messages, see below) currently under development;

- Extend the Janus logical data model and service-oriented architecture to support submission of CDISC-HL7 messages;
- Integrate with NCI's Enterprise Vocabulary Service (EVS);
- Test the integration and analysis of clinical study data stored in Janus with pharmacogenomic data currently being received through the Voluntary Genomic Data Submissions (VGDS) program.[4]

A desired outcome of the phase 3 pilot is a production environment that supports the routine processing and management of all structured clinical study data provided in regulatory submissions.

The phase 3 operational pilot will also test a new submission format. Currently, SDTM datasets are provided in SAS transport format. FDA recognizes the limitations of the outdated SAS transport format and intends to transition towards a new, more robust XML-based submission format. FDA is currently sponsoring a project within HL7[5] to develop a standard XML exchange format (called ''messages'') for standardized clinical study data content as defined by CDISC. This ''CDISC Content to HL7 Message Project'' will enable the exchange of clinical study data in a standardized HL7–XML-based format. We believe this will facilitate loading study data into Janus and provide additional benefits. A successful phase 3 pilot will also enable FDA to routinely accept HL7–XML-based clinical study data submissions.

Concurrent with the phase 3 pilot, CDER also will be exploring ways to integrate related data standards initiatives with the Janus effort. These related initiatives include the enhancement of the current Janus logical model to incorporate preclinical and pharmacogenomics data and product safety data. Future efforts will continue to focus on business information requirements for managing product life-cycle data across all FDA regulated products.

II. Pilot Project Description

This pilot project is part of an ongoing effort to improve the efficiency of the review of study data within CDER. As we gain additional experience from this pilot, CDER expects to update its study data submission technical specifications as part of a continuing process to improve the quality of clinical study data provided electronically.

A. Approach

CDER is seeking applicants who have submitted or are planning to submit in the near future (i.e., within 6 months of publication of this notice) SDTM files in a regulatory submission in accordance with existing guidance and technical specifications. Our experience during phase 2 has shown that SDTM files routinely fail the Janus validation procedures and cannot be loaded into Janus automatically. Pilot participants should agree to work closely with Janus technical staff to review the validation errors, correct them, and resubmit the files. The ability to successfully load data into the Janus repository is an important pilot milestone. Experience gained as a result of working with participating sponsors during this pilot will help us improve the validation criteria, which subsequently will help improve the quality of future study data submissions. Pilot participants will also gain valuable experience in creating and submitting quality standardized data submissions. Of particular interest are pilot participants who are also able to provide pharmacogenomic data (i.e., VGDS) with the CDISC data. This will enable us to test the integration of clinical data stored in Janus with pharmacogenomic data. Although a VGDS is not required to participate in this pilot, it is a desirable component of the pilot and is encouraged whenever possible.

From this pool of pilot participants, we are also seeking five to eight companies willing to supply study data in the new HL7 XML format (in addition to SDTM datasets) for testing, processing, and loading into Janus. FDA will provide some technical support with the new HL7 XML format, such as help in understanding and interpreting the new specifications. Those who participate in this part of the pilot also will be provided secure access to their data in Janus so they can test the integrity of their data within the Janus environment. Although the SDTM files are part of a regulatory submission, all of the activities involved in this pilot will be conducted outside of a regulatory setting. That is, the SDTM datasets will be reviewed according to current review practices for any electronic dataset submission, and pilot activities will not impact the regulatory review clock, will not affect or delay reviewability assessments, filability decisions, or any regulatory actions.

B. How to Participate

Requests to participate in the pilot project should be submitted to the Division of Dockets Management (see **ADDRESSES**). Requests are to be identified with the docket number found in brackets in the heading of this document. The pilot enrollment period will last 6 months following publication of this notice. The pilot is expected to last approximately 1 year, but this duration will be subject to change as the pilot progresses. Updates to the pilot will be publicly posted on the FDA Janus Operational Pilot Web page.[6]

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this pilot project. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 8, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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[4] See *http://www.fda.gov/cder/genomics/VGDS.htm.*

[5] Health Level Seven in an American Standards Institute (ANSI)-accredited standards development organization operating in the health care arena. See *http://www.hl7.org.* (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

[6] See *http://www.fda.gov/oc/datacouncil/janus_operational_pilot.html.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 30-Day Proposed Information Collection: Behavioral Health Preventive Care Assessment Focus Group

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 which requires 30 days for public comment on proposed information collection projects, the Indian Health Service (IHS) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection project was previously published in the

Federal Register (73 FR 23254) on April 29, 2008 and allowed 60 days for public comment. No public comment was received in response to the notice. The purpose of this notice is to allow 30 days for public comment to be submitted directly to OMB.

Proposed Collection: Title: 0917–NEW, ''Behavioral Health Preventative Care Assessment Focus Group.'' *Type of Information Collection Request:* Three year approval for this new information collection, 0917–NEW, ''Behavioral Health Preventive Care Assessment Focus Group Guide.'' *Form Number(s):* None. *Need and Use of Information Collection:* The IHS goal is to raise the health status of the American Indian and Alaska Native people to the highest possible level by providing comprehensive health care and preventive health services. To support the IHS mission, IHS uses the Government Performance Act (GPRA) to assess quality of care among its Federal, urban, and Tribal health programs. The IHS has been largely successful in meeting GPRA targets for selected clinical performance measures at the national level. However, there is significant variability in performance among IHS and Tribal service units.

Until this time, IHS has not undertaken any comprehensive studies to evaluate the reasons for that variability or the factors that contribute to high quality care at the local level. The IHS has three GPRA measures relating to behavioral health, a high priority for the Agency and one of the IHS Director's Initiatives. This study will focus on these three GPRA behavioral health measures: Depression Screening in adults age 18 and over, Domestic/Intimate Partner Violence screening in women ages 15–40 and Alcohol Screening (to prevent Fetal Alcohol Syndrome) in women ages 15–44.

Tribal programs voluntarily report their GPRA results quarterly and annually for national reporting. GPRA data collected for these three behavioral health measures includes: The number of patients eligible for a screening (denominator), number of eligible patients who receive a screening (numerator), and the resulting screening rate (percentage). IHS has developed methodology to identify superior and poor performers on these measures in both Tribal and Federal sites using fiscal year 2005, 2006, and 2007 GPRA performance results.

IHS will convene focus groups with employees at 17 of these programs (7 IHS and 10 Tribal) in order to identify the factors contributing to (and when appropriate, the barriers preventing) the provision of high quality behavioral health care at the local level. These focus groups will allow employees to provide detailed data regarding program practices, screening and documentation procedures, initiatives, resources, and other factors relating to the provision of behavioral health preventive care at their health program. A total of two to three focus groups, organized by occupational specialty, will be convened at each program.

Using the Chronic Care Model and Institute of Medicine recommendations, IHS will analyze the information collected during these site visits, along with background information that is publicly available (e.g., information found on clinic Web pages) on other qualitative and quantitative features of individual programs, such as staffing and funding levels, community demographics, and organizational structure, to develop a behavioral health preventive care model relevant to the unique system of IHS delivery. *Affected Public:* Individuals. *Type of Respondents:* Tribal employees at Tribal health programs.

The table below provides: Types of data collection instruments, Estimated number of respondents, Number of responses per respondent, Number of total annual responses, Average burden hour per response, and Total annual burden hour(s).

Data collection instrument(s)	Number of respondents	Responses per respondent	Total annual response	Burden hour per response	Annual burden hours
Administrators/Supervisor Focus Group Guide	30	1	30	2	60
Provider Focus Group Guide	30	1	30	2	60
Behavioral Health Provider Focus Group Guide	15	1	15	2	30
Data Entry Focus Group Guide	15	1	15	2	30
Total	90				180

There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

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 estimates are 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, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for IHS.

To request more information on the proposed collection or to obtain a copy of the data collection instrument(s) and/or instruction(s) contact: Ms. Janet Ingersoll, Acting IHS Reports Clearance Officer, 12300 Twinbrook Parkway, Suite 450, Rockville, MD 20852–1601; call non-toll-free (301) 443–1116; send via facsimile to (301) 443–2316; or send your e-mail requests, comments, and return address to: *JanetIngersoll@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: August 11, 2008.

Robert G. McSwain,

Director, Indian Health Service.

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