FOR FURTHER INFORMATION CONTACT: Patricio G. Garcia, Division of Management Services, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5216, Silver Spring, MD 20993–0002, 301–796–6875, email: *Patricio.Garcia@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members on TEPRSSC that include three general public representatives.

I. General Description of the Committee's Duties

The committee provides advice and consultation to the Commissioner of Food and Drugs (Commissioner) on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products, and may recommend electronic product radiation safety standards to the Commissioner for consideration.

II. Criteria for Voting Members

The committee consists of a core of 15 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of science or engineering, applicable to electronic product radiation safety. Members will be invited to serve for overlapping terms of up to 4 years. Terms of more than 2 years are contingent upon the renewal of the committee by appropriate action prior to its expiration.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address and/or home address, telephone number, and email address if available and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**). Nominations must also specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: January 10, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00733 Filed 1–16–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0578]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Form FDA 356h

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by February 18, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0338. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Form FDA 356h

OMB Control Number 0910–0338—Extension

Under section 351 of the Public Health Services Act (42 U.S.C. 262), manufacturers of biological products must submit a license application for FDA review and approval before marketing a biological product in interstate commerce. Licenses may be issued only upon showing that the establishment and the products for which a license is desired meets standards prescribed in regulations designed to ensure the continued safety, purity, and potency of such products. All such licenses are issued, suspended, and revoked as prescribed by regulations in part 601 (21 CFR part 601).

Section 130(a) of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding a new provision (section 506B of the FD&C Act (21 U.S.C. 356b)) requiring reports of postmarketing studies for approved human drugs and licensed biological products. Section 506B of the FD&C Act provides FDA with additional authority to monitor the progress of postmarketing studies that applicants have made a commitment to conduct and requires the Agency to make publicly available information that pertains to the status of these studies. Under section 506B(a) of the FD&C Act, applicants that have committed to conduct a postmarketing study for an approved human drug or licensed biological product must submit to FDA a status report of the progress of the study or the reasons for the failure of the applicant to conduct the study. This report must be submitted within 1 year after the U.S. approval of the application and then annually until the study is completed or terminated.

A summary of the collection of information requirements follows:

Section 601.2(a) (21 CFR 601.2(a)) requires a manufacturer of a biological product to submit an application on forms prescribed for such purposes with accompanying data and information, including certain labeling information, to FDA for approval to market a product in interstate commerce. The container and package labeling requirements are provided under §§ 610.60 through 610.65 (21 CFR 610.60 through 610.65). The estimate for these regulations is

included in the estimate under § 601.2(a) in table 1.

Section 601.5(a) (21 CFR 601.5(a)) requires a manufacturer to submit to FDA notice of its intention to discontinue manufacture of a product or all products. Section 601.6(a) (21 CFR 601.6(a) requires the manufacturer to notify selling agents and distributors upon suspension of its license, and provide FDA of such notification.

Section 601.12(a)(2) (21 CFR 601.12((a)(2)) requires, generally, that the holder of an approved biologics license application (BLA) must assess the effects of a manufacturing change before distributing a biological product made with the change. Section 601.12(a)(4) requires, generally, that the applicant must promptly revise all promotional labeling and advertising to make it consistent with any labeling changes implemented. Section 601.12(a)(5) requires the applicant to include a list of all changes contained in the supplement or annual report; for supplements, this list must be provided in the cover letter. The burden estimates for § 601.12(a)(2) are included in the estimates for supplements (§§ 601.12(b) and (c)) and annual reports (§ 601.12(d)). The burden estimates for § 601.12(a)(4) are included in the estimates under 601.12(f)(4) in table 1.

Sections 601.12(b)(1) and (3), (c)(1), (3), and (5), and (d)(1) and (3) require applicants to follow specific procedures to submit information to FDA of any changes, in the product, production process, quality controls, equipment, facilities, or responsible personnel established in an approved license application. The appropriate procedure depends on the potential for the change to have a substantial, moderate, or minimal adverse effect on the identity, strength, quality, purity, or potency of the products as they may relate to the safety or effectiveness of the product. Under § 601.12(b)(4), an applicant may ask FDA to expedite its review of a supplement for public health reasons or if a delay in making the change described in it would impose an extraordinary hardship of the applicant. The burden estimate for § 601.12(b)(4) is minimal and included in the estimate under § 601.12(b)(1) and (3) in table 1.

Section 601.12(e) requires applicants to submit a protocol, or change to a protocol, as a supplement requiring FDA approval before distributing the product. Section 601.12(f)(1) through (3) requires applicants to follow specific procedures to report certain labeling changes to FDA. Section 601.12(f)(4) requires applicants to report to FDA advertising and promotional labeling and any changes.

Under § 601.14 (21 CFR 601.14), the content of labeling required in 21 CFR 201.100(d)(3) must be in electronic format and in a form that FDA can process, review, and archive. This requirement is in addition to the provisions of §§ 601.2(a) and 601.12(f). The burden estimate for § 601.14 is minimal and included in the estimate under §§ 601.2(a) (BLAs) and 601.12(f)(1) through (3) (labeling supplements and annual reports) in table 1.

Section 601.45 (21 CFR 601.45) requires applicants of biological products for serious or life-threatening illnesses to submit to the Agency for consideration, during the preapproval review period, copies of all promotional materials, including promotional labeling as well as advertisements.

In addition to §§ 601.2 and 601.12, there are other regulations in 21 CFR parts 640, 660, and 680 that relate to information to be submitted in a license application or supplement for certain blood or allergenic products as follows: §§ 640.6, 640.17, 640.21(c), 640.22(c), 640.25(c), 640.56(c), 640.64(c), 640.74(a) and (b)(2), 660.51(a)(4), and 680.1(b)(2)(iii) and (d) (21 CFR 640.6, 640.17, 640.21(c), 640.22(c), 640.25(c), 640.56(c), 640.64(c), 640.74(a) and (b)(2), 660.51(a)(4), and 680.1(b)(2)(iii) and (d)).

In table 1, the burden associated with the information collection requirements in the applicable regulations is included in the burden estimate for §§ 601.2 and/or 601.12. A regulation may be listed under more than one paragraph of § 601.12 due to the type of category under which a change to an approved application may be submitted.

There are also additional container and/or package labeling requirements for certain licensed biological products including: § 640.74(b)(3) and (4) for Source Plasma Liquid; § 640.84(a) and (c) (21 CFR 640.84(a) and (c)) for Albumin; § 640.94(a) (21 CFR 640.94(a)) for Plasma Protein Fraction; § 660.2(c) (21 CFR 660.2(c)) for Antibody to Hepatitis B Surface Antigen; § 660.28(a) through (c) (21 CFR 660.28(a) through (c)) for Blood Grouping Reagent; § 660.35(a) through (d) (21 CFR 660.35(a) through (d)) for Reagent Red Blood Cells; § 660.45 (21 CFR 660.45) for Hepatitis B Surface Antigen; and § 660.55(a) and (b) (21 CFR 660.55(a) and (b)) for Anti-Human Globulin. The burden associated with the additional labeling requirements for submission of a license application for these certain biological products is minimal because the majority of the burden is associated with the requirements under §§ 610.60 through 610.65 or § 809.10 (21 CFR 809.10). Therefore, the burden estimates for these regulations are included in the estimate under §§ 610.60 through 610.65 in table 1. The burden estimates associated with § 809.10 are approved under OMB control number 0910–0485.

Section 601.27(a) (21 CFR 601.27(a)) requires that applications for new biological products contain data that are adequate to assess the safety and effectiveness of the biological product for the claimed indications in pediatric subpopulations, and to support dosing and administration information. Section 601.27(b) provides that an applicant may request a deferred submission of some or all assessments of safety and effectiveness required under § 601.27(a) until after licensing the product for use in adults. Section 601.27(c) provides that an applicant may request a full or partial waiver of the requirements under § 601.27(a) with adequate justification. The burden estimates for § 601.27(a) are included in the burden estimate under § 601.2(a) in table 1 because these regulations deal with information to be provided in an application.

Section 601.28 (21 CFR 601.28) requires sponsors of licensed biological products to submit the information in § 601.28(a) through (c) to the Center for Biologics Evaluation and Research (CBER) or to the Center for Drug Evaluation and Research (CDER) each year, within 60 days of the anniversary date of approval of the license. Section 601.28(a) requires sponsors to submit to FDA a brief summary stating whether labeling supplements for pediatric use have been submitted and whether new studies in the pediatric population to support appropriate labeling for the pediatric population have been initiated. Section 601.28(b) requires sponsors to submit to FDA an analysis of available safety and efficacy data in the pediatric population and changes proposed in the labeling based on this information. Section 601.28(c) requires sponsors to submit to FDA a statement on the current status of any postmarketing studies in the pediatric population performed by, on or behalf of, the applicant. If the postmarketing studies were required or agreed to, the status of these studies is to be reported under § 601.70 (21 CFR 601.70) rather than under this section.

Sections 601.33 through 601.35 (21 CFR 601.33 through 601.35) clarify the information to be submitted in an application to FDA to evaluate the safety and effectiveness of radiopharmaceuticals intended for in vivo administration for diagnostic and monitoring use. The burden estimates for §§ 601.33 through 601.35 are included in the burden estimate under

§ 601.2(a) in table 1 because these regulations deal with information to be provided in an application.

Section 601.70(b) requires each applicant of a licensed biological product to submit annually a report to FDA on the status of postmarketing studies for each approved product application. Each annual postmarketing status report must be accompanied by a completed transmittal Form FDA 2252 (Form FDA 2252 approved under OMB control number 0910–0001). Under § 601.70(d), two copies of the annual report shall be submitted to FDA.

Sections 601.91 through 601.94 (21 CFR 601.91 through 601.94) concern biological products for which human efficacy studies are not ethical or feasible. Section 601.91(b)(2) requires, in certain circumstances, such postmarking restrictions as are needed to ensure the safe use of the biological product. Section 601.91(b)(3) requires applicants to prepare and provide labeling with relevant information to patients or potential patients for biological products approved under part 601, subpart H, when human efficacy studies are not ethical or feasible (or based on evidence of effectiveness from studies in animals). Section 601.93 provides that biological products approved under part 601, subpart H are subject to the postmarketing recordkeeping and safety reporting applicable to all approved biological products. Section 601.94 requires applicants under part 601, subpart H to submit to the Agency for consideration during the preapproval review period copies of all promotional materials including promotional labeling as well as advertisements. Under §§ 601.91(b)(2) and 601.93, any potential postmarketing reports and/or recordkeeping burdens would be included under the adverse experience reporting (AER) requirements under 21 CFR part 600 (OMB control number 0910–0308). Therefore, any burdens associated with these requirements would be reported under the AER information collection requirements (OMB control number 0910–0308). The burden estimate for § 601.91(b)(3) is included in the estimate under §§ 610.60 through 610.65.

Section 610.9(a) (21 CFR 610.9(a)) requires the applicant to present certain information, in the form of a license application or supplement to the application, for a modification of any particular test method or manufacturing process or the conditions under which it is conducted under the biologics regulations. The burden estimate for § 610.9(a) is included in the estimate under §§ 601.2(a) and 601.12(b) and (c) in table 1.

Under § 610.15(d) (21 CFR 610.15(d)), the Director of CBER or the Director of CDER may approve, as appropriate, a manufacturer's request for exceptions or alternatives to the regulation for constituent materials. Manufacturers seeking approval of an exception or alternative must submit a request in writing with a brief statement describing the basis for the request and the supporting data.

Section 640.120 (21 CFR 640.120) requires licensed establishments to submit a request for an exception or alternative to any requirement in the biologics regulations regarding blood, blood components, or blood products. For licensed establishments, a request for an exception or alternative must be submitted in accordance with § 601.12; therefore, the burden estimate for § 640.120 is included in the estimate under § 601.12(b) in table 1.

Section 680.1(c) requires manufacturers to update annually their license file with the list of source materials and the suppliers of the materials. Section 680.1(b)(3)(iv) requires manufacturers to notify FDA when certain diseases are detected in source materials.

Sections 600.15(b) and 610.53(b) (21 CFR 600.15(b) and 610.53(b)) require the submission of a request for an exemption or modification regarding the temperature requirements during shipment and from dating periods, respectively, for certain biological products. Section 606.110(b) (21 CFR 606.110(b)) requires the submission of a request for approval to perform plasmapheresis of donors who do not meet certain donor requirements for the collection of plasma containing rare antibodies. Under §§ 600.15(b), 610.53(b), and 606.110(b), a request for an exemption or modification to the requirements would be submitted as a supplement. Therefore, the burden hours for any submissions under §§ 600.15(b), 610.53(d), and 606.110(b) are included in the estimates under § 601.12(b) in table 1.

Form FDA 356h, ''Application to Market a New or Abbreviated New Drug or Biologic for Human Use,'' is used for the applicable submissions to both CBER and CDER. The application form serves primarily as a checklist for firms to gather and submit certain information to FDA and helps to ensure that the application is complete and contains all the necessary information, so that delays due to lack of information may be eliminated. In addition, the form provides key information to FDA for efficient handling and distribution to the appropriate staff for review. FDA estimates an average of 24 hours to complete the application form, which is included in the average burden per response. The estimated burden hours for nonbiological product submissions to CDER using Form FDA 356h are approved under OMB control number 0910–0001 (an estimated 16,650 submissions × 24 hours = 399,600 hours).

For advertisements and promotional labeling (*e.g.,* circulars, package labels, container labels, etc.) and labeling changes, manufacturers of licensed biological products may submit to CBER or CDER Form FDA 2253. Form FDA 2253 can also be submitted electronically. Form FDA 2253 is approved under OMB control number 0910–0001.

Respondents to this collection of information are manufacturers of biological products. Under table 1, the numbers of respondents are based on the estimated annual number of manufacturers that submitted the required information to FDA or the number of submissions FDA received in fiscal year 2018. Based on information obtained from FDA's database systems, there are an estimated 424 licensed biologics manufacturers. The total annual responses are based on the estimated number of submissions (*i.e.,* license applications, labeling and other supplements, protocols, advertising and promotional labeling, notifications) for a particular product received annually by FDA. The hours per response are based on information provided by industry and past FDA experience with the various submissions or notifications. The hours per response include the time estimated to prepare the various submissions or notifications to FDA, and, as applicable, the time required to fill out the appropriate form and collate the documentation. Additional information regarding these estimates is provided below as necessary.

Under §§ 601.2 and 601.12, the estimated hours per response are based on the average number of hours to submit the various submissions. The estimated average number of hours is based on the range of hours to complete a very basic application or supplement and a complex application or supplement.

Under section 601.6(a), the total annual responses are based on FDA estimates that establishments may notify an average of 20 selling agents and distributors of such suspension, and provide FDA of such notification. The number of respondents is based on the estimated annual number of suspensions of a biologic license. In

table 1, FDA is estimating one in case a suspension occurs.

Under §§ 601.12(f)(4) and 601.45, manufacturers of biological products may use Form FDA 2253 to submit advertising and promotional labeling (which can include multiple pieces). Based on information obtained from FDA's database system, the estimate is based on the number of submissions received using Form FDA 2253 for advertising and promotional labeling.

Under §§ 601.28 and 601.70(b), FDA estimates that it takes an applicant approximately 24 hours (8 hours per study × 3 studies) annually to gather, complete, and submit the appropriate information for each postmarketing status report (approximately 2 to 4 studies per report) and the accompanied transmittal Form FDA 2252. Included in these 24 hours is the time necessary to prepare and submit two copies of the annual progress report of postmarketing studies to FDA under § 601.70(d).

Under § 610.15(d), FDA has received no submissions since the implementation of the final rule (''Revision of the Requirements for Constituent Materials'') in April 2011 (76 FR 20513, April 13, 2011). Therefore, FDA is estimating one respondent and one annual request to account for a possible submission to CBER or CDER of a request for an exception or alternative for constituent materials under § 610.15(d).

There were a total of 3,398 amendments to an unapproved application or supplement and resubmissions submitted using Form FDA 356h.

In the **Federal Register** of September 19, 2019 (84 FR 49310), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [10]
601.2(a),[2] 610.60 through 610.65 [3]	356h	36	1.28	46	860	39,560
601.5(a)	NA	8	1.13	9	0.33 (20 minutes)	3
601.6(a)	NA	1	1	1	0.33 (20 minutes)	1
601.12(a)(5)	NA	430	4.158	1,788	1	1,788
601.12(b)(1) and (3) and (e) [4]	[2] 356h	166	4.843	804	80	64,320
601.12(c)(1) and (3) [5]	[2] 356h	149	4.58	682	50	34,100
601.12(c)(5)	[2] 356h	7	1.14	8	50	400
601.12(d)(1) and (3) [6] and (f)(3) [8]	[2] 356h	245	3.575	876	24	21,024
601.12(f)(1) [7]	2253	65	3.169	206	40	8,240
601.12(f)(2) [7]	2253	43	2.05	88	20	1,760
601.12(f)(4)/601.45 [9]	2253	134	145.86	19,545	10	195,450
601.27(b)	NA	12	1.08	13	24	312
601.27(c)	NA	2	1	2	8	16
601.70(b) and (d)/601.28	2252	65	3.169	206	24	4,944
610.15(d)	NA	1	1	1	1	1
680.1(c)	NA	9	1	9	2	18
680.1(b)(3)(iv)	NA	1	1	1	2	2
Amendments/Resubmissions	356h	136	24.985	3,398	20	67,960
Total						439,899

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The reporting requirements under §§ 601.14, 601.27(a), 601.33, 601.34, 601.35, 610.9(a), 640.17, 640.25(c), 640.56(c), 640.74(b)(2), 660.51(a)(4), and 680.1(b)(2)(iii) are included in the estimate under § 601.2(a).
[3] The reporting requirements under §§ 601.93(b)(3), 640.74(b)(3) and (4), 640.84(a) and (c), 640.94(a), 660.2(c), 660.28(a) through (c), 660.35(a) through (d), 660.45, and 660.55(a) and (b) are included under §§ 610.60 through 610.65.
[4] The reporting requirements under §§ 601.12(a)(2) and (b)(4), 600.15(b), 610.9(a), 610.53(b), 606.110(b), 640.6, 640.17, 640.21(c), 640.22(c), 640.25(c), 640.56(c), 640.64(c), 640.74(a) and (b)(2), 640.120, and 680.1(d) are included in the estimate under § 601.12(b).
[5] The reporting requirements under §§ 601.12(a)(2), 610.9(a), 640.17, 640.25(c), 640.56(c), and 640.74(b)(2) are included in the estimate under § 601.12(c).
[6] The reporting requirement under § 601.12(a)(2) is included in the estimate under § 601.12(d).
[7] The reporting requirement under § 601.14 is included in the estimate under § 601.12(f)(1) and (2).
[8] The reporting requirement under §§ 601.12(a)(4) and 601.14 is included in the estimate under § 601.12(f)(3).
[9] The reporting requirement under § 601.94 is included in the estimate under § 601.45.
[10] The numbers in this column have been rounded to the nearest whole number.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]
601.6(a)	1	20	20	0.33 (20 minutes)	7

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The number in this column has been rounded to the nearest whole number.

Our estimated burden for the information collection reflects an overall increase of 105,948 hours and a corresponding decrease of 2,671 responses. We attribute this adjustment in the total hours to an increase in the number of submissions we have received under §§ 601.12(b)(1) and (3), (e), and (f)(4), and 601.45 over the last

few years. We attribute the decrease in total annual responses to a decrease in responses received under §§ 601.12(a)(5) and 601.27(b) over the last few years.

Dated: January 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00729 Filed 1–16–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Maternal, Infant, and Early Childhood Home Visiting Program Home Visiting Budget Assistance Tool, OMB No. 0906–0025—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this Notice has closed.

DATES: Comments on this ICR should be received no later than February 18, 2020.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

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

Information Collection Request Title: Maternal, Infant, and Early Childhood Home Visiting Program Home Visiting Budget Assistance Tool, OMB No. 0906–0025—Revision.

Abstract: HRSA is requesting continued approval of the Home Visiting Budget Assistance Tool (HV–BAT), as modified by HRSA in response to further testing and public comments, as further described below. The tool collects information on standardized cost metrics from programs that deliver home visiting services, as outlined in the HV–BAT. During Fiscal Year (FY) 2020, prior to required use of the tool by awardees starting in FY 2021, HRSA intends to conduct a follow-up study to test the feasibility of the HV–BAT for universal implementation across Maternal, Infant, and Early Childhood Home Visiting (MIECHV) programs and the tool's capacity to support program planning, budget forecasting, fiscal sub-recipient monitoring and to estimate national program costs. In addition, HRSA will investigate the necessary resources and support for successful execution of the HV–BAT prior to initiating the reporting requirement. Upon successful completion of the FY 2020 feasibility study, beginning in FY 2021, HRSA will require reporting of HV–BAT data for one-third of awardees in each 3-year cycle, resulting in collection of data from all awardees over a 3-year time period, to inform program planning and budgeting.

The MIECHV Program, authorized by section 511 of the Social Security Act, 42 U.S.C. 711, and administered by HRSA in partnership with the Administration for Children and Families, supports voluntary, evidence-based home visiting services during pregnancy and to parents with young children up to kindergarten entry. States, Tribal entities, and certain nonprofit organizations are eligible to receive funding from the MIECHV Program and have the flexibility to tailor the program to serve the specific needs of their communities. Funding recipients may subaward grant funds to local implementing agencies (LIAs) in order to provide services to eligible families in at-risk communities.

HRSA is revising its originally described HV–BAT data collection purpose. Original clearance under this OMB control number was for pilot testing the reliability of a standardized cost-reporting tool among evidence-based home visiting programs. HRSA has revised the data collection tool to reflect findings and recommendations from the pilot study and in response to public comments to ensure clarity, usability and fidelity, including changes to instructions, definitions and estimated burden.

A 60-day notice was published in the **Federal Register** on August 1, 2019, vol. 84, No. 148, pp. 37655–56. There were eight public comments.

HRSA announced a 60-day public comment period to solicit input on its HV–BAT data collection efforts. In response to this notice, HRSA received feedback on the following aspects:

- Utilization of Data Collection
- Documentation and Reporting Requirements
- Accuracy of the Estimated Burden
- Implementation

HRSA carefully reviewed the comments received and used them to guide the development of the a follow-up HV–BAT feasibility study to be conducted in FY 2020 that will further inform the FY 2021 HV–BAT reporting requirements.

Responses to Comments on the Proposed MIECHV HV–BAT

HRSA received eight responses to the request for public comment. Four commenters are current MIECHV awardees, two are home visiting model developers, one is a national association, and one is an individual respondent. Comments are summarized below.

Utilization of Data Collection

Summary of Comments

Commenters expressed concern over the utility of the HV–BAT as a budget planning tool and its ability to account for variables that differ across models, program populations, providers and settings which could impact cost comparisons. In addition, respondents requested more information on the intended long-term use of the HV–BAT data.

Response

HRSA intends the HV–BAT to inform future budget planning, monitoring, and review of the costs of implementing home visiting at the LIA level in a state and support other programmatic priorities such as cost-benefit analysis and reimbursement policies. The tool in its current state provides information to permit calculation of certain cost metrics, such as cost per family, which can be used to assist in program planning and budget forecasting. Further, the HV–BAT feasibility study will examine the use of the HV–BAT to conduct cost benefit calculations. The feasibility study will also examine how the HV–BAT accounts for other types of cost variation, such as cost of living and inflation. Information collected in the feasibility study will be used to establish standards for implementation.