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Foreword

This report was prepared primarily to inform Congressional members and key staff of ongoing assignments in the General Accounting Office's Health Services Quality and Public Health issue area. This report contains assignments that were ongoing as of January 2, 1997, and presents a brief background statement and a list of key questions to be answered on each assignment. The report will be issued quarterly.

This report was compiled from information available in GAO's internal management information systems. Because the information was downloaded from computerized data bases intended for internal use, some information may appear in abbreviated form.

If you have questions or would like additional information about assignments listed, please contact Bernice Steinhardt, Director, on (202) 512-6543.

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PUBLIC HEALTH

TITLE: **REVIEW OF STRUCTURE AND ACTIVITIES OF FOUNDATIONS RESULTING FROM NONPROFIT HOSPITALS' CONVERSION TO FOR-PROFIT STATUS (108295)**

BACKGROUND : Increasingly investor-owned corporations are buying/joint venturing with nonprofit hospitals. Nonprofit hospitals converting to for-profit status must direct the net value of their assets to a charitable purpose. Most hospitals endow these funds to a foundation. Congress is concerned about the trend in nonprofit hospital conversions and the impact on charity care.

KEY QUESTIONS : (1) What is the status of nonprofit hospital conversions to for-profit status? (2) To what extent are funds from conversions directed to foundations? and (3) How are foundations fulfilling their charitable mission?

TITLE: **COMPLIANCE WITH REQUIREMENTS FOR RESEARCH ON TRANSPLANTATION OF HUMAN FETAL TISSUE (108299)**

BACKGROUND : Transplantation of human fetal tissue has promise for patients with such conditions as juvenile diabetes and Parkinson's disease. Yet NIH supported research has been controversial due to ethical concerns. 1993 legislation stipulated certain donor protections.

KEY QUESTIONS : (1) To what extent has research on the transplantation of human fetal tissue adhered to informed consent procedures, audit requirements, state and local laws, and reporting requirements? (2) To what extent have there been reported violations in the acquisition of human fetal tissue for use in transplantation?

TITLE: **ASSESSMENT OF DRUG PREVENTION AND TREATMENT STRATEGIES (108300)**

PUBLIC HEALTH

TITLE: **REVIEW OF FDA'S EFFORTS TO ENSURE THE SAFETY OF HUMAN TISSUE FOR TRANSPLANTATION (108306)**

BACKGROUND : The American Association of Tissue Banks (AATB) has accreditated about 60 tissue banks but an unknown number of banks are not accredited. In 1993, because of concerns about human tissue safety, FDA issued interim rules for tissue bank operations, including donor screening and disease testing, to guard against disease transmission from tissue transplantation.

KEY QUESTIONS : Are tissue banks being adequately monitored to guard against the transmission of diseases? (1) To what extent has FDA identified the universe of tissue banks in the nation? (2) To what extent has FDA monitored the safety of human tissue? (3) What inspections has FDA conducted and what are their results?

OTHER ISSUE AREA WORK - HSQP

TITLE: **QUALITY OF CARE FOR MEDICARE ESRD PATIENTS (101497)**

BACKGROUND : Medicare pays about $7 billion per year for 250,000 victims of End Stage Renal Disease ESRD). HCFA has reported results from a study of the quality of care for ESRD beneficiaries showing room for improvement. However, the study does not differentiate among provider types. Some allege that ESRD patients enrolled in HMOs receive poorer quality care.

KEY QUESTIONS : 1. What are the accepted performance indicators for measuring the quality of care provided to ESRD patients? 2. Compared with these standards, how does the quality of care for patients with ESRD differ across provider types?

TITLE: **REVIEW OF THE IMPLEMENTATION OF THE SAFE MEDICAL DEVICES ACT OF 1990 (108236)**

BACKGROUND : To increase the amount and timeliness of data that FDA receives about medical devices, Congress passed the Safe Medical Devices Act of 1990 (SMDA). The Act requires device-user facilities to report medical device related deaths to FDA and injuries to manufacturers. Although the Act took effect in 1991, FDA has not yet issued its final rule on user reporting.

KEY QUESTIONS : (1) Are user facilities complying with the Act? (2) What action has FDA taken on medical device reports submitted by user facilities? (3) What actions are manufacturers taking in response to reports received? (4) What is the cost effectiveness of the Act's requirements and implementation? (5) What recommendations does GAO have for improvement?

OTHER ISSUE AREA WORK - HSQP

TITLE: **MEDICARE: ACCESS TO DIABETES CARE IN HMOS AND FFS (108255)**

BACKGROUND : Experts agree that many diabetics are not receiving the services needed for adequate disease management, whether they are enrolled in fee-for-service (FFS) or managed care. Because uncontrolled diabetes can result in excess worsening health and high costs, both Medicare beneficiaries and health providers have incentive to manage the disease more effectively.

KEY QUESTIONS : (1) What clinical practices are recommended for diabetes care? (2) To what extent are Medicare diabetics receiving recommended services? (3) How widespread are diabetes management programs among Medicare HMOs? What approaches are used by HMOs and FFS providers to manage diabetes care? (4) What data are available to show improvement in the utilization of services?

TITLE: **INTERNATIONAL MEDICAL GRADUATES PRACTICING UNDER VISA WAIVERS (108258)**

BACKGROUND : Under an educational/cultural exchange program, foreign physicians must return home after U.S. residency training. The return req. can be waived at fed./state agencies' request if a doctor agrees to work in a needy area. In 1995, there were over 1,000 waivers for physicians; however, there are concerns that the 4 agencies & states are not coordinating and monitoring placements.

KEY QUESTIONS : (1) Are federal and state programs for requesting J-1 visa waivers for physicians effectively coordinated to help meet the needs of medically underserved communities? (2) Do controls exist to assure that physicians are fulfilling commitments to practice in underserved communities?

TITLE: **REVIEW OF FDA'S ANNUAL INSPECTION OF MAMMOGRAPHY FACILITIES (108261)**

BACKGROUND : In 1995, under the Mammography Quality Standards Act (MQSA), FDA began contracting with states to annually inspect mammog. facilities. States report compliance problems to FDA for enforcement. FDA recovers inspection costs by charging facilities inspection fees. There are concerns re. excessive requirements/costs. This will be our second report mandated by the Act.

KEY QUESTIONS : Q1. To what extent does FDA's inspection criteria and procedures assure compliance with MQSA quality standards? Q2. Are there opportunities to improve efficiencies and reduce FDA inspection costs to facilities?

OTHER ISSUE AREA WORK - HSQP

TITLE: **FDA REGULATION OF TOBACCO PRODUCTS (108264)**

BACKGROUND : In 1995, FDA issued proposed regulations that would prohibit the sale of tobacco products to minors. The House Agriculture Subcommittee has been trying for almost 2 years to obtain information relative to the FDA personnel involved with tobacco issues and the documentation used to support the proposed regulation. GAO was asked in November 1995 to assist in this endeavor.

KEY QUESTIONS : Determine (1) FDA resources used to develop the rule; (2) how FDA concluded it has jurisdiction over tobacco products; (3) actions taken by FDA to develop the rule, and how FDA evaluated other regulatory options; (4) how FDA assessed the impact of the rule on tobacco production and farmers; and (5) how FDA responded to congressional requests on the matter.

TITLE: **MEDICARE HMOS: ENROLLMENT PATTERNS OF THE CHRONICALLY ILL (108269)**

BACKGROUND : Given their richer benefits, HMOs are expected to attract the chronically ill. Yet, there are indications that the chronically ill do not enroll in HMOs in proportion to their fee-for-service (FFS) numbers. If so, (a) the chronically ill may be dissatisfied with HMOs and (b) HCFA may be overpaying HMOs for serving a relatively healthy population.

KEY QUESTIONS : (1) What proportion of FFS beneficiaries have chronic conditions? How much more did Medicare spend on the chronically ill than the nonchronic? (2) Do chronically-ill beneficiaries transfer from FFS to HMOs in proportion to their representation in FFS? (3) Do beneficiaries with chronic conditions stay or rapidly disenroll from HMOs?

TITLE: **FDA INSPECTIONS OF FOREIGN DRUG MANUFACTURING FACILITIES (108279)**

BACKGROUND : FDA inspects foreign facilities to ensure that only safe, pure, and high quality drugs are sold in the U.S. But, FDA studies have identified serious problems with the foreign inspection program, and raised concerns about whether deficiencies identified during inspections of foreign drug facilities may be exposing American consumers to unsafe and adulterated drugs.

KEY QUESTIONS : (1) How does FDA manage inspections of foreign drug manufacturing facilities? (2) How has FDA corrected management problems that were identified in two internal studies of the foreign inspection program? (3) What manufacturing problems have been found during inspections of facilities in China and India and how were these problems addressed?

OTHER ISSUE AREA WORK - HSQP

TITLE: **OUTCOMES OF PURCHASER USE OF PERFORMANCE MEASUREMENT INFORMATION (108291)**

BACKGROUND : Corporate purchasers now have available to them quality of health care information that was unavailable several years ago. Little is known, however, about how purchasers use this information to make health insurance purchasing decisions or its effect on the quality of care furnished. HCFA, in its new purchasing role, could learn from these experiences.

KEY QUESTIONS : (1) What performance criteria are set by purchasers for health plans and what process is used by purchasers to influence the achievement of these criteria? (2) What process is used by health plans in reacting to such criteria? (3) What are the results of the interaction between purchaser and health plans? (4) What can HCFA learn from purchasers?

TITLE: **STATE AND LOCAL GOVERNMENT ACCESS TO FEDERAL SUPPLY SCHEDULE PRICES FOR PHARMACEUTICALS (108294)**

BACKGROUND : In proposed regulations for opening federal supply schedules (FSS) to state, local, and Indian tribal governments, GSA excluded the FSS for pharmaceuticals because of concerns that it could result in higher drug prices for government purchasers. The Congress required that GAO assess the economic implications of extending FSS drug prices to other government entities.

KEY QUESTIONS : (1) What is the potential effect of opening the pharmaceutical FSS to state and local governments on drug prices paid by federal, state, and local government entities? (2) What is the potential economic effect of opening the pharmaceutical FSS to state and local governments on businesses that sell pharmaceuticals?

TITLE: **PHARMACY BENEFITS IN SELECTED FEHBP PLANS (108298)**

BACKGROUND : In 1995, Federal Employee Health Benefits Program (FEHBP) plans spent $2.4 billion on prescription drugs for about 4.1 million enrollees. Moreover, prescription drug payments have grown from 14% in 1990 to 21% in 1995 of total FEHBP health care costs. FEHBP plans are using pharmacy benefit managers (PBMs) to manage their prescription drug benefits and control rising costs.

KEY QUESTIONS : (1) Why have these FEHBP plans contracted with PBMs to provide pharmacy benefits? (2) What types of services do the PBMs provide these FEHBP plans? (3) How do these FEHBP plans evaluate PBM performance in terms of savings and quality of care? (4) Why are some still concerned about the quality of pharmacy services provided by PBMs and their effect on retail pharmacies?

OTHER ISSUE AREA WORK - HSQP

TITLE: **IMPACT OF PURCHASER REQUIREMENTS ON HMOS (108302)**

BACKGROUND : Health care purchasers, including HCFA, are increasingly asking for information from HMOs about HMO performance, especially clinical performance. However, little objective information is available about how HMOs generate and validate the information they disseminate, or how they use the information to improve health care.

KEY QUESTIONS : (1) What types of information are purchasers requesting? (2) How are HMOs generating and validating the information they provide? (3) What HMO resources are devoted to collecting and analyzing this data? (4) How do HMOs use the information and what effect does it have on their quality improvement efforts? (5) Is there a need for greater standardization of measures?