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Health Services Quality and Public Health Issue Area Plan

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Foreword

As the investigative arm of the Congress and the nation's auditor, the General Accounting Office is charged with following the federal dollar wherever it goes. Reflecting stringent standards of objectivity and independence, GAO's audits, evaluations, and investigations promote a more efficient and cost-effective government; expose fraud, waste, abuse, and mismanagement in federal programs; help the Congress target budget reductions; assess financial and information management; and alert the Congress to developing trends that may have significant fiscal or budgetary consequences. In fulfilling its responsibilities, GAO performs original research and uses hundreds of databases or creates its own when information is unavailable elsewhere.

To ensure that GAO's resources are directed toward the most important issues facing the Congress, each of GAO's 32 issue areas develops a strategic plan that describes the significance of the issues it addresses, its objectives, and the focus of its work. Each issue area relies heavily on input from congressional committees, agency officials, and subject-matter experts in developing its strategic plan.

The Health Services Quality and Public Health issue area is responsible for GAO's work on national and public health issues. The issue area focuses on ensuring patient and beneficiary access to quality care in a changing health system and on measuring the outcomes and effectiveness of federally funded programs, research, and regulatory activities. The issue area's operational oversight includes the programs of the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), Centers for Disease Control and Prevention (CDC), and other public health service agencies in the Department of Health and Human Services (HHS).

GAO's work on health services quality and public health issues generally focuses on the following issues:

- identifying opportunities for improving the nation's access to health care and ensuring accountability for performance in fee-for-service and managed care systems;
- identifying opportunities for improving the quality of health care financed with federal dollars;
- evaluating the efficiency and effectiveness of FDA's regulation of pharmaceutical and medical device products and assessing developments in the pharmaceutical and medical device industries;

- determining if the public health service agencies are meeting the public health needs of the nation efficiently and effectively; and
- assessing emerging legal, technical, confidentiality, and efficacy issues related to health care information.

In the pages that follow, we describe our key planned work on these pivotal issues.

Because events may significantly affect even the best of plans and because periodic measurement of success against any plan is essential, our planning process allows for updating and provides flexibility to respond quickly to emerging issues. If you have any questions or suggestions about this plan, please call me at (202) 512-7119.

Bernice Steinhardt
Director
Health Services Quality and Public Health Issues

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Table I: Key Issues

Issue	Significance
Access and accountability in health service delivery: How can the United States improve access to health care and ensure accountability for performance in both fee-for-service and managed care systems?	As health care is increasingly taking place in a managed care environment, there are bipartisan concerns about access to care, particularly for vulnerable populations, and how to hold plans accountable for performance. Questions also are being raised throughout the health system about outcome measurement and how to influence care provided to ensure equity—including in rural areas—and efficacy of results.
Quality of care: Given pressures to control costs, what measures should be taken to ensure that the quality of the nation's health care is maintained?	The federal government finances Medicaid and Medicare and public health care systems, which provide health care to millions of people each year. In addition, the private sector has launched a number of major initiatives in the field of quality of care with implications for oversight of health care programs. These include the growing use of standardized performance measures by major public and private purchasers of care. As the Congress considers ways to curb rising health care costs and make further cuts to control the deficit, information about existing quality problems, developments in the field of quality of care, and ways the Congress can safeguard quality of care will be crucial.
Drug and medical device development and regulation: How do FDA regulatory processes and cost factors influence the development of and access to drugs, medical devices, and other medical products?	In recent years, advances in medical technology have held promise for providing better methods to identify diseases and therapies for treating them. However, the drug, device, and biotechnology industries claim that excessive FDA regulation causes unwarranted delays in product approval and, as a result, delays patient access to these new products. These critics have proposed fundamental changes in the role and policies of FDA, including increased recognition of drugs and devices approved in other countries. In response, FDA is changing some procedures, and the Congress is considering a wide range of reforms. The Congress will require the best possible evidence on how well these alternatives work and how they affect patients and insurers, who must pay the ever increasing costs of new therapies and treatments.

Table I: Key Issues

Objectives	Focus of Work
—Provide the Congress with a better understanding of available management-of-care techniques. —Identify emerging trends regarding access and quality in managed care and fee-for-service medicine. —Identify alternative approaches to funding graduate medical education.	—Increasing the use of screening services for Medicare diabetics —Enrollment patterns of the chronically ill in Medicare managed care plans —Access to new and costly AIDS drugs —Basis for current Health Care Financing Administration subsidies of graduate medical education and possible improvements to the payment methodology —Impact on the supply of qualified physicians in restructuring payments for graduate medical education
—Identify ways to maintain and improve quality of care financed with federal funds. —Investigate differences in the quality of care provided in the fee-for-service and managed care systems. —Identify the quality implications of anticipated or proposed legislative health care initiatives.	—Initiatives of state governments to monitor and improve quality of care through the use of quality data reporting —Provider efforts to ensure quality services for Medicare beneficiaries with end-stage renal disease —Ensuring that quality care is provided to residents in assisted living environments —Public and private sector initiatives to provide purchasers, consumers, and providers with information about the quality of care —Private sector efforts to develop performance measures and require their use by health plans and providers to improve quality of care —Recent legislation intended to better ensure access to quality care
—Analyze and assess the impact of changes in the pharmaceutical industry on federal programs and on federal beneficiaries. —Assess changes in FDA's processes for reviewing and approving new medical products. —Determine the adequacy of FDA's post-market surveillance programs in identifying and analyzing adverse product experiences. —Provide a factual basis for assessing various regulatory reform proposals.	—FDA's regulation of the drug advertising and promotion activities of pharmaceutical companies —FDA's regulation of information on off-label uses of approved drugs —Clinical drug research in children —FDA's regulatory standards and approval processes for new medical devices —Alternative approaches to expedite FDA's approval of new drugs and medical devices while maintaining safety and efficacy standards —FDA's post-market surveillance activities for medical products, including adverse reaction reporting processes —Adequacy of surveillance and enforcement operations associated with importing drugs —FDA's inspection of foreign drug manufacturing facilities —Evaluation of the impact of the Prescription Drug User Fee Act of 1992

(continued)

Table I: Key Issues

Issue	Significance
Public health: How effectively are federal agencies and public institutions meeting public health needs given budget constraints and the shift to managed care?	Within the context of budget deficit reduction and reinventing government, many changes are occurring in HHS' eight major public health agencies and their numerous subagencies and programs. Specific HHS discretionary programs are to be consolidated into Performance Partnerships or block grants. These changes will have a significant impact on community health centers, public hospitals, and other institutions charged with meeting the nation's public health needs. Furthermore, the shift to managed care is affecting the operation of public health programs and traditional safety net providers in all parts of the health system.
Emerging issues in health information: How will new health information and information systems affect patient care and privacy?	With expanded computerization of patient data, an increase in demand for assessment of the outcomes of patient care, and research into human genetics, many difficult questions are being raised. In the recently enacted Kassebaum-Kennedy insurance portability bill, provisions exist for the development of an extensive health information network. Of paramount concern in developing such a network are the trade-offs among ethical issues, cost, privacy, and efficiency.

Table I: Key Issues

Objectives	Focus of Work
—Assess the ability of public health service agencies and programs to conduct health service activities after organizational and structural changes have been made and in light of the shift to managed care. —Assess the need for and type of federal oversight and accountability measures that can be used to ensure federal dollars are effectively used under Performance Partnerships. —Review the capacity of essential providers to meet public health needs. —Study the problem of substance abuse, particularly among teens, and the effectiveness of the federal response and programs to prevent substance abuse.	—CDC's capacity to respond to public health threats —The quality of state and local government surveillance data provided to CDC and the risks associated with underreporting of emerging diseases —Effectiveness of current federal organ transplantation program in light of shift to managed care —Development of performance measures for block grants or Performance Partnerships —Financial and administrative oversight of NIH research projects —Impact of health system changes on safety net providers, teaching hospitals, and centers of excellence —Effectiveness of SAMHSA's Community Partnership Demonstrations for Substance Abuse Prevention —Substance abuse by adolescents
—Explore the impact of recent developments in health information on patients and providers. —Examine the effectiveness of, and barriers to, dissemination of information about discoveries and innovations affecting patient care. —Review the safeguards to ensure patients are treated ethically (i.e., maintain privacy and obtain informed consent).	—Patient confidentiality and the trade-offs involving uses of data for research and oversight —NIH's human genome project —Development and use of automated patient records by integrated health networks and managed care organizations

Table II: Planned Major Work

Issue	Planned Major Job Starts
Access and accountability in health service delivery	—Examine use of federal practice guidelines in health plans to ensure access to quality care. —Assess the effectiveness of the 1992 Mammography Quality Standards Act. —Evaluate access to specialty services in managed care plans, particularly for vulnerable populations. —Assess cost-effectiveness of federally funded rural and other underserved area programs. —Examine how Medicare beneficiaries with diabetes receive recommended services from managed care and fee-for-service providers. —Examine whether managed care's richer benefits attract and retain chronically ill Medicare beneficiaries. —Examine the impact of insurance coverage limits on access to emergency room services. —Examine the underlying causes for significant variations in direct medical education payments made to hospitals by Medicare.
Quality of care	—Identify alternative quality assurance models for the Medicare program. —Describe state monitoring of the quality of managed care organizations. —Examine current initiatives to provide consumers with information about the quality of long-term care services. —Examine why physicians terminate their contracts with managed care organizations. —Assess the effectiveness of Medicaid's Early and Periodic Screening Diagnosis and Treatment Program. —Determine the impact of quality measurement by insurance purchasers on provider or plan behavior.
Drug and medical device development and regulation	—Examine FDA's regulation of the advertising and promotion activities of pharmaceutical companies. —Examine FDA's guidance on disseminating information on off-label uses of approved drugs. —Examine clinical drug research in children. —Identify opportunities to increase the efficiency of drug development research conducted during the clinical phase. —Analyze alternative approaches to expedite FDA's approval of new drugs while maintaining safety and efficacy standards. —Examine third-party review and approval of medical devices. —Examine the effectiveness of FDA's drug evaluation and approval process. —Assess FDA's post-market drug surveillance activities, including adverse reaction reporting processes. —Evaluate the adequacy of surveillance and enforcement operations associated with importing human drugs from overseas. —Examine FDA inspections of foreign drug manufacturing facilities and imported pharmaceutical products. —Examine FDA actions on medical device surveillance reports. —Evaluate the impact of the Prescription Drug User Fee Act of 1992 on expediting FDA drug approvals.

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Table II: Planned Major Work

Issue	Planned Major Job Starts
Public health	—Evaluate CDC's management and priorities in responding to public health threats. —Examine the impact of managed care on organ transplantation facilities and transplantation recipients. —Review the development of performance measures for block grants/Performance Partnerships. —Examine the effect of for-profit hospitals acquiring the assets of not-for-profit institutions. —Evaluate SAMHSA's Community Partnership Program for Substance Abuse.
Emerging issues in health information	—Review the impact of new technology and new research—notably genetic discoveries—on patient care and access to health insurance. —Assess the impact on patients of integrated data systems. —Examine confidentiality and privacy implications of, and safeguards for, collection of extensive patient data by health networks.

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