NATIONAL PRACTITIONER DATA BANK (NPDB) REGULATIONS 2900-0621

1. Explain the circumstances that make the collection of information necessary. Identify legal or administrative requirements that necessitate the collection of information.

Under the provisions of the Health Care Quality Improvement Act of 1986, which established the National Practitioner Data Bank – Health Integrity and Protection Data Bank (NPDB – HIPDB), and a Memorandum of Understanding (MOU) between the Department of Veterans Affairs (VA) and the Department of Health and Human Services (HHS), VA medical treatment facilities are required to query the NPDB at the time of initial appointment to a VA medical treatment facility, any time a change in privileges occurs and at the time of reappointment to the medical staff of the facility (a minimum of every 2 years) of any licensed independent healthcare professional. In 2007, at the direction of the Under Secretary for Health, VA medical treatment facilities enrolled all licensed independent provider in the NPDB Proactive Disclosure/Continuous Query Service which provides an automatic, ongoing monitoring against the NPDB. In accordance with 38 CFR, Chapter 1, Part 46, information is collected so that VA can consider if malpractice payments were made related to substandard care, professional incompetence, or professional misconduct on the part of a physician, dentist, or other licensed health care practitioner.

Additionally, complete and thorough credentialing is required to assure that only qualified healthcare professionals provide care to our Nation's veterans. The term credentialing refers to the systematic process of screening and evaluating qualifications and other credentials, including licensure, required education, relevant training and experience, current competence and health status.

2. Indicate how, by whom, and for what purposes the information is to be used; indicate actual use the agency has made of the information received from current collection.

VA credentialers designated in each medical treatment facility verify information provided on the 10-2850, Application for Physicians, Dentists, Podiatrists, Optometrists & Chiropractors, 10-2850a Application for Nurse and Nurse Anesthetist, and 10-2850c, Application for Associated Health Occupations approved under OMB number 2900-0205. The information is verified by the primary source (the organization that provided the education or training or granted the license). The primary sources include state licensing board, the educational institution (over 125 medical schools, 7800 training program in over 400 facilities), registrations and certification, and references through written correspondence, documented telephone calls, internet web sites, and electronic requests through VetPro, VHA's electronic credentials system by the credentialing staff at the medical center. VetPro facilitates many of these queries by allowing the credentialing staff to click a button for a letter generation to the primary source or electronic query. Information received is documented in VetPro including incorporation of a scanned document so that in the future additional queries are not required. The collected information is used by the medical center leadership to evaluate the qualifications, skills, and abilities and make decisions whether to appoint of these healthcare practitioners to care for our Nation's veterans.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g. permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also described any consideration of using information technology to reduce burden.

In the past few years, many State licensing boards have facilitated the ability to obtain these verifications electronically through automated facsimile or the Internet. Where it is possible, VA is encouraging the electronic verification of credentials and has facilitated this through electronic interfaces between VA's VetPro and the NPDB – HIPDB as well as the Federation of State Medical Boards (FSMB). Technology has afforded VA the ability to verify the non-time limited information of education and training once and incorporate it into the electronic record (VetPro). This eliminates the need for reverification when a healthcare provider moves or is shared between facilities. However, much of the process involves an individual responding to VA's query. In March 2011, the Records Control System, RCS 10-1, 10Q, Health Care Provider Credentialing and Privileging Records, was amended to move to a paperless environment so all records are maintained electronically, but an individual is required to obtain the verification and document the response. The burden reflects the time expended on these verifications of education and training information as well as personal references.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

When VA introduced VetPro in 2001, one objective was to reduce the duplication created when a provider transfers to another facility. The incorporation of the verification into the electronic credentials record (VetPro) has reduced this duplication since the electronic file is now shared or transferred as appropriate.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

No small businesses or other small entities are impacted by the NPDB information collection. The remaining collection of information is a standard business practice in the healthcare industry. Every effort has been made to streamline the data collection and to limit the data collected to that considered an industry standard. VA facilitates the queries completed on paper by providing a self-addressed, stamped envelope.

6. Describe the consequences to Federal program or policy activities if the collection is not conducted or is conducted less frequently as well as any technical or legal obstacles to reducing burden.

The collection is performed once at the time of initial appointment to a VA medical treatment facility with all time limited information reverified at expiration and at the time of reappraisal, a minimum of every two years. This is required by the Joint Commission (TJC) who accredits VA healthcare facilities. The query of the NPDB – HIPDB is required by the MOU with the Department of Health and Human Services (HHS) in order to be in compliance with the Health Care Quality Improvement Act. Frequency cannot be reduced or we violate compliance with TJC Accreditation Standards and the Memo of Understanding (MOU) with Health and Human Services (HHS)

maintained.

7. Explain any special circumstances that would cause an information collection to be conducted more often than quarterly or require respondents to prepare written responses to a collection of information in fewer than 30 days after receipt of it; submit more than an original and two copies of any document; retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years; in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study and require the use of a statistical data classification that has not been reviewed and approved by OMB.

There are no such special circumstances.

8. a. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the sponsor's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the sponsor in responses to these comments. Specifically address comments received on cost and hour burden.

The notice of Proposed Information Collection Activity was published in the Federal Register on June 7, 2011, page 33032. VA received one comment in response to this notice. The VA program office Director, Katherine Enchelmayer, Credentialing and Privileging, provided a response on 7/11/2011 (see attachment in the Supplementary Documents/ROCIS).

National Practitioner Data Bank Regulation;

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b. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, clarity of instructions and recordkeeping, disclosure or reporting format, and on the data elements to be recorded, disclosed or reported. Explain any circumstances which preclude consultation every three years with representatives of those from whom information is to be obtained.

These collection requirements are discussed regularly with our accreditation partners (TJC) as well as other Federal healthcare agencies, and professional organizations. These collections are a standard in the healthcare industry. There are no circumstances which would preclude consultation. Additionally, the 30- and 60-day Federal Register Notices constitute outside consultation.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

Some verification entities require payment of a processing fee that can be as low as \$4.50 to the Federation of State Medical Boards for a history of licensure and adverse actions, to \$25 for verification of a medical license in the District of Columbia. The costs of these queries vary from one entity to another and are paid by the respective VA medical treatment facility.

10. Describe any assurances of privacy, to the extent permitted by law, provided to respondents and the basis for the assurance in statue, regulation, or agency policy.

Assurances of privacy are contained in the system of records identified as, 77VA10Q, Health Care Provider Credentialing and Privileging Records-VA as set forth in the Federal Register March 25, 2008 and available at http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi?
position=all&page=16097&dbname=2008 register. The responses are received and maintained in credentialing files that were previously stored in locked file cabinets and currently in VetPro, the electronic credentials system https://fcp.vetpro.org. The files can be retrieved only by the facility that made the query. The VetPro electronic system is a secure system maintained at National Institutes of Health, Center for Information Technology, a Level 3 secure site (the same level of security as the high level DoD sites, with multiple firewalls of differing technology, that are monitored 7 days a week, 24 hours a day).

11. Provide additional justification for any questions of a sensitive nature (Information that, with a reasonable degree of medical certainty, is likely to have a serious adverse effect on an individual's mental or physical health if revealed to him or her), such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private; include specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

The information collected may be considered sensitive in that there is personally identifiable information as well the possibility that there is a report containing information on the type of action taken by a medical State licensing board; an adverse action taken by a health care or professional organization; or a medical malpractice payment. Any of these will contain general description of the basis of the incident and action. Practitioners are given the opportunity provide information that they want to provide concerning the specific care that led to the claim.

12. Estimate of the hour burden of the collection of information:

a. The annual burden is estimated at 2,500 hours. This is based on the sum of the time expended by each of the different organizations asked to verify data.

	Respondent	Frequency	Responses Annually	Hours Each	Annual Burden Hours
NPDB	500	1	500	5	2,500
TOTAL	500	1	500	5	2,500

b. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB 83-I.

There is no form in this submission.

c. Provide estimates of annual cost to respondents for the hour burdens for collections of information. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.

The cost to the respondents for completing this information is \$200,000. We do not require any additional recordkeeping.

	Burden Hours	Cost	Total
NPDB	2,500	\$80	\$200,000

- 13. Provide an estimate of the total annual cost burden to respondents or recordkeepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12 and 14).
 - a. There is no capital, start-up, operation or maintenance costs.
- b. Cost estimates are not expected to vary widely. The only cost is that for the time of the respondent.
- c. There is no an anticipated capital start-up cost component or requests to provide information.
- 14. Provide estimates of annual cost to the Federal Government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operation expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.

There is no cost to the Federal Government since the process has been automated.

15. Explain the reason for any program changes or adjustments reported in Items 13 or 14.

The change in hours is due to the increase in reports with the implementation of the Proactive Disclosure/Continuous Query Service (PD/CQS). The enrollment in PD/CQS does not wait for the biannual review or change in privileges but rather directly transmits to VA any new report to the NPDB requiring following with the reporting entity.

VA form 10-490 was made obsolete by VetPro, VHA's electronic credentialing system and is therefore no longer used.

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and *ending* dates of the collection of information, completion of report, publication dates, and other actions.

There are no plans to publish the results of the information collected.

17. If seeking approval to omit the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

Since the use of the VA 10-490 is no longer used, there is no need for approval to omit an expiration date.

18. Explain each exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions," of OMB 83-I.

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

No statistical methods are used in this data collection