United States General Accounting Office

GAO

Health, Education and Human Services Division

July 1995

National and Public Health Issues Issue Area

Active Assignments

GAO/AA-95-18(3)

Foreword

This report was prepared primarily to inform Congressional members and key staff of ongoing assignments in the General Accounting Office's National and Public Health Issues issue area. This report contains assignments that were ongoing as of July 6, 1995, 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 Sarah Jaggar, Director, on (202) 512-7119; or Mark Nadel, Associate Director, on (202) 512-7119.

Contents

PUBLIC HEALTH SERVICE

TITLE: **REVIEW OF FDA'S PLAN FOR CONSOLIDATING FIELD LABORATORIES (108222)**

BACKGROUND : FDA is proposing to restructure its 18 field laboratories. The proposal includes closing completely 10 field laboratories, changing the duties of others, and building 5 large regional laboratories. The requesters are concerned if FDA properly considered its long-term goals and efficiency in its proposal.

KEY QUESTIONS : (1) How adequate are the criteria used to identify laboratories for closure or retention? (2) What are the costs and savings related to the restructuring? (3) How well did FDA measure the mission impact of such a proposal?

TITLE: **NIH OVERSIGHT OVER INTRAMURAL AND EXTRAMURAL RESEARCH (108223)**

BACKGROUND : In 1993 the National Institutes of Health (NIH) spent almost $ 10 billion supporting biomedical research. Recently, there have been instances of serious problems with NIH supported research. In view of these problems, Senators Cohen and Kassebaum have asked us to assess the adequacy of NIH oversight over the intramural and extramural research it funds.

KEY QUESTIONS : (1) What oversight mechanisms does NIH have to assure that research monies are spent for the projects for which they are intended, and that the research meets appropriate quality standards? (2) How does NIH assure that when problems with funded research do arise, they are promptly and appropriately corrected?

TITLE: **ARE AHCPR (AGENCY FOR HEALTH CARE POLICY AND RESEARCH) CLINICAL PRACTICE GUIDELINES EFFICIENT AND EFFECTIVE? (108226)**

BACKGROUND : Congress established the Agency for Health Care Policy and Research (AHCPR) in 1989, in part to develop clinical practice guidelines to inform providers and consumers of the most effective treatment for certain conditions. The House Budget Committee has voted to eliminate the agency, but the Ways and Means Committee wants more information on the agency's effectiveness.

KEY QUESTIONS : 1)How are AHCPR's guidelines developed and to whom are they disseminated? 2)To what extent has AHCPR been successful in its guideline development efforts? 3)What criticisms are voiced about AHCPR's guideline development efforts? 4)What actions is the agency taking or planning to take in response to these criticisms? 5) What are the issues that the agency continues to face?

PUBLIC HEALTH SERVICE

TITLE: **REVIEW OF IMPACT OF FDA MANAGEMENT CHANGES (108227)**

BACKGROUND : FDA is responsible for ensuring the safety of food, drugs, medical devices, and other products. Critics accuse FDA of delays in approving products, inappropriate centralization and excessive regulation. The Chairman was concerned about reports on the growth of overhead inefficiency in FDA.

KEY QUESTIONS : (1) Has decision-making authority become more or less decentralized since 1991? (2) How has the increase of resources been distributed since 1991? (3) What has been the trend in the time for product approvals and other regulatory actions?

TITLE: **REVIEW OF FDA MEDICAL DEVICE APPROVAL PROCESS (108230)**

BACKGROUND : FDA regulates medical devices for safety and effectiveness. FDA's approval process for new devices has been criticized as taking too long and delaying the availability of devices to the public. Critics cite the approval process used by the European Union as an example of a system that gets products to the public more quickly without sacrificing public health and safety.

KEY QUESTIONS : 1. What are the strengths and weaknesses of FDA's current system for approving medical devices and system changes under consideration? 2. Could FDA improve its system by adopting features of the European system? 3. Would other changes improve FDA's ability to approve devices more quickly without damaging the public's health?

TITLE: **EUROPEAN UNION DRUG APPROVAL PROCESS (108235)**

BACKGROUND : The European Union (EU) uses a centralized authorization process for innovative medicinal products. Conventional medicinal products are subject to a decentralized process, mutually recognized by the member countries. Critics of the U.S. drug approval process cite the EU's approach as a model system that ensures new drugs are safe, effective, and of good quality.

KEY QUESTIONS : We will (1) determine how the EU reviews and approves new drugs, (2) determine how the UK reviews and approves new drugs and (3) compare specific aspects of this process with the procedures followed by FDA.

PUBLIC HEALTH SERVICE

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

BACKGROUND : The Safe Medical Devices Act of 1990 requires device-user facilities to report medical device related deaths to FDA and serious illnesses and injuries to manufacturers. Although the Act took effect in November 1991, FDA has not yet issued its final rules on user reporting requirements. Since FY 1993, FDA has received about 246,000 medical device reports.

KEY QUESTIONS : (1) What action has FDA taken on medical device reports submitted by user facilities? (2) Are user facilities complying with the Act? (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?

TITLE: **REVIEW OF ACTIVITIES OF HHS' OFFICE OF RESEARCH INTEGRITY (108997)**

BACKGROUND : GAO was asked to examine how the Office of Research Integrity (ORI) handles scientific misconduct for researchers awarded grants from HHS' Public Health Service (PHS). ORI primarily investigates misconduct claims related to federal government PHS grant awardees and oversees investigations for non-federal awardees.

KEY QUESTIONS : (1) How does ORI investigate misconduct allegations for federal government grant awardees? (2) How does ORI monitor investigations for non-federal grant awardees conducted by institutions? (3) Does ORI's structure, staffing, procedures, or caseload adversely affect its ability to fulfill its duties? (4) How does ORI protect persons reporting misconduct against retaliation?

TITLE: **REVIEW OF THE NATIONAL CANCER INSTITUTE'S CLINICAL TRIALS OF HYDRAZINE SULFATE (108998)**

BACKGROUND : Some studies suggest that hydrazine sulfate interrupts the weight loss and physical deterioration in advanced cancer patients, known as cachexia. Encouraged by earlier studies, the National Cancer Institute (NCI) sponsored three clinical trials that failed to show any benefit from the drug, but questions remain about the research protocols followed in these trials.

KEY QUESTIONS : (1) Did the National Cancer Institute (NCI) follow its protocols in testing hydrazine sulfate? (2) Did NCI knowingly include concomitant therapies that are incompatible with hydrazine sulfate?

PUBLIC HEALTH SERVICE

TITLE: **BLOCK GRANT FORMULA FOR HEALTH REFORM PROPOSAL TO PROVIDE STATES FUNDING FOR CORE PUBLIC HEALTH FUNCTIONS CURRENTLY ADMINISTERED BY THE CENTERS FOR DISEASE CONTROL (CDC) (118106)**

BACKGROUND : The senator asked GAO to develop formula alternatives for a new block grant program to replace categorical grants that would enable states to finance 18 core public health functions. Under a Senate proposal, the $7 billion currently allocated annually to the Center For Disease Control (CDC) to finance the core functions would be redirected to the new block grant program.

KEY QUESTIONS : (1) What indicators exist that adequately reflect the health status of state populations, the cost of providing core public health services and the capacity of states to fund such services from state resources? (2) How can the formula for distributing funds appropriately reflect states' public health needs and funding capabilities?

TITLE: **ANALYSIS AND DESIGN OF GRANT FORMULAS FOR TITLES I & II OF THE RYAN WHITE CARE ACT (118109)**

BACKGROUND : The Ryan White CARE (Comprehensive AIDS Resources Emergency) Act of 1990 funds state and metropolitan areas for the care of AIDS victims. The program is funded by federal, state, and local jurisdictions. Federal funding is allocated among states and metropolitan areas by formula.

KEY QUESTIONS : Do the federal formulas adequately reflect: (1) the resident AIDS population in need of services, (2) the geographic variation in the cost of providing services, (3) the capacity of state and local governments to fund services?

TITLE: **TESTIMONY ON THE RYAN WHITE CARE ACT OF 1990: OPPORTUNITIES ARE AVAILABLE TO IMPROVE FUNDING EQUITY (118114)**

BACKGROUND : The Ryan White CARE (Comprehensive AIDS Resources Emergency) Act of 1990 funds state and metropolitan areas for the care of AIDS victims. The program is funded by federal, state, and local jurisdictions. Federal funding is allocated among states and metropolitan areas by formula.

KEY QUESTIONS : Do the federal formulas adequately reflect: (1) the resident AIDS population in need of services, (2) the geographic variation in the cost of providing services, (3) the capacity of state and local governments to fund services?

NATIONAL ACCESS TO HEALTH CARE

TITLE: **ERISA PREEMPTION OF STATE HEALTH PLAN REGULATION (108206)**

BACKGROUND : ERISA exempts health plans sponsored by self-insured employers from state regulation. States contend that ERISA presents a major obstacle to their efforts to achieve universal coverage, effective cost controls, or meaningful consumer protection. Self-insured employers claim that ERISA protection leads to better benefits for the consumer and better control of health costs.

KEY QUESTIONS : (1) How does the Employee Retirement Income Security Act of 1974 (ERISA) relate to our employer-based health care system? (2) What kinds of state actions are preempted by ERISA? (3) What benefits does ERISA preemption provide to employers that provide health care coverage to their workers?

TITLE: **THE STATUS OF COCAINE TREATMENT IN THE U.S. (108209)**

BACKGROUND : The Senate Judiciary Committee has estimated more than two million weekly cocaine users. Fifteen Drug Use Forecasting sites (1990) show booked arrestee use in excess of 40%. Yet, we know relatively little about the types of cocaine treatment currently being offered, the novel approaches being developed, and their levels of success.

KEY QUESTIONS : (1) What major types of drug treatment are being provided to cocaine users? (2) What do cognizant federal agencies know about their relative effectiveness? (3) Are there promising new treatments under clinical investigation? (4) What are the major gaps in our knowledge about cocaine treatment?

TITLE: **STUDY OF THE FEDERAL MAMMOGRAPHY CERTIFICATION PROGRAM (MANDATED BY P.L. 102-539) (108215)**

BACKGROUND : The Mammography Quality Standards Act (MQSA) requires FDA to establish a program whereby all mammography facilities must be accredited as meeting FDA standards and pass annual inspectons. The Act requires GAO to issue two reports, one in 1995 and the other in 1997, on the program's impact on quality and accessibility of mammography services.

KEY QUESTIONS : The major questions that we will answer in the interim report are: (1) What is the status of FDA's implementation of MQSA? (2) Are there early indications that MQSA has affected access to mammography services? (3) What are the initial indications of MQSA's impact on the quality of mammography services?

NATIONAL ACCESS TO HEALTH CARE

TITLE: **DEMOGRAPHICS OF UNINSURED CHILDREN AND CHILDREN ON MEDICAID (108217)**

BACKGROUND : In 1993 9.3 million children lacked health insurance and 13.7 million had coverage through the Medicaid program. Since 1989 children's coverage through private employment-based insurance has decreased and coverage through Medicaid has increased. This year the Congress may be considering changes to the Medicaid program and subsidies for children's health insurance.

KEY QUESTIONS : (1) How have the number and demographic characteristics of uninsured and Medicaid children--including the percent in working families-- changed since 1989? (2) What has been the impact of Medicaid policy changes on number and type of children currently in the Medicaid program and on uninsured children?

TITLE: **REVIEW OF THE HEALTH PROFESSIONAL SHORTAGE AREA SYSTEM (108218)**

BACKGROUND : HHS uses the Health Professional Shortage Area (HPSA) system to designate urban and rural communities requesting federal assistance to improve access to care. At least 26 federal programs allocate funding based on HPSA designation.

KEY QUESTIONS : Does the Health Professional Shortage Area (HPSA) system accurately identify and prioritize the need for federal assistance?

TITLE: **CLINICAL TRIALS AND COVERAGE DECISIONS FOR AUTOLOGOUS BONE MARROW TRANSPLANT FOR BREAST CANCER (108219)**

BACKGROUND : High dose chemotherapy with autologous bone marrow transplant (ABMT) is widely considered an investigational treatment for breast cancer. Clinical trials are underway but may not yield results for years. Meanwhile, patient demand, law suits, and mandates by at least five states, have led some insurers, including the FEHBP, to cover this treatment.

KEY QUESTIONS : (1) What role have technology assessment and clinical trials had in ABMT coverage decisions? (2) Has insurer coverage of ABMT adversely impacted the ability to conduct clinical trials? (3) What impact have the coverage decisions had on the use and diffusion of ABMT for breast cancer? (4) What are the broader implications for the use of technology assessment by insurers?

NATIONAL ACCESS TO HEALTH CARE

TITLE: **ASSESSING STATE/LOCAL EFFORTS TO PROVIDE HEALTH INSURANCE FOR UNINSURED CHILDREN (108220)**

BACKGROUND : In 1992, 8.3 million children lacked health insurance. Many more would have been uninsured without recent Medicaid expansions and waivers that increased access to health insurance. Some states and localities have developed programs to expand coverage for children. Many Congressmen remain interested in expanding coverage for uninsured children.

KEY QUESTIONS : (1) What programs insure uninsured children and what are their costs, eligibility, coverage, and administrative structures? (2) What critical issues do states and localities face to finance and implement these efforts? (3) What lessons can be learned for improving coverage for uninsured populations?

TITLE: **THE EFFECTS OF ERISA AND STATE LEGISLATION ON SMALL BUSINESS INSURANCE (108232)**

BACKGROUND : Many states have implemented a combination of initiatives designed to make private health insurance more accessable and affordable to small firms. States fear that small firms are undermining their efforts by switching to self-insurance to obtain ERISA protections from state regulation.

KEY QUESTIONS : We will determine (1) whether sufficient data are available to measure the impact of state small business reforms, (2) what administrative or implementation difficulties states have encountered, and (3) whether existing state regulations are undermined by shifts of small firms to self-insurance?

TITLE: **LETTTER TO THE BUREAU OF PRIMARY HEALTH CARE (BPHC) ON THEIR ADMINISTRATION OF GRANTS FOR THE COMMUNITY HEALTH CENTER (CHC) PROGRAM (108240)**

BACKGROUND : In preparation for congressional hearings on community health centers, GAO briefed staff on the program's grants administration (job code 118922). Bureau staff requested that GAO issue a management letter summarizing the results of our work.

KEY QUESTIONS : 1. In the Bureau of Primary Health Care (BPHC) in compliance with Public Health Service (PHS) policies that require competition for grants? 2. Have HHS actions removed bias from PHS-required independent reviews? 3. Do grant award amounts comply with the CHC law, that grants not be more than the difference between cneter costs and revenues?

NATIONAL ACCESS TO HEALTH CARE

TITLE: **SMALL EMPLOYER HEALTH INSURANCE PROVIDED THROUGH TRADE ASSOCIATIONS AND OTHER PRIVATE GROUP PURCHASING ARRANGEMENTS (108241)**

BACKGROUND : About 17 percent of small employer health insurance nationally is purchased through trade associations or similar privately pooled purchasing arrangements. However, little is known about their prevalence locally, and many regulatory uncertainties exist. Also, some association plans "cherry pick," resist state regulation, and are difficult for regulators to identify.

KEY QUESTIONS : (1) What is known about the structure of association plans, their market penetration, and how penetration varies by state or market? (2) How do states regulate association plans, what are the sources of uncertainty, and what are regulators' concerns? (3) What are the advantages and disadvantages of these types of arrangements?

TITLE: **UPDATE OF CERTAIN ASPECTS OF THE NATIONAL ORGAN ALLOCATION POLICY (108242)**

BACKGROUND : Federal legislation has established a national network for organ procurement and allocation. The network includes a national contractor, organ procurement organizations (OPO), and transplant centers. In an April 1993 report we noted that certain OPO and transplant center practices did not assure equitalbe organ allocation.

KEY QUESTIONS : (1) What is the status of OPO and transplant center variations to the national allocation policy? (2) Are OPOs considering all patients in their area when allocating organs? (3) What is the median waiting time for transplant candidates by OPO?

TITLE: **SURVEY OF NATIONAL HEALTH SERVICE CORPS ISSUES (108999)**

BACKGROUND : The purpose of the National Health Service Corps (NHSC) is to eliminate shortages of health personnel in federally- designated health professional shortage areas (HPSAs). NHSC offers scholarships and loan repayment to providers who agree to serve in these areas. There have been proposals to increase funding and expand the NHSC.

KEY QUESTIONS : Q1: How effective are the NHSC placement strategies in meeting the needs of medically underserved areas? Q2: How do the costs and benefits of the NHSC scholarship and loan repayment programs compare?

OTHER ISSUE AREA WORK

TITLE: **FEDERAL INFORMED CONSENT PROCESS TO PROTECT HUMAN RESEARCH SUBJECTS (108207)**

BACKGROUND : NIH regulations protect human subjects enrolled in drug or NIH-funded research projects. NIH negotiates agreements ("assurances") with NIH-funded institutions to implement HHS regulations. NIH and FDA investigate noncompliance at research institutions. Institutional review boards (IRBs) in those institutions monitor research projects locally.

KEY QUESTIONS : (1) What examples of harm to subjects and noncompliance by research institutions exist? (2) What evidence exists to show that NIH's assurance process is weak; what should be done to improve it? (3) Are there weaknesses in FDA's inspection process? (4) What improvements can be made to federal human protection efforts?

TITLE: **IMPLEMENTATION OF "PATIENT SELF-DETERMINATION" PROVISIONS IN OBRA 1990 (108208)**

BACKGROUND : Advance directives are instructions on the provivision of health care when the individual is incapacitated. Examples of advance directives include living wills and durable powers-of-attorney. OBRA 1990 included several provision on advance directives (termed Patient Self-Determination or "PSD" provisions).

KEY QUESTIONS : 1) How good a job has HHS done in complying with the PSDA? 2) What efforts have states made to regulate advance directives? 3) Have providers (hospitals, nursing homes, etc.) complied with the provisions in the PSDA? 4) Are advance directives being used effectively?

TITLE: **REVIEW OF HUD'S HOSPITAL AND NURSING HOME INSURANCE PROGRAMS (108213)**

BACKGROUND : HUD/FHA and HHS jointly administer a program which provides insurance against losses to private lenders who finance mortgages for hospital construction or renovation. Outstanding loans total about $5 billion. Legislation requires that GAO report on the program and factors that could raise the potential for financial losses.

KEY QUESTIONS : (1) How can certain risk factors, including health care trends and anticipated policy changes, impact the stability of the hospital projects HUD insures? (2) Is an appropriate methodology being used to estimate loan loss reserves?

OTHER ISSUE AREA WORK

TITLE: **FAMILY PLANNING AND REPRODUCTIVE HEALTH SERVICES (108239)**

BACKGROUND : The federal government funds family planning and reproductive health services through multiple funding streams. One primary recipient is Planned Parenthood Federation of America and the International Planned Parenthood Federation.

KEY QUESTIONS : (1) How much federal funding is going to the Planned Parenthood Federation of America, and the International Planned Parenthood Federation?