

and vitamin D analogs, systemic drugs, biologic products, and phototherapy. FDA is interested in the perspectives of patients with psoriasis on (1) the impact of their skin disease, including the extent and location (e.g., nail, palm, scalp, genital) of involvement, (2) treatment approaches, and (3) decision factors taken into account when selecting a treatment.

The questions that will be asked of patients and patient stakeholders at the meeting are listed in this section, organized by topic. For each topic, a brief initial patient panel discussion will begin the dialogue. This will be followed by a facilitated discussion inviting comments from other patient and patient stakeholder participants. In addition to input generated through this public meeting, FDA is interested in receiving patient input addressing these questions through written comments, which can be submitted to the public docket (see **ADDRESSES**).

Topic 1: Disease Symptoms and Daily Impacts That Matter Most to Patients

(1) Of all the symptoms that you experience because of your condition, which one to three symptoms have the most significant impact on your life? (Examples may include red, thickened, scaling skin, itching, burning, or soreness, etc.)

(2) Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your condition? (Examples of activities may include sleeping through the night, daily hygiene, participation in sports or social activities, intimacy with a spouse or partner, etc.)

(3) How do your symptoms and their negative impacts affect your daily life on the best days? On the worst days?

(4) How have your condition and its symptoms changed over time?

(a) Would you define your condition today as being well managed?

(5) What worries you most about your condition?

Topic 2: Patients' Perspectives on Current Approaches to Treatment

(1) What are you currently doing to help treat your condition or its symptoms? (Examples may include prescription medicines, over-the-counter products, phototherapy, and other therapies including non-drug therapies such as diet modification.)

(a) How has your treatment regimen changed over time, and why?

(2) How well does your current treatment regimen control your condition?

(a) How well do your treatments address specific skin symptoms? Which symptoms are not addressed as well?

(b) How well have these treatments worked for you as your condition has changed over time?

(3) What are the most significant downsides to your current treatments, and how do they affect your daily life? (Examples of downsides may include going to the hospital or clinic for treatment, time devoted to treatment, etc.)

(4) Assuming there is no complete cure for your condition, what specific things would you look for in an ideal treatment for your condition?

(a) What would you consider to be a meaningful improvement (for example symptom improvements or functional improvements) in your condition that a treatment could provide?

(5) What factors do you take into account when making decisions about selecting a course of treatment?

(a) What information on the potential benefits of these treatments factors most into your decision?

(b) How do you weigh the potential benefits of these treatments versus the common side effects of the treatments? (Common side effects could include headache, nausea, injection site reactions.)

(c) How do you weigh potential benefits of these treatments versus the less common but serious risks associated with the treatments? (Examples of less common but serious risks are infections, cancer, liver damage, kidney damage, birth defects, blood disorders, etc.)

B. Meeting Attendance and Participation

If you wish to attend this meeting, visit <https://psoriasispfdd.eventbrite.com>. Please register by March 10, 2016. If you are unable to attend the meeting in person, you can register to view a live Webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of a disability, please contact Meghana Chalasani (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Patients who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These patients also must send to PatientFocused@fda.hhs.gov a brief summary of responses to the topic questions by February 29, 2016. Panelists will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

Docket Comments: Regardless of whether you attend the public meeting, you can submit electronic or written responses to the questions pertaining to Topics 1 and 2 to the public docket (see **ADDRESSES**) by May 17, 2016.

Transcripts: As soon as a transcript is available, FDA will post it at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm470608.htm>.

Dated: November 19, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than January 25, 2016.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 10-29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: 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 Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: HIV Quality Measures (HIVQM) Module OMB No. 0915-xxxx-New.

Abstract: The Ryan White HIV/AIDS Program (RWHAP) provides entities funded by the program with flexibility to respond effectively to the changing HIV epidemic, with an emphasis on providing life-saving and life-extending services for people living with HIV. Under the Ryan White HIV/AIDS Treatment Extension Act of 2009, RWHAP Parts A-D recipients are required to establish clinical quality management programs in order to assess their HIV services according to the most recent Department of Health and Human Services guidelines and to develop strategies to improve access to quality HIV services. The HIV Quality Measures (HIVQM) module will be the HIV/AIDS Bureau's (HAB) voluntary online reporting tool created to help facilitate recipients in meeting these requirements. Recipients and their providers will enter aggregate data in the HIVQM module on HAB performance measures and then will be able to generate reports to assess their performance and compare their results

to results at the state, regional, and national levels. The HAB performance measures include the following priority performance measure categories: (1) Core (those measures that emphasize essential aspects of care and treatment, align with the milestones along the HIV care continuum, and are most feasible for data collection); (2) all ages; (3) adolescent/adult; (4) HIV-positive children; (5) HIV-exposed children; (6) medical case management; (7) oral health; (8) AIDS Drug Assistance Program (ADAP); and (9) system level measures. The use of the HIVQM module will be voluntary for RWHAP recipients and services providers.

Need and Proposed Use of the Information: The HIVQM Module will be a voluntary online reporting tool that supports recipients in monitoring their performance in serving patients particularly in access to care and the provision of quality HIV services, and to reduce HIV-related morbidity and mortality among people living with HIV/AIDS. These data will help RWHAP recipients document their strengths, identify gaps in performance and areas for improvement, and plan how to enhance future delivery of quality care to their patients.

The HIVQM module will also assist RWHAP recipients in meeting the requirement to construct quality assurance structures in their provision of HIV care services. In addition, for recipients and service providers participating in the Centers for Medicare and Medicaid Incentive Programs, such as the Medicare and Medicaid Electronic Health Records Incentive Program and the Physician Quality Reporting System, the module will be consistent to qualify and comply with the requirements to receive incentives from these programs. Finally, the module will assist HAB in identifying recipients and service providers that are

supporting the aims of the National HIV/AIDS Strategy in establishing a system that links HIV positive individuals to continuous and coordinated quality care.

The module will be available for data entry 3 times a year. The module will be accessible via the HRSA Electronic Handbook (EHB) Ryan White Services Report (RSR) portal, an existing online tool that RWHAP recipients already use for required data collection on their services. Recipients will choose which performance measures they want to monitor and enter data accordingly. Reports of performance measures can be generated and reviewed by the recipients or their service providers and can be compared to results at the state, regional, and national levels.

Likely Respondents: Ryan White HIV/AIDS Program Part A, Part B, Part C, and Part D recipients and their service providers and the AIDS Drug Assistance Program recipients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

Total Estimated Annualized burden hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
HIVQM module	1,100	3	3,300	4	13,200
Total	1,100	3	3,300	4	13,200

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the

estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information

technology to minimize the information collection burden.

Jackie Painter,
 Director, Division of the Executive Secretariat.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than January 25, 2016.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 10C-24, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: 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 Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Rural Health Care Coordination Network Partnership Program Performance Improvement Measurement System.

OMB No. 0915-xxxx—New.

Abstract: The Rural Health Care Coordination Network Partnership (Care Coordination) Program is authorized under Section 330A(f) of the Public Health Service (PHS) Act (42 U.S.C. 254(c)(f)), as amended, to support the development of formal, mature rural health networks that focus on care coordination activities for the following chronic conditions: Diabetes, congestive heart failure (CHF), and chronic obstructive pulmonary disease (COPD). This authority permits the Federal Office of Rural Health Policy (FORHP) to support grants for eligible entities to promote, through planning and implementation, the development of integrated health care networks that have combined the functions of the entities participating in the networks in order to: (i) Achieve efficiencies; (ii) expand access to, coordinate, and improve the quality of essential health care services; and (iii) strengthen the rural health care system as a whole.

Need and Proposed Use of the Information: For this program, performance measures were drafted to provide data 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. These measures cover the principal topic areas of interest to the Federal Office of Rural Health Policy including: (a) Access to care; (b) population demographics; (c) staffing; (d) consortium/network; (e) sustainability; and (f) project specific domains. Several measures will be used for this program. All measures will speak to FORHP's progress toward meeting the goals set.

Likely Respondents: The respondents would be recipients of the Rural Health Care Coordination Network Partnership grant program funding.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Rural Health Care Coordination Network Partnership Grant Program Measures	8	1	8	3.5	28
Total	8	1	8	3.5	28

HRSA specifically requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information

technology to minimize the information collection burden.

Jackie Painter,
 Director, Division of the Executive Secretariat.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.