

Respondent	Number of respondents	Responses per respondent	Hours per response (minutes)	Total Burden hours
	3,600	560

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: October 23, 1998.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 98-29111 Filed 10-29-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA)

publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Application for NHSC Recruitment and Retention Assistance (in Use Without Approval)

The National Health Service Corps (NHSC) of the HRSA's Bureau of Primary Health Care assists underserved communities through the development, recruitment, and retention of primary health care clinicians dedicated to serving people in health professional shortage areas.

The Application for NHSC Recruitment and Retention Assistance submitted by sites or clinicians requests information on the practice site, sponsoring agency, recruitment contact, staffing levels, service users, site's 5-year infant mortality or low birth rate averages, and next nearest site. The information on the application is used for determining eligibility of sites and to verify the need for NHSC providers. Sites must submit applications annually or when they need a provider.

Estimates of annualized reporting burden are as follows:

Type of report	Number of respondents	Responses per respondent	Hours per response	Total burden hour
Application	1,000	1	.75	750

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Wendy A. Taylor, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: October 23, 1998.

Jane Harrison,

Director, Division of Policy Review and Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of the OIG's Provider Self-Disclosure Protocol

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This **Federal Register** notice sets forth the OIG's recently-issued Provider Self-Disclosure Protocol. This Self-Disclosure Protocol offers health care providers specific steps, including a detailed audit methodology, that may be undertaken if they wish to work openly and cooperatively with the OIG to efficiently quantify a particular problem and, ultimately, promote a higher level of ethical and lawful conduct throughout the health care industry.

FOR FURTHER INFORMATION CONTACT: Ted Acosta, Office of Counsel to the Inspector General, (202) 619-2078.

SUPPLEMENTARY INFORMATION: The OIG has long stressed the role of the health care industry in combating health care fraud, and believes that health care providers can play a cooperative role in identifying and voluntarily disclosing program abuses. The OIG's use of voluntary self-disclosure programs, for example, is premised on a belief that health care providers must be willing to police themselves, correct underlying problems and work with the

Government to resolve these matters. Based on insights gained from a pilot program undertaken as part of Operation Restore Trust, discussions with the provider community and the growing need for an effective disclosure mechanism, the OIG has now developed a more open-ended process, or protocol, for making a disclosure and allowing a health care provider to cooperative work with the OIG. Unlike the previous voluntary disclosure pilot programs, this self-disclosure protocol gives detailed guidance to the provider on what information is appropriate to include as part of an investigative report and how to conduct an audit of the matter, while setting no limitations on the conditions under which a health care provider may disclose information to the OIG.

A reprint of the OIG's Provider Self-Disclosure Protocol follows.

Provider Self-disclosure Protocol

I. Introduction

The Office of Inspector General (OIG) of the United States Department of

Health and Human Services (HHS) relies heavily upon the health care industry to help identify and resolve matters that adversely affect the Federal health care programs (as defined in 42 U.S.C. 1320a-7b(f)). The OIG believes that, as participants in the Federal health care programs, health care providers have an ethical and legal duty to ensure the integrity of their dealings with these programs. This duty includes an obligation to take measures, such as instituting a compliance program, to detect and prevent fraudulent, abusive and wasteful activities. It also encompasses the need to implement specific procedures and mechanisms to examine and resolve instances of non-compliance with program requirements. Whether as a result of voluntary self-assessment or in response to external forces, health care providers must be prepared to investigate such instances, assess the potential losses suffered by the Federal health care programs, and make full disclosure to the appropriate authorities. To encourage providers to make voluntary disclosures, the OIG issues this Provider Self-Disclosure Protocol (Protocol).

The concept of voluntary self-disclosure is not new to the OIG. For many years, the OIG has worked informally with providers and suppliers that came forward to cooperate with OIG to resolve billing, marketing or quality of care problems. In 1995, as part of the Operation Restore Trust (ORT) initiative, HHS and the Department of Justice (DOJ) announced a pilot voluntary disclosure program, which embraced OIG's longstanding policy favoring voluntary self-disclosure. The demonstration program was developed in coordination with representatives of the OIG, DOJ, various United States Attorneys' Offices, the Federal Bureau of Investigation and the Health Care Financing Administration (HCFA). The pilot program was limited to five States (New York, Florida, Illinois, Texas and California) and four different types of providers (home health agencies, skilled nursing facilities, durable medical equipment suppliers, and hospice providers). It gave those qualifying entities a formal mechanism for disclosing and seeking the resolution of matters relating to the Medicare and Medicaid programs. In 1997, the pilot voluntary disclosure program was concluded. While there was limited participation in the pilot, the OIG gained valuable insight into the variables influencing the decision to make a disclosure to the Government.

The OIG believes it must continue encouraging the health care industry to conduct voluntary self-evaluations and

providing viable opportunities for self-disclosure. By establishing this Protocol, the OIG renews its commitment to promote an environment of openness and cooperation. The Protocol has no rigid requirements or limitations. Rather, it provides the OIG's views on what are the appropriate elements of an effective investigative and audit working plan to address instances of non-compliance. Providers that follow the Protocol expedite the OIG's verification process and thus diminish the time it takes before the matter can be formally resolved. Failure to conform to each element of the Protocol is not necessarily fatal to the provider's disclosure, but will likely delay the resolution of the matter.

The OIG's principal purpose in producing the Protocol is to provide guidance to health care providers that decide voluntarily to disclose irregularities in their dealings with the Federal health care programs. Because a provider's disclosure can involve anything from a simple error to outright fraud, the OIG cannot reasonably make firm commitments as to how a particular disclosure will be resolved or the specific benefit that will enure to the disclosing entity. In our experience, however, opening lines of communication with, and making full disclosure to, the investigative agency at an early stage generally benefits the individual or company. In short, the Protocol can help a health care provider initiate with the OIG a dialogue directed at resolving its potential liabilities.

The decision to follow the OIG's suggested Protocol rests exclusively with the provider. While the OIG can offer only limited guidance on what is inherently a case-specific judgement, there are several considerations that should influence the decision. First, a provider that uncovers an ongoing fraud scheme within its organization immediately should contact the OIG, but should not follow the Protocol's suggested steps to investigate or quantify the scope of the problem. If the provider follows the Protocol in this type of situation without prior consultation with the OIG, there is a substantial risk that the Government's subsequent investigation will be compromised.

Second, the OIG anticipates that a provider will apply the Protocol's suggested steps only after an initial assessment substantiates there is a problem with non-compliance with program requirements. The initial identification of potential risk areas should be less intensive and need not conform to the Protocol's suggested procedures. Similarly, when the OIG

conducts a national review of a particular billing practice, providers should consider the option of conducting a limited assessment of the practice under OIG review, rather than incur the expense of a comprehensive audit. In such cases, an audit that conforms to the Protocol's guidelines may be appropriate only in instances where a preliminary assessment suggests the provider has in fact engaged in the practices under OIG scrutiny.

II. The Provider Self-Disclosure Protocol

Unlike the earlier pilot program, there are no pre-disclosure requirements, applications for admission or preliminary qualifying characteristics that must be met. The Provider Self-Disclosure Protocol is open to all health care providers, whether individuals or entities, and is not limited to any particular industry, medical specialty or type of service. While no written agreement setting out the terms of the self-assessment will be required, the OIG expects the commitment of the health care provider to disclose specific information and engage in specific self-evaluative steps relating to the disclosed matter. In contrast to the pilot disclosure program, the fact that a disclosing health care provider is already subject to Government inquiry (including investigations, audits or routine oversight activities) will not automatically preclude a disclosure. The disclosure, however, must be made in good faith. The OIG will not continue to work with a provider that attempts to circumvent an ongoing inquiry or fails to fully cooperate in the self-disclosure process. In short, the OIG will continue its practice of working with providers that are the subject of an investigation or audit, provided that the collaboration does not interfere with the efficient and effective resolution of the inquiry.

The Provider Self-Disclosure Protocol is intended to facilitate the resolution of only matters that, in the provider's reasonable assessment, are potentially violative of Federal criminal, civil or administrative laws. Matters exclusively involving overpayments or errors that do not suggest that violations of law have occurred should be brought directly to the attention of the entity (e.g., a contractor such as a carrier or an intermediary) that processes claims and issues payment on behalf of the Government agency responsible for the particular Federal health care program (e.g., HCFA for matters involving Medicare). The program contractors are responsible for processing the refund and will review the circumstances surrounding the initial overpayment. If

the contractor concludes that the overpayment raises concerns about the integrity of the provider, the matter may be referred to the OIG. Accordingly, the provider's initial decision of where to refer a matter involving non-compliance with program requirements should be made carefully.

The OIG is not bound by any findings made by the disclosing provider under the Provider Self-Disclosure Protocol and is not obligated to resolve the matter in any particular manner. Nevertheless, the OIG will work closely with providers that structure their disclosures in accordance with the Provider Self-Disclosure Protocol in an effort to coordinate any investigatory steps or other activities necessary to reach an effective and prompt resolution. It is important to note that, upon review of the provider's disclosure submission and/or reports, the OIG may conclude that the disclosed matter warrants a referral to DOJ for consideration under its civil and/or criminal authorities. Alternatively, the provider may request the participation of a representative of DOJ or a local United States Attorney's Office in settlement discussions in order to resolve potential liability under the False Claims Act or other laws. In either case, the OIG will report on the provider's involvement and level of cooperation throughout the disclosure process to any other Government agencies affected by the disclosed matter.

III. Voluntary Disclosure Submission

The disclosing provider will be expected to make a submission as follows.

A. Effective Disclosure

The disclosure must be made in writing and must be submitted to the Assistant Inspector General for Investigative Operations, Office of Inspector General, Department of Health and Human Services, 330 Independence Avenue, SW, Cohen Building, Room 5409, Washington, DC 20201. Submissions by telecopier, facsimile or other electronic media will not be accepted.

B. Basic Information

The submission should include the following—

1. The name, address, provider identification number(s) and tax identification number(s) of the disclosing health care provider. If the provider is an entity that is owned, controlled or is otherwise part of a system or network, include a description or diagram describing the

pertinent relationships and the names and addresses of any related entities, as well as any affected corporate divisions, departments or branches. Additionally, provide the name and address of the disclosing entity's designated representative for purposes of the voluntary disclosure.

2. Indicate whether the provider has knowledge that the matter is under current inquiry by a Government agency or contractor. If the provider has knowledge of a pending inquiry, identify any such Government entity or individual representatives involved. The provider must also disclose whether it is under investigation or other inquiry for any other matters relating to a Federal health care program and provide similar information relating to those other matters.

3. A full description of the nature of the matter being disclosed, including the type of claim, transaction or other conduct giving rise to the matter, the names of entities and individuals believed to be implicated and an explanation of their roles in the matter, and the relevant periods involved.

4. The type of health care provider implicated and any provider billing numbers associated with the matter disclosed. Include the Federal health care programs affected, including Government contractors such as carriers, intermediaries and other third-party payers.

5. The reasons why the disclosing provider believes that a violation of Federal criminal, civil or administrative law may have occurred.

6. A certification by the health care provider or, in the case of an entity, an authorized representative on behalf of the disclosing entity stating that, to the best of the individual's knowledge, the submission contains truthful information and is based on a good faith effort to bring the matter to the Government's attention for the purpose of resolving any potential liabilities to the Government.

C. Substantive Information

As part of its participation in the disclosure process, the disclosing health care provider will be expected to conduct an internal investigation and a self-assessment, and then report its findings to the OIG. The internal review may occur after the initial disclosure of the matter. The OIG will generally agree, for a reasonable period of time, to forego an investigation of the matter if the provider agrees that it will conduct the review in accordance with the Internal Investigation Guidelines and the Self-Assessment Guidelines set forth below.

IV. Internal Investigation Guidelines

All disclosures to the OIG under the Provider Self-Disclosure Protocol should include a report based on an internal investigation conducted by the health care provider. While a provider is free to discuss its preliminary findings with the OIG prior to completion of its investigation, the matter cannot be resolved until a comprehensive assessment has been completed pursuant to the following guidelines:

A. Nature and Extent of the Improper or Illegal Practice

A voluntary disclosure report should demonstrate that a full examination of the practice has been conducted. The report should contain a written narrative that—

1. Identifies the potential causes of the incident or practice (e.g., intentional conduct, lack of internal controls, circumvention of corporate procedures or Government regulations);

2. Describes the incident or practice in detail, including how the incident or practice arose and continued;

3. Identifies the division, departments, branches or related entities involved and/or affected;

4. Identifies the impact on, and risks to, health, safety, or quality of care posed by the matter disclosed, with sufficient information to allow the OIG to assess the immediacy of the impact and risks, the steps that should be taken to address them, as well as the measures taken by the disclosing entity;

5. Delineates the period during which the incident or practice occurred;

6. Identifies the corporate officials, employees or agents who knew of, encouraged, or participated in, the incident or practice and any individuals who may have been involved in detecting the matter;

7. Identifies the corporate officials, employees or agents who should have known of, but failed to detect, the incident or practice based on their job responsibilities; and

8. Estimates the monetary impact of the incident or practice upon the Federal health care programs, pursuant to the Self-Assessment Guidelines below.

B. Discovery and Response to the Matter

The internal investigation report should relate the circumstances under which the disclosed matter was discovered and fully document the measures taken upon discovery to address the problem and prevent future abuses. In this regard, the report should—

1. Describe how the incident or practice was identified, and the origin of the information that led to its discovery.

2. Describe the entity's efforts to investigate and document the incident or practice (e.g., use of internal or external legal, audit or consultative resources).

3. Describe in detail the chronology of the investigative steps taken in connection with the entity's internal inquiry into the disclosed matter including the following—

(a) A list of all individuals interviewed, including each individual's business address and telephone number, and their positions and titles in the relevant entities during both the relevant period and at the time the disclosure is being made. For all individuals interviewed, provide the dates of those interviews and the subject matter of each interview, as well as summaries of the interview. The health care provider will be responsible for advising the individual to be interviewed that the information the individual provides may, in turn, be provided to the OIG. Additionally, include a list of those individuals who refused to be interviewed and provide the reasons cited;

(b) A description of files, documents, and records reviewed with sufficient particularity to allow their retrieval, if necessary; and

(c) A summary of auditing activity undertaken and a summary of the documents relied upon in support of the estimation of losses. These documents and information must accompany the report, unless the calculation of losses is undertaken pursuant to the Self-Assessment Guidelines, which contain specific reporting requirements.

4. Describe the actions by the health care provider to stop the inappropriate conduct.

5. Describe any related health care businesses affected by the inappropriate conduct in which the health care provider is involved, all efforts by the health care provider to prevent a recurrence of the incident or practice in the affected division as well as in any related health care entities (e.g., new accounting or internal control procedures, increased internal audit efforts, increased supervision by higher management or through training).

6. Describe any disciplinary action taken against corporate officials, employees and agents as a result of the disclosed matter.

7. Describe appropriate notices, if applicable, provided to other Government agencies, (e.g., Securities and Exchange Commission and Internal

Revenue Service) in connection with the disclosed matter.

C. The internal investigation report must include a certification by the health care provider, or in the case of an entity an authorized representative on behalf of the disclosing health care provider, indicating that, to the best of the individual's knowledge, the internal investigation report contains truthful information and is based on a good faith effort to assist the OIG in its inquiry and verification of the disclosed matter.

V. Self-Assessment Guidelines

To estimate the monetary impact of the disclosed matter, the health care provider also should conduct an internal financial assessment and prepare a report of its findings. This self-assessment may be performed at the same time as the internal investigation, or commenced after the scope of the non-compliance with program requirements has been established. In either case, the OIG will verify a provider's calculation of Federal health care program losses and it is strongly recommended that, at a minimum, the review conform to the following guidelines.

A. Approach

The self-assessment should consist of a review of either—(1) all of the claims affected by the disclosed matter for the relevant period; or (2) a statistically valid sample of the claims that can be projected to the population of claims affected by the matter for the relevant period. This determination should be based on the size of the population believed to be implicated, the variance of characteristics to be reviewed, the cost of the self-assessment, the available resources, the estimated duration of the review, and other factors as appropriate.

B. Basic Information

Regardless of which of these two approaches is used, the disclosing provider should submit to the OIG a work plan describing the self-assessment process. The OIG will review the proposal and, where appropriate, provide comments on the plan in a timely manner. At its option, the OIG may choose to carry out any necessary activities at any stage of the review to verify that the process is undertaken correctly and to validate the review findings. While the OIG is not obligated to accept the results of a provider's self-assessment, findings based upon procedures which conform to the Protocol will be given substantial weight in determining any program overpayments. In addition, the OIG will use the validated provider self-assessment report in preparing a

recommendation to DOJ for resolution of the provider's False Claims Act or other liability. Among the issues that should be addressed in the plan are the following—

1. *Review Objective*—There should be a statement clearly articulating the objective of the review and the review procedure or combination of procedures applied to achieve the objective.

2. *Review Population*—The plan should identify the population, which is the group about which information is needed. In addition, there should be an explanation of the methodology used to develop the population and the basis for this determination.

3. *Sources of Data*—The plan should provide a full description of the source of the information upon which the review will be based, including the legal or other standards to be applied, the sources of payment data and the documents that will be relied upon (e.g., employment contracts, rental agreements, etc.).

4. *Personnel Qualifications*—The plan should identify the names and titles of those individuals involved in any aspect of the self-assessment, including statisticians, accountants, auditors, consultants and medical reviewers, and describe their qualifications.

C. Sample Elements

If the provider, in consultation with the OIG, determines that the financial review will be based upon a sample, the work plan should also include the sampling plan as follows—

1. *Sampling Unit*—The plan should define the sampling unit, which is any of the designated elements that comprise the population of interest.

2. *Sampling Frame*—The plan should identify the sampling frame, which is the totality of the sampling units from which the sample will be selected. In addition, the plan should document how the audit population differs from the sampling frame and what effect this difference has on conclusions reached as a result of the audit.

3. *Sample Size*—The size of the sample must be determined through the use of a probe sample. Accordingly, the plan should include a description of both the probe sample and the full sample. At a minimum, the full sample must be designed to generate an estimate with a ninety (90) percent level of confidence and a precision of twenty-five (25) percent. The probe sample must contain at least thirty (30) sample units and cannot be used as part of the full sample.

4. *Random Numbers*—Both the probe sample and the sample must be selected through random numbers. The source of

the random numbers used must be shown in the sampling plans. The OIG strongly recommends the use of its Office of Audit Services' Statistical Sampling Software, also known as "RAT-STATS," which is currently available free of charge through the "internet" at "www.hhs.gov/progorg/oas/ratstat.html".

5. *Sample Design*—Unless the disclosing provider demonstrates the need to use a different sample design, the self-assessment should use simple random sampling. If necessitated, the provider may use stratified or multistage sampling. Details about the strata, stages and clusters should be included in the description of the audit plan.

6. *Estimate of Review Time per Sample Item*—The plan should estimate the time expended to locate the sample items and the staff hours expended to review a sample item.

7. *Characteristics Measure by the Sample*—The sampling plan should identify the characteristics used for testing each sample item. For example, in a sample drawn to estimate the value of overpayments due to duplicate payments, the characteristics under consideration are the conditions that must exist for a sample item to be a duplicate. The amount of the duplicate payment is the measurement of the overpayment. The sampling plan must also contain the decision rules for determining whether a sample item entirely meets the criterion for having characteristics or only partially meets the criterion.

8. *Missing Sample Items*—The sampling plan must include a discussion of how missing sample items were handled and the rationale.

9. *Other Evidence*—Although sample results should stand on their own in terms of validity, sample results may be combined with other evidence in arriving at specific conclusions. If appropriate, indicate what other substantiating or corroborating evidence was developed.

10. *Estimation Methodology*—Because the general purpose of the review is to estimate the monetary losses to the Federal health care programs, the methodology to be used must be variables sampling using the difference estimator. To estimate the amount implicated in the disclosed matter, the provider must use the mean point estimate. The statistical estimates must be reported using a ninety (90) percent confidence level. The use of RAT-STATS to calculate the estimates is strongly recommended.

11. *Reporting Results*—The sampling plan should indicate how the results will be reported at the conclusion of the

review. In preparing the report, enough details must be provided to clearly indicate what estimates are reported.

D. Certification

Upon completion of the self-assessment, the disclosing health care provider, or in the case of an entity its authorized representative, must submit to the OIG a certification stating that, to the best of the individual's knowledge, the report contains truthful information and is based on a good faith effort to assist OIG in its inquiry and verification of the disclosed matter.

VI. OIG's Verification

Upon receipt of a health care provider's disclosure submission, the OIG will begin its verification of the disclosure information. The extent of the OIG's verification effort will depend, in large part, upon the quality and thoroughness of the internal investigative and self-assessment reports. Matters uncovered during the verification process, which are outside of the scope of the matter disclosed to the OIG, may be treated as new matters outside the Provider Self-Disclosure Protocol.

To facilitate the OIG's verification and validation processes, the OIG must have access to all audit work papers and other supporting documents without the assertion of privileges or limitations on the information produced. In the normal course of verification, the OIG will not request production of written communications subject to the attorney-client privilege. There may be documents or other materials, however, that may be covered by the work product doctrine, but which the OIG believes are critical to resolving the disclosure. The OIG is prepared to discuss with provider's counsel ways to gain access to the underlying information without the need to waive the protections provided by an appropriately asserted claim of privilege.

VII. Payments

Because of the need to verify the information provided by a disclosing health provider, the OIG will not accept payments of presumed overpayments determined by the health care provider prior to the completion of the OIG's inquiry. However, the provider is encouraged to place the overpayment amount in an interest-bearing escrow account to minimize further losses. While the matter is under OIG inquiry, the disclosing provider must refrain from making payment relating to the disclosed matter to the Federal health care programs or their contractors

without the OIG's prior consent. If the OIG consents, the disclosing provider will be required to agree in writing that the acceptance of the payment does not constitute the Government's agreement as to the amount of losses suffered by the programs as a result of the disclosed matter, and does not affect in any manner the Government's ability to pursue criminal, civil or administrative remedies or to obtain additional fines, damages or penalties for the matters disclosed.

VIII. Cooperation and Removal from the Provider Self-Disclosure Protocol

The disclosing entity's diligent and good faith cooperation throughout the entire process is essential. Accordingly, the OIG expects to receive documents and information from the entity that relate to the disclosed matter without the need to resort to compulsory methods. If a provider fails to work in good faith with the OIG to resolve the disclosed matter, that lack of cooperation will be considered an aggravating factor when the OIG assesses the appropriate resolution of the matter. Similarly, the intentional submission of false or otherwise untruthful information, as well as the intentional omission of relevant information, will be referred to DOJ or other Federal agencies and could, in itself, result in criminal and/or civil sanctions, as well as exclusion from participation in the Federal health care programs.

Dated: October 21, 1998.

June Gibbs Brown,

Inspector General.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute: Opportunities for Cooperative Research and Development Agreements (CRADAs) for the Joint Evaluation and Development of Methods to Generate and Expand In- Vitro Modified Dendritic Cell Populations in Order to Elicit Phenotype Specific Immune Responses

The NCI is looking for CRADA Collaborators to jointly develop this dendritic cell immunology technology.

AGENCY: National Cancer Institute, National Institutes of Health, PHS, DHHS.