Committees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: During the morning session, the committee will discuss supplemental new drug application (sNDA) 022059/014 with the trade name Tykerb (lapatinib) tablets, application submitted by SmithKline Beecham (Cork) Ltd, Ireland d/b/a GlaxoSmithKline. The proposed indication (use) for this product is in combination with trastuzumab for the treatment of patients with metastatic breast cancer whose tumors overexpress HER2 and who have received prior trastuzumab therapy(s).

During the afternoon session, the committee will discuss the evaluation of radiographic review in randomized clinical trials using progression-free survival (PFS) as a primary endpoint in non-hematologic malignancies. They will consider the merits of an independent audit of investigator progression assessment in a pre-specified subgroup of patients instead of an independent review of all progression assessments. The expectation is that an independent audit would streamline the conduct of clinical trials, as well as avoid missing data when no additional protocol specified progression assessments are mandated. Hematologic malignancies are excluded from this discussion because other issues (e.g., blood counts, lymph node exams, and other biomarkers) influence the assessment of PFS.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 10, 2012. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m., and 3:30 p.m. to 4 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 29, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 2, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Caleb Briggs at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings. Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 24, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–13156 Filed 5–30–12; 8:45 am]

BILLING CODE 4160–01–P

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 (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). To request a copy of the clearance requests submitted to OMB for review, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office on (301) 443–1984.

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

Proposed Project: Rural Health Information Technology Network Development (OMB No. 0915–xxxx)—[New]

The purpose of the Rural Health Information Technology Network Development (RHITND) Program, authorized under the Public Health Service Act, Section 330A(f) (42 U.S.C. 254c(f)) as amended by Section 201, Public Law 107–251, of the Health Care Safety Net Amendments of 2002, is to improve health care and support the adoption of Health Information Technology (HIT) in rural America by providing targeted HIT support to rural health networks. HIT plays a significant role in the advancement of the Department of Health and Human Services' (HHS) priority policies to improve health care delivery. Some of these priorities include: Improving health care quality, safety, efficiency and reducing disparities, engaging patients and families in managing their health, enhancing care coordination, improving population and public health and ensuring adequate privacy and security of health information.

The intent of the RHITND Program is to support the adoption and use of electronic health records (EHR) in coordination with the ongoing HHS activities related to the Health Information Technology for Economic and Clinical Health (HITECH) Act (Pub. L. 111–5). This legislation provides HHS with the authority to establish programs to improve health care quality, safety, and efficiency through the promotion of health information technology, including EHR. For this program, performance measures were drafted to provide data useful to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993 (Pub. L. 103–62). These measures cover the principal topic areas of interest to the Office of Rural Health Policy, including: (a) Access to care; (b) the underinsured and uninsured; (c) workforce recruitment and retention; (d) sustainability; (e) health information technology; (f) network development; and (g) health related clinical measures. Several measures will be used for this program. These measures will speak to the Office's progress toward meeting the goals set.

The Agency received no comments in response to the 60-day notice published in the **Federal Register** on February 21, 2012, vol. 77, No. 34; page 9949.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Rural Health Information Technology Network Development Program	41	1	41	3.77	154.57
Total	41	1	41	3.77	154.57

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

Dated: May 24, 2012.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2012–13125 Filed 5–30–12; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c) (2) (A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1984.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Sickle Cell Disease Treatment Demonstration Program—Quality Improvement Data Collection for the Hemoglobinopathy Learning Collaborative (OMB No. 0915–xxxx)—[New]

Background: In response to the growing need for resources devoted to sickle cell disease and other hemoglobinopathies, the United States Congress, under Section 712 of the American Jobs Creation Act of 2004 (Pub. L. 108–357), authorized a demonstration program for the prevention and treatment of sickle cell disease (SCD) to be administered through the Bureau of Primary Health Care and the Maternal and Child Health Bureau (MCHB) of the Health Resources and Services Administration (HRSA) in the U.S. Department of Health and Human Services. The program is known as the *Sickle Cell Disease Treatment Demonstration Program* (SCDTDP). The SCDTDP is designed to improve access to services for individuals with sickle cell disease, improve and expand patient and provider education, and improve and expand the continuity and coordination of service delivery for individuals with sickle cell disease and sickle cell trait.

To achieve the goals and objectives of the program, the Hemoglobinopathy Learning Collaborative (HLC) uses a process known as the Model for Improvement, a widely used approach to quality improvement (QI) in healthcare settings. The Model for Improvement utilizes a structured process that asks grantee teams to build on small tests of change in their healthcare setting, while providing monthly reporting on measurements. The proposed QI data collection and reporting system is an integral component of the HLC.

Purpose: The purpose of the proposed QI Data Collection strategy is to implement a system to monitor the progress of MCHB-funded activities in improving care and health outcomes for individuals living with sickle cell disease/trait and meeting the goals of the SCDTDP. Each grantee team will be asked to report on a core set of measures related to quality improvement for hemoglobinopathies. Through an evidence-based process, a bank of QI measures within each grantee network has been developed to assess health care utilization of the SCD population as well as several aspects of the system of care.

The QI Data Collection strategy will provide an effective and efficient mechanism to do the following: (1) Assess the services provided by grantees under the SCDTDP and monitor and drive improvement on quality measures; (2) collect, coordinate, and distribute data, best practices, and findings from network sites; (3) refine a common model protocol regarding the prevention and treatment of sickle cell disease; (4) examine/address barriers that individuals and families living with sickle cell disease face when accessing quality health care and health education; (5) evaluate the grantees' performance in meeting the objectives of the SCDTDP; and (6) provide HRSA/Congress information on the overall progress of the program.

Respondents: Grantees funded by HRSA under the SCDTDP will be the respondents for this data collection activity. Each month, SCDTDP teams will complete up to three data collection forms for 20 patients with SCD or sickle cell trait who were seen in their network that month. The Participant Profile form will collect demographic and basic health information. The Acute Care Visit and Ambulatory Care Visit forms will assess care in acute and ambulatory care settings, respectively.

All information will be collected via chart review. Data will be entered directly into a secure web-based data collection tool, called Research Electronic Data Capture (REDCap). The data entered into REDCap will be analyzed via a custom measurement generator that will calculate and export the QI measures for viewing by grantee teams and the National Coordinating Center.