

August 1990

# INFORMATION SYSTEM

## National Health Practitioner Data Bank Has Not Been Well Managed



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**Information Management and  
Technology Division**

B-239814

August 21, 1990

The Honorable Tom Harkin  
Chairman, Subcommittee on Labor,  
Health and Human Services,  
Education, and Related Agencies  
Committee on Appropriations  
United States Senate

The Honorable William H. Natcher  
Chairman, Subcommittee on Labor,  
Health and Human Services,  
Education, and Related Agencies  
Committee on Appropriations  
House of Representatives

This report responds to your requests for information on the Health Resources and Services Administration's (HRSA) development of the National Practitioner Data Bank. This data bank will enable HRSA to collect and release information on malpractice litigation and adverse professional actions involving physicians, dentists, and other health care practitioners. The data bank, which HRSA expects to begin operating in September 1990, will basically be an exception list containing the names of and other information on practitioners whose professional competence or conduct has been questioned in such actions. Because data bank information will be used to make judgments about the professional competence of health care practitioners, a system compromise could seriously affect the credibility of the data bank. As agreed with your offices, we reviewed HRSA's progress in developing the data bank, including actions taken to ensure that user needs are met at the lowest cost. (See app. I for details of our scope and methodology.)

**Results in Brief**

HRSA's failure to follow a sound managerial approach in developing the National Practitioner Data Bank casts serious doubt on whether HRSA can open the bank by September 1990. HRSA has not yet ensured that the data bank will protect the confidentiality of practitioner information from unauthorized access and manipulation. Good system development practices dictate that effective security measures be included in a system's design. HRSA began developing the data bank before system threats and vulnerabilities were identified. As a result, HRSA cannot ensure that appropriate security measures will be installed to prevent unauthorized access and manipulation of data bank information.

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HRSA has not effectively managed its data bank project. No one person has been accountable for the project since it began. Instead, accountability is shared by at least 14 HRSA officials. Also, HRSA has either misplaced or not developed critical documentation necessary to ensure effective management control and oversight of the project. Additionally, some critical functions, such as ensuring that privacy requirements are met and establishing schedules and budgets, have been assigned to the contractor developing the data bank because HRSA did not believe it had the staff with the training and experience to perform them.

Furthermore, the project's total cost is uncertain at this time and could increase substantially. Currently, HRSA is modifying the contract which will require further negotiations. HRSA said the modification is needed to cover certain requirements that existed at the time the data bank contract was awarded, but which had not been defined to the degree necessary for any offeror to address in a cost proposal. Completing these tasks could increase the project contract cost from \$15.8 million to a total of \$25 million.

A successful system development project needs to be well managed, conform to generally accepted systems development standards, and incorporate appropriate management controls. HRSA has not done this in the case of the National Practitioner Data Bank. We are making a series of recommendations aimed at ensuring that the data bank is not opened until corrective actions are taken by the Department of Health and Human Services.

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## Background

Title IV of the Health Care Quality Improvement Act of 1986 (P.L. 99-660), as amended, authorizes the Secretary of Health and Human Services to establish a data bank to ensure that unethical or incompetent practitioners do not compromise health care quality. This bank is to be created to help meet a national need to restrict the ability of incompetent practitioners to move from state to state without disclosure or discovery of the practitioner's previous damaging or incompetent performance.

The data bank is to contain information on adverse actions taken against a practitioner's license, clinical privileges, and professional society memberships, as well as information on medical malpractice payments. Hospitals, group medical practices, professional societies, and

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state licensing boards will have access to bank information. In addition, practitioners with data bank records will have access to their own records.

Title IV requires that actions taken against physicians' or dentists' licenses be reported. Section 5 of the Medicare and Medicaid Patient and Program Protection Act of 1987 (P.L. 100-93) expanded the scope of the data bank to include all licensed health care practitioners, as well as health care entities such as hospitals. Title IV required that reporting was to begin by November 1987.

Although the bank was originally scheduled to be operational in 1987, funding for the data bank was not approved by the Congress until the fall of 1988. In addition, the regulations for implementing Title IV provisions were not finalized until October 1989.

In December 1988 HRSA awarded a 5-year \$15.8 million cost-plus-fixed-fee contract to the Unisys Corporation to establish and operate the data bank, which will be housed at the company's computer facility in Camarillo, California. HRSA expects to have the bank operating by September 30, 1990. The bank will open under Title IV requirements only. Implementation of Section 5 provisions is expected to follow about 1 year after the data bank opens. No information will be reported to the data bank until it opens. Except for malpractice awards or settlements paid through an annuity, no retroactive reporting on actions occurring before the opening date will be required. HRSA officials stated that a report must be made if a payment under an annuity is made after the data bank opens. Once HRSA establishes the opening date, it will be published in the Federal Register. The Unisys facility is expected to process over 1 million queries and about 57,000 malpractice and adverse action reports each year. Except for erroneous information, HRSA plans to maintain the information collected on practitioners indefinitely, without any provision for purging information. HRSA believes that purging information from the data bank is inconsistent with its statutory purpose of protecting the public.

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## Who Must Report and What Must Be Reported

Once the bank is open, individuals or entities, such as insurance companies and self-insured hospitals who pay a malpractice claim or judgment must report the incident to the data bank. State medical and dental boards must also report disciplinary actions taken against a dentist or physician. Further, hospitals and other health care entities, such as health maintenance organizations and certain medical and dental group

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practices, must report adverse actions taken against a physician's or dentist's clinical privileges. These are actions, taken on the basis of the practitioner's professional competence or conduct, that will last more than 30 days. Also, professional societies must report an adverse action taken against a practitioner's membership through a formal peer review process. Section 5 provisions require states to report certain adverse actions taken against licensed health care practitioners or health care entities by any licensing authority of the state.

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## Verifying Accuracy of the Data Bank Information

Reports will be submitted by mail to the data bank using a standard form. Reports will be assigned a unique document control number that allows for identification and tracking from receipt through final disposition. Unsigned reports or reports missing required information will not be accepted by the data bank, according to HRSA officials.

After the report data are entered, the data bank contractor will (1) verify that the data were entered correctly and (2) send a verification document to the reporting entity. This verification document is to be reviewed and returned to the data bank. If errors or omissions are found, the entity who reported it must send an addition or correction to the data bank.

The subject practitioner will be notified that a report has been received by the data bank and given 60 days to dispute the accuracy of the report. If this practitioner believes there is an inaccuracy in the report, the practitioner is to discuss the disagreement with the reporting entity. Information contained in a disputed report will be released 30 days after receipt in response to queries, however, the practitioner can request that a notation be placed in the report stating that it is in dispute.

If the reporting entity amends or retracts a disputed report, all inquiring parties who had previously received the information will be notified by the data bank about the changes. If the reporting entity chooses not to change the report, the practitioner may request the Secretary of Health and Human Services to review the dispute. The Secretary then makes the final determination.

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## Sanctions for Not Reporting

The Department's Office of the Inspector General has been delegated the authority to impose civil money penalties in accordance with Sections 421(c) and 427(b) of Title IV of the Health Care Quality Improvement

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Act. Under the statute, an individual or entity that fails to report malpractice payments will be subject to a civil penalty of not more than \$10,000 for each unreported payment.

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### Who Must Query the Data Bank

Queries will be submitted to the data bank by mail using a standard form. Hospitals are required by the act to query the bank every 2 years on any physician, dentist, or other health care practitioner who is on its medical staff or has clinical privileges at the hospital. Hospitals also must request information from the data bank when they are considering hiring a physician, dentist, or other health care practitioner or granting clinical privileges. Hospitals may also request information from the data bank when they deem it necessary or while conducting professional review activities. While hospitals are the only entities that must request information from the data bank, other health care entities, including health maintenance organizations and group medical practices, may query the data bank as needed. Also, physicians, dentists, and other health care practitioners may request information concerning themselves. Any person who violates the confidentiality of data bank information may be subject to a civil penalty of up to \$10,000 for each violation.

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### User Fees

A request for information from the data bank will be regarded as an agreement to pay the associated fee. Initially the fee for querying the data bank will range somewhere between \$2 and \$5 for each practitioner name submitted. Fee changes will be announced periodically in the Federal Register. User fees are estimated by HRSA to produce about \$2 million a year. Additional funds needed to operate the bank will be requested by HRSA in its annual appropriation.

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### Status of the Data Bank

As of June 1990, the regulations, forms, and users' guidebook for implementing Title IV requirements have been completed; however, much work still needs to be done, specifically:

- the 19 software programs for implementing Title IV requirements need to be finalized, tested, and accepted;
- a software program to account for user fees needs to be finalized, tested, and accepted;
- acceptance and performance criteria for the software need to be developed;

- an adequate test plan for validating the data bank's software programs needs to be prepared; and
- system security features need to be identified and an assessment of system security vulnerabilities needs to be performed.

HRSA expects to distribute the finalized forms, instructions, and users' guidebook about 4 weeks before the bank becomes operational. This short amount of time will make it difficult for users who plan to use computer systems to help generate the data required for the bank report and query forms, according to users we spoke to, since the bank requires information they do not routinely collect. For example, an official of a large malpractice insurer stated that it will take over 5 months to program the company's computers so that the data bank reports can be prepared using information in the company's automated claims processing systems. In addition, it will take several months to train the 1,000 employees who will be responsible for preparing data bank reports or dealing directly with practitioners on malpractice payments, according to the company official. Because the documentation on the data bank's design was not finalized at the time we completed our work in June 1990, we could not assess the data bank's ability to collect data and generate reports relating to the professional competence and conduct of health care practitioners.

## Data Bank Development Started Before Requirements Made Final

HRSA awarded the data bank contract before the system's requirements were finalized. Although the data bank contract was awarded in December 1988, development of the data bank did not begin until after the regulations for Title IV provisions were finalized and approved in October 1989.

Federal system development practices require that a comprehensive requirements analysis defining and documenting an automated system's functional, data, and operational requirements be prepared before an automated system is acquired. HRSA officials did not prepare such an analysis before awarding the data bank contract because they believed that the Congress, through the legislative process, had adequately defined and documented the data bank's data requirements. HRSA's decision to award a contract before finalizing the operational processes by which data bank information was to be gathered and disclosed was a mistake.

We found indications that the contractor developing the data bank recognized the incompleteness of HRSA's requirements for the data bank.

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The contractor, in a November 1989 Draft Narrative on Design and Implementation of the Bank, stated that the system design requirements identified in HRSA's request for proposals were extremely general. According to the contractor, HRSA's requirements focused on the content of the data bank by providing lists of data elements to be captured, but established neither firm requirements nor constraints on the development and operational processes by which the data bank was to be constructed and data was to be gathered and disclosed.

The data bank's development was delayed 10 months until the regulations for implementing Title IV provisions were finalized in October 1989. During this time the contractor held a series of educational conferences for potential users on the data bank legislation. HRSA finalized the processes in its October 1989 regulations, which describe the actual data to be collected and impose requirements and constraints on the data bank's design and architecture.

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## Sound Project Management Practices Are Not Being Followed

HRSA's approach to managing the development of the data bank has not followed federal system development requirements, which describe prudent management actions to minimize cost and performance risks. These requirements are embodied in the Federal Acquisition Regulation, Federal Information Resources Management Regulation, Office of Management and Budget guidelines, and the requirements of the Department of Health and Human Services, of which HRSA is a part. The requirements provide a structured means for ensuring that automated systems are successfully implemented. Flaws in HRSA's approach to develop the data bank cast serious doubt on whether a successful system can be deployed by the planned September 1990 opening date.

The Department requires bureaus and offices requesting approval to acquire computer services to follow a set of disciplined procedures to justify the procurement and to ensure that user needs are met at the lowest cost. In addition, the Department has established special requirements that apply to support services contracts that are for the development of a software application, such as the National Practitioner Data

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Bank. The Department requires that these procurements follow its systems development life cycle methodology<sup>1</sup> and federal information processing standards.<sup>2</sup>

To ensure HRSA's compliance with Department requirements, the Department's Division of Telecommunications and Automated Data Processing, in its July 1988 memorandum approving HRSA's procurement request for the data bank, urged HRSA officials to take particular care to comply with the Department's Information Resources Management Manual, which summarizes federal system development requirements applicable to the Department's information resources activities, by thoroughly documenting system requirements. Failure to comply with this condition could render HRSA's delegation of procurement authority from the Department voidable, according to the Acting Director of the Department's Division of Telecommunications and Automated Data Processing who signed the memorandum.

HRSA is not following the Department's systems development life cycle methodology and neither is it complying with the Department's Information Resources Management Manual. HRSA officials said they were not aware that they were supposed to be following the Department's systems development methodology or that the Department had established special requirements applicable to support services contracts. We examined HRSA's official acquisition file and found that documentation the Department deems necessary for ensuring effective management control over the project was missing. This documentation included the cost/benefit analysis of alternative approaches, and an explanation of how the approach selected would meet users' needs at the lowest overall cost over the system's life, and a test plan for evaluating the software programs being developed by the contractor to ensure that they will attain the bank's stated objectives.

We asked HRSA officials why the studies and analyses were not in the acquisition file. The officials speculated that some of the required studies and analyses, such as the cost/benefit study, may be in the original acquisition file; however, agency officials have been unable to locate the file since 1988. Other documents, such as the test plan, have

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<sup>1</sup>Department of Health and Human Services Information Resources Management Manual (Chapters 2 and 4), November 1, 1985.

<sup>2</sup>Federal Information Processing Standards Publication 64, Guidelines for Documentation of Computer Programs and Automated Data Systems for the Initiation Phase and Publication 38, Guidelines for Documentation of Computer Programs and Automated Data Systems, National Technical Information Service, Department of Commerce.

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not been prepared because HRSA does not have staff with necessary training, experience, and knowledge to prepare them. In the absence of this documentation, HRSA cannot ensure that the project will have effective management control.

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### Confidentiality Concerns Have Not Been Adequately Addressed

The confidential receipt, storage, and disclosure of information is essential to the data bank's operation. Any unauthorized access or manipulation of practitioner information could have wide-ranging and serious consequences on the professional and personal lives of competent practitioners. To ensure proper identification of each individual on whom data is stored, as well as to ensure that those reporting to or requesting information from the data bank are authorized to do so, a system of unique identification numbers will be used. However, HRSA has not complied with Department and governmentwide security requirements in determining what security features should be included in the data bank's computer system to prevent unauthorized access and manipulation of data bank information.

The Department's Information Resources Management Manual states that organizations responsible for the operation of computer systems must ensure that computer programs and systems include adequate safeguards to prevent the unauthorized access and manipulation of the system. Also, the Department requires the development and use of risk analyses in the system development process to identify system threats and vulnerabilities and to provide managers and systems designers with recommended safeguards. The Department requires that the risk analysis be reviewed and revised during each phase of the system development life cycle to ensure that appropriate security measures are installed.

We found that the required risk analyses were missing from HRSA's acquisition file. HRSA officials provided us with documents that they believed met the key features of the Department's procedural requirements for risk analyses and data sensitivity studies.

We reviewed the documents and concluded that they did not meet the Department's requirements. For example, the documents did not include any analysis of the damage that could occur by the unauthorized disclosure or manipulation of practitioner data or identify the security measures that were needed to prevent this from happening. The documents provided us by HRSA officials did show that as of May 1990 HRSA had not yet evaluated the actual software and operational aspects of the data

bank. In the absence of this documentation, HRSA cannot ensure that the appropriate security measures are being installed to prevent unauthorized access and manipulation of data bank information.

In May 1990, as a result of concerns about security and project documentation, HRSA officials decided to engage the Federal Systems Integration and Management Center to evaluate the data bank's security system and to validate the system's software. As part of the evaluation, the Center was to identify system threats and vulnerabilities and effective countermeasures to these threats. The Center expects to issue a final report on the results of its evaluation by September 1990. In our view, this action while needed, may be too late to ensure that appropriate security measures will be in place by September 1990. An assessment of system security vulnerabilities and the defining of system security specifications should have been completed prior to writing data bank computer programs.

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## HRSA Has Not Effectively Managed the Data Bank Contract

The Department has designated the data bank a major information resources management initiative, which means, according to federal regulations, that it should be headed by a project manager. Among other things the regulations require the project manager to be given budget guidance and a written charter of his or her authority, responsibility, and accountability for accomplishing project objectives.

The project manager is responsible for seeing that a system is properly designed to meet the sponsors' and users' needs, and is developed on schedule. The project manager is also responsible for seeing that all system documentation is prepared as the system is being developed. If the system is being developed by a contractor, the project manager is responsible for certifying that the delivered system meets all technical specifications, including security specifications. In addition, the project manager is responsible for establishing a team with the required skills and experience to manage the development of the system. The data bank is being developed without a HRSA project manager because HRSA does not believe it has anyone with the necessary expertise to oversee the technical aspects of the contractor's efforts. Currently, at least 14 different HRSA officials are involved in developing and implementing the data bank. However, HRSA officials acknowledged that there is no one among the 14 with the necessary training and experience to ensure that the system delivered by the contractor will meet all technical specifications, including security.

Consequently, HRSA is relying on the contractor developing the data bank to carry out the critical project management functions of establishing plans, schedules, and budgets; and conducting most technical activities, such as testing computer programs before they are implemented. Because of HRSA's lack of expertise, other critical project management functions, such as ensuring that system sizing assumptions and work load volume are valid, identifying system internal control and security vulnerabilities, and ensuring that the Department's security requirements are being met, are not being carried out.

In May 1990, HRSA officials recognized the shortcoming of their project management approach and decided to bring in the Federal Systems Integration and Management Center to evaluate data bank development. Accordingly, HRSA entered into an agreement that, among other things, provides for validation of the data bank's software programs and an evaluation to determine whether the system meets the Department's security requirements. The Center's tasks include preparing documentation describing the data bank's performance requirements and each of the data bank's software programs and their function, as well as developing a test plan for validating the data bank's software programs.

HRSA is to be commended for recognizing it needs help in managing this contract, however, we believe this action may have come too late to ensure that an effective data bank can be opened in September. Time will be needed by the Center to replace missing documents and prepare documents that are vital for managing this contract.

## Project Cost May Increase

We have found in the past that not preparing studies and analyses, such as those required by the Department, and the absence of a qualified project manager during critical acquisition and implementation phases of a project lead to problems. These problems include millions spent for systems that did not meet users' needs, were not cost effective, experienced cost increases, were costly to maintain, or simply did not work.<sup>3</sup>

HRSA has begun to experience the effects of not preparing the required studies and analyses. Although \$15.8 million was approved for the project over a 5-year period beginning in January 1989, currently, HRSA is modifying the contract, which will require additional negotiations. HRSA

<sup>3</sup>Computer Acquisition: Navy's Aviation Logistics System Not Ready For Deployment (IMTEC-90-11, Feb. 22, 1990), Tax Administration: Replacement of Service Center Computers Provides Lessons for the Future (GGD-87-109, Sept. 23, 1987), and Mining Violations: Interior Needs Management Control Over Automation Effort (IMTEC-86-27, July 28, 1986).

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officials believe that the changes they are proposing will not significantly increase project cost. In commenting on a draft of this report, the Department of Health and Human Services said the modification is needed to cover certain requirements that existed at the time the data bank contract was awarded, but which had not been defined to the degree necessary for any offeror to address in a cost proposal. The additional requirements include the development of a user-fee system and development of software to implement the requirements of Section 5 of the Medicare and Medicaid Patient and Program Protection Act. Our discussion with contractor officials indicates they believe that about \$9 million may have to be added to complete the data bank project.

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## Conclusions

The Congress considers the National Practitioner Data Bank to be essential for helping track and monitor potentially dangerous licensed health care providers. Because of the anticipated cost of developing and maintaining the bank, the Secretary of Health and Human Services needs to rethink HRSA's approach to implementing the National Practitioner Data Bank. Allowing HRSA to continue along its current development approach is risky given that much design work still needs to be completed, as evidenced by the need to finalize many of the data bank's software programs and to identify and install appropriate system security features. The fact that the writing of software programs was initiated prior to the establishment of effective management controls raises serious questions regarding the usefulness of those software programs developed to date.

Further, HRSA's failure to develop documentation necessary to safeguard the confidentiality of the information collected raises questions about HRSA's ability to ensure that proper safeguards are being built into the system to prevent the unauthorized disclosure and use of highly sensitive practitioner information. Any violation of privacy could have an adverse effect on the health community and health care practitioners. In our opinion, the bank should not be operated until it has been tested to ensure that proper safeguards have been built into the system to ensure against the unauthorized disclosure or manipulation of bank information.

Additionally, the development of the data bank has been adversely affected by a breakdown in management controls at HRSA. Because HRSA has not designated a project manager and has either misplaced or did not prepare critical documentation that is necessary for ensuring effective management control over the project, it is questionable whether efforts to develop the data bank will result in the development of a

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system that effectively and efficiently meets the Congress' expectations and the Department's requirements. Although HRSA has invested many months of work, the agency has begun to experience the effects of mismanaging the data bank project. The \$15.8 million approved for the data bank over a 5-year period may not be enough to complete the project. An undetermined amount of additional funds—the contractor estimates at least \$9 million—may be needed to cover the costs incurred in developing and operating the data bank over its 5-year life.

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## Recommendations

We recommend that the Secretary of Health and Human Services direct the Deputy Assistant Secretary of the Office of Information Resources Management, which is responsible for ensuring consistency with information resources management statutory provisions and the Department's requirements, to provide independent technical oversight of the development, implementation, and operation of the data bank.

We further recommend that the data bank not be opened until the Secretary has assurance from the Deputy Assistant Secretary of the Office of Information Resources Management that effective security procedures have been implemented and that software programs have been successfully tested.

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## Agency Comments and Our Evaluation

In its July 16, 1990, comments on a draft of this report, the Department stated that it was committed to the effective operation of the data bank, including the application of all appropriate safeguards, and that our report provides insights that will help it achieve this goal (see app. II). The Department further said that our report touches on a number of concerns under consideration within HRSA. For example, as part of its final preparations for opening the data bank, HRSA has initiated efforts to ensure that the system will operate as required by law and regulation, with adequate provisions for security and the protection of individual privacy.

The Department said it intends to open the data bank on or about September 1, 1990, but agreed that the data bank should not be opened until the system's security measures have been tested and their adequacy verified. The Department said it strongly believes that it will have all appropriate safeguards in place and tested before the data bank opens. However, should any major deviation from specified system goals be discovered, the Department said it would delay implementation

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rather than risk consequences that would degrade public confidence in or violate the essential integrity of the system.

We believe that a September 1 opening date is optimistic given the amount of work remaining. Weaknesses identified by the General Services Administration's Federal Systems Integration and Management Center, an independent consultant engaged by HRSA to evaluate the data bank's security system and software programs, will need to be addressed before the data bank can open.

In July 1990 the Center reported that during its preliminary review of the system's security, it had identified several weaknesses that will, if not corrected, affect data bank security. For example, the Center found that as presently designed, the data bank does not contain a complete audit trail. An audit trail provides information for detecting unauthorized changes to data bank information and associating those changes with specific individuals or processes so that appropriate action may be taken. In the absence of an audit trail changes can be made to the data bank without the possibility of detection by simulating or masquerading as corrective actions.

The Center concluded that until audit trails can be clearly established, the Department and practitioners will not have reasonable assurance that the data bank contains only accurate information and that erroneous information will not be disseminated. Further, the Center advised HRSA that without a complete audit trail, certification of an acceptable data bank security environment is not recommended.

The Center expects to have a final report on the results of its security review and software validation issued in September 1990. On the basis of the results of the Center's findings and our own, we believe that the Department should not open the data bank until the Center has issued its final report, all security concerns identified by the Center are satisfactorily addressed, and the system has been certified as ready to operate.

Out of concern over the manner in which HRSA is managing the data bank contract, the House Committee on Appropriations in a July report<sup>4</sup> directed that funds provided for the data bank for fiscal year 1991 not be obligated until the Secretary of Health and Human Services is satisfied that the deficiencies we have identified in the management of the

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<sup>4</sup>House Report No. 101-591, July 12, 1990.

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data bank contract have been adequately addressed. In addition, the Committee directed the Secretary to conduct a review of the likely total capitalization and operating costs of the data bank under current law and report these findings to the Committee.

After receiving the Department's written comments, we met with Department and HRSA officials to further discuss our concerns. In a July 24, 1990, memorandum to us confirming agreements reached during this meeting, the Administrator of HRSA discussed actions the Deputy Assistant Secretary for Information Resources Management and HRSA will take to ensure that the data bank is not opened until it is ready to open (see app. III). The Administrator agreed that (1) there should be a specific HRSA official who is responsible for the overall management of the data bank's implementation, (2) the Department's Deputy Assistant Secretary for Information Resources Management will provide technical oversight to HRSA, and (3) the data bank will not be opened until the Deputy Assistant Secretary for Information Resources Management provides assurances that effective security procedures have been established and that software programs have been successfully tested. We believe that, if successfully implemented, the actions HRSA plans to take will effectively address our concerns.

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As arranged with your offices, unless you publicly announce the contents of this letter earlier, we plan no further distribution of it until 30 days after the date of this letter. At that time, we will send copies to the Secretary of Health and Human Services; the Assistant Secretary for Health, Public Health Service; the Director, Office of Management and Budget; and other interested parties. Copies will also be made available to others upon request. This report was prepared under the direction of Frank W. Reilly, Director, Human Resources Information Systems, who can be reached at (202) 275-3462. Other major contributors are listed in appendix IV.



Ralph V. Carlone  
Assistant Comptroller General

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# Contents

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Letter	1
Appendix I Scope and Methodology	18
Appendix II Agency Comments and Our Evaluation	19 34
Appendix III Memorandum From the Administrator of HRSA	38
Appendix IV Major Contributors to This Report	40

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## Abbreviations

GAO	General Accounting Office
GGD	General Government Division
HRSA	Health Resources and Services Administration
IMTEC	Information Management and Technology Division



# Scope and Methodology

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Our review was conducted from March 1990 to June 1990 at the Health Resources and Services Administration headquarters in Rockville, Maryland, the Department of Health and Human Services headquarter's in Washington, D.C., and the office of the contractor who is developing the National Practitioner Data Bank. In addition, we interviewed the project director and assistant project director for the contractor hired to develop the data bank. We performed our audit work in accordance with generally accepted government auditing standards. The Department of Health and Human Services provided written comments on a draft of this report. These comments are discussed in the report and are presented and evaluated in appendix II.

To ascertain HRSA's approach for developing the data bank, we reviewed its procurement request. We also interviewed responsible agency officials, future users of the data bank, and the contractor who is developing and will operate the data bank and obtained their views on the adequacy of the approach that HRSA is using to develop the data bank. To determine whether HRSA was complying with the conditions established in the delegation of procurement authority and was following procurement procedures in the Department's Information Resources Management Manual, we reviewed documentation submitted by HRSA to the Department and compared it with Health and Human Service's requirements applicable to automated data processing procurements. We also discussed Health and Human Service's policies and procedures with the Department's Office of Information Resources Management who reviewed the approved the request. We discussed the facts presented in this report with Health Resources and Services Administration and Department of Health and Human Services Office of Information Resources Management officials during the course of our work and have incorporated their views where appropriate.

# Agency Comments and Our Evaluation

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

JUL 16 1990

Mr. Ralph V. Carlone  
Assistant Comptroller General  
United States General  
Accounting Office  
Washington, D.C. 20548

Dear Mr. Carlone:

Enclosed are the Department's comments on your draft report, "Automated Data Processing: HRSA's National Practitioner Data Bank Is Not Ready To Operate." The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely yours,

A handwritten signature in cursive script that reads "Daniel W. Blades".

Daniel W. Blades  
Assistant Inspector General  
for Public Health Service Audits

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES' COMMENTS ON  
THE GENERAL ACCOUNTING OFFICE DRAFT REPORT ENTITLED  
"NATIONAL PRACTITIONER DATA BANK IS NOT READY TO OPERATE"

General Comments

We appreciate the opportunity to provide comments on the General Accounting Office's (GAO) draft report on the Health Resources and Services Administration's (HRSA) development of the National Practitioner Data Bank (NPDB).

This report provides additional insights which will assist us as we work for the fully successful implementation of this most critical system.

The NPDB, when operational, will play a vital role in identifying and protecting the public from incompetent or unethical health care professionals. We believe the management processes employed by HRSA are both reasonable and adequate to achieve this goal.

The draft report touched on a number of concerns already under active consideration within HRSA. For example, as part of its final preparations for opening the NPDB, HRSA has initiated efforts to assure that the system will operate as required by law and regulation, with adequate provisions for security and the protection of individual privacy.

We are absolutely committed to the effective operation of the NPDB, including the application of all appropriate safeguards. At this time, indications are that a September 1 start date is feasible. However, should we discover any major deviation from the specified system goals, we would delay implementation rather than risk consequences which would degrade public confidence in the system, or violate the essential integrity of the system.

The following are our comments on the recommendations.

GAO Recommendation

1. We recommend that the Data Bank not be opened and further funding for the contract to develop and implement the Data Bank not be provided until the Administrator, HRSA: (1) adopts an approach that conforms to the Federal system development requirements, including the Department's Information Resources Management Manual; (2) explicitly defines the Data Bank's requirements, performance standards, and security features; (3) ensures that appropriate management control elements are introduced into the project; (4) develops adequate test plans for validating Data Bank software programs; (5) establishes a formal project quality control

system; and (6) determines what security features should be included to prevent the unauthorized access and manipulation of Data Bank information.

Department Comment

See comment 1

We do not concur. HRSA has approached the information resources management (IRM) system development in an overall acceptable manner. HRSA's statement of work in the contract contained adequate functional requirements for the contractor to initiate development of the NPDB; and the decision to use the competitive market place to determine the best approach to system design requirements is consistent with Departmental policy. The marketplace responded with diverse technical proposals, and we believe the systems approach of the contractor selected by HRSA is consistent with applicable Federal requirements. It also needs to be pointed out that HRSA has incorporated major elements of IRM life cycle management, including security, into the contractual requirements sufficient for the contractor to respond with an acceptable technical proposal.

See comment 2.

As a result of ongoing monitoring and site visits which revealed concerns about certain aspects of security and project documentation, HRSA executed an interagency agreement with the General Services Administration's Federal Systems Integration and Management Center (GSA/FEDSIM) to evaluate system security and to verify and validate software. The independent consultant provided by GSA/FEDSIM has confirmed that the system requirements are adequate, and asserts that confidentiality concerns have been adequately addressed. The independent consultant further believes it is possible for the system to be tested, validated, and major issues satisfactorily addressed for the NPDB to be certified to operate as planned, by September 1.

See comment 3.

NPDB project management activities have followed a systematic and typical Departmental approach throughout the course of system design and development. This approach begins with the line responsibility of the program project officer (who must receive specific project officer training), the contracting officer, and their respective management chains, buttressed by support from IRM and financial management staff. Due to the need for expertise in fields such as insurance and hospital administration, and the need for outreach to user groups, a Panel of Experts and an Executive Committee have also provided advice regarding the NPDB.

As of today, the NPDB is on schedule for a September opening and within budget for the work for which HRSA originally contracted. The contractor's initial proposal regarding a planned contract

modification was out of line. It has subsequently been withdrawn by the contractor. Moreover, additional funding to be negotiated with the contractor will be for expenses associated with the full implementation of legislative requirements contained in Section 5 of Public Law 100-93, and for a 10-month extension in the period of operations to compensate for a delay in the issuance of regulations. This work is unrelated to the system implementation and September 1 remains a viable target.

GAO Recommendation

2. We further recommend that the Secretary for Health and Human Services:

- direct the Department's Director of Telecommunications and ADP to reconsider HRSA's Delegation of Procurement Authority (DPA) because the agency has failed to comply with the conditions established in the delegation for the agency's NPDB; and
- direct the Department's Deputy Assistant Secretary of the Office of Information Resources Management, which is responsible for ensuring consistency with information resources management statutory provisions and the Department's requirements, to take over management of the project until the Administrator of HRSA can demonstrate that appropriate management controls have been introduced into the project.

Department Comment

We do not concur. The GAO has provided no analysis of management alternatives, but has chosen and recommended a single option. The Assistant Secretaries for Health and for Management and Budget intend to support HRSA at this critical juncture in the project by providing an appropriate level of assurance that the management of the project and the final decisions leading to opening the NPDB are technically sound, take into account consultant and staff recommendations, and fully weigh any indicated risks.

See comment 1.

Technical Comments

1. Will the National Practitioner Data Bank Open in a Timely Fashion?

Page 2: "The Data Bank is not ready to begin operating in September 1990." There is no assurance that appropriate security measures will have been installed to prevent unauthorized access and manipulation of Data Bank information.

Pages 19-20: "The Bank should not be operated until it has been tested to ensure that proper safeguards have been built into the system to ensure against the unauthorized disclosure or manipulation of Data Bank information."

Page 9: Four weeks' lead time for distribution of the Data Bank forms, instructions, and user guidebook is not sufficient.

Comment: The Department intends to open the Data Bank on or about September 1, 1990. We are strongly of the opinion that all appropriate safeguards will be in place and their adequacy tested and documented before the Data Bank opens. The Department will not proceed with the opening of the Data Bank unless it has assurance from an independent source that the system is secure and, moreover, that it will operate in accord with design specifications. The preliminary report of the independent contractor, whose services we engaged through GSA/FEDSIM to evaluate the system's security and efficacy, indicates that the remaining tasks needed to open the Data Bank can be feasibly completed within existing time and resource constraints. Please refer to Section E, Security Concerns, following, for detailed discussion on these issues.

Insofar as the issue of lead time is concerned, steps have already been taken by Data Bank program and contractor staff to ensure that the entities with Data Bank reporting and querying responsibilities will have in their possession, well in advance of the Data Bank's opening, the materials they will need to carry out these responsibilities. For example, the Data Bank reporting and querying form, the instructions for their completion, and the user guidebook (which is a detailed reference for individuals and entities reporting to and querying the Data Bank) all have been printed through GPO auspices and delivered to the Unisys Corporation's Camarillo Computer Facility site, which is the locus of the Data Bank computer operations. Nationwide distribution of these materials by the Department, through the Data Bank contractor, will proceed on schedule. Delivery of the Data Bank forms,

instructions, and guidebook to the Nation's hospitals and other health care entities, medical malpractice insurers, State medical and dental boards, and professional societies (an estimated total of 16,000 entities) has already begun and all addressees will have received them by the end of July. This means that the entities with Data Bank reporting and querying responsibilities would have the necessary program materials at least a month before the scheduled opening of the Data Bank.

Moreover, advance copies of the Data Bank forms, instructions, and Guidebook have already been provided to organizations representing the major user groups, e.g., the American Hospital Association (AHA), American Medical Association (AMA), American Dental Association (ADA), malpractice insurance consortia, etc., in May 1990. They in turn have duplicated them and are currently distributing them to their respective memberships and constituencies. Thus, critical documents are in their hands well before the formal mailing.

Additionally, Data Bank program and contractor staff held over 12 educational conferences nationwide in February and March 1990 to orient entities with Data Bank reporting and querying responsibilities to the Data Bank requirements, forms, and related materials. These conferences were announced in the Federal Register. Further, Federal representatives of the Data Bank have addressed, upon invitation, numerous national professional health care and related organizations regarding Data Bank requirements, as well as their interpretation, reporting and querying policies and procedures. Through these and other activities, major professional organizations and entities have been kept fully and periodically informed about what they needed to know in order to help their constituencies fulfill their responsibilities to report to, or query the Data Bank.

Throughout the developmental phase of the Data Bank, counsel and assistance have also been solicited from, and provided by, a variety of health professionals, professional health care and other associations and organizations, including public interest groups, with expertise essential to the establishment and implementation of the Data Bank. These are described below.

In February 1987, the former HRSA Administrator, Dr. David Sundwall, convened an ad hoc Title IV advisory committee comprised of Government personnel drawn from offices and agencies involved in programs bearing on medical liability and malpractice, licensing and discipline in the health

professions, quality assurance and risk management, and other matters relevant to the Data Bank. A major contribution of this committee was to lay out the conceptual design and framework for the Data Bank, in relation to requirements set forth in the Title IV statute.

Responsibility for drawing up more detailed design elements for the Data Bank, the specification of requirements for the Data Bank procurement, and the eventual contract scope of work, was given to a Technical Advisory Panel whose membership included several senior Federal employees with distinctive knowledge and expertise in computer technology and ADP system design.

Two bodies comprising representatives of leading health care related professional organizations, the Data Bank Executive Committee and the Data Bank Panel of Experts (PoE), have provided advisory guidance and assistance to the Department and the contractor throughout the Data Bank's development and pre-implementation phases. The Executive Committee's membership includes the AMA, ADA, AHA, and other national organizations and consumer groups. The PoE includes nationally recognized professionals in areas such as hospital administration, medical liability insurance, licensure and discipline of health care practitioners, computer science.

The Executive Committee has been involved in virtually all aspects of the Data Bank's development and implementation and has assisted with the formulation of operational policies and procedures for the Data Bank, including, for example, those dealing with security, confidentiality, and reporting and querying methods. The Executive Committee also had direct input into the formulation of the content of the NPDB Guidebook, which is the principal reference and resource document for individuals and entities with Data Bank reporting and querying requirements. The PoE was integrally involved with the design and development of the Data Bank reporting and querying instruments, including the formulation of specific reporting codes, and with the preparation of the instructions for completing the forms. The PoE met collectively on several occasions and individual members were called upon separately, as needed, for their particular expertise.

The HRSA Data Bank staff have been diligent in their efforts to seek out, engage, and listen to outside interest groups and the general public in the Data Bank development process. Public forums were held on the Data Bank on October 2 and November 27, 1989; a broad cross-section of professional health-related organizations and other interest groups, and

representatives of the lay, consumer public and public media participated in these sessions.

Other examples of major Data Bank outreach efforts include a December 14, 1989 Invitational Conference for National Professional Associations; and a January 11, 1990 conference with representatives of national hospital associations and HMO/group practice organizations to help plan Educational Conferences for Hospitals and Other Health Care Entities; and, as noted, during the period February 5 - March 29, 1990, the convening of a series of conferences, nationwide, to provide guidance for entities and individuals in meeting their responsibilities to report to or query the Data Bank, viz., medical malpractice insurers, State medical and dental boards, hospitals and other health care entities, and professional medical and dental societies. Recommendations on Data Bank policy and procedural proposals made at these conferences were considered, and often incorporated, as appropriate into the pertinent Data Bank policies, procedures, and user materials.

2. Process and Timing of Developmental Steps

Page 10: Data bank development started before requirements were finalized.

Page 2: HRSA began developing the data bank before system threats and vulnerabilities were identified.

Page 11: HRSA's decision to award a contract before finalizing the operational processes by which data bank information was to be gathered and disclosed was a mistake.

See comment 4.

Comment: As already indicated, the Data Bank was not a proposal that originated within the Executive Branch, but was mandated by Congress. Thus, there was not the opportunity to develop the options analysis that would have typically been associated with the development of a new system. HRSA was required to implement this legislative requirement with little lead time. Funding did not become available until October 1988 (FY 1989), thereby delaying the awarding of a contract until December 1988. The final regulations implementing Title IV requirements were not published until October 1989 principally because of the Department's effort to comply with OMB directives regarding the scope of data elements to be covered in those final regulations.

See comment 5.

To have waited until after publication of the final regulations to award a contract would have further delayed implementation of the program by a year. Such deferral was

unnecessary because the basic Data Bank requirements had already been specified in the NPRM (which was provided to the Unisys) and which, ultimately did not change significantly when the final regulations were promulgated. The contractor knew what was expected of it well before the final Title IV regulations were published, since such requirements were reflected in the contractor's technical proposal of August 1988. The RFP/scope of work was carefully written to provide specific guidance in the areas of Data Bank systems design and security requirements. The contractor recognized and accepted the need to meet those requirements in its technical proposal of August 15, 1988 (Page A.2 - 49, Section 2.1.2). Further, in its "Draft Narrative on Design for and Implementation of the Data Bank" (Contract Deliverable Item 32, November 1989), the Data Bank contractor acknowledged the detailed requirements and that the security constraints in the RFP/scope of work were "extensive in scope and detailed in their requirements, covering all aspects of security." The GSA/FEDSIM preliminary report confirms that Unisys believed the specification level to be adequate.

3. Adherence to Departmental Procedures

Page 13: HRSA is not following the Department's systems development life cycle methodology and neither is it complying with the Department's Information Resources Management Manual.

Page 13: Missing documentation: cost-benefit analysis of alternative approaches; explanation of how the approach selected would meet users' needs at the lowest overall cost over the system's life; test plan for evaluating the software program.

Comment: The decision to contract out both the development and operation of the Data Bank was made by former HHS Secretary Otis R. Bowen.

In his communication of October 30, 1987 to James C. Miller, III, Director, OMB, requesting a \$3.2 million budget amendment to the President's FY 1988 request for HRSA to implement the Health Care Quality Improvement Act of 1986 (the Act), Secretary Bowen stated that he had decided "that HRSA should secure the services of a private contractor to act as the Government's agent in the collection and release of the(se) data" which the Act required be reported to the Data Bank. In his communication to the President regarding that budget amendment request, Mr. Miller affirmed the Secretary's decision to engage the services of a private contractor in establishing the Data Bank.

Dr. Bowen's decision was based on the sensitivity of the subject, the relative lack of in-house capability, and the urgency of carrying out the congressional requirements. Separate contracts for the design and the implementation of the Data Bank would, perhaps, have been desirable (although not required by departmental procedures) but would have significantly delayed implementation of the legislative mandate.

See comment 6.

Further, HRSA has complied with all required departmental procedures. According to Chapter 2, Section 2-20-00, of the HHS IRM Manual, HHS managers may tailor their management approach to life cycle guidelines "where appropriate to meet the particular needs of their own programs."

See comment 7.

The documentation associated with the Delegation of Procurement Authority (DPA) adequately addresses departmental requirements. In particular, the requirement to develop a test plan was placed on the contractor (Unisys), and the adequacy of the test plan is being evaluated separately by the GSA/FEDSIM contractor.

The contractor's technical proposal of August 1988 ("Quality Assurance/Configuration Management") commits to adhering to appropriate systems development methodology as specified by HHS in the RFP/scope of work.

4. HRSA's Management Process

Page 2: HRSA has not designated a project manager, so no one has been accountable for the project since it began.

Pages 2-3: HRSA has either misplaced or not developed critical documentation necessary to ensure effective management control and oversight of the project.

Pages 11-12: Sound project management practices are not being followed. Flaws in HRSA's approach to develop the data bank cast serious doubt on whether a successful system can be deployed by the planned September 1990 opening date.

Pages 16-17: HRSA has not effectively managed the data bank contract. According to Federal regulations. . .it should be headed by a project manager;" "Currently, at least 14 different HRSA officials are involved in developing and implementing the data bank;" ". . .critical project management functions. . .are not being carried out.

Page 20: The development of the data bank has been adversely affected by a breakdown in management controls at HRSA. Because HRSA has not designated a project manager. . .

See comment 8.

Comment: The main thrust of GAO's criticism stems from the premise that this project should have been managed in accordance with established guidelines for a "major systems acquisition," requiring the designation of someone with "project manager" responsibilities at the beginning of the developmental process. A "project manager" in the sense used by GAO has much broader authorities than are generally delegated below a Bureau level in this Department and is not required by the Department for a project of the size of the Data Bank. Although HRSA has not designated one individual as the "project manager," the NPDB has been managed responsibly and effectively through established line management structures, methodologies, and controls. The project officer for the contract meets all departmental requirements for a contract project officer and he reports to a Division Director, who reports to a Bureau Director. The contracting officer and the HRSA Financial Management Office do not report to the project officer or Bureau Director and this does not fit the GAO view of how a project of this magnitude should be managed. It is our view, however, that the normal departmental line management system is sufficient to assure appropriate management controls. This method/approach of management is entirely consistent with that successfully used for similar projects in the Department. While different from the model GAO contends is necessary, we believe this approach will result in the opening of a secure data bank on or about September 1, 1990.

In fact, a combination of contractual requirements and program policies have consistently been used by HRSA to implement sound management practices.

Planning for the Data Bank began in February 1987 when a series of ad hoc advisory committee meetings were held to formulate a plan to develop a Data Bank to meet the requirements of Title IV of Public Law 99-660, the Health Care Quality Improvement Act of 1986. Senior representatives from the Office of the Secretary, ASH, HRSA, BHPr, and other Federal organizations, attended these meetings. The meetings served as a basis for developing the Data Bank RFPs and NPRM. An RFP was first issued in June 1987. The scope of work was carefully written to provide specific guidance in the areas

of Data Bank systems design and security requirements. In March 1988 the RFP was withdrawn because no funds were available. An updated RFP was issued in August 1988.

On December 30, 1988, a 5-year \$15.9 million contract was awarded to Unisys Corporation to develop and operate the Data Bank. In their technical proposal, the contractor assured the Department of their expertise in systems design, security, and with the Privacy Act. Soon after the contract was awarded, Unisys was provided with a copy of the Data Bank NPRM to be used as a basic blueprint along with the scope of work in order to begin the development of the systems design. Although the final regulations were not published until October 1989, Unisys was instructed to continue development of the systems design based on continuous input from the Department regarding the shape of the draft final regulations.

The scope of work called for a Data Bank Executive Committee and PoE (formerly the Technical Assistance Group). The committee is advisory to the contractor. Two of the functions of the committee are to review and comment on the Data Bank policies and procedures for its operation and to advise on criteria against which the Data Bank will be assessed, including issues such as security and confidentiality. The PoE consists of individuals with expertise in computer science and other "technical" areas of systems design. Since January 1989, the Executive Committee has met four times and the PoE three times. Both the committee and panel have provided valuable assistance and expertise to Unisys and the Department regarding the development of the Data Bank.

Legal and program staff of the Department have worked closely with the contractor to develop policies and procedures to assure a secure environment for the confidential receipt, storage, and controlled dissemination of data from the Data Bank. Contract Deliverable Item 39 - "Draft Policies and Procedures for the Initial NPDB Operation" expands on the scope of work to provide the contractor with a detailed description of Data Bank policies and procedures (PPDs) for reporting to and requesting information from the Data Bank. In addition to this document, the Department and the contractor have worked closely on development of Data Bank output documents, reporting and querying forms and instructions, and the Guidebook for individuals and entities reporting to and querying the Data Bank.

The "output" materials consist of a series of documents which include reporting entity verification of information sent to the Data Bank, practitioner notification that a report has

been made to the Data Bank about them, and a practitioner's dispute of the accuracy of information in the Data Bank. The reporting and querying forms and instructions were carefully crafted following extensive discussions regarding systems design, confidentiality and security between the Department, Unisys, and affected organizations in the Federal and non-Federal sectors.

Other management and oversight procedures have already been described above, e.g., regular meetings between HRSA, BHPr, and Unisys since the first year of the contract regarding Data Bank policies, procedures and systems design. Contrary to the impression created by GAO, the RFP/scope of work is studded with specific operational requirements developed by HRSA for the Data Bank which the contractor, in various documents, affirms and commits itself to fulfilling. The GAO allegation that the contract was awarded before the system requirements were finalized is, therefore, misleading; the contractor knew what was expected of it well before final regulations were published.

In summary, HRSA has exercised a style of management of this project that is entirely consistent with that successfully used in the case of other projects for which it is or has been responsible. While different from the inapplicable management model which GAO seems committed to imposing, the fact remains that the approach employed by HRSA will result in the opening of a secure Data Bank on or about September 1, 1990. The Data Bank has been designed according to RFP/scope of work requirements by a contractor employed by the Department for the specific purpose of doing so. The contractor has been continuously guided and advised by a variety of oversight mechanisms in the process of achieving the result desired by the agency according to its own timetable.

5. Security Concerns

Page 14: HRSA has not complied with Department and Governmentwide security requirements.

Page 15: HRSA cannot ensure that the appropriate security measures are being installed to prevent unauthorized access and manipulation of data bank information.

Page 20: The bank should not be operated until it has been tested to ensure that proper safeguards have been built into the system to ensure against the unauthorized disclosure or manipulation of bank information.

Comment: We agree that the Data Bank should not be opened until the system's security measures have been tested and their adequacy verified. Assuring the security of the Data Bank has been a concern to which the Department has devoted much attention and effort since the beginning of the project. As mentioned earlier, the contract scope of work is replete with requirements/specifications bearing on system security and integrity. Further, security reviews were conducted by HRSA staff in April 1989 and March 1990, each lasting several days. As a result of these reviews, HRSA implemented its Phase II systems review, involving more technical expertise than was available within the Agency. It was at that point that HRSA entered into an agreement with GSA/FEDSIM to provide independent evaluation, test, and certification reviews. The initial site visit and documentation review has been completed and their preliminary analysis indicates "all deficiencies identified to date are correctable within a time frame which will not significantly impact the NPDB schedule."

6. Cost

Page 3: Project's cost could increase substantially.

Page 18: PROJECT COST MAY INCREASE.

Comment: GAO also raised concerns about cost overrun and contended that prospective increased contract costs were due to HRSA's failure to "prepare the required studies and analyses in sufficient detail prior to award of any contract." This statement is inaccurate.

HRSA initiated a proposed contract modification to the original statement of work with the issuance of a Request for Proposal (RFP) to Unisys. The purpose of this RFP was to define "new" statement of work requirements confirmed by the final approval of the NPDB regulations. The new requirements dealt with aspects of the Data Bank's operation that were known to exist at the time of contract award, but not to the degree necessary for any offeror to address in a cost proposal, e.g., the development of a user fee system, the determination of the actual user fee based on cost criteria identified in the regulations, and the implementation of the NPDB to accommodate the requirements contained in the Section V of Public Law 100-93 which requires reporting of disciplinary actions executed on all licensed health professionals such as nurses and therapists. The original contract was for a period of 5 years but because of a 10 month delay in issuing regulations, a corresponding 10 month extension and associated funding were also proposed.

See comment 3.

Thus, the negotiations identified by the GAO were essential to contract administration and not attributable to an unanticipated cost overrun. The contractor responded to the proposed modification inappropriately with a re-baselining of the entire contract costs rather than individual pricing of the new statement of work requirements and the 10 month delay. HRSA advised the contractor that their proposal was inappropriate and unacceptable. The contractor's proposal was withdrawn in its entirety.

At the present time, HRSA has not requested the contractor to submit a revised proposal, but has informed the contractor that negotiations and a contract modification are expected shortly.

It is the position of HRSA that a modification is necessary to cover the modifications described above, the extension of the contract period and otherwise cover certain changes in technical direction. However the contractor's estimate that costs are expected to increase by \$9 million are unfounded.

7. GAO's Identification of Procurement Sensitive Information

The GAO report indicates that HRSA decided to bring in a contractor in May 1990. This statement, which is also made on Pages 2 and 15, should indicate that HRSA entered into an Interagency Agreement with GSA/FEDSIM. Also, the value of a referenced "contract" is procurement sensitive and should be deleted. Page 7 of Project Element Plan (PEP) No. 2, which is part of HRSA's Interagency Agreement with GSA/FEDSIM, states non-disclosure requirements relating to information contained in the PEP.

See comment 9.

## GAO Comments

1. In its July 16, 1990, comments on our draft report, the Department disagreed with our proposed recommendations. After receiving the Department's comments, we met with Department and HRSA officials to further discuss our concerns. Overall, the Department officials agreed that the data bank should not be opened until the Department's Deputy Assistant Secretary for Information Resources Management provides assurances that effective security procedures have been implemented and that software programs have been successfully tested. In addition, the Department agreed to designate a project manager to ensure that the data bank is properly managed. The Department also said that the Deputy Assistant Secretary for Information Resources Management will provide technical oversight to the data bank project. On the basis of these agreements, we have refined our recommendations to reflect our general concern that the data bank not be opened until it is ready.

2. We reviewed a preliminary report on system security issued by the independent consultant in July 1990. We disagree with the Department's assertion that the consultant has confirmed that the data bank's system requirements are adequate and that confidentiality concerns have been adequately addressed. The consultant's report found several vulnerabilities that will affect the security of the data bank if they remain uncorrected. The report also found that the documents identified by HRSA as containing the data bank design did not contain sufficient information to provide a reasonable level of assurance that the functional security requirements identified by HRSA in the solicitation for the data bank were being effectively implemented. The report further found that although Unisys had defined an effective approach for development and implementation of the data bank, the approach was not being followed. Additionally, the report found one security vulnerability that would result in a recommendation not to certify the acceptability of the data bank. The data bank lacks the capability to detect unauthorized changes to the data bank, according to the report. The report concluded that until this vulnerability is adequately addressed HRSA and practitioners will not have reasonable assurance that the data bank contains only accurate information.

3. The draft has been modified to show the current status of HRSA's proposed modification to the data bank contract's original statement of work.

4. According to the Department, HRSA did not have the opportunity to develop analyses that are typically associated with the development of a new system because HRSA was required to implement the data bank

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with little lead time. We disagree. We believe the 4 years that have been spent by HRSA in developing the data bank provided sufficient time to prepare the various studies and analyses typically associated with the development of a new system.

5. The Department asserts that waiting until after publication of the data bank's final regulations to award a contract was unnecessary because the basic requirements for the data bank had been specified in documents HRSA provided to the contractor. The Department said the solicitation documents and contract's scope of work provided specific guidance in the areas of systems design and security. We disagree. We found, and the contractor and Federal Systems Integration and Management Center agree, the basic requirements contained in the Department's solicitation documents are extremely general and do not constitute an adequate description that would permit development of a system design. Furthermore, the contractor in a December 1989 letter to HRSA stated that

The delay in publishing implementing regulations for the data bank has had a significant impact on the design and development of the data bank. On the one hand, the delay in publishing regulations has required slowing down the development process and the project's rate of spending; but, on the other hand actual development activities will need to be extended over a longer period of time, particularly in connection with the implementation of Section 5 requirements.

Had HRSA waited to award the contract until the regulations were finalized it could have had a more specific set of requirements to be used in designing the system because the regulations establish criteria and procedures for collecting and releasing information from that data bank.

6. The Department stated that HRSA has complied with all required departmental procedures. We disagree. We found evidence showing that HRSA did not always comply with required departmental procedures. For example, in June 1988 the Department directed HRSA to prepare a cost/benefit analysis which was to include the development of and pricing for at least three alternative methods for developing the data bank. The Department requires cost/benefit analyses so that managers, users, designers, and others have adequate information to analyze and evaluate alternative approaches to meeting mission needs. HRSA officials said that the cost/benefit analysis was not prepared because they had assumed the Department had approved HRSA's request to have the requirement waived. However, HRSA officials could not provide documentation showing the requirement had been waived.

The Federal Systems Integration and Management Center also found that HRSA had not always complied with departmental requirements. For example, the Center found that the data bank does not contain an audit trail as required by Department and federal guidelines. An audit trail provides the information necessary to detect unauthorized changes to an automated system. The Center concluded that because the data bank does not have an audit trail, HRSA and practitioners will not have reasonable assurance that the data bank contains only accurate information.

7. The Department stated that the documentation associated with the delegation of procurement authority adequately addresses departmental requirements. We examined the Department's official acquisition file and found that the documentation associated with the delegation of procurement authority was missing. When we asked HRSA officials why the documentation was not in the acquisition file, they speculated that it was in a file that they have been unable to locate since 1988. In the absence of documentation we cannot determine whether the documentation adequately addresses departmental requirements.

8. The Department stated it does not require project managers for projects the size of the data bank. The Department believes that these projects can be managed responsibly and effectively through established line management structures, methodologies, and controls. We disagree. We found that the data bank development effort has not been effectively managed through the Department's project management approach. HRSA line managers responsible for managing the data bank's development said they lack the necessary expertise to oversee the technical aspects of the contractor's efforts. Because of HRSA's lack of expertise, we found that critical project management functions, such as ensuring that system sizing assumptions and work load volume are valid, identifying system internal control and security vulnerabilities, and ensuring that the Department's security requirements are being met, are not being carried out. Consequently, HRSA has been relying on the contractor to carry out critical project management functions.

The Federal Systems Integration and Management Center, in its review of the data bank's security system, also discovered evidence of problems resulting from HRSA's management approach. The Center found that, although the system development approach described in the contractor's technical proposal was consistent with applicable federal requirements, the contractor failed to implement these procedures, which resulted in documentation deficiencies. According to the Center, this occurred as a

result of HRSA's failure to monitor contractor compliance with its technical proposal.

As stated in comment 1, the Administrator of HRSA has now agreed that there should be a specific HRSA official who is responsible for management of all aspects of data bank implementation and has designated the director of HRSA's Bureau of Health Professions to be the data bank program manager. The Administrator also said that a qualified systems analyst will be assigned to work with the data bank program manager.

9. We agree that the language suggested by the Department is more precise and have modified our draft.

# Memorandum From the Administrator of HRSA



DEPARTMENT OF HEALTH & HUMAN SERVICES  
HEALTH RESOURCES AND SERVICES ADMINISTRATION

Public Health Service

## Memorandum

Date . JUL 24 1990

From Administrator

Subject Follow up Action on the General Accounting Office Draft Report Entitled "The National Practitioner Data Bank Is Not Ready to Operate"

To Thomas Jurkiewicz, GAO

This memorandum documents the agreements we reached in the meeting chaired by Congressman Ronald Wyden (D-Oregon) on July 20 concerning GAO's draft report on the NPDB. These agreements are as follows:

- o GAO is concerned that there be a single point of overall responsibility for managing the NPDB implementation. We agree, and the Department's Office of Information Resources Management agrees that, to the extent permissible under currently mandated organizational functions and authorities, HRSA should identify the specific official who is responsible for oversight of all aspects of the NPDB implementation, with authorities commensurate with that responsibility. That individual is Fitzhugh Mullan, M.D., Director, Bureau of Health Professions. In his capacity as NPDB program manager, Dr. Mullan will have, among other staff members, a qualified systems analyst as a full-time member of his project team.
- o GAO is concerned about HRSA's relative lack of technical expertise in automated systems design and implementation, but recognizes that HRSA has significantly augmented its internal staff capability through an inter-agency agreement with FEDSIM. We agree that HRSA will expeditiously augment its capability in this area but in the interim will continue to use FEDSIM. GAO will recommend that the Deputy Assistant Secretary for Information Resources Management provide technical oversight to HRSA. The Deputy Assistant Secretary agrees to provide such oversight and will also assure appropriate system documentation is in place in a timely fashion.

Appendix III  
Memorandum From the Administrator  
of HRSA

Page 2 - Mr. Jurkiewicz

- o At the time of the initial GAO study, the FEDSIM consultants had not yet begun their independent assessment, and GAO was concerned that HRSA could not assure the security of confidential practitioner information. GAO has now reviewed the initial FEDSIM report and will recommend that the data bank not be opened until the Deputy Assistant Secretary for Information Resources Management assures that effective security procedures and software programs have been successfully tested. We agree. As stated in the original Department comments, should we discover any major deviation from the specified system goals, we would delay implementation rather than risk consequences which would degrade public confidence in the system, or violate the essential integrity of the system. Additionally, at the time of the GAO study, HRSA was precluded from designing audit trail capability into the system. That previous barrier has now been overcome and audit trail capability will be built into the system before it becomes operational.
- o GAO was concerned about "cost overruns." GAO now understands that the contractor's proposed cost increase was withdrawn and will modify their report to reflect that understanding.

It is our understanding that GAO will revise their recommendations in accordance with the agreements reached in this meeting to reflect their general concern that the NPDB not open until it is ready to open. As stated above, that has been and remains the Department's position.

A copy of this memorandum is being provided to Congressman Wyden's office and other DHHS components as documentation of the agreements reached in the July 20 meeting.



Robert G. Harmon, M.D., M.P.H.

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