EXECUTIVE SUMMARY

PURPOSE

The purpose of this management advisory report is to recommend that the Public Health Service (PHS) strengthen controls over authorized agents to assure that information provided by the National Practitioner Data Bank (Data Bank) is not misused.

BACKGROUND

Information maintained by the Data Bank is considered confidential and cannot be disclosed outside the Department of Health and Human Services as specified in the Data Bank regulations, 42 CPR 60.

During planning for the Data Bank, staff from the Bureau of Health Professions, PHS, expressed concern to us regarding the confidentiality of the Data Bank information that was provided to "authorized agents." Specifically, there was concern that the apparent growth of this industry could lead to "authorized agents" that did not always follow appropriate procedures or standards involving the handling of Data Bank information.

FINDINGS

We determined that controls over authorized agents are insufficient. Procedural guidelines and forms relating to agents do not adequately address the issue of confidentiality.

RECOMMENDATIONS

We recommended that PHS implement policies to assure that authorized agents are reputable and that such agents utilize appropriate security measures to assure the confidentiality of Data Bank information. We also recommended that Data Bank forms be modified to describe the confidentiality requirement.

COMMENTS

PHS concurred with most of the recommendations in our draft report. PHS did not agree to the recommendation that, if the agent is a company or organization, it must be incorporated, licensed or otherwise legally permitted to do business. Based on the PHS response, we have modified our recommendation.

Because the PHS response to our recommendation that they modify the Data Bank response form is not clear, we are asking for clarification.
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INTRODUCTION

PURPOSE

The purpose of this management advisory report is to recommend that the Public Health Service (PHS) strengthen controls over authorized agents to assure that information provided by the Data Bank is not misused.

BACKGROUND

Information maintained by the Data Bank is considered confidential and cannot be disclosed outside the Department except as specified in the Data Bank regulations, 42 CFR 60. According to Section 60.13 "...Persons or entities which receive information from the Data Bank either directly or from another party must use it solely with respect to the purpose for which it was provided." For each violation of confidentiality, civil money penalty of up to $10,000 can be levied.

During planning for the Data Bank, staff from the Bureau of Health Professions, PHS, expressed concern to us regarding the confidentiality of Data Bank information that was provided to "authorized agents" who queried the Data Bank on behalf of health care entities. Specifically, there was concern that the apparent growth of the credential verification industry could lead to "authorized agents" that did not always follow appropriate procedures or standards involving the handling of Data Bank information.

Authorized Agents

Sections 60.10 and 60.11 of the Data Bank regulations allow access to the Data Bank by certain persons or entities, or their authorized agents. According to the Data Bank Guidebook, an authorized agent is "...an individual or organization (e.g. county medical society, State hospital association), which the health care entity or individual designates to request information from the Data Bank on its behalf..." However, since the term "authorized agent" is not restricted by the Guidebook or defined in the statute or regulation, it is possible that an authorized agent could be a credential verification business or individual engaged in activities completely unrelated to credential verification.

Concerns regarding the integrity of authorized agents were expressed in comments that the PHS received in response to the March 21, 1988 Notice of Proposed Rulemaking (NPRM), National Practitioner Data Bank. These concerns were set forth in the October 17, 1989 final regulation as follows:
"Numerous respondents questioned what information would be given in response to authorized agents' requests concerning physicians, dentists or other health care practitioners... The majority of the respondents expressed concern over verification of the identity of individuals and entities who request information from the Data Bank... The Secretary shares these concerns about maintaining the confidentiality of the information in the Data Bank and will take measures to insure the proper release of this information. Since the Data Bank has not been established at this time, it is impossible to detail the precise procedures which will be used for the verification of the identity of the requesters. At the time of the operation of the Data Bank, the Department intends to provide this information to the public in the form of guidelines..."
FINDINGS

Controls Over authorized Agents Are Insufficient

The only guidelines concerning the use of authorized agents are found on page 15 of the Data Bank Guidebook, as follows:

"An entity or individual that is eligible to request information from the Data Bank, may, at its discretion, use an agent to represent it for purposes of requesting information. Before an agent may submit request for information, the entity or individual must register the agent with the Data Bank at any time by writing to the Data Bank."

The "registration" information required by the Guidebook for any authorized agent is limited to basic information relating to their name, address, telephone number, authorized signature and effective date of registration. This information is provided by letter to the Data Bank by the entity or individual who will be using the authorized agent.

The registration procedure does not fully address the concern over the identity of authorized agents that was expressed by respondents to the Data Bank regulation. The policy for "registration" does not assure that an authorized agent is responsible or reputable. While hospitals or other established entities may not warrant such concern, the PHS will have no assurances that an authorized agent, for which there is no restrictive definition, will be accountable.

In addition, the current Data Bank forms do not address the issue of keeping information confidential. According to the Guidebook, when an entity, individual or authorized agent requests information for the Data Bank, it must use Office of Management and Budget (OMB) Form #0915-0126, Request For Information Disclosure. This form contains a certification, as follows:

"I certify that the requesting entity identified in Section A of this form is authorized, under the provisions of P.L. 99-660, as amended, as specified in 42 CFR Part 60, to request and receive information from the Data Bank. I further certify that the information provided on this form is true and complete, and that the requesting entity identified in Section A of this form has authorized me to request this information."

The certification is followed by a "warning" that "Any person who knowing makes a false statement or misrepresentation to the Data Bank is subject to a fine and imprisonment under Federal statute."
The form entitled "Response To Information Disclosure Request" does not mention the confidentiality requirements of the law. This form, of course, is used to transmit Data Bank information to both authorized agents and health care entities.
RECOMMENDATIONS

In order to strengthen controls over the use of authorized agents, the PHS should consider requiring such agents to meet certain conditions. We have the following suggestions:

1. If the agent is incorporated, licensed or otherwise legally permitted by a State to do business, require that the health care entity determine whether any complaints or lawsuits have been filed or if any investigations or sanctions have been instituted against the prospective agent.

2. The proposed agent must possess adequate, i.e. secure, storage facilities and have procedures in place to insure meeting confidentiality practices (e.g. background checks on employees).

3. There should be a certification from the health care entity that it has supplied the authorized agent with a copy of the regulation and guidelines relating the disclosure of Data Bank information.

As an added protection to the confidentiality of Data Bank information, we recommend that the form currently used by the Data Bank for responding to queries be modified to include language describing the confidentiality requirement and the penalty provision for violating the requirement. Also, PHS may wish to add a statement to the Data Bank query form (OMB # 0915-0126) indicating that the authorized agent and entity understand that the information must be used solely with respect to the purpose it is being provided, and for each violation of confidentiality, a civil money penalty of up to $10,000 can be levied.

PHS Response

The PHS concurred with most of our recommendations. According to PHS, the next time the Guidebook is revised, it will require that health care entities assure, in their agreements with authorized agents, that there be physical, technical and administrative safeguards to assure the confidential and safe treatment of information received in behalf of entities. The Guidebook will also be revised to require that the registration letter from a health care entity to the Data Bank include a statement that the health care entity has supplied the agent with a copy of the regulation and guidelines relating to the disclosure of Data Bank information. In addition, during the next revision of the form "Request for Information Disclosure," PHS will include a statement concerning confidentiality and the penalty for disclosing information in violation of the law.
The PHS response to another recommendation is not clear. We recommended that, as an added protection to the confidentiality of Data Bank information, the form currently used for responding to queries be modified to include language describing the confidentiality requirement. The second paragraph of the PHS transmittal memorandum suggests agreement with the recommendation. However, the third paragraph of the transmittal memorandum outlines the PHS corrective action on those recommendations to which they have concurred; yet no specific corrective action is mentioned for the form used to respond to queries. Furthermore, on page 3 (three) of the PHS detailed response to our recommendations, PHS indicates that they have "...already covered the handling of information when it is disclosed. Each response...includes a cover sheet notifying the recipient that the information is confidential and warning of penalties."

If PHS is disagreeing with our recommendation, we wish to point out that a cover sheet can be easily separated from the response form and that if the statements are printed on the response form itself, then anyone who receives a copy of the response form will be on notice that the information is confidential and may not be used for non-Data Bank purposes.

Finally, PHS disagreed with our earlier recommendation that if an authorized agent was a company or organization, it should be incorporated, licensed or otherwise legally permitted by a State to do business. We agree with PHS that licensure, incorporation or other approval, per se, would not assure that the agent is reputable. However, what licensure, etc. might do is provide an additional source of information for checking up on a particular business, i.e. have any complaints been filed or any investigations been conducted and how have they been resolved. Therefore, we suggest that PHS should consider revising the Handbook guidelines to indicate that if a prospective agent is licensed, etc. the health care entity determine if any complaints or lawsuits have been filed or if any investigations or sanctions have been instituted. We have modified our recommendation accordingly.

A copy of the PHS response is attached as Appendix A.
APPENDIX A

MARCH 29, 1991

From

Assistant Secretary for Health

Subject


To

Inspector General, OS

Attached are the PHS comments on the subject OIG management advisory report.

We concur with the report's recommendations that in order to strengthen controls over the use of authorized agents, PHS should require them to meet the following conditions: (1) the agent must possess adequate and secure storage facilities and have procedures in place to meet confidentiality practices, (2) there should be a certification from the health care entity that it has supplied the authorized agent with a copy of the regulation and guidelines relating to the disclosure of Data Bank information, and (3) that the Data Bank form for responding to queries be modified to include language describing the confidentiality requirement and the penalty for violating the requirement.

We will update the National Practitioner Data Bank User's Guide to provide additional guidance and direction in the selection and monitoring of authorized agents engaged by health care entities, as recommended under (1) and (2) above. Regarding the third recommendation cited above, during the next revision of the form Request for Information Disclosures, we will include a statement concerning confidentiality and the penalty for disclosing information in violation of the law.

We disagree with the recommendation that an agent must be incorporated, licensed or otherwise legally permitted by a State to do business. Existing procedures already require that the agents must be identifiable, locatable, accountable, and suable. We believe these goals are served by the current arrangements which require the registration of agents.

James O. Mason, M.D., Dr.P.H.
General Comments

While our overall concerns regarding confidentiality are covered in the existing National Practitioner Data Bank User’s Guide (Guidebook) the Public Health Service agrees that a health care entity’s election to use an authorized agent raises particular concerns. Accordingly, we intend to address these issues in subsequent editions of the Guidebook to provide additional guidance and direction in the selection and monitoring of authorized agents engaged by health care entities.

OIG Recommendation

1. In order to strengthen controls over the use of authorized agents, the Public Health Service should consider requiring such agents to meet certain conditions. We have the following suggestions.

a. If a company or organization, the agent must be incorporated, licensed or otherwise legally permitted by a State to do business.

PHS Comment

It is difficult to see what additional measure of protection will be provided by such a requirement. We appreciate the point of the recommendation: the agents must be identifiable, locatable, accountable, and, indeed, suable. As a matter of fact, we believe that these goals are served by the present arrangements. Existing procedures require the registration of agents. Any querying entity using an agent must advise the Data Bank of the complete name, address, and telephone number of the agent. The agents are formally accountable to the institutions that engage them, and are clearly identified to the Data Bank. The technical status of incorporation or licensure would seem to add little in the way of accountability. Such requirements as those suggested would not assure that the agent is "reputable."

OIG Recommendation

b. The proposed agent must possess adequate, i.e., secure, storage facilities and have procedures in place to insure meeting confidentiality practices (e.g., background checks on employees).
PHS Comment

We agree that agents should possess such facilities and have other procedures in place to insure their meeting confidentiality practices. While we believe it is not necessary to impose these requirements formally by regulation, we will include in our next edition of the Guidebook technical guidance for those entities executing agreements with agents.

Specifically, we will recommend that the entities require, in their agreements with agents, that there be physical, technical and administrative safeguards to assure the confidential and safe treatment of information received on behalf of the entities. We will also recommend that these agreements (1) explicitly prohibit the agent from using the information obtained in Data Bank transactions for any other purpose, (2) require that this information be segregated from the agent's other information, and (3) permit immediate revocation of the agreement for non-compliance with these confidentiality provisions.

OIG Recommendation

c. There should be a certification from the health care entity that it has supplied the authorized agent with a copy of the regulation and guidelines relating to the disclosure of Data Bank information.

PHS Comment

When we revise our Guidebook we will add instructions for registering an agent with the Data Bank. We will include a requirement that the registration letter from a health care entity to the Data Bank include a statement that the health care entity has supplied the agent with a copy of the regulation and guidelines relating to the disclosure of Data Bank information. We expect to complete the revision of the Guidebook by March 1992.

OIG Recommendation

2. As an added protection to the confidentiality of Data Bank information, we recommend that the form currently used by the Data Bank for responding to queries be modified to include language describing the confidentiality requirement and the penalty provision for violating the requirement. Also, you may wish to add a statement to the Data Bank query form indicating that the authorized agent and entity understand that the information must be used solely with respect to the purpose it is being provided, and for each violation of confidentiality, a civil money penalty of up to $10,000 can be levied.
PHS Comment

This is effectively being done, although the relevant material is not actually printed on the forms.

The instructions which must be used in completing the Request for Information Disclosure form clearly address the issue of confidentiality and describe the penalty for disclosing information in violation of the law. When we next revise the form, we will include an explicit statement on the form regarding this, although there are form size constraints that may limit us in this regard.

More importantly, we have already covered the handling of information when it is disclosed. Each response by the Data Bank to a request for information includes a cover sheet notifying the recipient that the information is confidential and warning of penalties to be imposed.

We believe these notices effectively serve the purpose intended by the recommended actions.