Healthcare Integrity and Protection Data Bank for Final Adverse Information on Health Care Providers, Suppliers and Practitioners (45 CFR 61)

SUPPORTING STATEMENT

A. Justification

1. Circumstances of Information Collection

This is a request for extension of OMB approval of the information collections contained in regulations found in 45 CFR part 61 governing the Healthcare Integrity and Protection Data Bank (HIPDB) and the forms to be used in reporting information to and requesting information from the HIPDB cleared under OMB No. 0915-0239. This approval expires August 31, 2007. The HIPDB is authorized by section 1128E of the Social Security Act (hereinafter referred to as section 1128E), as added by section 221(a) of the Health Insurance Portability and Accountability Act of 1996. Section 1128E directs the Secretary of Health and Human Services (the Secretary) to establish a national health care fraud and abuse data collection program for the reporting and disclosing of certain final adverse actions (excluding settlements in which no findings of liability have been made) taken against health care providers, suppliers, or practitioners. It also directs the Secretary to maintain a database of final adverse actions taken against health care providers, suppliers, or practitioners. The regulations implementing section 1128E governing the operation of the HIPDB are codified at 45 CFR part 61. The HIPDB became operational November 22, 1999.

Approval is requested to continue the following reporting data collection and disclosure requirements and the ensuing HIPDB forms along with the instructions. The recordkeeping, reporting, and disclosure requirements are specified in the regulations to implement the HIPDB.

REPORTING REQUIREMENTS:

§61.6 Reporting errors, omissions, revisions or whether an action is on appeal.

(a) If errors or omissions are found after information has been reported, the reporter must send an addition or correction to the HIPDB.

(b) A reporter that reports information on licensure, criminal convictions, civil or administrative judgments, exclusions, or adjudicated actions or decisions under § 61.7, §61.8, § 61.9, § 61.10 or § 61.11 of this part also must report any revision of the action originally reported. Revisions include, but are not limited to, reversal of a criminal conviction, reversal of a judgment or other adjudicated decisions or whether the action is on appeal, and reinstatement of a license. The subject will receive a copy of all reports, including revisions and corrections to the report.

§61.7 Reporting licensure actions taken by Federal or State licensing and certification agencies.

This section requires Federal or State licensing and certification agencies to report certain final adverse actions taken against a health care provider, supplier, or practitioner. Reportable actions are as follows: revocation or suspension of a license (and the length of any such suspension), reprimand, censure, probation, voluntary surrender, non-renewability, or any other negative action or finding by such Federal or State agency that is publicly available information. Under this section, a reportable final adverse action must be a formal or official action. Since disciplinary licensure actions by State licensing authorities in the National Practitioner Data Bank (NPDB) overlap with this statute, the estimate will include all licensure actions that will be reported to both the NPDB and the HIPDB. Actions taken against health care providers and suppliers, however, will

only be reported to the HIPDB.

§61.8 Reporting Federal or State criminal convictions related to the delivery of a health care item or service.

Federal and State prosecutors must report criminal convictions against health care providers, suppliers or practitioners related to the delivery of health care items or services. Criminal convictions unrelated to the delivery of health care items or services are not reported under this section.

§61.9 Reporting of civil judgments in Federal or State court related to the delivery of a health care item or service.

Federal and State attorneys and health plans must report civil judgments against health care providers, suppliers or practitioners related to the delivery of health care items or services (except those resulting from medical malpractice). Civil judgments must be entered or approved by a Federal or State court.

§61.10 Reporting Exclusions from participation in Federal or State health care programs.

Federal and State Government agencies must report health care providers, suppliers, or practitioners excluded from participating in Federal or State health care programs, including exclusions that were made in a matter in which there was also a settlement that is not reported because no findings or admissions of liability have been made.

§61.11 Reporting other adjudicated actions or decisions.

Although not specifically required by the statute, the Department believes that the term *"other adjudicated actions or decisions"* should relate to the delivery of health care items or services, as do criminal convictions and civil judgments collected under this statute. In addition, the Department require that a due process mechanism be associated with all adjudicated actions or decisions. Examples of an adjudicated action or decision include, but are not limited to, orders by an administrative law judge, civil monetary penalties and assessments, revocations, debarments or other restrictions from participating in Federal or State government contracts or programs, liquidation, dissolution, license cancellation or revocations, and health plan contract terminations. The Department believes that this definition encompasses actions that are consistent with the characteristics of the specific final adverse actions already defined in the statute.

§61.12 Requesting information from the Healthcare Integrity and Protection Data Bank.

This section identifies individuals or entities, or their authorized agents who, under specified conditions, will have access to information contained in the HIPDB. These include:

(1) Federal and State government agencies;
(2) Health Plans;
(3) A health care practitioner, provider, or supplier that requests information concerning himself, herself, or itself; and
(4) A person or entity requesting statistical information, which does not permit identification of any individual or entity. (For example, researchers can use statistical information to identify the total number of practitioners excluded from the Medicare and Medicaid programs. Similarly, health plans can use statistical information to develop outcome measures in their efforts to monitor and improve quality of care.)

Since some of the above entities have access to both the NPDB and the HIPDB, the burden associated with their queries and with eligibility verification is already cleared under OMB No. 0915-0126. Burden for queries submitted directly to the HIPDB is included in this clearance

request, as is the burden for verifying eligibility for those entities authorized to query only the HIPDB.

§61.15 How to dispute the accuracy of Healthcare Integrity and Protection Data Bank information.

This section describes the process to be followed by a health care provider, supplier, or practitioner in disputing the factual accuracy of a report to the HIPDB.

FORMS

All HIPDB forms are available on the Data Bank Web site. Reporting and querying is accomplished electronically over a secure Internet connection.

Reporting Forms:

(1) Adverse Action Report Form: This form is used to report licensure actions taken by Federal or State licensing and certification agencies (61.7), and to report other adjudicated actions or decisions (61.11) and exclusions from Federal and State health care programs (61.10). The form also will be used to report errors, omissions, or revisions to the reports of these licensure and certification actions (61.6).

(2) Judgment or Conviction Report Form: This form is used for all reports of criminal convictions or civil judgments submitted under 45 CFR 61.8 and 61.9. The form also will be used to report errors, omissions, or revisions to the reports of these actions (61.6).

Information Disclosure (Query) Forms:

(3) Practitioner Request for Information Disclosure and Organization Request for Information Disclosure Forms (Self-Query): Suppliers, providers, and practitioners will use this form to self-query, as authorized in 45 CFR 61.12.

(4) Entity Request for Information Disclosure (Query) on Individual Subject: This form is used to request information on an individual practitioner from the HIPDB as authorized in 45 CFR 61.12.

(5) Entity Request for Information Disclosure (Query) on Organization: This form is used to request information from the HIPDB on an organization that is the provider or supplier of medical goods and or services as authorized in 45 CFR 61.12.

Access and Administrative Forms:

The burdens for Administrative Forms are included in the NPDB OMB clearance submission. These Forms, which are electronic, are used by both the NPDB and HIPDB and as such are difficult to separate.

(6) Entity Registration, Update, and Reactivation Form: In order for eligible users to access the HIPDB, they must meet section 1128E reporting and querying requirements. These forms will be used by entities to verify their eligibility to query the HIPDB and to update their profile information (e.g., the name of the entity's authorized representative).

(7) Authorized Agent Registration Form (Agent Registration, Agent Registration Update, and Reactivation): Eligible users may elect to have an outside organization query or report to the HIPDB on their behalf. These entities are referred to as authorized agents. Before an authorized agent acts on behalf an entity, the authorized agent must complete this form. If there are changes to the authorized agent's information (e.g., the address, telephone number), the authorized agent must update the information.

(8) Account Discrepancy: This one-page form is used if an eligible entity cannot reconcile the *Credit Card Charge Receipt*.

(9) Electronic Funds Transfer Authorization: This two-page form is used by an eligible entity to authorize payment of the NPDB/HIPDB user fees directly from its bank account.

(10) Subject Statement and Dispute Initiation Form: Enables a practitioner or entity subject of a HIPDB Report to dispute factual information in that report, and/or request Secretarial Review of the report. This form is now completed and submitted online.

2. Purpose and Use of Information

The statute requires the Secretary to assure that HIPDB information is provided and utilized in a manner that appropriately protects the confidentiality of the information and the privacy of individuals receiving health care services. Thus, the Secretary has specified that information from this system be used to improve the quality of patient care and to prevent health care fraud and abuse activities. Appropriate use of the information would include licensing decisions by professional licensing boards, credentialing and contracting decisions by health plans, and investigation by law enforcement agencies, investigative units and health plan special investigative units of health care fraud perpetrators and schemes. Information from the HIPDB also may be used for research purposes. This information must be in a form that does not allow the identification of any particular health care provider, supplier, practitioner or individual receiving health care services.

The statute also identifies four elements or types of data that Federal or State government agencies and health plans must report. These elements are as follows: name and Tax Identification Number (TIN); name (if known) of any health care entity with which the subject of the final adverse action is affiliated or associated; the nature of the action and whether such action is on appeal; and a description of the acts or omissions and injuries upon which the action is based. The statute also allows the Secretary to require the reporting of additional information. In consultation with numerous representatives of the law enforcement and health care communities, the Secretary has determined additional data elements (e.g., National Provider Identifier, date of

birth, professional school and year of graduation, and license, certification, or registration numbers) are necessary in order to:

- Maximize the accuracy of a match between the names of queried practitioners, providers or suppliers with existing reports in the HIPDB.
- Provide access to information about health care fraud activity nationwide by promoting efficient coordination of investigative efforts among health care insurers and law enforcement agencies.
- Prevent the erroneous reporting and identification of health care providers, suppliers and practitioners.

Changes to Forms and Instructions

There have been minor changes only to the HIPDB data collection forms since the last OMB clearance renewal (2004). These changes were done to provide further convenience and/or clarification for users.

3. Use of Improved Technology

The HIPDB forms are completely automated to allow easy completion and processing. Among these forms are the Entity Registration Form, the Authorized Agent Designation Form and the Subject Response and Dispute Initiation Form. Further, the reporting and querying forms (including the Medical Malpractice Payment Report, the Adverse Action Report and the Request for Information Disclosure Forms) are completely electronic. In addition, the Electronic Funds Transfer Form also is completed and submitted online. The program has eliminated the use of paper forms for these functions.

The HIPDB has increased its use of the Internet and all administrative and access forms are available on the Web site for downloading.

Entities complete and submit the above listed forms over a secure Internet connection from the Data Bank Web site. They may also submit reports via diskette; however, the NPDB continues to discourage reporting by this method.

A number of security features are employed to assure the confidentiality of the information transmitted as well as to prevent unauthorized access. These features include data encryption of all submissions across the Internet, entry of user names and passwords by all registered users, and firewall protection of the HIPDB network and server to prevent unauthorized access from the Internet. The system security plan is reviewed and updated annually to address changes in guidance or industry standards needed to continue providing secrecy and privacy for the system. In addition, every three years the NPDB-HIPDB is required under the Federal Information System Management Act (FISMA) to conduct and renew the system's Certification and Accreditations (C&A). The C&A process involves convening a panel of information technology professionals who conducts a security review risk assessment, security test and evaluation, technical vulnerability assessment, and a Continuity of Operation Plan (COOP) exercised.

Self-query forms for individuals and organizations are also submitted via the Internet at the Data Bank Web site. Individuals or organizations complete query information and submit self-queries online. The computer system automatically verifies that the online form has been completed correctly, reducing the chance for errors or missing data fields. Self-queriers need only to print the form for signature and notarization. In addition to online reporting and querying, entities may

update certain registration information e.g., address, telephone number, directly via the Internet. These updates have replaced updates submitted via paper forms.

4. Efforts to Identify Duplication

We have contacted numerous public and private sector agencies regarding existing databases that contain health care fraud-related information. Although various sources such as National Crime Information Center, Provider Indexing Network System, Financial Crimes Enforcement Network and National Practitioner Data Bank contain disciplinary licensure actions, criminal convictions, or civil judgments, there is no centralized source of comprehensive health care fraud information accessible to law enforcement officials, regulatory agencies, or health insurance plans. According to the May 1996 GAO report on Healthcare Fraud, “There is no centralized national data bank to track criminal activity in the health care system that would assist Federal, State, and industry anti-fraud enforcement efforts.” The HIPDB is the first to track such information and make it available in a centralized location for law enforcement officials, regulatory agencies, and health plans.

To the extent possible, information collected by the HIPDB is coordinated with the development and implementation of the NPDB as required by section 1128E of the *Social Security Act,* as amended.

5. Involvement of Small Entities

The information collected is not expected to have a significant effect on small businesses. The electronic forms incorporate the data elements found in the regulations. Attempts are made to keep data collections to the minimum needed to differentiate adequately among individuals with similar names and to comply with statutory requirements. An eligible entity may use an authorized agent to report to and request information from (query) the HIPDB at the discretion of that entity.

6. Consequences if Information is Collected Less Frequently

Information required under §61.7, § 61.8, § 61.9, and §61.11 must be submitted to the Healthcare Integrity and Protection Data Bank within 30 calendar days from the date when the reporting entity became aware of the final adverse action or by the close of the entity’s next monthly reporting cycle. If information is reported to the HIPDB less frequently, the HIPDB will not be able to provide accurate and timely information to law enforcement officials, regulatory agencies, or health insurance plans for their investigations.

7. Consistency with the Guidelines in 5 CFR 1320.5(d)(2)

The statute requires that Federal and State government agencies and health plans report final adverse actions “regularly but not less often than monthly.” Therefore, information must be submitted to the HIPDB within 30 calendar days from the date when the reporting entity became aware of the final adverse action or by the close of the entity’s next monthly reporting cycle. This requirement will ensure that the information contained in HIPDB is up-to-date, accurate and timely.

8. Consultation Outside the Agency

The notice required by 5 CFR 1320.8(d) was published in the Federal Register on March 12, 2007, Vol. 72, No. 47, pages 11028-11029. We received one comment from the National Association Medical Staff Services, which is contained in a separate attachment.

The commenter requests access to a list of all healthcare entities and licensing boards that have queried on the practitioner. In response, we have reviewed and considered this suggestion; however, such a list raises concerns regarding the release of personal information on individuals. Section 1128C(a)(3)(B)(ii) of the Act requires individuals and entities receiving information from the

HIPDB, either directly or from another party, to use the information for the purpose for which it was provided. As a result of concerns related to the Privacy Act regarding the release of personal information and the confidentiality requirements of the Social Security Act, the program has decided against such a change.

In preparing this request for extension, we have consulted with users of the HIPDB to detect any problems they may have had with electronic querying and reporting. As part of this effort, we attended the 2005 and 2006 conferences of the National Association of Medical Staff Services. We also attended the 2006 annual conference of the National Health Care Anti-Fraud Association Can organization whose constituents have mandatory reporting requirements under Section 1128E. In addition, we conducted the Integrated Query and Report System (IQRS) Users Group Panels and Data Bank Policy Forums to elicit feedback on the system and get suggestions for changes. These meetings were conducted annually and comprised of approximately 30 representative users of the NPDB/HIPDB's Internet-based reporting and querying service.

We also interacted extensively with HIPDB users by conducting feedback sessions in eleven different cities across the United States in order to determine if offering a Proactive Disclosure Service would assist entities in more effectively monitoring the practitioners, suppliers and providers they hire or maintain business relationships with. During these sessions, users were given the opportunity to comment on current operations. Feedback was then analyzed and this information is continuously considered as we decide the best way to improve the reporting and querying process.

9. Remuneration of Respondents

There will be no remuneration of respondents.

10. Assurance of Confidentiality

The confidentiality requirements that apply to all information obtained from the HIPDB are specified in sections 1128E(b)(3) and 1128C(a)(3)(B)(ii) of the Act. Section 1128E(b)(3) requires the Secretary to protect the privacy of individuals receiving health care services in determining what information is required. Section 1128C(a)(3)(B)(ii) requires individuals and entities receiving information from the HIPDB, either directly or from another party, to use the information for the purpose for which it was provided. Appropriate uses of the information would include the prevention of fraud and abuse activities and improving the quality of patient care. In accordance with the requirements of the Privacy Act, the Office of the Inspector General (OIG) created a system of records (Federal Register/Volume. 64, No. 30/Tuesday, February 16, 1999) to implement the requirements of the statute. This system of records determines the parameters for disclosing final adverse actions and for disclosing information about who has submitted queries on health care providers, suppliers and practitioners.

11. Questions of a Sensitive Nature

The purpose of section 1128E is to facilitate the exchange of health care fraud-related information among law enforcement agencies, regulatory agencies, and health plans. The Department has determined that the reporting of Social Security Numbers and/or Federal Employer Identification Numbers is mandatory to differentiate between health care providers, suppliers and practitioners with similar names. However, the Department discloses these numbers only to individuals or organizations permitted by the statute to obtain such information from the HIPDB.

12. Estimates of Annualized Burden

The following table illustrates the burden hours and dollar expenditures associated with the HIPDB regulations and forms.

In several cases, burden and expenditure estimates of the HIPDB are captured as part of the burden for the NPDB. This is a result of the overlap between the NPDB and the HIPDB with respect to the reporting and querying requirements. Specifically, the burdens associated with:

1) reports submitted by State licensing boards [including those licensure actions required under 60.8(b)];
2) self queries by health care practitioners [60.11(a)(2)]; and
3) practitioner disputes, secretarial reviews and subject statements [60.14(b)] submitted for licensure actions.

Based on recent operational statistics, these estimates more than accommodate the combined NPDB and HIPDB burdens. More information about each of these specific estimates is provided in the burden descriptions by regulation section.

There are several cases in which overlap between the HIPDB (section 1128E) and the NPDB (Title IV) requirements are more difficult to separate. Certain entities may query under Title IV and section 1128E. These entities include health care practitioner licensing boards, certain managed care organizations, and Federal and State hospitals and health care entities. These entities may register, using electronic administrative forms, to query one or both Data Banks. If they choose to query both, they submit only one query via the Internet, and the system automatically queries both Data Banks for them.

Because the decision to query one or both Data Banks is up to each eligible entity, and because entities sometimes change these preferences during the course of a year, it is difficult at this time to estimate the percentage of duplicate queries for NPDB and HIPDB. Consequently, the estimate of the query burden for each Data Bank is based on the number of queries each receives, recognizing that a certain percentage of these queries are duplicates, which results in a potential overestimate of burden hours and expenditures.

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Distribution of Burden by Regulatory Citation

Regulation Citation	No. of Respondents	Responses Per Respondent	Total Responses[1]	Hours per Response	Total Burden Hours	Wage Rate	Total Cost
§61.6 (a), (b) Errors & Omissions	188	4.4	817	15 min.	204.25 hrs	$25	$5,106
§61.6 Revisions/ Appeal Status	130	26.9	3,492	30 min.	1,746 hrs	$25	$43,650
§61.7 Reporting By State Licensure Boards	305	80.8	24,640	45 min.	18,480 hrs	$25	$462,000
§61.8 Reporting of State Criminal Convictions	45	56.0	2,518	45 min.	1,888.5 hrs	$43	$81,205
§61.9 Reporting of Civil Judgments	4	2.5	10	45 min.	7.5 hrs	$43	$322
§61.10 (b) Reporting Exclusions from participation in Federal and State Health Care Programs	9	320.3	2,883	20 min.	961.0 hrs	$38	$36,518
§61.11 Reporting of Adjudicated Actions/Decisions	92	17.0	1562	45 min.	1,171.5 hrs	$43	$50,375
§61.12 Request for Information: State and Federal Agencies	855	279.3	238,814	5 min.	19,901.26 hrs	$25	$497,531.5
§61.12 Request for Information Health Plans	1,239	532.4	659,617	5 min.	54,968.1 hrs	$30	$1,649,043
§61.12 Request for Information Health Care Providers, Suppliers and Practitioners (self query)	50,416	1	50,416	25 min.	21,006.7 hrs	$45	$945,301.5
§61.12 (a) (4) Requests by Researchers for Aggregate Data	1	1	1	30 min.	.5 hrs	$38	$19
§61.15 Dispute Report	300	1	300	5 min	25 hrs	$45	$1,125
§61.15 Add Report Statement	669	1	669	45 min	501.8 hrs.	$100	$50,180
§61.15	15	1	15	480 min	120 hrs	$200	$24,000

[1] Numbers in the table may not add up exactly due to rounding.

Regulation Citation	No. of Respondents	Responses Per Respondent	Total Responses	Hours per Response	Total Burden Hours	Wage Rate	Total Cost
Request for Secretarial Review							
Administrative Forms*	0	0	0	0	0	0	0
TOTAL	54,268		985,754		120,982.11		$3,846,376

***Note**: The burden for Administrative Forms has been accounted for in the NPDB OMB clearance renewal submission.

BASIS FOR BURDEN ESTIMATES

§61.6 Reporting correction of errors, and omissions

Reports made under § 61.7, § 61.8, § 61.9 and §61.11 sometimes contain omissions or errors that will be noted by the reporting entity and a correction reported. A correction to a report requires less time than the original report because corrections can be made on an electronic copy of the original report via the HIPDB Web site, enabling the reporter to change only those elements of the report that require correction. This estimate is based on current operational statistics for the HIPDB and includes corrections submitted to the HIPDB by reporters of State and Federal health care-related criminal convictions, civil judgments, and other adjudicated actions. It also includes corrections submitted by reporters of State Licensure actions to both the HIPDB and the NPDB. The burden for the NPDB is subsumed under this burden due to overlap in the reporting requirement for each Data Bank.

(817 responses X 15 min. = 204.25 hours)

§61.6 Revisions to Reports/Appeal Status

Of the *Adverse Action Reports* and *Judgment or Conviction Reports* submitted to the HIPDB each year, approximately 3,492 are revised or placed on appeal. These numbers are based on current operational statistics for the HIPDB and include revisions submitted by State licensure boards to *Adverse Action Reports* contained in the NPDB, as well as revisions to *Judgment or Conviction Reports* submitted to the HIPDB. To file a revision to action report, or appeal, the reporter must prepare a new report; however, the reporter no longer has to complete an entire reporting form. The web-based reporting system enables the reporter to retrieve a copy of the report to be revised with the subject-related information pre-populated. If this information is unchanged since the last report submission, the entity does not need to complete that section. As a result, the time to complete the revision report is less than that of an initial report. The estimate to prepare a report of a revised action or appeal is 30 minutes.

(3,492 responses X 30 min. = 1,746 hours)

§61.7 Reporting licensure actions taken by Federal or State licensing and certification agencies.

Current operational statistics reflect an increased burden associated with reporting adverse licensure actions by Federal and State licensing and certification organizations. These statistics show that 24,640 reports are submitted annually by Federal and State Licensure or certification agencies. Since disciplinary licensure actions by State licensing authorities in the NPDB overlap with this statute, this estimate includes all licensure actions reported to both the NPDB and the HIPDB. The HIPDB uses similar forms and procedures for reporting as the NPDB. The estimated time needed to prepare a report of an adverse action is 45 minutes.

(24,640 responses X 45 min. = 18,480 hours)

§61.8 Reporting Federal or State criminal convictions related to the delivery of a health care item or service.

Based on current operational statistics, there were 2,518 State health care related criminal convictions reported to the HIPDB annually for an average of about 50.36 convictions per respondent. The estimated time needed to prepare a report is 45 minutes.

(**2,518 responses X 45 min. = 1,888.5 hours)**

§61.9 Reporting of civil judgments in Federal or State court related to the delivery of a health care item or service.

Based on current operational statistics, we estimate that 10 civil judgments are reported each year to the HIPDB. We estimate that it will take 45 minutes to complete and submit each report.
(10 responses X 45 min. = 7.5 hours)

§61.10 (b) Reporting Exclusions from State and Federal Health Care Programs
Current operational statistics show that approximately 2,883 exclusions are reported annually, including individual and organizations. About 90 percent of the reports are expected from the HHS OIG with the remaining 10 percent from State Government Agencies. Current estimates show that it takes 45 minutes to submit an exclusion/debarment to the HIPDB.
(2,883 responses X 20 min. = 961.0 hours)

§61.11 Reporting other adjudicated actions or decisions.
Based on current operational statistics, we estimate that there are 1,562 adjudicated actions or decisions submitted to the HIPDB each year. We estimate that it will take 45 minutes to complete and submit each report.
(1,562 responses X 45 min. = 1,171.5 hours)

§61.12 Requesting information from the Healthcare Integrity and Protection Data Bank (State and Federal Agencies)
Based on current operational statistics, the Department estimates that there will be 238,814 queries submitted by State and Federal Agencies to the HIPDB per year on health care providers, suppliers, and practitioners. Current time estimates indicate that it will take an entity 5 minutes to complete and submit a query.
(238,814 responses X 5 min. = 19,901.26 hours)

§61.12 Requesting information from the Healthcare Integrity and Protection Data Bank (Health Plans)
Based on current operational statistics, the Department estimates that there will be 659,617 queries submitted by Health Plans to the HIPDB per year. Current time estimates indicate that it will take an entity 5 minutes to complete and submit a query.
(659,617 responses X 5 min. = 54,968.1 hours)

§61.12 Requesting information from the Healthcare Integrity and Protection Data Bank (Submitting self-queries).
In addition, an estimated 50,416 self-queries will be submitted by practitioners, providers and suppliers requesting information about themselves. It currently takes 25 minutes to submit a self-query.
(50,416 responses X 25 min. = 21,006.7 hours)

§61.12 Requests by Researchers for Aggregate Data
Current operational statistics show that the HIPDB receives one (1) request per year for aggregate data for use in research. We estimate that it takes 30 minutes to write a letter requesting this information.
(1 response X 30 min. = 30 min.)

§61.15 How to dispute the accuracy of Healthcare Integrity and Protection Data Bank information.
Based on current operational statistics, we estimate that 300 reports on practitioners, suppliers and providers will be entered into "disputed status." We estimate that it will take a health care provider, supplier, or practitioner 5 minutes to log-in to the online system and place their report in dispute. It

is no longer necessary for a subject to make this request in writing, as the process now happens online.
(300 responses X 5 min. = 25 hours)

Of the 300 reports place in disputed status, we estimate that 669 practitioners, providers and suppliers will elect to add a 4,000 character statement to a report contained in the HIPDB. We estimate that it will take the subject of a report 45 minutes to log-in to the system and add a statement.
(669 X 45 min. = 501.8 hours)

Of the 300 disputed reports, we estimate that only 15 reports will be forwarded to the Secretary for review. We estimate that it will take a health care provider, supplier, or practitioner 8 hours to describe, in writing, which facts are in dispute and to gather supporting documentation related to the dispute.
(15 responses X 480 min. = 120 hours)

13. **Estimates of Annualized Cost Burden to Respondents**
Cost burden estimates that are based on the time it takes a respondent to submit a request for or report information to the HIPDB are included in the table "Distribution of Burden by Regulatory Citation." This table shows that we estimate that this program will cost respondents $**3,838,685** annually. In addition, respondents are charged fees to submit queries to obtain information on practitioners, providers or suppliers. The current fee to query the HIPDB is $4.75 per subject. Fees are also charged to practitioners, providers or suppliers who wish to self-query to obtain any reports that are contained in the HIPDB on themselves. The fee to self-query the HIPDB is $8.00.

Based on 2006 data, the estimated annual query fees are:

Queries from Entities	$3,452,884.25
Self-Queries	$ 412,394.00
Total	$3,865,278.25

14. **Estimates of Annualized Cost to the Government**
Since the last clearance, DHHS Office of Inspector General has provided funds to supplement the income raised through HIPDB query fees for the continued operation of the HIPDB. It is estimated that the HIPDB program will require supplemental income of approximately $450,320 annually in fiscal years 2007 and 2008 in order to remain operational.

15. **Changes in Burden**
There are currently 116,146.5 hours in the OMB inventory for this program. This request is for 120,982.11 hours for an increase of 4,835.61 hours. Some of the larger contributors to the overall burden increase included reports by State Licensure Boards, reports of State Criminal Convictions, and self-queries by Health Care Practitioners, Suppliers and Providers. This increase in burden is a program adjustment.

§61.6 Reporting Errors and Omissions
The burden for reporting corrections, errors or omissions increased 19.35 hours since the last OMB Clearance request. The increase is due in part to an increase in the amount of reports submitted to HIPDB. In turn, of those reports submitted, there were some that required correction.
Previous Burden = 184.9 hours Current Burden = 204.25 hours
Increase = 19.35 hours

<u>§61.6 Reporting Revisions/Appeal Status</u>

Operational statistics indicate that approximately 3,492 revisions to action/ appeals are submitted annually. The time burden associated with submitting reports is 30 minutes.
Previous Burden = 1,243.9 hours   Current = 1,746 hours
Increase = 502.1 hours.

<u>§61.7 Reporting Licensure Actions</u>

The burden for reporting licensure actions has increased to 18,480 hours. In previous submissions, estimates assumed that licensure boards would file reports to State certification agencies that would review reports and then submit them to the Data Banks. This estimate included all licensure reports submitted to the National Practitioner Data Bank and the HIPDB. Since that time, through experience and operation of the Data Banks, it is clear that most Boards submit actions directly to the Data Banks. The increase in licensure reports is also attributable to successful staff compliance efforts targeting the State Licensure Boards. The current estimate is taken from operational statistics, and, includes licensure actions for both Data Banks due to an overlap in reporting requirements for the NPDB and HIPDB.
Previous Burden = 14,499.4   Current = 18,480 hours
Increase = 3,980.6 hours

<u>§61.8 Reporting State Criminal Convictions</u>

The burden for reporting of State criminal convictions increased 1,516.5 hours since the last clearance request. This increase in burden is due to the increased volume of reports to the HIPDB.
Previous Burden = 372 hours   Current Burden = 1,888.5 hours
Increase = 1,516.5 hours

<u>§61.9 Reporting Civil Judgments</u>

The burden for reporting criminal convictions is reduced by 519 hours since the last clearance. Current estimates show that the time burden associated with filing a report is 45 minutes.
Previous Burden = 526.5 hours   Current Burden = 7.5 hours
Decrease= -519 hours

§61.10 (b) Reporting of Exclusions from State and Federal Health Care Programs

The amount of time it takes to submit each report is 20 minutes, resulting in a time burden of 961 hours. The last clearance request did not specifically assign burden for exclusion reports. Current estimates show that the time burden associated with filing a report is 20 minutes.
Previous Burden = 3,310.5 hours Current Burden = 961 hours
Decrease = -2,349 hours

§61.11 Reporting of Adjudicated Actions/Decisions

The burden associated with reporting of adjudicated actions or decisions has decreased significantly since the last clearance request. This change is based on a decline in the amount of reports submitted for other adjudicated actions or decisions. Current estimates show that the time burden associated with filing a report is 45 minutes.
Previous Burden = 3,843.8 hours Current Burden = 1,171.5 hours
Decrease = -2,672.3 hours

§61.12 Request for information: Federal and State Government Agencies

In determining the previous burden, we combined estimated queries from Federal and State Agencies with estimated queries from Health Plans. We are now able to identify and estimate the burden separately for the two eligible entity groups. The burden associated with receiving information from the HIPDB decreased by 3,824.94 hours since the last clearance request. Current estimates show that the time burden associated with filing a query is 5 minutes.
Previous Burden = 23,726.2 hours Current Burden = 19,901.26 hours
Decrease = -3,824.94 hours.

§61.12 Request for information: Health Plans

In determining the previous burden, we combined estimated queries from Federal and State Agencies with estimated queries from Health Plans. We are now able to identify and estimate the burden separately for the two eligible entity groups. The burden associated with receiving information from the HIPDB decreased by 7,461.6 hours since the last clearance request. Current estimates show that the time burden associated with filing a query is 5 minutes.
Previous Burden = 62,429.7 hours Current Burden = 54,968.1 hours
Decrease = -7,461.6 hours.

§61.12 Self-Queries Submitted by Practitioners, Providers, Suppliers

The burden for submitting self-queries has increased by 5,207.1 hours since the last clearance package. The new estimate is based on current operational statistics which estimate 37,925 self-queries. The increase is most likely attributable to a greater awareness by practitioners, providers, and suppliers, that they can have access to their information in the HIPDB database.
Previous Burden = 15,799.6 hours Current Burden = 21,006.7 hours
Increase = 5,207.1 hours

§61.12 Requests by Researchers for Aggregate Data
Current operational statistics show that the HIPDB receives one request per year for aggregate data for use in research. We estimate that it takes 30 minutes to write a letter requesting this information.
Previous Burden = 30 minutes   Current Burden = 30 minutes
Unchanged

§61.15 Disputed Reports/Add a Statement/Secretarial Review
The burden for placing a report in dispute and adding a subject statement has increased since the last clearance request, primarily because the burden for adding a Subject Statement has grown. This growth is attributable to the marked increase in the total number of respondents and responses. Many reports are contained in both the HIPDB and NPDB (specifically, licensure reports for physicians and dentists). When a report is contained in both Data Banks the subject must only submit a statement once. The statement will then be assigned automatically to the report in both Data Banks. As a result, a majority of statements are already cleared under the clearance package for the NPDB. Statements received for reports contained in the HIPDB only are counted as part of this clearance. In the following chart, these three components of the Secretarial Review process are identified for the purpose of comparing the change of their specific burden.
Place Report in Dispute
Previous Burden = 38.2 hours   Current Burden = 25 hours
Decrease = -13.2 hours

Add a Statement
Previous Burden = 178.5 hours   Current Burden = 501.8 hours
Increase = 323.3 hours

Request for Secretarial Review
Previous Burden = 344 hours   Current Burden = 120 hours
Decrease = -224 hours

Table of Changed Hours of Response Burden

Regulatory Section	Old Burden Estimate	New Burden Estimate	Change (+ or -)
§61.6 Errors/Omission**s**	184.9	204.25	+19.35
§61.6 Revisions/Appeals	1,243.9	1,746	+502.1
§61.7 Licensure Boards	14,499.4	18,480	+3,980.6
§61.8 Criminal Convictions	372	1,888.5	+1,516.5
§61.9 Civil Judgements	526.5	7.5	-519
§61.10 Exclusions from State and Federal Health Care Programs	3,310.5	961	-2,349
§61.11 Adjudicated Actions/Decisions	3,843.8	1,171.5	-2,672.3
§61.12 Requests for Information: Federal and State Agencies (query)	23,726.2	19,901.2	-3,824.94
§61.12 Requests for Information: Health Plans	62,429.7	54,968.1	-7,461.6
§61.12 Access to Data (Self-query)	15,799.6	21,006.7	+5,207.1
§61.12 (a) Research Request for Aggregate Data	.5	.5	Unchanged
§61.15 Place a Report in Dispute	38.2	25	-13.2
§61.15 Add a Statement	178.5	501.8	+323.3
§61.15 Request for Secretarial Review	344	120	-224
Total	**116,146.5**	**120,982.11**	**+4,835.61**

16. Time Schedule, Publications and Analysis Plan

There are no plans for publication of the data to be collected on these forms for statistical purposes. Ultimately, data, stripped of identifiers, will be available to HRSA for use in preparation for Reports to Congress, and to HRSA and others for research purposes.

17. Exemption for Display of Expiration Date

The expiration date will be displayed.

18. Certifications

This data collection activity meets the requirements of 5 CFR 1320.9. The required certifications are included in the package.