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Active Assignments

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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 National and Public Health Issues issue area. This report contains assignments that were ongoing as of October 2, 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.

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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: **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 differences between the procedures and outputs of the medical device approval systems used by the FDA and the European Union? (2) Could the FDA adopt features of the European approval system, such as the use of private device approval bodies, to allow new technology to reach the public more quickly without compromising the public's health?

PUBLIC HEALTH SERVICE

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

BACKGROUND : FDA's critics cite drug approval in European countries as a model system that ensures new drugs are safe, effective, and of good quality. The European Union (EU) uses a centralized process for approving new biotech and innovative drugs. Other drugs are subject to a decentralized process, in which a drug's approval in one country is mutually recognized by the member countries.

KEY QUESTIONS : (1) How does the European Medicines Evaluation Agency (EMEA) review and approve new drugs? (2) How does the UK review and approve new drugs? (3) How do specific aspects of these processes compare with the procedures followed by FDA?

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 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?

ACCESS AND ACCOUNTABILITY

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?

ACCESS AND ACCOUNTABILITY

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 : NIH considers high dose chemotherapy with autologous bone marrow transplant (ABMT) an experimental treatment for breast cancer. In spite of this, many doctors and health insurers are adopting this treatment in response to patient demand, law suits, and mandates by several states.

KEY QUESTIONS : (1) What factors have influenced insurers in making coverage decisions about ABMT? (2) What are the economic implications of the use of ABMT? (3) What is the status of clinical research and practice in the use of ABMT?

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?

ACCESS AND ACCOUNTABILITY

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 accessible and affordable to small firms. States are concerned that small firms may undermine their efforts by switching to self-insurance to obtain Employee Retirement Incomes Security Act (ERISA) protections from state regulation.

KEY QUESTIONS : We will determine (1) the initial effects of state small group insurance reform on the small business health insurance market; (2) what administrative or implementation difficulties state insurance regulators, small employers, and insurers have encountered; and (3) whether a shift by small employers to self-insurance is emerging in response to state reform efforts.

TITLE: **PROMISING TREATMENTS FOR COCAINE (108234)**

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

KEY QUESTIONS : (1) What types of cocaine treatment approaches are currently being investigated by the federal drug treatment agencies? (2) Are any of these cocaine treatment approaches demonstrating evidence of success? (3) What gaps remain in our knowledge of cocaine treatment research?

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?

ACCESS AND ACCOUNTABILITY

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: **REVIEW OF THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK'S EFFORTS TO CREATE AN EFFECTIVE, EFFICIENT, AND EQUITABLE NATIONAL ORGAN ALLOCATION SYSTEM (108244)**

BACKGROUND : The Organ Procurement and Allocation Network has established principles and objectives for organ allocation. Waiting time is a commonly used indicator of equitable organ allocation and varies considerably. HHS is considering alternative allocation policies which may improve equity, efficiency, and effectiveness. HRSA and HCFA within HHS monitor the network.

KEY QUESTIONS : (1)To what extent do alternative allocation policies meet established criteria for an effective, efficient, and equitable organ allocation system? (2)To what extent is waiting time a useful measure of equitable, efficient, and effective organ allocation? (3)How effective is HHS's policy of delegating responsibility for organ allocation to both HRSA and HCFA?

TITLE: **NUMBER OF PEOPLE AFFECTED BY NATIONAL HEALTH INSURANCE PORTABILITY STANDARDS (108250)**

BACKGROUND : Recently introduced legislation would attempt to increase the portability of health insurance so that individuals can maintain health coverage without limitations in coverage when they change jobs. These proposals would also include provisions that guarantee issue and renewability of health insurance and require limits on preexisting condition exclusions.

KEY QUESTIONS : (1) What previous state and federal efforts have attempted to improve portability of health insurance? (2) How many people would potentially be affected by legislation that provides minimum federal standards on portability of health insurance?

ACCESS AND ACCOUNTABILITY

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: **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: **USE OF CLINICAL PRACTICE GUIDELINES BY MANAGED CARE ORGANIZATIONS (108243)**

BACKGROUND : In 1989, Congress established the Agency for Health Care Policy and Research (AHCPR). The agency, along with other public and private organizations, issues practice guidelines designed to improve patient outcomes and control costs. Little is known, however, about the extent to which providers use these guidelines, and even less is known about the effectiveness of guideline use.

KEY QUESTIONS : 1. To what extent do managed care plans use clinical practice guidelines, including those sponsored by AHCPR? 2. How do health plans choose and implement practice guidelines, monitor their use, and determine their effectiveness? 3. What role should the federal government play in developing and/or facilitating the use of clinical practice guidelines?

TITLE: **RYAN WHITE CARE ACT: COMPARISON OF TWO TITLE II FORMULAS (118118)**

BACKGROUND : The Labor and Human Resources Committee recently passed S-641 which would change the formulas currently used to distribute title I and II funds under the Ryan White CARE Act. The National Association of State and Territorial AIDS Directors (NASTAD) and other organizations have proposed alternative formulas to those found in S-641.

KEY QUESTIONS : (1) To what extent do the formulas found in S-641 address the inequities described in our earlier testimony? (2) How do the alternative formulas, proposed by NASTAD and other organizations, compare to the S-641 formulas in terms of redressing the inequities identified by our work?

TITLE: **CARE ACT: EFFECTS OF THE INCLUSION AND EXCLUSION OF A COST FACTOR IN TITLES I AND II FORMULAS (118119)**

KEY QUESTIONS : (1) How does the inclusion and exclusion of a cost factor in the formulas proposed by Sen. Kassebaum's S-641 affect the distribution of Title I and II funds?

OTHER ISSUE AREA WORK

TITLE: **SAMHSA: REVIEW OF RAND'S STUDY OF THE MENTAL HEALTH AND SUBSTANCE ABUSE BLOCK GRANT FUNDING FORMULAS (118120)**

BACKGROUND : P.L.102-321 mandates that GAO provide to the authorizing committees its views on a study of the need to further modify formulas used to allocate the Mental Health and Substance Abuse Block Grants. The committees will consider GAO's assessment in deciding whether to change these funding formulas.

KEY QUESTIONS : (1) In GAO's judgement, do the results of the RAND study of the SAMHSA Block Grant funding formulas indicate that the existing formulas should be modified?

TITLE: **REVIEW OF SAMHSA'S DISTRIBUTION OF BLOCK GRANT FUNDS TO STATES (118121)**

BACKGROUND : In FY 1992, the Congress enacted legislation incorporating new funding formulas for the Mental Health and Substance Abuse Block Grants. GAO was instrumental in developing these formulas. Since then, complaints have been expressed about how Substance Abuse & Mental Health Services Admin. (SAMHSA) has used these formulas to distribute these block grant funds.

KEY QUESTIONS : 1) Is SAMHSA applying the Mental Health and Substance Abuse Block Grant funding formulas in conformance with legislative intent? (2) If not, what changes to agency policy are needed to achieve legislative intent?