

Hearings Division, Enforcement Bureau, Federal Communications Commission, 445 12th Street SW, Washington, DC 20554.

12. *It is further ordered* that Entertainment Media Trust, Dennis J. Watkins, Trustee, pursuant to section 311(a)(2) of the Act, 47 U.S.C. 311(a)(2), and section 73.3594 of the Commission's rules, 47 CFR 73.3594, shall give notice of the hearing within the time and in the manner prescribed in such Rules, and shall advise the Commission of the publication of such notice as required by section 73.3594(g) of the Commission's rules, 47 CFR 73.3594(g).

13. *It is further ordered* that copies of the Hearing Designation Order and Notice of Opportunity for Hearing shall be sent via Certified Mail, Return Receipt Requested, and by regular first class mail to the following: Entertainment Media Trust, Dennis J. Watkins, Trustee, 6500 West Main Street, Suite 315, Belleville, IL 62223; Anthony Lepore, Esq., P.O. Box 823662, South Florida, FL 33082-3662; Davina S. Sashkin, Esq., Fletcher, Heald & Hildreth, 1300 North 17th Street, 11th Floor, Arlington, VA 22209; Mark A. Kern, 111 South High Street, Belleville, IL 62220; Richard A. Helmick, Esq., and Howard M. Liberman, Esq., 1800 M Street NW, Suite 800N, Washington, DC 20036.

14. *It is further ordered* that a copy of this document, or a summary thereof, shall be published in the **Federal Register**.

Federal Communications Commission.

**Thomas Horan,**

*Chief of Staff, Media Bureau.*

[FR Doc. 2019-12479 Filed 6-12-19; 8:45 am]

**BILLING CODE 6712-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10434]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the

PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by August 12, 2019.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number \_\_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

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

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:**

## Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

### CMS 10434 Medicaid and CHIP Program (MACPro)

Under the 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 requires federal agencies to publish a 60-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.

### Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid and CHIP Program (MACPro); *Use:* The MACPro system is being transitioned to become the system of record that will be used by both state and CMS officials to: Improve the state application and federal review processes, improve federal program management of Medicaid programs and CHIP, and standardize Medicaid program data. Specifically, it will be used by state agencies to: Submit and amend Medicaid state plans, CHIP state plans and ADPs (Information System Advanced Planning Documents); submit applications and amendments for state waivers, demonstrations, and benchmark and grant programs; and submit reporting data. Among the collections submitted for approval under MACPro will be relevant collections that are currently approved under our generic umbrella information collection request (CMS-10398; OMB control number 0938-1148), certain collections approved as a regular stand-alone information collections, and upcoming collections. A list of those collections is included in our PRA package. *Form Number:* CMS-10434

(OMB control number: 0938–1188); *Frequency*: Monthly, yearly, quarterly, semi-annually, once, or occasionally; *Affected Public*: State, Local, or Tribal Governments; *Number of Respondents*: 56; *Total Annual Responses*: 3,360; *Total Annual Hours*: 96,844. (For policy questions regarding this collection contact Annette Pearson at 410–786–6858).

Dated: June 10, 2019.

**William N. Parham, III,**

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

[FR Doc. 2019–12489 Filed 6–12–19; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2019–D–2105]

#### Mouse Embryo Assay for Assisted Reproduction Technology Devices; Draft Guidance for Industry and Food and Drug Administration Staff; 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 the draft guidance entitled “Mouse Embryo Assay for Assisted Reproduction Technology Devices.” This draft guidance document provides recommendations on conducting the Mouse Embryo Assay (MEA) to support premarket submissions and lot release of assisted reproduction technology devices. This draft guidance is not final nor is it in effect at this time.

**DATES:** Submit either electronic or written comments on the draft guidance by August 12, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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–2019–D–2105 for “Mouse Embryo Assay for Assisted Reproduction Technology Devices.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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 submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and

contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the

**SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled “Mouse Embryo Assay for Assisted Reproduction Technology Devices” to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

#### FOR FURTHER INFORMATION CONTACT:

Yun-shang Piao, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G119, Silver Spring, MD 20993–0002, 301–796–5592.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Assisted Reproduction Technology (ART) devices can directly or indirectly contact gametes and/or embryos during use. ART devices are typically assessed for their embryotoxic potential using the MEA to determine whether they negatively affect gametes and/or embryos. Several classification regulations under 21 CFR part 884 include special controls that require MEA testing or information. MEA may also be used by sponsors to support