

and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Annual Eligibility Redetermination, Product Discontinuation and Renewal Notices; *Use:* Section 1411(f)(1)(B) of the Affordable Care Act directs the Secretary of Health and Human Services (the Secretary) to establish procedures to redetermine the eligibility of individuals on a periodic basis in appropriate circumstances. Section 1321(a) of the Affordable Care Act provides authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs and other components of title I of the Affordable Care Act. Under section 2703 of the PHS Act, as added by the Affordable Care Act, and former section 2712 and section 2741 of the PHS Act, enacted by the Health Insurance Portability and Accountability Act of 1996, health insurance issuers in the group and individual markets must guarantee the renewability of coverage unless an exception applies. The final rule “Patient Protection and Affordable Care Act; Annual Eligibility

Redeterminations for Exchange Participation and Insurance Affordability Programs; Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges” (79 FR 52994), provides that an Exchange may choose to conduct the annual redetermination process for a plan year (1) in accordance with the existing procedures described in 45 CFR 155.335; (2) in accordance with procedures described in guidance issued by the Secretary for the coverage year; or (3) using an alternative proposed by the Exchange and approved by the Secretary. The guidance document “Guidance on Annual Redeterminations and Re-enrollment for Marketplace Coverage for 2017” contains the procedures that the Secretary is specifying for the 2017 coverage year, as noted in (2) above. These procedures will be adopted by the Federally-facilitated Exchange. The final rule also amends the requirements for product renewal and re-enrollment (or non-renewal) notices to be sent by Qualified Health Plan (QHP) issuers in the Exchanges and specifies content for these notices. The accompanying guidance document “Updated Federal Standard Notices of Product Discontinuation and Renewal” provides standard notices for product discontinuation and renewal to be sent by issuers of individual market QHPs and issuers in the individual market. Issuers in the small group market may use the draft Federal standard small group notices released in the June 26, 2014 bulletin “Draft Standard Notices When Discontinuing or Renewing a Product in the Small Group or Individual Market”, or any forms of the notice otherwise permitted by applicable laws and regulations. States that are enforcing the guaranteed renewability provisions of the Affordable Care Act may develop their own standard notices for product discontinuances, renewals, or both, provided the State-developed notices are at least as protective as the Federal standard notices. *Form Number:* CMS-10527 (OMB control number 0938-1254); *Frequency:* Annually; *Affected Public:* Private Sector, State Governments; *Number of Respondents:* 2,945; *Total Annual Responses:* 12,224; *Total Annual Hours:* 149,186. (For policy questions regarding this collection contact Russell Tipps at 301-492-4371).

Dated: September 13, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Personal Responsibility Education Program (PREP) Performance Measures and Adult Preparation Subjects (PMAPS) Studies—Data Collection Related to the Performance Measures Study.

OMB No.: New Collection.

Description: The Office of Planning, Research, and Evaluation (HHS/ACF/OPRE) and the Family and Youth Services Bureau (HHS/ACF/ACYF/FYSB) in the Administration for Children and Families (ACF) propose a data collection activity as part of the Personal Responsibility Education Program (PREP) Performance Measures and Adult Preparation Subjects (PMAPS) Studies. The goals of the PMAPS studies are to collect, analyze, and report on performance measure data for PREP programs and to develop and test Adult Preparation Subjects (APS) conceptual models.

The PMAPS studies consist of two components: The “Performance Measures Study,” and the “Adult Preparation Subjects Study.” This notice is specific to data collection activities for the Performance Measures Study only. The Performance Measures Study component includes collection and analysis of performance measure data from State PREP (SPREP), Tribal PREP (TPREP), Competitive PREP (CPREP), and Personal Responsibility Education Innovative Strategies (PREIS) grantees. Data will be used to determine if PREP and PREIS grantees are meeting performance benchmarks related to the program’s mission and priorities.

Respondents: Performance measurement data collection instruments will be administered to individuals representing SPREP, TPREP, CPREP, and PREIS grantees, their subawardees, and program participants.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Entry Survey	414,747	138,249	1	0.13333	18,433
Exit Survey	331,797	110,599	1	0.25	27,650
Core measures	16,000	5,333	3	0.08	1,280
Performance Measures Data Report Form (grantees).	279	93	2	18 for S/T; 14 for CPREP and PREIS.	3,076
Performance Measures Data Report Form (sub-awardees).	1,248	416	2	14 for S/T; 12 for CPREP	11,472
Estimated Total Annual Burden Hours.	61,911

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: OPREinfocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project. Email: OIRA_SUBMISSION@OMB.EOP.GOV. Attn: Desk Officer for the Administration for Children and Families.

Naomi Goldstein,

ACF/OPRE Certifying Officer.

[FR Doc. 2016-22316 Filed 9-15-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-2843]

Qualification of Biomarker—Total Kidney Volume in Studies for Treatment of Autosomal Dominant Polycystic Kidney Disease; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a

guidance for industry entitled “Qualification of Biomarker—Total Kidney Volume in Studies for Treatment of Autosomal Dominant Polycystic Kidney Disease.” This guidance provides a qualified context of use (COU) for total kidney volume (TKV), measured at baseline, to be used as a prognostic enrichment biomarker to select patients with autosomal dominant polycystic kidney disease (ADPKD) at high risk for a “progressive decline” in renal function, defined as a confirmed 30 percent decline in the patient’s estimated glomerular filtration rate (eGFR), for inclusion in interventional clinical trials. This guidance also describes the experimental conditions and constraints for which this biomarker is qualified through the Center for Drug Evaluation and Research (CDER) Biomarker Qualification Program. This biomarker can be used by drug developers for the qualified COU in submissions of investigational new drug applications (INDs), new drug applications (NDAs), and biologics license applications (BLAs) without the relevant CDER review group reconsidering and reconfirming the suitability of the biomarker.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comment as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted,

such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2015-D-2843 for “Qualification of Biomarker—Total Kidney Volume in Studies for Treatment of Autosomal Dominant Polycystic Kidney Disease; Availability.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available submit your comments only as a written/paper