

++ Determine the adequacy of ACHC's staff and other resources.  
 ++ Confirm ACHC's ability to provide adequate funding for performing required surveys.

++ Confirm ACHC's policies with respect to surveys being unannounced.  
 ++ Confirm ACHC's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ Obtain ACHC's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the September 28, 2020 proposed notice also solicited public comments regarding whether ACHC's requirements met or exceeded the Medicare CoPs for HHAs. No comments were received in response to our proposed notice.

#### IV. Provisions of the Final Notice

##### *A. Differences Between ACHC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements*

We compared ACHC's HHA accreditation requirements and survey process with the Medicare CoPs of parts 409 and 484, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of ACHC's HHA application, which were conducted as described in section III. of this final notice, yielded the following areas where, as of the date of this notice, ACHC has completed revising its standards and certification processes in order to meet the following requirements:

- Section 484.102(b) to include the requirement to review and update emergency preparedness policies and procedures at least every 2 years.
- Section 484.105(b)(1)(i) to ensure that the administrator is appointed by and reports to the governing body.
- Section 488.26(b) to ensure surveyor documentation relating to non-compliance with particular Medicare conditions reflects the manner and degree of non-compliance, cited at the appropriate level (that is, condition versus standard level).
- Section 488.5(a)(4)(vii) to describe ACHC's procedures and timelines for monitoring provider's or supplier's correction of identified non-compliance with relevant standards, including the criteria ACHC uses to determine when a desk review versus an on-site review

would be acceptable for monitoring the correction of non-compliance.

#### *B. Term of Approval*

Based on our review and observations described in section III. of this final notice, we approve ACHC as a national accreditation organization for HHAs that request participation in the Medicare program, effective February 24, 2021 through February 24, 2025.

#### V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Acting Administrator of the Centers for Medicare & Medicaid Services (CMS), Elizabeth Richter, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: February 24, 2021.

**Lynette Wilson,**

*Federal Register Liaison, Centers for Medicare & Medicaid Services.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Administration for Children and Families

##### Submission for OMB Review; Comment Request; Healthy Marriage and Responsible Fatherhood Performance Measures and Additional Data Collection (New Collection)

**AGENCY:** Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

**ACTION:** Request for public comment.

**SUMMARY:** The Administration for Children and Families (ACF), Office of Family Assistance (OFA) has had administrative responsibility for federal funding of programs that strengthen families through healthy marriage and relationship education and responsible fatherhood programming since 2006, through the Healthy Marriage (HM) and Responsible Fatherhood (RF) Grant Programs. ACF required the 2015 cohort of HMRF grantees—which received 5-

year grants in September 2015—to collect and report performance measures about program operations, services, and clients served (OMB #0970-0460). A performance measures data collection system called nFORM (Information, Family Outcomes, Reporting, and Management) was implemented with the 2015 cohort to improve the efficiency of data collection and reporting and the quality of data. This system allows for streamlined and standardized submission of grantee performance data through regular progress reports and supports grantee-led and federal research projects. ACF will continue performance measure and other data collection activities for the HMRF grant program with a new cohort of grantees who received 5-year awards in September 2020. ACF is requesting comment on a new data collection to support these activities with the 2020 HMRF grantee cohort. ACF has made changes to the previous cohort's data collection instruments and performance reports for use in the new cohort. This new grantee cohort is expected to begin collecting performance measure data and reporting to ACF in April 2021.

**DATES:** *Comments due within 30 days of publication.* OMB must make a decision about 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.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

#### **SUPPLEMENTARY INFORMATION:**

*Description:* ACF proposes to collect a set of performance measures from all HMRF grantees. These measures collect standardized information in the following areas:

- Applicant characteristics;
- Program operations;
- Service delivery; and
- Participant outcomes:
  - Entrance survey, with five versions: (1) HM Program Entrance Survey for Adult-Focused Programs; (2) HM Program Entrance Survey for Youth-Focused Programs; (3) RF Program Entrance Survey for Community-Based Fathers; (4) RF Program Entrance Survey for Community-Based Mothers; and (5)

RF Program Entrance Survey for Reentering Fathers.

○ Exit survey, with five versions: (1) HM Program Exit Survey for Adult-Focused Programs; (2) HM Program Exit Survey for Youth-Focused Programs; (3) RF Program Exit Survey for Community-Based Fathers; (4) RF Program Exit Survey for Community-Based Mothers; and (5) RF Program Exit Survey for Reentering Fathers.

The measures used by the 2015 grantee cohort were developed in 2014 after extensive review of the research literature and grantees' past measures. The performance measures, data collection instruments, and data collection system were revised in 2020

based on a targeted analysis of existing measures, feedback from key stakeholders, and discussions with ACF staff and the 2015 cohort of grantees. ACF required the 2015 cohort of grantees to submit data on these standardized measures on a quarterly basis and proposes the same requirement for the 2020 cohort. In addition to the performance measures mentioned above, ACF proposes to repeat collection for these data submissions:

- Semi-annual Performance Progress Report (PPR), with two versions: (1) Performance Progress Report for HM Programs, and (2) Performance Progress Report for RF Programs; and

- Quarterly Performance Report (QPR), with two versions: (1) Quarterly Performance Progress Report for HM Programs, and (2) Quarterly Performance Progress Report for RF Programs.

Grantees in the new cohort will also be required to engage in continuous quality improvement (CQI) planning and implementation using a proposed CQI plan template developed by ACF. The estimated burden for completing and updating this template is included in the table below.

*Respondents:* Respondents include HM and RF grantee staff and program applicants and participants (participants are called "clients").

#### ANNUAL BURDEN ESTIMATES

Instrument	Respondent	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
1: Applicant Characteristics .....	Program applicants .....	273,840	1	0.25	68,460.0	22,820.0
	Program staff .....	408	672	0.10	27,417.6	9,139.2
2: Program Operations .....	Program staff .....	136	12	0.32	522.24	174.08
3: Service Delivery Data .....	Program staff .....	2,040	126	0.50	128,520.0	42,840.0
4: Entrance and Exit Surveys .....	Program clients (entrance) .....	257,409	1	0.42	108,111.78	36,037.26
	Program clients (exit) .....	169,965	1	0.42	71,385.3	23,795.1
	Program staff (entrance and exit on paper) .....	32	3,506	0.10	11,219.2	3,739.73
5: Semi-annual Performance Progress Report (PPR) .....	Program staff .....	136	6	3	2,448.0	816.0
6: Quarterly Performance Report (QPR) .....	Program staff .....	136	6	1	816.0	272.0
7: CQI Plan .....	Program staff .....	136	3	4	1,632	544.0

*Estimated Total Annual Burden Hours:* 140,177.37.

**Authority:** Sec. 403. [42 U.S.C. 603].

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing to achieve expeditious commercialization of results of federally-funded research and development.

**FOR FURTHER INFORMATION CONTACT:** Licensing information and copies of

patent applications may be obtained by emailing Brian W. Bailey, Ph.D., [bbailey@mail.nih.gov](mailto:bbailey@mail.nih.gov), the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive, Room 4A29, MSC2479, Bethesda, MD 20892-2479; telephone: 301-402-5579. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

#### SUPPLEMENTARY INFORMATION:

Technology description follows.

#### Use of Statins To Treat or Prevent Drug-Induced Hearing Loss

##### Description of Technology

Available for licensing and commercial development are patent rights covering methods of using atorvastatin and related statin compounds and derivatives to reduce or prevent drug-induced hearing loss that is caused as a side effect by ototoxic drugs such as cisplatin, which is commonly used in cancer therapies. At present, permanent hearing loss occurs in approximately half of all patients

treated with cisplatin; consequently, every year many thousands of individuals experience partial loss of hearing and associated quality of life issues as a result of medically necessary chemoradiation therapies to treat their cancers. This technology addresses a large unmet need to eliminate or reduce hearing loss in patients that must undergo therapies involving ototoxic drugs.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

#### Potential Commercial Applications

- Repurposing existing statins, including atorvastatin, to treat or protect against permanent hearing loss arising from chemoradiation therapy involving ototoxic drugs.

- Development of statin analogues or derivatives with enhanced abilities to treat or protect against hearing loss resulting from therapies involving cisplatin or other ototoxic drugs.