient hospital care. The Omnibus Budget Reconciliation Act of 1986 requires each PRO to devote a reasonable proportion of its activities to reviewing the quality

[4]P.L. 97-248, Section 1862(d)(1)(C); 42 U.S.C.1395(y).

of services in additional settings, including postacute and ambulatory care settings, and HMOs and CMPs. PROs will review health care provided to Medicare beneficiaries enrolled in HMOs and CMPs beginning in the spring of 1987. However, the act's provisions apply to contracts negotiated on or after January 1, 1987. Therefore, the most recently negotiated PRO contracts do not reflect the 1986 mandate. The act also stipulates that review of physicians' services in office settings can not be required until January 1, 1989. Thus, PROs are not currently reviewing health care services provided in skilled nursing facilities, by home health agencies, or in other subacute care settings covered by Medicare; their activities continue to focus primarily on inpatient hospital care.

The carriers that administer Medicare part B (primarily payments to physicians and for other outpatient services paid from the Supplemental Health Insurance trust fund) do not currently review medical care for the specific purpose of identifying quality-of-care problems. The carriers are authorized by law to determine whether billed services meet Medicare criteria for necessity and appropriateness, but there are no specific requirements to review claims for "quality of care" or "acceptable standards of care" in either the statute or the regulations governing Medicare[5] , and HCFA has not assigned these responsibilities to the carriers.

The carriers profile the practices of physicians including hospital-based physicians in order to identify problems of use, such as unnecessary care. This activity of the carriers is organized independently from intermediary reviews and the hospital inpatient reviews by PROs. However, carriers are notified when hospital claims that may be associated with physicians services under part B are denied payment—as happens under a ruling of inappropriate admission. The carriers then disallow payment for the provision of a physician's services during noncovered inpatient stays.

The intermediaries administer Medicare part A payments, primarily for inpatient hospital services, skilled nursing facilities, and home health and hospice claims from the Hospital Insurance trust fund[6]. Like the carriers, they are generally responsible for reviewing the use of services

[5]Section 1842(a) (42 U.S.C. 1395u(a)) authorizes HHS to enter into contracts with carriers to assure correct use and make correct payments. The regulations at 42 C.F.R. Part 421 help to implement these sections of the statute.

[6]Section 1816 (a) of the Social Security Act (42 U.S.C. sec. 1395h (a)) authorizes HHS to enter into contracts with intermediaries to make payments to providers and it describes other responsibilities of these entities that may be included in the contracts.

rather than the quality of care. The PROs are assigned the responsibility of reviewing the quality of inpatient part A claims. Intermediaries review the quality of hospice care. In their review of the use of home health care, they report to HCFA survey and certification officials problems of home health care quality related to facility standards, staffing, and the like.

In addition, intermediaries perform what HCFA officials described to us as a "quasi-quality review" of skilled nursing facility claims and home health claims. Intermediaries must ascertain the level of skilled care that beneficiaries require, in order to determine whether the care meets Medicare's coverage criteria. Patients needing more extensive, more specialized, or more highly skilled care than the guidelines allow are termed "level-of-care problems": patients "too sick" to qualify for the Medicare skilled nursing home benefit who should be in hospitals and patients "too sick" for the home health benefit who should be in inpatient facilities. Therefore, in reviewing coverage, the intermediaries may identify cases in which patients who need hospital care have been discharged from hospitals inappropriately.

Intermediaries do not consistently coordinate these "level-of-care" issues with inpatient hospital review throughout the Medicare program. For example, HCFA reported to us that one intermediary reports suspected cases of premature discharges found in reviews of skilled nursing facilities and home health care directly to the local PRO, while another reports directly to HCFA's regional offices all cases denied skilled nursing home or home health care coverage because the level of care required exceeds Medicare coverage guidelines for posthospital care. HCFA's regional offices may then refer the cases to the appropriate PRO, but there appear to be no uniform procedures for following up on the cases of denial of posthospital care that could indicate inappropriate hospital discharges.

Within HCFA, there is no formally designated responsibility or organizational capacity for integrating the results of these separate review activities or assessing the overall quality of medical care. The oversight of the medical review activities of the PROs is conducted by HCFA's Health Standards and Quality Bureau (HSQB), while the oversight of medical review for carriers and intermediaries is conducted in the Bureau of Program Operations. The primary focus of these oversight activities is contract compliance rather than quality assessment, which is conducted by PROs.

HSQB maintains only summary data for each PRO, except for hospital data on patients' average length of stay, discharges, transfers, admission denials, and deaths. Practically no information that can be directly linked to quality of care problems is available from carriers or intermediaries. Thus HSQB is not able to generate data that can be used to monitor quality of care across Medicare services or over time. Efforts to produce such information must use program data independent of that developed through medical review systems of the carriers, intermediaries and PROs.

Building a Knowledge Base

There is no clearly defined "organizational structure" for developing, coordinating or disseminating information about either the methods and procedures for quality assessment or about their findings in a manner that will improve the overall effectiveness of Medicare's quality assurance activities.

The process of determining the duties of the intermediaries, carriers, and PROs with respect to the use of services and reviews of quality involves negotiations between HCFA and the individual contractors. The negotiated responsibilities include both common prescribed duties for all contractors and the performance of individually agreed-upon computerized screening protocols and in-depth case reviews by medical experts. Generally, HCFA provides basic specifications for the contractors, review and reporting procedures, and guidelines for their performance in given areas, but contractors have a great deal of latitude in devising and applying procedures for completing the work they have agreed to perform. This flexibility allows the contractors to work out their own approaches for organizing work and addressing issues particular to the geographic areas they serve.

With this same flexibility, however, the contractors have developed very different systems for implementing HCFA policies, because HCFA does not generally provide them with technical support in the form of hardware, software, or computer specifications for implementing new or revised review procedures. Therefore, the contractors may each face a different problem when they try to build the logic of a new automated screen into their own software. For example, some systems may not permit contractors to construct screens requiring precise treatment dates in the manner set out in HCFA instructions. This increases the possibility of error, and lessens the chances of detecting errors in the implementation of new review procedures. Determining the effectiveness of the new procedures is also more difficult with multiple systems.

HCFA generally provides only limited guidance on the development and implementation of quality review procedures and the implementation of required sampling and statistical procedures. For example, in 1986 when HCFA mandated that all PROs apply to all cases selected for review a "generic quality screen" consisting of six sets of medical criteria, it provided very little initial guidance on the application of the screen. We also found some indications of possibly serious problems with the introduction of the new sampling procedure critical to developing representative data from a random sample of hospital admissions. As a result, the baseline random samples may not be truly random.[7] Under the provisions of the current contracts, each PRO in its quality of care review is responsible for developing criteria for determining the adequacy of discharge planning arrangements. HCFA reviews their criteria but does not provide examples or guidelines for developing them. All these differences in the implementation of review methods and criteria limit the comparability of review findings.

Individual contractors independently develop their approaches to using quality review findings to improve levels of quality. There is little systematic sharing of knowledge or experiences of the effectiveness of different ways of communicating information about problems in order to change the behavior of physicians or providers or correct the problems in other ways, such as through education programs or the administration of formal sanctions.

Assuring compliance with contract specifications is a primary responsibility for HCFA. However, devising systematic approaches for developing and disseminating information on review methods and their effectiveness is also important for advancing the state of knowledge regarding the measurement of quality of care. While HCFA has not been specifically required to assume these broader responsibilities, building this knowledge base seems essential if the agency is fulfill its mandate with respect to assuring the quality of Medicare services.

The Role of the Medical Community

The way the medical community is now integrated into the process of developing approaches to quality review does not ensure that quality assessments incorporate the best methods and judgment available.

[7]As HHS has pointed out in comments on a draft of this report (appendix III) efforts were made to ensure that PROs selected cases correctly. Nevertheless, PROs reported difficulty in understanding how to report statistics on sampled cases for which medical reviews could not be completed within the stipulated time frame.

The statute and regulations require that the criteria for assessing the appropriateness and quality of care delivered to Medicare beneficiaries are based on professionally recognized standards of care. These standards are determined and interpreted in a peer review process by medical practitioners. The official charge to PROs is to

"apply professionally developed criteria of care, diagnosis and treatment based upon typical patterns of practice within your geographic area or national criteria where appropriate, to evaluate the medical necessity, quality or appropriateness of the items or services furnished by providers and practitioners."[8]

The statute and the regulations do not specify when the application of national standards or criteria is appropriate. Because local and regional standards of medical care may vary, the criteria and standards peer reviewers apply can differ. Although it is not likely that professional opinion would differ significantly on most basic issues, professional interpretations of what constitutes appropriate and inappropriate care may vary from area to area.

At present, the channels of communication between HCFA and local, state, and national professional organizations are informal and generally designed to address immediate policy needs. For example, in commenting on a draft of this report, HHS noted that the agency consulted extensively with professional societies in developing criteria to implement the Medicare second surgical opinion provisions (appendix III). An ad hoc approach, however, does not ensure that the best information about clinical medicine and review methodologies is incorporated into program policy on an on-going basis. Standards should reflect the best available information about the provision of medical care and the design of quality assurance systems. This requires the input of clinical researchers, medical professional societies ranging from family practice to medical and surgical subspecialties, and from physicians and other health care providers who must deal with Medicare daily. Health care professionals may not feel comfortable with review methodologies that they are convinced do not represent the best ones available or do not reflect a complete understanding of the way they believe medicine ought to be practiced.

[8]Health Care Financing Administration, Peer Review Organization Manual, rev. 3 (Washington, D.C.: August 1985), p. 1-7 which paraphrases the language of Section 1154(a)(6) the Social Security Act and 42 U.S.C. 1320c-3(a)(6).

The Consistency of HCFA's Objectives

HCFA's objective of developing better information about the quality of the care that Medicare supports is in potential conflict with its objective of moving toward systems of prepaid health care which provide less information about patients than is currently available.

Currently, almost 1.7 million Medicare beneficiaries (about 5 percent of all Medicare beneficiaries) are enrolled in prepaid or "capitated" health care plans, in which a fixed monthly fee is paid to a health care provider in return for providing Medicare services to beneficiaries who enroll in the provider's plan. "Capitation" has become an integral component of HCFA's payment policy, and HCFA is contemplating expansion that would bring a wider array of providers and beneficiaries into capitated arrangements.[9]

From the standpoint of efficiency and administrative burden, a basic advantage of capitated systems is that the amount of utilization and billing information that must be submitted to and processed by claims processors is substantially reduced. At present, capitated plans report no data on patients' use of any outpatient services to HCFA. Thus, capitation may also reduce the amount of information available for monitoring the care given to Medicare patients.

HCFA has begun implementing the legislative requirement to assess the quality of care in capitated plans. If new systems for producing patient-specific information on the quality of care are not developed, the Medicare program may not be able to assure the adequacy of care provided to beneficiaries under capitated systems. Conversely, efforts to improve methods to measure and monitor quality of care using available administrative data, discussed in the following section, will be of diminished importance if information on services rendered to a growing proportion of Medicare beneficiaries is not captured by the Medicare data system.

[9]K.M. Langwell and J.P. Hadley, "Capitation and the Medicare Program," Health Care Financing Review, 1986 Annual Supplement (December, 1986).

Four Short-Term Strategies to Improve Monitoring

We were asked to consider possibilities for implementing short-term changes that could increase the capacity of the program to produce useful information on the quality of care. In this section, we summarize four potential strategies. We will be more specific about how they might be implemented in our final report, depending on the results of our feasibility analyses.

Adding Diagnostic Data to Part B and Merging Parts A and B Data

The planned development of an automated data system merging parts A and B is a prerequisite for effective quality assurance. Adding uniformly coded diagnostic data to part B (physician) claims in the merged system could greatly increase the program's ability to measure and monitor the quality of care in individual settings and throughout entire episodes of illness.

We have previously noted the importance of merging Medicare parts A and B data for evaluating changes in the program and so has the Office of Technology Assessment.[10] Data on the use of all Medicare services during the entire course of an illness, including both the acute and recuperative periods, are particularly important for identifying problems related to the inappropriate use of or access to ambulatory, hospital, and posthospital services.

A merged data base lacking diagnostic information on ambulatory visits would be useful for a limited set of analyses of the quality of care. For example, in some instances billing data on specific procedures performed in physicians' offices, such as procedures associated with the treatment of postoperative infections might help identify posthospital complications. But with diagnostic data, it would be much easier to assess patterns of ambulatory treatment. Some protocols for reviewing the quality of ambulatory care focus on individual diagnoses; without diagnostic data these techniques cannot be applied. The lack of diagnostic information also makes it more difficult to establish how ambulatory care is related to inpatient care—whether visits to a physician reflect posthospital problems, for example, or treatment for an entirely unrelated condition, or whether a hospitalization is associated with inadequate ambulatory care. These issues will take on added importance if

[10]U.S. General Accounting Office, Post-Hospital Care: Efforts to Evaluate Medicare Prospective Payment are Insufficient, GAO/PEMD-86-10 (Washington D.C.: June, 1986), pp. 71-72, 146-147.; Office of Technology Assessment, Medicare's Prospective Payment System: Strategies for Evaluating Cost, Quality, and Medical Technology (Washington, D.C.: U.S. Government Printing Office, October 1985), p. 87-89; 199.

PROs begin reviewing the quality of care provided in physicians' offices, which could begin in 1989.

Currently, only limited information from part B bills and no information at all on diagnosis is transmitted to HCFA's central administrative data system. Parts A and B files are maintained separately. Although some carriers and intermediaries have developed automated systems that allow them to track an individual patient's use of part A and part B services, most have not. HCFA is committed to the completion of a research file, its "Medicare Automated Data Retrieval System," that will include billing data on both parts. But merging the information from both parts during bill processing would be required if problems in the quality of care were to be flagged expeditiously.

Adding diagnostic information to part B claims would require a change in Medicare's procedures governing the submission of physicians' bills. Physicians who do not accept Medicare reimbursement rates as payment in full and, therefore, do not bill Medicare directly may not fill out patients' Medicare claims forms. If the program required diagnostic data for part B bills, those patients would have to obtain the data from their physicians.

The value of adding diagnostic information to physician claims would depend to a large extent on the accuracy and comprehensiveness of the information recorded on the claims forms. Current levels of data quality would have to be examined and possibilities for ensuring accuracy identified. There is reason to believe, however, that this may not be an insurmountable task. Claims forms already contain space for recording diagnoses, and some physicians routinely fill in this information. Evidence from studies of hospital claims and medical records abstracts suggests that when physicians have an incentive to provide accurate diagnostic information, the quality of this information can be reasonably good.

A more serious problem is that some information on health care is not recorded on Medicare bills: about 3 percent of the persons who are enrolled in part A hospital insurance are not enrolled in part B, the supplementary medical insurance program. More importantly, Medicare does not cover such medical costs as drugs and nursing home care provided in facilities other than Medicare-certified skilled nursing facilities. Therefore, merged data showing all Medicare payments for an episode of illness may not provide a complete record of a patients' medical care.

It should, however, provide a reasonably accurate account of their use of basic acute care and physicians' services.

The Medicare program is planning to redesign its computer and administrative data systems. In addition to its project to combine parts A and B billing data for research purposes, HCFA is planning a complete restructuring of its entire Medicare and Medicaid data systems. If new data elements or new methods of linking data are necessary for quality assurance purposes, it would be useful to coordinate the analyses of their administrative and technical feasibility with the analyses for the broader redesigning of the system.

Evaluating Current Screening Methods

Producing information on the validity and effectiveness of current methods of screening for possible problems in the quality of care and of profiling the provision of services or care outcomes could significantly increase the credibility of HCFA's quality assessment activities.

Screens can serve a variety of purposes: simply flagging bills that contain inconsistent, incomplete, or erroneous information; preventing payment for services that are not covered; identifying bills for services where utilization problems are common and which should therefore be subjected to greater scrutiny; and identifying less common utilization problems with a high probability of severely adverse patient outcomes. Screens are an efficient means of sorting through all cases to identify obvious problems. But, given the volume of Medicare claims, it is not efficient to use screens to identify cases for indepth review unless the cases have a high probability of error.

Medicare claims processors apply to automated bill data a large set of screens and edits designed to identify claims that require additional review or verification, both before and after claims have been paid. These screens were not specifically designed to identify problems in the quality of care, but some do identify potential quality problems. PROs apply the generic quality of care screen discussed in section 2. In addition, they screen the intermediaries' files for possible quality and utilization problems, including possibly inappropriate hospital admissions, identified by specific diagnosis codes (such as a primary diagnosis of elevated blood pressure without a diagnosis of hypertension), and for hospital readmissions, which could indicate problems of quality as well as unnecessary or inappropriate use of hospital services.

The cost-effectiveness of the carriers' screens is being examined in another GAO study and HCFA is gathering similar information. However, we are aware of only very limited evidence regarding the validity and effectiveness of screens used in Medicare review systems to identify potential deficiencies in the quality of care.

Profiles of providers or practitioners are developed from administrative data by both claims processors and PROs. These profiles involve the comparative analysis of patterns of billing and hospital discharges as they appear in information submitted by physicians, hospitals, and other Medicare providers. Comparisons of numbers of visits billed, billed amounts on part B bills, and average lengths of inpatient stay and mortality rates are calculated, and "outliers" are identified for additional review.

HCFA and California Medical Review, Inc. (the California PRO) have released analyses of comparative rates of mortality following hospitalizations, but little evidence has been produced to establish the validity, reliability, or sensitivity of such data. In March 1986, in response to a Freedom of Information Act request, HCFA released the names and summary statistics of all Medicare-certified hospitals for which 1984 mortality rates differed significantly from the rate HCFA had predicted based on the demographic and diagnosis-related characteristics of each hospital's discharges for that year.[11] When HCFA released the data, it cautioned that they should be viewed in the context of other relevant information and that there were many legitimate reasons why a hospital could appear on the list without having had any quality of care problems. Under the terms of its contract, each PRO is required to develop a plan for "validating" these data for each hospital identified in its review area as unusual with respect to overall mortality rates. However, HCFA prescribed no methodology for validating a PRO's list of such hospitals. The PROS were to initiate case reviews when they had reason to suspect that the mortality data reflected a problem in practices or procedures of care. They were then to implement programs of corrective action where problems were identified.

[11]The factors used to predict hospital mortality rates in that HCFA analysis were: proportion of Medicare discharges who were male, average age of Medicare discharges, proportion of Medicare discharges who were black, proportion of Medicare discharges who were other non-white, proportion of discharges in each of the most common 50 Diagnosis-Related Groups (DRGs), proportion of discharges in all other cancer DRGS not in the most common 50, and the Medicare average length of hospital stay in the state in which the hospital was located.

HCFA has not compared the findings of the individual PRO follow-ups on unusual mortality rates in order to assess the effectiveness of this method of identifying problems. That is, HCFA has not produced evidence about whether the hospitals identified as having mortality rates statistically higher than expected are engaging in questionable practices which are responsible for higher mortality rates, or whether hospitals providing substandard care are not being identified by this analytical approach.

To establish the validity of HCFA's screening and profiling methods it would be necessary to examine the accuracy and reliability of the data being reviewed and the appropriateness of the analytic methods. Some data elements in the Medicare administrative data files are validated, such as the diagnostic codes essential for determining hospital payments. There is little solid information on the extent or distribution of error in other data elements in those files, particularly those that are not used in determining eligibility, coverage or payment amounts (such as source or type of admission, or discharge destination).

In screening, the accuracy of data affects the level of precision that can be expected. For example, if a screen is used to identify diagnostic codes that indicate inappropriate care, and if these codes are frequently incorrect, then the screen may falsely identify many cases that should not be reviewed or fail to identify those that should be reviewed. In profiling, inaccurate data can undermine the validity of an analysis as a whole. For example, there is reason to be concerned about the reliability of data reported under "discharge destination," which is supposed to indicate whether a patient died before discharge, as well as whether a patient's destination after discharge was to some form of posthospital care or home without further care and whether the patient was discharged against medical advice. If this data element is used to calculate inpatient mortality rates, and if inpatient mortality is systematically underreported in some hospitals, then analyses of the mortality rate data could show relatively high mortality rates for hospitals that are providing complete and accurate data.

These problems can be mitigated by using mortality data from the updated beneficiary files that the Social Security Administration maintains (using mortality data supplied by HCFA, hospitals, and intermediaries, as well as notifications from survivors). HCFA's analysts and the California PRO have used these linked SSA data in mortality rate studies, but PROs do not generally verify mortality data from discharge

destination codes in producing profiles of hospital mortality rates. Nevertheless, hospital inpatient mortality profiles are mandatory under the contract of all PROs.

Practically no information is available on the validity of profiling methods in identifying meaningful problems with the care of patients. There are possible problems with both the measures of quality and the statistics applied in recent studies of health care outcome data. High mortality rates in individual facilities or physicians' practices may reflect unusually severe medical conditions rather than deficiencies in care.[12]

The lack of an adequate adjustor for the severity of patients' conditions in the analysis of inpatient mortality data undermines the validity of HCFA's analyses of death rates in hospitals. Experts have also questioned the validity of the statistical techniques being used to analyze these data.[13] For example, the use of standard statistical tests to analyze the distribution of infrequent events, such as inpatient deaths, could lead to the identification of too many or too few "outliers".

The Omnibus Budget Reconciliation Act of 1986 mandates the development of a research program, to be administered by the National Center for Health Services Research and Health Care Technology Assessment, to investigate the outcomes of selected medical treatments and surgical procedures. HCFA is also funding some research designed to examine whether data on outcomes provide valid indications of deficiencies in the process of medical care.[14] Although this research addresses only a limited range of medical conditions, it may provide some evidence about the validity or the utility of screens and other reviews that the PROs are required to conduct.

[12]HCFA is currently supporting research into the possibility of incorporating into Medicare hospital data measures of severity drawn from clinical information in patients' medical records. Eight PROs are participating in a pilot project to test an approach to identifying unsatisfactory and superior patterns of care for specific medical conditions. To standardize the acquisition of clinical data and to ascertain and quantify the severity of patients' conditions when they are admitted to hospitals, the PROs are using a commercially developed system for medical record abstracting, a byproduct of which is a score of severity of illness upon admission. HCFA's Office of Research and Demonstrations is providing supplemental funding to PROs so that they can collect and evaluate additional information relating to unusually long lengths of stay or high costs.

[13]For example, M. S. Blumberg, "Comments on HCFA Hospital Death Rate Statistical Outliers," Health Services Research, 21:6 (February 1987) and Luft. H. S. and S. S. Hunt, "Evaluating Hospital Quality through Outcome Statistics," Journal of the American Medical Association 225:20 (May 23-30, 1986).

[14]The project, the "Noninstrusive Outcomes Study", is being conducted by the Rand Corporation. The study is examining outcomes (primarily mortality and hospital readmissions) for two conditions, congestive heart failure and myocardial infarction.

Developing Quality Assessment Techniques for Alternative Delivery Systems

The new legislative requirement to review the quality of care provided to Medicare beneficiaries enrolled in capitated health care plans (HMOs and CMPs) provides an excellent opportunity to develop improved assessment techniques that can generate comparative information on levels of quality across alternative delivery systems.

If Medicare beneficiaries are to choose rationally among competing health care plans, they need information on the quality of care each plan provides and assurances that individual cases of poor quality can be identified and dealt with in a timely manner. HCFA needs similar information to monitor the performance of the HMOs and CMPs that work under contract with Medicare. HCFA collects enrollment data from capitated plans, but no data on their members' use of specific medical services or on the quality of care provided. The major alternatives for developing such information seem to be (1) implementing a system similar to the Medicare administrative data system for reporting uniform information on Medicare beneficiaries in capitated plans and (2) systematizing the periodic evaluation of quality in capitated plans by reviewing samples of medical records and data on health care outcomes.

The Medicare program is awarding contracts to peer review groups to review the quality of care in Medicare HMOs and the CMPs. Under the provisions of the Omnibus Budget Reconciliation Act of 1986, contracts will be awarded competitively in up to 25 states containing up to 50 percent of the Medicare beneficiaries enrolled in these plans; the PROs will review these services in the remaining states.

In HCFA's March 1987 request for proposals, it outlined an extensive set of review activities for contractors, including inpatient and post-hospital reviews modeled after the current PRO reviews and two types of review of ambulatory care. One type is a focused review of inpatient and ambulatory medical records based on 13 diagnoses which may indicate inadequate or poor quality care in ambulatory settings; the other is focused on reviews of medical records for selected cases and will use a methodology to be determined by negotiation between HCFA and the contractors. Developing information on the methods and findings of the quality of care reviews performed in HMOs and CMPs by the contractors could be extremely valuable.

Because information on individual patients is currently limited, there may be problems in implementing any review system in the HMOs and CMPs. Inpatient hospital reviews for patients in capitated plans will be based on samples of "HMO paid bills", hospital bills processed by

intermediaries. These bills are not used for reimbursement when HMOs contract directly with hospitals to pay for inpatient services; the bills they send to intermediaries are used only to keep track of days of care and the use of services with limited coverage (for example, units of blood). Thus, there is little incentive for hospitals to make sure the bills they send to intermediaries are either accurate or complete. Further, because there is no Medicare automated system for recording each ambulatory visit or health care encounter, each plan's files will have to be sampled, sometimes manually, sometimes using the plans' own computer systems, to select cases for random record reviews. Therefore, it will be important to determine the extent to which reliance on nonstandard data sources affects the efficiency or effectiveness of the review methodologies.

The legislative requirement provides an opportunity to address other key evaluation issues as well. Determining what, if any, administrative data are necessary to monitor quality of care in capitated plans is a particularly important one. HCFA is encouraging review organizations to develop and experiment with innovative methods of reviewing ambulatory care. This could provide an opportunity to compare the relative costs and benefits of reviews based on administrative data with reviews based on carefully selected samples of medical records. The usefulness of sampling cases for formal in-depth case review could be compared with the application of standard patient care screening tools. To the extent that individual contractors apply their own methods and technologies, there is an opportunity to compare and contrast the effectiveness and efficiency of a wide range of review systems. Doing this, however, would require the development of an overall evaluation plan; standard information would have to be collected from each contractor on review techniques, health services provided, health care outcomes, and quality of care problems identified.

HCFA's plans for evaluating the quality assessment methods of the contractors reviewing capitated health care plans are not yet clear. It is not likely that any substantial evaluation will be possible for the first round of contracts, considering the limited time HCFA had to plan the solicitation. In subsequent rounds, it may be possible to develop a systematic approach to evaluating the contractors' review methodologies.

Collecting Data on Long-Term Subacute Care

Nationally-representative data on the quality of care and the care needs of Medicare patients in posthospital care settings, and longitudinal data on the quality of care in skilled nursing homes could be generated from information included in Medicare and Medicaid survey and certification inspections.

Medicare provides only limited coverage for posthospital subacute care in nursing homes and does not cover the costs of long-term care. The importance of subacute services in long-term care settings for the growing number of frail and chronically ill elderly, intensified by payment incentives to reduce their time in hospitals, has nevertheless focused attention on the quality of the care provided to Medicare beneficiaries by skilled nursing facilities and home health agencies.

The survey and certification process for long-term care facilities (through which eligibility to participate in the Medicare and Medicaid programs is determined) has added a component for interviewing patients that is designed to produce information on residents' health care needs, the provision of services to them, and their outcomes. A patient-related survey of home health agencies has also been implemented.

Sampling experts under contract to HCFA have examined the feasibility of basing samples of patients on facility size and using them to develop a representative national sample of nursing home patients. Beginning in September 1986, surveyors began randomly sampling 20 percent of the patients in each facility. To allow flexibility in state surveys, they were given the authority to select additional patients to interview if necessary for following up on suspected problems. Because these additional cases are aggregated with the random 20 percent, the sample may not be representative of the nursing home population as a whole.

Currently, only summary data for each facility are reported to HCFA. The only survey data on patients that are recorded in HCFA's automated files are data on the average disability level of skilled nursing home patients by facility. The detailed patient-level interview data that are recorded on standardized worksheets are maintained by the states. With appropriate samples, these data could be aggregated, creating a data base that could be used to monitor levels of quality and needs for care over time in states, regions, and the nation. Together with the data on facilities collected in the survey and certification process, this information might help program analysts and policymakers determine how structural characteristics, such as staff size and qualifications, and use of technology

and equipment, are related to the quality of care patients receive. Similarly, appropriate sampling methodologies could turn home health surveys into an important source of national data on the needs Medicare patients have for care while recuperating at home and the ability of home health agencies to meet those needs.

Three Long-Term Strategies to Improve Quality Assessment

The decentralized structure of Medicare claims payment and restrictions in coverage both limit the development of comprehensive information on the quality of care provided to the program's beneficiaries. The Medicare program is vast and complex: more than 240 million Medicare claims for thousands of different types of services will be processed in 1987. Separate reimbursement and management information systems have been created to process these claims, which vary by type of service, site of service delivery, and medical insurance fund (part A or part B). Utilization review and quality assurance functions occur within these various systems, and in separate activities conducted by PROs and the survey and certification process administered by HCFA. Optimal quality assurance requires a very careful and intricate system of data collection, analysis, and feedback extending across the various components of the program and levels of review now operating. Clearly, such a system was not anticipated in the development of the Medicare program. Just as clearly, the introduction of quality review in separate parts of the program has not produced a systematic approach to assessing overall quality of care.

If HHS is to make a commitment to developing comprehensive and systematic information on the quality of medical care for Medicare beneficiaries, the agency will have to consider long-term strategies for integrating or coordinating existing Medicare review systems and, possibly, for creating new ones. We discuss three such strategies below. We are continuing to examine the feasibility of implementing these strategies and will discuss them in greater detail in our final report.

Integrating Contractors' Data Collection and Monitoring

A better integration of the data collection and monitoring responsibilities of the intermediaries and carriers that process claims with the activities of the PROs could result in more efficient detection and correction of problems in the quality of care.

Quality assessment may be designed to address a range of substantively different problems: detecting the unnecessary use of services, identifying substandard medical practitioners or facilities, and determining whether changes in Medicare payment methods have affected the quality of care. Some types of problems may be most efficiently detected by screening all bills, while other problems may be most efficiently detected by reviewing carefully selected medical records. Specifying the objectives of quality assessment is a prerequisite for determining which review methods are best applied and by whom.

Currently, intermediaries and carriers apply hundreds of computerized and manual edits and screens designed to detect inappropriate care, unnecessary care, and care that might not otherwise qualify for reimbursement under Medicare. Claims processors do not generally apply screens designed to detect quality of care problems per se. They do, however, work with medical professionals to conduct in-depth medical care reviews to establish the appropriateness and necessity of medical services. PROs use data from the intermediaries to identify cases for review, and, in the course of analyzing the files, apply some of the same automated screens or computer edits that intermediaries are required to apply (for example, the Medicare consistency editor program). This means that in addition to identifying cases with diagnostic codes that could indicate inappropriate or unnecessary hospital admissions, PROs identify cases with inconsistent or illogical information related to reported diagnoses and determine whether information necessary to calculate reimbursement levels is missing or inconsistent.

Exploring the feasibility of integrating what are now essentially independent and possibly redundant stages of claims processing and quality review is particularly important in view of the plans to expand PRO review to include ambulatory and physician services, and to redesign the Medicare computer and data systems. Coordinating effective screening and profiling with intensified case reviews using medical records could lead to a more efficient allocation of tasks.

Evaluating Ways of Incorporating Medical Records Review Methods Into PRO Review

An organized effort to evaluate options for incorporating valid and reliable medical records review methodologies using professionally recognized standards of care into PRO quality reviews could lead to less variability and greater effectiveness in quality assessment.

The criteria and standards peer reviewers apply in the assessment of the quality of care reflect both the generally recognized standards of medical practice and local or regional standards. The difficulty in agreeing on standards both reflects and is reflected in variation in medical practice across regions, between rural and urban areas, in different types of health care organizations (fee for service versus capitated) and in the professional literature about what constitutes appropriate medical care. Little is known about whether the variation reflects actual differences in quality.

Much has been learned from research on health care quality assessment since the Medicare program was created. Methods of addressing significant quality of care issues that might be applied across the Medicare range of services have been designed, tested, and implemented, but important questions about the validity and usefulness of various methods and approaches are widely debated.[15] One question has to do with the basic trade-offs between the application of explicit criteria that are detailed in written protocols and implicit criteria that set out general guidelines but demand a more extensive application of reviewers' medical knowledge and judgment. Some approaches to case review incorporate aspects of both; they might begin, for example, with explicit sets of criteria that allow a variety of contingencies to be taken into consideration (using a "branching" approach); or two-stage systems that base first-stage reviews on explicit criteria which are then followed by more definitive reviews using implicit criteria.

The problem facing the Medicare peer review system today is that no system continuously evaluates the available methods and furthers their development.[16] A coordinated effort to review the strengths and weaknesses of the PROs' case review methods could help systematize efforts to validate case review data for monitoring levels of quality within or across regions. A formal system for identifying, testing, and overseeing the use of improved medical record review methods could also be developed. The system would have to include routine input from the medical professional and research communities. Determining the appropriate organization of such a system would be a crucial part of this strategy.

Developing Epidemiological Data Bases

Because policy-relevant information on the overall quality of health care for the elderly and disabled cannot be obtained from Medicare's current administrative data base, epidemiological data bases might be developed for the entire Medicare population or for specific subpopulations potentially at risk with respect to access to health care or its quality. The data drawn from nationally representative samples could provide in-depth longitudinal information on the full range of Medicare beneficiaries' health care needs, use of services, and health outcomes.

[15]A. Donabedian, Explorations in Quality Assessment and Monitoring, vol.3, The Methods and Findings of Quality Assessment and Monitoring: An Illustrated Analysis (Ann Arbor, Mich.: Health Administration Press, 1985).

[16]R. H. Brook and K. N. Lohr, "Efficacy, Effectiveness, Variations and Quality: Boundary - Crossing Research," 23:5 (May 1985). 715.

Medicare does not cover all medical services and therefore its administrative data cannot provide all the information necessary for fully understanding the nature of health care services the elderly and disabled receive. Furthermore, national population surveys such as those conducted by the National Center for Health Statistics and the medical care expenditures surveys conducted by the National Center for Health Services Research and Health Care Technology Assessment currently cannot determine the extent or distribution of problems of quality or unmet need associated with access to or the use of the full range of health services over time.

However, data on the distribution of levels of quality in a population or over time could be developed from national samples.[17] Such epidemiological data bases might include samples of (1) Medicare beneficiaries dying each year, (2) patients identified each year through diagnostic data as having chronic diseases or conditions likely to be associated with impairments or limitations in their ability to perform the basic activities of daily living, (3) beneficiaries enrolled in health plans operating under alternative payment or reimbursement structures (fee-for-service arrangements, HMOs, CMPS and the like), or (4) cohorts of newly eligible Medicare beneficiaries.

All these data sources could provide information on use of health care services not covered by Medicare as well as about health status and health care outcomes. Using data from medical records and interviews with patients where appropriate, the first two types of samples would be particularly helpful in identifying possible problems with quality of care in populations likely to be at risk. The third type of sample would provide useful information regarding the relative costs and health benefits, including the quality of health care, associated with different approaches to providing and financing health care. The fourth would provide baseline information on the health care needs of the population entering the Medicare system and could track changes in the need for and access to appropriate health care services as the population ages. This approach could also assist in assessing problems of selection bias in different types of health care plans, that is, the possibility that beneficiaries with health care problems more extensive than those of the elderly population as a whole may be enrolling with particular providers, such as prepaid plans, or that prepaid plans are avoiding beneficiaries with extensive health care needs.

[17] A. Donabedian, "The Epidemiology of Quality," Inquiry, 22 (Fall 1985), 282.

While the costs of developing epidemiological data bases would vary according to the size of the samples and the populations they were drawn from, costs might be reduced by merging data collection efforts with ongoing health monitoring activities or by routinely requesting information through the Social Security Administration's systems for communicating with the elderly and disabled or by adjusting the case-review requirements of the PROs. Depending on who collects the data, obtaining full medical records could pose privacy problems. In organizing and using the data, privacy issues would require careful consideration.

Request Letter

March 3, 1986

The Honorable Charles Bowsher
Comptroller General of the United States
441 G Street, N.W.
Washington, D.C. 20548

Dear Mr. Bowsher:

As you know, budgetary pressures have forced a shift toward aggressive cost control in the administration of the medicare program. Prudent purchasing requires reliable information as to price and quality. However, in the area of health care, it is far easier to measure dollar savings than assess quality. As a result, gaps in information about quality could limit the government's ability to purchase the best available care at the lowest possible price.

In view of these considerations, the Subcommittee on Health of the Committee on Ways and Means would like the General Accounting Office to conduct a study which would examine options for monitoring and evaluating quality. We would like GAO to undertake two closely related tasks:

(1) Examine options for short-term improvements in the measurement of the quality of care in the medicare program.

We would like GAO to describe and analyze measures and methodologies that are currently available for the evaluation of quality of care. This review would focus on data elements that are routinely incorporated in medicare's administrative data system and elements which could be incorporated in the system with little additional cost.

(2) Develop recommendations for a long-term effort with regard to measuring and monitoring quality of care.

We would also like GAO to develop recommendations concerning a long-term strategy for monitoring and monitoring quality of care. This should include recommendations regarding future research efforts. In developing these recommendations, we would like GAO to comment on the adequacy of funding and the focus and direction of quality-related research activities currently supported or planned by the Department of Health and Human Services.

Because of the high level of interest and the importance of these issues, the Subcommittee would like this work to begin as soon as possible. We would like a briefing by January 1987 on your initial findings and recommendations and a final report by June 1987.

If you or your staff have any questions related to this request, please contact Stephen Bandeian of the Subcommittee staff at 225-7785.

Sincerely,

Fortney H. (Pete) Stark
Chairman

FHS/shb

Consultant Panel Members

In selecting consultants for this review, we sought individuals who could address quality assessment issues from a variety of perspectives, including clinical medicine, health services research, utilization and quality review, health care administration, and policy. We also wanted individuals familiar with all aspects of the Medicare program as it affects various health care settings, including skilled nursing facilities and home health services as well as hospital and physician services, and individuals knowledgeable about the needs and interests of Medicare beneficiaries. With the advice of health services researchers and medical care experts from a variety of national organizations, including the Institute of Medicine, the National Center for Health Services Research and Health Care Technology Assessment, and the American Medical Peer Review Association, we drew up a list of potential consultants, all of whom agreed to serve.

Robert Brook M.D
Senior Health Services Researcher
The Rand Corporation
Santa Monica, California

Earl David Buchanan
Executive Director
Utah PRO
Salt Lake City, Utah
Currently, Director, Quality Assurance Program,
Hospital Corporation of America,
Nashville, Tennessee

Margaret Cushman
President
VNA Group, Inc.
Plainville, Connecticut

Frederick Dettman, M.D.
Medical Director
Wisconsin Peer Review
Milwaukee, Wisconsin

Avedis Donabedian, M.D.
Nathan Sinai Distinguished Professor
Department of Health Services Management and Policy
School of Public Health
University of Michigan
Ann Arbor, Michigan
Did not attend January 8-9, 1987, panel meeting.

Richard Farmer, M.D.
Chairman
Division of Medicine
Cleveland Clinic Foundation
Cleveland, Ohio

Judith Lave
Professor of Health Economics
University of Pittsburgh
Pittsburgh, Pennsylvania

Vita Ostrander
Immediate Past President
American Association for Retired Persons
Atlanta, Georgia

Bruce Sams, M.D.
Executive Director
Permanente Medical Group
Oakland, California

Marvin Shapiro, M.D.
Vice President for Medical Affairs
U.S. Administrators
Los Angeles, California

Peter Shaughnessy
Director, Center for Health Services Research
University of Colorado
Denver, Colorado
Did not attend January 8-9, 1987, panel meeting.

Bruce Vladeck
President
United Hospital Fund of New York
New York, New York

Comments From the Department of Health and Human Services

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General

Washington, D.C. 20201

MAY 1 1987

Mr. Richard L. Fogel
Assistant Comptroller General
U.S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Fogel:

The Secretary asked that I respond to your request for the Department's comments on your draft report, "Measuring Quality: Preliminary Findings on Strategies for Assessing Medicare Health Care Quality." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

Richard P. Kusserow
Inspector General

Enclosure

Comments of the Department of Health and Human Services
on the General Accounting Office Draft Report,
"Measuring Quality: Preliminary Findings on
Strategies for Assessing Medicare
Health Care Quality"

GAO's report examines several basic contextual issues which affect the structure and operation of quality of care assessment activities. The report outlines two sets of strategies which, according to GAO, could be undertaken to improve the Department's ability to generate information on the quality of care provided to Medicare beneficiaries. GAO's analysis of these shorter-term and longer-term strategies is continuing and a subsequent final report will address these and other related issues in detail, as well as present any specific recommendations GAO may have.

As stated under the section describing the scope of the study (page 4), this report has been designed to address "...all of the quality-related activities performed by the Health Care Financing Administration (HCFA) for all Medicare-covered services," with an emphasis on measuring and monitoring the processes and outcomes of health care services.

The report, however, does not take into account the extensive projects relating to quality of care assessment currently underway within HCFA. These studies form a comprehensive quality assessment program and draw heavily upon epidemiological analyses utilizing existing Medicare population-based data. Additionally, HCFA has invested heavily in medical record-based clinical analyses of the process of in-hospital care and in the development of hospital-specific quality indicators.

In addition, HCFA is initiating major studies in the area of post-hospital services by tracking patients over time using linked (longitudinal) data bases, and in the development of survey methods to assess the appropriateness of aftercare. In revising this report, GAO should either limit the scope of the study appropriately, or take these studies directly into account in its evaluation.

Now page 21.

More specifically, in describing strategies for improving efforts to monitor or measure quality of care (beginning on page 24), we have the following comments:

See comment 1.
Now page 25.

1. In discussing HCFA's efforts to assess the reliability and validity of post-hospital mortality data (page 31), the report should take into account a current study HCFA is conducting with the Rand Corporation to identify and validate nonintrusive quality outcome measures.

See comment 2.
Now page 28.

2. The discussion of nationally representative longitudinal post-hospital data (beginning on page 38) similarly fails to take into account several linked data bases HCFA is utilizing to evaluate patterns of post-hospital usage and outcomes. Additionally, this section fails to acknowledge a major survey-based study to assess the appropriateness of aftercare.

The comments which follow are divided into three areas to address GAO's: short-term strategies; long-term strategies; and, other comments.

SHORT-TERM STRATEGIES

1. The planned development of a merged Part A and Part B automated data system is a prerequisite for effective program-wide quality assurance. Adding uniformly-coded diagnostic data to Medicare Part B (physician) claims in this merged file system could greatly increase the program's ability to measure and monitor the quality of care delivered in individual settings of care, as well as throughout entire episodes of illnesses.

Department Comment

This suggestion is most appropriate. The need for this type of data base has been recognized by HCFA for some time and measures are being taken to develop it. We are currently assembling an on-line combined Part A - Part B data base for 1987. The linkage of Part A and Part B data is critical if we are to follow patients longitudinally beyond discharge from the hospital. This is an integral component of the analyses of quality of care.

In addition, HCFA has a project under way called CABLE, Combined A/B Local Eligibility System, which will merge Part A and Part B utilization and eligibility data in a beneficiary specific file and be made available to HCFA contractors. CABLE pilot tests are being planned at two processing sites.

2. Producing information on the validity and effectiveness of current methods used 1) to screen for possible quality of care problems, and 2) to profile provider performance or patient care outcomes, could significantly increase the credibility of HCFA quality assessment activities.

See comment 3.

Department Comment

We concur with the need to develop and validate effective procedures to screen for problems in the quality of care and to profile performance. We are developing a methodology for the uniform and systematic screening of cases for PRO review. Our plans are to pilot test and validate the effectiveness of this methodology in the 1988 PRO contract cycle.

As GAO indicated, the absence of measures of severity of illness from our data base does limit confidence in the profiling of provider performance. We are, in collaboration with a group of PROs, as indicated in the GAO report, exploring an approach to the acquisition of the data needed to effectively assess the severity of illness. Based on the results of these efforts, consideration will be given to mandating the collection of selected clinical data to assist us in assessing and measuring quality of care.

Under this short-term strategy, GAO criticized HCFA for not effectively evaluating the effectiveness of the hospital outlier list published in March of 1986. The information was developed not as a definitive statement on hospital performance but as a problem identification tool to be used by the PROs to first confirm the data and then, using specific medical review and understanding of the environment, validate the existence of actual problems. Where problems were confirmed, PROs were expected to address the problem as objectives which outline a strategy to correct the shortcoming and a target for determining achievement. As a result of this activity, many hospital, physician and DRG specific objectives were negotiated and are currently being implemented by PROs. In addition, the PROs, after in-depth review, found that many of the apparently aberrant performers' appearance on the lists could be explained in terms of patient case mix factors such as severity of illness or referral patterns. HCFA will continue to analyze the effects of the hospital outlier list as a screening tool.

In this regard, HCFA plans a second release on hospital performance late this year. However, a more refined methodology will be developed for this purpose with advice obtained from outside experts. Current plans provide for data analysis of overall hospital performance using mortality rates and rates in certain DRG areas. This information will be developed on all providers and made public after they have been given adequate opportunity to review the information and submit written explanations to be included with the public release.

Again, the PROs will be required to validate the information and develop objectives or corrective action plans to resolve any confirmed problems. To complete the cycle of the data analysis and follow-up, 12 months after the information is released, HCFA plans to

publish an update for 1987 which will consist of hospitals where problems were identified, what the problems were/are, and what actions were being taken to correct the problems found. This, in effect, would assess the effectiveness of the profiling methodology in identifying problem providers.

See comment 4.

3. The new legislative requirement to review the quality of care provided to Medicare beneficiaries enrolled in capitated health care plans (HMOs and CMPs) provides an excellent opportunity to develop improved assessment techniques that can generate comparative information on levels of quality across alternative delivery systems.

Department Comment

GAO recognizes that this is not possible in the upcoming "round" of health maintenance organization/competitive medical plan (HMO/CMP) reviews. Therefore, GAO suggests that we develop such a system in the next round. HCFA concurs. Naturally, we plan to explore the development of a methodology to evaluate the effectiveness and efficiencies of alternative systems.

Furthermore, despite the limited time, HCFA expects to have a systematic, substantial approach to the evaluation of HMO/CMP quality review in place by the end of the first contract cycle. HCFA's evaluation approach will involve review of contractor reports, periodic monitoring of contractor performance by central and regional offices, a survey of HMO/CMP beneficiaries and rereview of a sample of contractor decisions by an independent review entity.

See comment 5.

4. Nationally-representative data on the quality of care and the care needs of Medicare patients in post-hospital care settings, and longitudinal data on quality of care in skilled nursing homes, could be generated from new information to be included in Medicare and Medicaid survey and certification inspections.

Department Comment

We agree with this suggestion in principle (which is also a recommendation of the Institute of Medicine Report on Nursing Home Regulation). However, extensive research is necessary to achieve enough data to incorporate the suggestion in the survey and certification system. We have requested $3.5 million for a 5-year period to gather this needed data.

LONG-TERM STRATEGIES

1. Better integration of the data collection and monitoring responsibilities of claims processors (intermediaries and carriers) and PROs could result in more efficient detection and correction of quality of care problems.

See comment 6.

Department Comment

We concur. In the next scope of work, we plan to require pilot testing of screening based on a uniform data set in a variety of PRO settings. In addition, HCFA continues to work diligently on improving the integration of the data systems of fiscal intermediaries, carriers, and PROs. We strive to reduce duplication, increase timeliness and to assure common definitions. The activities performed by HCFA have already resulted in improved data analysis capability.

2. An organized effort to evaluate options for incorporating valid and reliable medical record review methodologies into PRO quality review could lead to less variability and greater effectiveness in Medicare quality assessment activities.

Department Comment

We agree. We have understood the need to develop effective and uniform medical record review strategies and have taken action.

Currently we have eight pilot studies to develop a medical record abstracting methodology which will accurately and efficiently develop individual and composite profiles. This will facilitate PRO quality review.

We plan to use the findings of these studies to establish a general abstracting requirement in the next PRO scope of work. In conjunction with this, we will require a number of PROs to utilize these abstracts in a medical review system that will use computer programming to identify cases with potential quality problems which will require physician review.

See comment 7.

3. Because policy-relevant information on the overall quality of health care provided to the elderly and disabled populations cannot be obtained from the current Medicare administrative data base, policymakers might consider developing a set of epidemiological data bases, either for the entire beneficiary population or from specific subpopulations potentially at risk with respect to access to health care or deficient levels of quality. These data could be drawn from nationally representative samples and could provide in-depth longitudinal data on the full range of Medicare beneficiaries' health care needs, utilization, and outcomes.

Department Comment

We recognize the importance of data as a tool for both the Government in assessing appropriate quality and utilization as well as for beneficiaries to use to make informed decisions as to the appropriate setting and the expected outcome for a proposed treatment. As part of our ongoing process of monitoring the quality of care and assessment of PRO impacts, we have constructed a series of epidemiologic data bases which link Part A and Part B data. We are expanding these data sets to include more complete clinical data and will extend this effort further in the 1988 cycle of PRO contracts.

OTHER COMMENTS

See comment 8.
Now page 14.

- On page 12, GAO characterizes responsibility for assessing quality of care within HCFA as being not clearly defined. It would be more accurate to state that responsibility is shared among several HCFA components. The rationale describes which components have responsibility for the different provider types.

See comment 9.
Now page 15.

- Page 13 states that PRO review of physicians' services in office settings will begin January 1, 1989. Actually, OBRA does not mandate review by this date, but rather precludes review in physician's office settings until that date.

See comment 10.
Now page 15.

- Page 13 states that recently negotiated PRO contracts do not reflect the OBRA mandates for review of post hospital settings. Again, this phrasing is misleading as the OBRA provisions are effective only for contracts entered into on or after 1/1/87: OBRA provisions will be included in HMO/CMP review effective 6/1/87.

See comment 11.
Now page 15.

- The description of the A/B link on page 15 is not correct. When the PRO denies surgery because it is medically unnecessary, the carrier automatically effectuates a denial of the associated physicians' services.

See comment 12.
Now page 17.

- On page 18, GAO criticizes the flexibility given to PROs to use locally developed criteria and to identify local problems. The PRO statute requires this flexibility.

See comment 13.
Now page 18.

- On page 19, GAO criticizes HCFA for not providing adequate guidance regarding sampling or statistical procedures. We disagree. In addition to explicit instruction as a supplement to the Request for Proposal, we have held national and regional data meetings to discuss our procedures and answer questions. As validation of the effectiveness of this training, our preliminary assessments indicate that the great majority of PROs are correctly sampling. The problems which PROs have in the data area do not appear to be a lack of understanding, but rather systems problems which have impeded implementation.

See comment 14.
Now page 19.

- On page 20, GAO questions the process HCFA uses to get input from the professional medical community. As we have done in the past, we plan to continue dialogue with the professional community. Almost all policies and procedures developed are developed after discussion with appropriate organizations and individuals in the community. In addition, we seek specific guidance on criteria and review methodologies from affected professional societies. For example, the criteria we will issue shortly for the surgical second opinion program were developed after dynamic discussions with specialists from various interest groups, including the American Medical Association, the American College of Osteopathic Surgeons, the American College of Surgeons, the American Hospital Association, the Federated Ambulatory Surgery Association, and the Society of Office Based Surgery. In addition, HCFA recently held a series of meetings with representatives of the medical community including hospitals, physicians, and PROs to discuss the development of HCFA's quality assurance program.

See comment 15.
Now page 20.

- On page 22, GAO reports that no patient level data are reported to HCFA by capitated plans. This is incorrect. The UB-82 requires such reporting for all Medicare beneficiaries discharged from a hospital including all HMO enrollees.

See comment 16.
Now page 21.

- On page 25, GAO's call for diagnostic data on ambulatory claims might be contested. We are getting the HCFA Common Procedure Coding System but not diagnostic data through outpatient and Part B Medicare Annual Data claims. Our only experience with diagnosis on Part B claims, a 5 percent sample through 1969 which was discontinued, was not successful due to the ambiguities of entries on the forms. Whether the possible benefits derived from such ambiguous data would be outweighted by the administrative burden of maintaining a Part B diagnostic data base is questionable. Perhaps samples of medical discharge and physician contacts obtained on an ad hoc basis, rather than on administrative payment forms, would be more useful and less costly.

See comment 17.
Now page 25.

- On page 33, GAO suggests that SSA files be used to obtain mortality rates, a procedure that HCFA has followed for some time.

See comment 18.
Now page 25.

- Also on page 33, GAO discusses the reliability of data reported in the "discharge destination" field. Analyses of data reported in the "discharge destination" field of the inpatient hospital bill does not accurately reflect beneficiary use of post-hospital services. HCFA has checked the "Died" indicator against mortality data found on the master beneficiary record and found this information to be reasonably accurate. However, when indicators for other destinations, such as "to SNF" and "to HHA," were checked against Medicare bills submitted for services after hospitalization, we found the data grossly inaccurate, and not an adequate measure of Medicare services received after hospitalization.

GAO Comments

HHS has agreed or concurred in whole or in part with the appropriateness of all the short and longer-term strategies discussed in this report. The agency believes, however, that the report does not sufficiently take into account the studies underway at HCFA to address quality of care issues, and asserts that these studies "form a comprehensive quality of care assessment program." A series of technical points are also raised.

Because this report has been designed to present only a brief summary of our preliminary analyses, we have not provided details about the data sources or research efforts reviewed in the course of our work. These details will be presented in greater depth in our final report. We recognize the importance of the work currently being done by HCFA to examine quality of care issues, and we did in fact refer to several research projects HHS has described, both in the text of the report and in footnotes. We do not, however, agree that these studies can be viewed as a comprehensive quality assessment program in the absence of an organizational structure for developing, coordinating and disseminating information about methods or procedures for assessing quality of care, or a mechanism for integrating the results of ongoing review activities. (See p. 17, and comments 1 and 6 below).

Specific responses to HHS comments (keyed to the numbers indicated in the margins of the comments), are presented below.

1. The study of nonintrusive quality outcome measures referred to by HHS was discussed briefly on page 35 of the review draft. It examines whether outcomes (primarily mortality and hospital readmissions) are valid indicators of quality of care with respect to two conditions (congestive heart failure and myocardial infarction). A footnote adds information about the outcome measures and who is conducting the study. (Page 35 is now page 26).

2. This section of the report focuses on the development of longitudinal, nationally representative information on patient care needs, the provision of services, and health care outcomes in subacute care settings, rather than on tracking the use of and access to care for Medicare patients discharged from acute care hospitals. While we agree that HHS efforts to develop better information on posthospital care for Medicare beneficiaries are important, neither the analysis of linked data on the use of Medicare services nor the aftercare study mentioned by HHS addresses the overall levels of quality of care provided to patients in subacute care settings.

3. HHS discusses the process for using hospital outliers lists to identify possible problems in patient care. This process provides a mechanism for implementing and assessing one aspect of PRO contract performance, but it does not assess the effectiveness of the methodology. HCFA has instituted a process for determining whether the hospitals identified as outliers have quality of care problems, characterizing the problems, and correcting them. This is clearly an important program responsibility. However, as HHS has pointed out, the inclusion of many of the apparently aberrant performers on the outliers lists could be explained by factors such as severity of patients' conditions, etc.. HHS states that HCFA will continue to analyze this screening tool. In the meantime, PROs will be required to determine whether hospitals identified as outliers are really outliers with respect to mortality rates. (We outlined the process HHS discusses on pp. 24-25).

What we are emphasizing in this section of the report, however, is the need to determine whether this profiling tool (or any screening or profiling method used by PROs or other Medicare contractors) effectively targets quality of care reviews. There does not seem to be a system in place to review what the individual PROs have learned in the course of their work with the screens and profiles, or to evaluate the relative effectiveness of alternative methods PROs and others may have developed for screening cases and profiling providers or patient care outcomes. This would require confirming that an acceptable proportion of cases identified as potentially aberrant on either screens or profiles were truly aberrant, and also that equally aberrant cases were not missed.

4. We are pleased that HHS plans to have a systematic approach to the evaluation of HMO/CMP quality review programs. We reiterate our concerns, however, that evaluation plans should include attention to relative effectiveness of review methods in identifying quality of care problems, as well as to contract compliance issues.

5. We support HHS's efforts to improve the quality and usefulness of survey and certification data. Our final report will address the issues of design and cost in greater detail.

6. The 8 pilot projects referred to by HHS are described on p. 26 of the review draft (p. 26)

7. While we agree that developing epidemiological data from existing administrative data files will improve HCFA's quality assessment capabilities, we also believe it is important to consider developing longitudinal data on the use of services and access to appropriate care, including services not covered by Medicare or other federal programs, and on beneficiaries health care needs and outcomes of care. These issues cannot be addressed with current administrative data.

8. We agree that the responsibility for assessing quality of care is divided among several components, but the fact remains that there is no single unit within HCFA with responsibility for assessing the overall quality of care provided to beneficiaries.

9. The wording about the legal provisions for PRO review of physicians' services in office settings, now on p. 15, has been revised to reflect HHS's concerns.

10. The wording about expanding PRO responsibilities to reflect the provisions of the Omnibus Budget Reconciliation Act of 1986, now on p. 15 has been clarified.

11. The wording about carrier denials of physician claims associated with PRO denials of medically unnecessary surgery, now on p. 15, has been clarified.

12. We acknowledge both the legal requirements and the benefits which can derive from the flexibility PROs have to use locally developed criteria and to identify local problems. The problems we discuss are not criticisms of the concept of flexibility; they are statements of problems which may be associated with it and which therefore need to be addressed. (See p. 16).

13. Our concern that PROs received only limited guidance on the new sampling procedures introduced in the second round contracts was initiated by discussions with the members of our consultant panel, who had been in contact with many PRO officials and technical staff. We were told that PROs had considerable difficulty understanding HCFA instructions for developing the random 3 percent sample, and, as a result, the reviews actually completed for the baseline random sample might not be truly random. Our interviews with HSQB staff reinforced our concerns that problems with drawing and completing review of sampled cases were significant, and that HCFA efforts to address these problems were limited. (See p. 18)

14. While HCFA has sought the input of the professional medical community on a number of occasions, these contacts generally have been designed to address particular issues of immediate concern. The strategy reviewed in this section is to create a structured, on-going system whereby the professional community has the opportunity to provide input into HCFA quality assurance programs and policies on a regular basis. We believe this strategy could alleviate concerns about the intent and implementation of quality review that might otherwise undermine the program's credibility. (See pp. 18-19).

15. We discussed the submission of hospital "HMO paid bills" on p. 37 of the review draft. Intermediaries process and submit to HCFA bills from hospitals for beneficiaries enrolled in Medicare HMO/CMPs. While HHS is technically correct in pointing out that information on hospital discharges for beneficiaries enrolled in capitated plans is reported to HCFA, less than one-quarter of Medicare beneficiaries are hospitalized in any given year. No patient-level information is available for enrollees in capitated plans who have not been hospitalized, and no information on any use of medical services other than inpatient care is reported. (See p. 20).

16. Our analysis thus far suggests that the importance of ambulatory diagnostic information in designing effective quality reviews outweighs potential problems. A report issued in July, 1986 by the National Committee on Vital and Health Statistics on Statistical Aspects of Physician Payment Systems also reached this general conclusion. HCFA's reference to a sample discontinued after 1969 is not particularly germane, given the changes in diagnostic coding systems and practice that have occurred as a result of the transition from IDCA-8 to IDC-9-CM, and the fact that some carriers already gather and analyze diagnostic data on a routine basis.

17. We do not disagree with HHS. The issue is not whether HCFA central or regional offices can use Social Security Administration data to obtain mortality rates (as we discuss on p. 33 of the review draft) but whether individual PROs use Social Security data to verify mortality when they produce the mandated profiles of inpatient mortality for HCFA. In most cases, they do not. (See p. 24).

18. Other studies of the accuracy of codes in the discharge destination field indicating inpatient death have shown the codes to be seriously inaccurate. For example, a study of discharges in a period covering 1984 through 1986 (funded by HSQB and conducted by California Medical

Review, Inc.) found that 544 of 2,364 cases (23 percent) reviewed had incorrect discharge disposition codes, and of these, 315 were coded as discharged alive when the patient had actually died in the hospital (see comment 17).

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