maintained at all health care facilities in the United States that are verified for completeness and accuracy varied greatly across the Nation.

The application process has been streamlined and is using information technology to make the application electronically available on the Internet.

Affected Public: Individuals and households.

Type of Respondents: Individuals.

The table below provides: Types of data collection instruments, Estimated number of respondents, Number of annual number of responses, Average burden per response, and Total annual burden hours.

Data collection instrument(s)	Estimated number of respondents	Responses per respondent	Average burden hour per response*	Total annual burden hours
Application to Medical Staff	570	1	1.00 (60 mins) ..	570
Reference Letter	1710	1	0.33 (20 mins) ..	570
Reappointment Request	190	1	1.00 (60 mins) ..	190
Ob-Gyn Privileges	20	1	1.00 (60 mins) ..	20
Internal Medicine	325	1	1.00 (60 mins) ..	325
Surgery Privileges	20	1	1.00 (60 mins) ..	20
Psychiatry Privileges	13	1	1.00 (60 mins) ..	13
Anesthesia Privileges	15	1	1.00 (60 mins) ..	15
Dental Privileges	150	1	0.33 (20 mins) ..	50
Optometry Privileges	21	1	0.33 (20 mins) ..	7
Psychology Privileges	30	1	0.17 (10 mins) ..	5
Audiology Privileges	7	1	0.08 (5 mins)	1
Podiatry Privileges	7	1	0.08 (5 mins)	1
Radiology Privileges	8	1	0.33 (20 mins) ..	3
Pathology Privileges	3	1	0.33 (20 mins) ..	1
Total	3,089	.....	.....	1,791

*For ease of understanding, burden hours are provided in actual minutes. There are no capital costs, operating costs and/or maintenance costs to respondents.

Request For Comments: Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the agency processes the information collected in a useful and timely fashion; (c) the accuracy of public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether the methodology and assumptions used to determine the estimate is logical; (e) ways to enhance the quality, utility, and clarity of the information being collected; and (f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Send your written comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time to: Office of Management and Budget, Office of Regulatory Affairs, *Attention:* Desk Officer for IHS, New Executive Office Building, Room 10235, Washington, DC 20503.

Send Comments and Requests for Further Information: To request more information on the proposed collection or to obtain a copy of the data collection instrument(s) and/or instruction(s) contact: Mr. Hershel Gorham, Reports Clearance Officer, 801 Thompson Avenue, TMP, Suite 450, Rockville, MD 20852–1627; call non-toll free (301) 443–5932; send via facsimile to (301) 443–9879; or send your e-mail requests, comments, and return address to: *Hershel.Gorham@ihs.gov.*

Comment Due Date: Comments regarding this information collection are best assured of having full effect if received within 30 days of the date of this publication.

Dated: March 19, 2010.

Yvette Roubideaux,

Director, Indian Health Service.

[FR Doc. 2010–7253 Filed 3–30–10; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Common Formats for Patient Safety Data Collection and Event Reporting

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of Availability—Common Formats Version 1.1.

SUMMARY: The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b–21 to b–26, (Patient Safety Act) provides for the formation of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information regarding the quality and safety of healthcare delivery. The Patient Safety Act (at 42 U.S.C. 299b–23) authorizes the collection of this information in a standardized manner, as explained in the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008: 73 FR 70731–70814. As authorized by the Secretary of HHS, AHRQ coordinates the development of a set of common definitions and reporting formats (Common Formats) that allow healthcare providers to voluntarily collect and submit standardized information regarding patient safety events. The purpose of this notice is to announce the availability of the expanded and enhanced Common Formats Version 1.1—including updated event descriptions, reports, data elements, and technical specifications for software developers—and the process for their continued refinement.

DATES: Ongoing public input.

ADDRESSES: The Common Formats Version 1.1 can be accessed electronically at the following HHS Web site: *http://www.PSO.AHRQ.gov/index.html.*

FOR FURTHER INFORMATION CONTACT: Marcy Opstal, Center for Quality Improvement and Patient Safety, AHRQ, 540 Gaither Road, Rockville, MD 20850; Telephone (toll free): (866) 403–3697;

Telephone (local): (301) 427–1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; E-mail: *PSO@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act and Patient Safety Rule establish a framework by which doctors, hospitals, and other healthcare providers may voluntarily report information regarding patient safety events and quality of care. Information that is assembled and developed by providers for reporting to PSOs and the information received and analyzed by PSOs—called "patient safety work product"—is privileged and confidential. Patient safety work product is used to identify events, patterns of care, and unsafe conditions that increase risks and hazards to patients. Definitions and other details about PSOs and patient safety work product are included in the Patient Safety Rule.

The Patient Safety Act and Patient Safety Rule require PSOs, to the extent practical and appropriate, to collect patient safety work product from providers in a standardized manner in order to permit valid comparisons of similar cases among similar providers. The collection of patient safety work product allows the aggregation of sufficient data to identify and address underlying causal factors of patient safety problems. Both the Patient Safety Act and Patient Safety Rule can be accessed electronically at *http://www.PSO.AHRQ.gov/regulations/regulations.htm.*

In order to facilitate standardized data collection, the Secretary of HHS authorized AHRQ to develop and maintain the Common Formats to improve the safety and quality of healthcare delivery. In August 2008, AHRQ issued the initial release of the formats, Version 0.1 Beta. The second release of the Common Formats, Version 1.0, was announced in the **Federal Register** on September 2, 2009: 74 FR 45457–45458.

Definition of Common Formats

The term "Common Formats" is used to describe clinical definitions and technical requirements developed for the uniform collection and reporting of patient safety data, including all supporting material. The Common Formats are not intended to replace any current mandatory reporting system, collaborative/voluntary reporting system, research-related reporting system, or other reporting/recording system. The scope of Common Formats applies to all patient safety concerns including:

- Incidents—patient safety events that reached the patient, whether or not there was harm,
- Near misses or close calls—patient safety events that did not reach the patient, and
- Unsafe conditions—circumstances that increase the probability of a patient safety event.

Common Formats Version 1.1 is currently limited to patient safety reporting for acute care hospitals and is designed to support the first stage in the improvement cycle. Version 1.1 includes two general types of formats, generic and event specific. The generic Common Formats pertain to all patient safety concerns. The three generic formats are: Healthcare Event Reporting Form, Patient Information Form, and Summary of Initial Report. The event-specific Common Formats pertain to frequently-occurring and/or serious patient safety events. The eight event-specific formats are: Blood or Blood Product, Device or Medical/surgical Supply, Fall, Healthcare-Associated Infection, Medication or Other Substance, Perinatal, Pressure Ulcer, and Surgery or Anesthesia.

The Common Formats Version 1.1 has a defined focus on patient safety reporting for acute care hospitals. It should be noted, however, that the privilege and confidentiality protections of the Patient Safety Act and Patient Safety Rule apply to patient safety work product developed under the aegis of a PSO with respect to healthcare in any setting. Future versions of the Common Formats are being developed for other settings such as: Skilled nursing facilities (SNFs), ambulatory surgery centers, and physician and practitioner offices.

AHRQ's Common Formats Version 1.1 includes:

- Descriptions of patient safety events and unsafe conditions to be reported (event descriptions),
- Specifications for patient safety aggregate reports and individual event summaries,
- Delineation of data elements to be collected for specific types of events,
- A user's guide and quick guide, and
- Technical specifications for electronic data collection and reporting.

Common Formats Development

In anticipation of the need for Common Formats, AHRQ began their development in 2005 by creating an inventory of functioning private and public sector patient safety reporting systems. This inventory provides an evidence base that informs construction of the Common Formats. The inventory now numbers 69 and includes many systems from the private sector, including prominent academic settings, hospital systems, and international reporting systems (*e.g.,* from the United Kingdom and the Commonwealth of Australia). In addition, virtually all major Federal patient safety reporting systems are included, such as those from the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Department of Defense (DoD), and the Department of Veterans Affairs (VA).

Since February 2005, AHRQ has coordinated an interagency Federal Patient Safety Work Group (PSWG) to assist AHRQ with developing and maintaining the Common Formats. The PSWG includes major health agencies within the HHS CDC, Centers for Medicare & Medicaid Services, FDA, Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, the National Library of Medicine, the Office of the National Coordinator for Health Information Technology, the Office of Public Health and Science, the Substance Abuse and Mental Health Services Administration—as well as the DoD and the VA.

The PSWG assists AHRQ with assuring the consistency of definitions/formats with those of relevant government agencies as refinement of the Common Formats continues. To the extent practicable, the Common Formats are also aligned with World Health Organization (WHO) concepts, framework, and definitions, contained in their draft International Classification for Patient Safety (ICPS).

Common Formats Version 1.1—Technical Specifications Enhancements

The technical specifications promote standardization by ensuring that data collected by PSOs and other entities are clinically and electronically comparable. The specifications also provide direction to software developers, so the Common Formats can be implemented electronically, and to PSOs, so the Common Formats can be submitted electronically to the PSO Privacy Protection Center (PPC) for data de-identification and transmission to the Network of Patient Safety Databases (NPSD).

The technical specifications consist of the following:

- Data dictionary—defines data elements and their attributes (data element name, answer values, field length, guide for use, etc.) included in Common Formats Version 1.1;

• Clinical document architecture (CDA) implementation guide—provides instructions for developing a Health Level Seven (HL7) CDA Extensible Markup Language (XML) file to transmit the Common Formats patient safety data from the PSO to the PPC using the Common Formats;
• Validation rules and errors document—specifies and defines the validation rules that will be applied to the Common Formats data elements submitted to the PPC;
• Common Formats flow charts—diagrams the valid paths to complete generic and event specific formats (a complete event report);
• Local specifications—provides specifications for processing, linking and reporting on events and details specifications for reports; and
• Metadata registry—includes descriptive facts about information contained in the data dictionary to illustrate how such data corresponds with similar data elements used by other Federal agencies and standards development organizations [*e.g.,* HL–7, International Standards Organization (ISO)].

Commenting on Common Formats Version 1.1

To allow for greater participation by the private sector in the subsequent development of the Common Formats, AHRQ engaged the National Quality Forum (NQF), a non-profit organization focused on healthcare quality, to solicit comments and advice to guide the further refinement of the Common Formats. The NQF began this process with feedback on AHRQ's 0.1 Beta release of the Common Formats. The NQF also convened an expert panel to review the comments received on Common Formats Version 1.0 and provide feedback to AHRQ. Based upon the expert panel's feedback, AHRQ, in conjunction with the PSWG, has further revised and refined the Common Formats that are now available as Version 1.1.

AHRQ is committed to continuing refinement of the Common Formats. The Agency is specifically interested in obtaining feedback from both the private and public sectors, particularly from those who use the Common Formats, to guide their improvement. Although AHRQ's Version 1.1 has been developed based on evidence, consensus of the PSWG, public comments and input, and feedback from the NQF expert panel, the formats do not fully reflect the refinement that comes from large-scale use and repeated revision. The process for updating and refining the formats will be an iterative one.

More information on the Common Formats Version 1.1, including the feedback process, can be obtained through AHRQ's PSO Web site: *http://www.PSO.AHRQ.gov/index.html.*

Dated: March 19, 2010.

Carolyn M. Clancy,

Director.

[FR Doc. 2010–6781 Filed 3–30–10; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

FY 2010 Special Diabetes Program for Indians Community-Directed Grant Program

Announcement Type: New/Competing Continuation.
Funding Opportunity Number: HHS–2010–IHS–SDPI–0004.

Catalog of Federal Domestic Assistance Number: 93.237

Key Dates:

Application Deadline: April 30, 2010.
Review Date: June 21–24, 2010.
Earliest Anticipated Start Date: July 15, 2010.

Other information: This announcement will be open throughout Fiscal Year (FY) 2010 based on existing budget cycles. Refer to application instructions for additional details. This current announcement targets grantees that currently operate under a budget cycle that begins on June 1.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting grant applications for the FY 2010 Special Diabetes Program for Indians (SDPI) Community-Directed grant program. This competitive grant announcement is open to all existing SDPI grantees that have an active grant in place and are in compliance with the previous terms and conditions of the grant. This program is authorized under H.R. 6331 "Medicare Improvement for Patients and Providers Act of 2008" (Section 303 of Pub. L. 110–275) and the Snyder Act, 25 U.S.C. 13. The program is described in the Catalog of Federal Domestic Assistance (CDFA) under 93.237.

Overview

The SDPI seeks to support diabetes treatment and prevention activities for American Indian/Alaska Native (AI/AN) communities. Grantees will implement programs based on identified diabetes-related community needs. Activities will be targeted to reduce the risk of diabetes in at-risk individuals, provide services that target those with new onset diabetes, provide high quality care to those with diagnosed diabetes, and/or reduce the complications of diabetes.

The purpose of the FY 2010 SDPI Community-Directed grant program is to support diabetes treatment and prevention programs that have a program plan which integrates at least one IHS Diabetes Best Practice and that have a program evaluation plan in place which includes tracking outcome measures.

This is not an application for continued funding as was previously available for Community-Directed grant programs.

Background

Diabetes Among American Indian/Alaska Native Communities

During the past 50 years, type 2 diabetes has become a major public health issue in many AI/AN communities, and it is increasingly recognized that AI/AN populations have a disproportionate burden of diabetes (Ghodes, 1995). In 2006, 16.1% of AI/ANs age 20 years or older had diagnosed diabetes (unpublished IHS Diabetes Program Statistics, 2006) compared to 7.8% for the non-Hispanic white population (CDC, 2007). In addition, AI/AN people have higher rates of diabetes-related morbidity and mortality than the general U.S. population (Carter, 1996; Harris, 1995; Gilliland, 1997). Strategies to address the prevention and treatment of diabetes in AI/AN communities are urgently needed.

Under the Balanced Budget Act of 1997, Congress authorized the IHS to administer the SDPI grant program. SDPI grants are programmatically directed by the IHS Division of Diabetes Treatment and Prevention (DDTP).

Special Diabetes Program for Indians

The SDPI is a $150 million per year grant program. Over 330 programs have received SDPI Community-Directed grants annually since 1998. In addition, 66 demonstration projects have been funded annually since 2004 to address prevention of type 2 diabetes or cardiovascular disease risk reduction. A Congressional re-authorization in 2008 extended the SDPI through FY 2011.

II. Award Information

Type of Awards

Grants.

Estimated Funds Available

The total amount of funding identified for FY 2010 SDPI