

**DATES:** Only written comments and/or complete applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before March 5, 2021 will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: David A Lambertson, Ph.D., Senior Technology Transfer Manager, at Telephone (240)-276-5530 or Email: david.lambertson@nih.gov.

**SUPPLEMENTARY INFORMATION:**

**Intellectual Property**

The following represents the intellectual property to be licensed under the prospective agreement:

(A) U.S. Provisional Patent Application 62/006,313 entitled "Chimeric Antigen Receptors Targeting CD-19" [HHS Ref. E-042-2014-0-US-01], PCT Patent Application PCT/US2015/033473 entitled "Chimeric Antigen Receptors Targeting CD-19" [HHS Ref. E-042-2014-0-PCT-02], Australian Patent 2015270912 entitled "Chimeric Antigen Receptors Targeting CD-19" [HHS Ref. E-042-2014-0-AU-03], Canadian Patent Application 2951045 entitled "Chimeric Antigen Receptors Targeting CD-19" [HHS Ref. E-042-2014-0-CA-04], Chinese Patent Application 201580033802.5 entitled "Chimeric Antigen Receptors Targeting CD-19" [HHS Ref. E-042-2014-0-CN-05], European Patent 3149044 entitled "Chimeric Antigen Receptors Targeting CD-19" [HHS Ref. E-042-2014-0-EP-06] (validated in Germany [HHS Ref. E-042-2014-0-DE-19], Spain [HHS Ref. E-042-2014-0-ES-20], France [HHS Ref. E-042-2014-0-FR-21], the United Kingdom [HHS Ref. E-042-2014-0-GB-22], Italy [HHS Ref. E-042-2014-0-IT-23], and Ireland [HHS Ref. E-042-2014-0-IE-24], and lodged in Hong Kong [E-042-2014-0-HK-16]), Israeli Patent Application 249305 entitled "Chimeric Antigen Receptors Targeting CD-19" [HHS Ref. E-042-2014-0-IL-07], Indian Patent Application 291647041047 entitled "Chimeric Antigen Receptors Targeting CD-19" [HHS Ref. E-042-2014-0-IN-08], Japanese Patent Application 2016-571017 entitled "Chimeric Antigen Receptors Targeting CD-19" [HHS Ref. E-042-2014-0-JP-09], South Korean Patent Application 2016-7036828 entitled "Chimeric Antigen Receptors Targeting CD-19" [HHS Ref. E-042-2014-0-KR-10], Mexican Patent Application MX/a/2016/015834 entitled "Chimeric Antigen Receptors Targeting CD-19" [HHS Ref. E-042-2014-0-MX-11], New

Zealand Patent Application 727167 entitled "Chimeric Antigen Receptors Targeting CD-19" [HHS Ref. E-042-2014-0-NZ-12], Saudi Arabian Patent Application 516380406 entitled "Chimeric Antigen Receptors Targeting CD-19" [HHS Ref. E-042-2014-0-SA-13], Singaporean Patent Application 11201609960Q entitled "Chimeric Antigen Receptors Targeting CD-19" [HHS Ref. E-042-2014-0-SG-14], United States Patent 10,287,350 entitled "Chimeric Antigen Receptors Targeting CD-19" [HHS Ref. E-042-2014-0-US-15], United States Patent Application 16/360,281 entitled "Chimeric Antigen Receptors Targeting CD-19" [HHS Ref. E-042-2014-0-US-17], New Zealand Patent Application 764530 entitled "Chimeric Antigen Receptors Targeting CD-19" [HHS Ref. E-042-2014-0-NZ-18], European Patent Application 20197459.9 entitled "Chimeric Antigen Receptors Targeting CD-19" [HHS Ref. E-042-2014-0-EP-25], Australian Patent Application 2020267211 entitled "Chimeric Antigen Receptors Targeting CD-19" [HHS Ref. E-042-2014-0-AU-26], and Japanese Patent Application XXX entitled "Chimeric Antigen Receptors Targeting CD-19" [HHS Ref. E-042-2014-0-JP-27], and all continuing U.S. and foreign patents/patent applications for the technology family.

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the following:

"The development, production and commercialization of an anti-CD19 targeting chimeric antigen receptor (CAR)-based immunotherapy using autologous (meaning one individual is both the donor and the recipient) T lymphocytes transfected using a lentivirus, wherein the vector expresses a CAR having at least:

- (1) The complementary determining region (CDR) sequences of the anti-CD19 antibody known as Hu19;
- (2) a CD8a hinge and transmembrane domain;
- (3) and a CD28z T cell signaling domain; for the treatment of autoimmune diseases."

This technology discloses the development of chimeric antigen receptors that recognize the CD19 cell surface protein. CD19 is expressed on the cell surface of several autoimmune disease cells, including lupus nephritis. For many autoimmune diseases there are no FDA-approved therapies, underscoring that there is an unmet need. The development of an autoimmune disease therapeutic

targeting CD19 will benefit public health by providing a treatment for patients who may not have any options.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a completed license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: February, 4, 2021.

**Richard U. Rodriguez,**

*Associate Director, Technology Transfer Center, National Cancer Institute.*

[FR Doc. 2021-03222 Filed 2-17-21; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Legal Services for Unaccompanied Alien Children (New Collection)**

**AGENCY:** Office of Refugee Resettlement, Administration for Children and Families, Department of Health and Human Services.

**ACTION:** Request for Public Comment.

**SUMMARY:** The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is inviting public comment on the proposed collection. The request consists of several forms that allow the Unaccompanied Alien Children (UAC) Program to provide legal services to UAC.

**DATES:** *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of

the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described in this notice.

**ADDRESSES:** Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *infocollection@acf.hhs.gov*. Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation (OPRE), 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

**Description**

The components of this information request include:

1. Legal Service Provider List for UAC in ORR Care (Form LRG-5/5s): This instrument is provided to UAC by their case manager. The instrument contains a list of legal services providers available to UAC. UAC initial and sign the instrument upon admission and release of ORR custody to acknowledge receipt of documents contained in ORR's Legal Resource Guide. This form was previously approved under OMB Number 0970-0498 and is being reinstated without changes under this new OMB number.
2. Request for a *Flores* Bond Hearing (Form LRG-7/7s): This instrument is provided to UAC placed by their case manager. The instrument is always provided to UAC placed in a restrictive setting (secure, staff secure, and residential treatment center facilities) and to UAC placed in other types of facilities upon request. UAC may use this instrument to request or withdraw a request for a *Flores* bond hearing.

3. Motion to Request a Bond Hearing—Secure or Staff Secure Custody (Form LRG-8A): This instrument is completed by case managers upon receipt of a *Request for a Flores Bond Hearing* for a UAC in secure or staff secure custody and provided to ORR. ORR files the motion with the local immigration court.

4. Motion to Request a Bond Hearing—Non-Secure Custody (Form LRG-8B): This instrument is completed by case managers upon receipt of a *Request for a Flores Bond Hearing* for a UAC placed in a non-secure program (e.g., shelter, foster care) and provided to ORR. ORR files the motion with the local immigration court.

5. Request for Specific Consent to Juvenile Court Jurisdiction (Form L-1): This instrument is used by legal service providers and attorneys of record to request specific consent from ORR in cases where they are seeking Special Immigrant Juvenile legal relief for their UAC client and are also seeking to invoke the jurisdiction of a state court to determine or alter the UAC's custody status or placement. This form is currently approved under OMB Number 0970-0385, but has been revised and is being moved under this new OMB number consisting of related forms.

6. Specific Consent Request Case Summary (Form L-2): This instrument is completed by ORR Federal Field Specialists (FFS) when ORR receives a request for specific consent. FFS provide case information that will allow the ORR Director to make an informed decision on whether to grant specific consent.

7. Notice of Attorney Representation (Form L-3): This instrument is completed by attorneys of record for UAC to notify ORR of the purpose of legal representation and the

representation timeframe. ORR uses this instrument to ensure that case updates are provided to attorneys of record. This instrument may also be used by attorneys of record when requesting a copy of their client's case file.

8. UAC Legal Information (Form L-4): This instrument is used by case managers to document, as applicable, referrals to the Office of Trafficking in Persons; meetings between the UAC and their legal service provider or attorney of record; the provision of ORR's Legal Resource Guide to the UAC; information about the UAC's legal service provider or attorney of record; immigration and administrative hearings; and provision of the *Notice of Placement in a Restrictive Setting* to the UAC. The instrument also includes an area to upload legal documents.

9. Legal Service Provider Record (Form L-6): This instrument is used by case managers to create a record containing certain information and documents that ORR makes accessible to ORR-funded legal service providers without requiring a formal records request.

10. Motion for Change of Venue (Form L-7): This instrument is used by case managers to file a motion for change of venue when a UAC is transferred or discharged to a new immigration court jurisdiction.

11. Post Legal Status Plan (Form L-8): This instrument is used by case managers to create and obtain Federal Field Specialist Supervisor approval for a plan for UAC expected to obtain legal status, at which time the UAC must be released from ORR custody.

*Respondents:* ORR grantee and contractor staff; UAC; parents/legal guardians of UAC; attorneys of record; and legal service providers.

**ANNUAL BURDEN ESTIMATES**

Instrument	Annual total number of respondents	Annual total number of responses per respondent	Average burden minutes per response	Annual total burden hours
Legal Service Provider List for UAC in ORR Care (Form LRG-5/5s)	216	556.0	15	30,024
Request for a Flores Bond Hearing (Form LRG-7/7s)	216	0.2	10	7
Motion to Request a Bond Hearing—Secure or Staff Secure Custody (Form LRG-8A)	8	3.0	10	4
Motion to Request a Bond Hearing—Non-Secure Custody (Form LRG-8B)	208	0.1	10	3
Request for Specific Consent to Juvenile Court Jurisdiction (Form L-1)	40	1.0	15	10
Specific Consent Request Case Summary (Form L-2)	216	0.2	20	14
Notice of Attorney Representation (Form L-3)	13,000	1.0	15	3,250
UAC Legal Information (Form L-4)	216	241.0	60	52,056
Legal Service Provider Record (Form L-6)	216	241.0	5	4,338
Change of Venue (Form L-7)	216	208.0	10	7,488
Post Legal Status Plan (Form L-8)	216	24.0	15	1,296
<b>Estimated Annual Burden Hours Total:</b>				<b>98,490</b>

*Comments:* The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

*Authority:* 6 U.S.C. 279; 8 U.S.C. 1232; Flores v. Reno Settlement Agreement, No. CV85-4544-RJK (C.D. Cal. 1996)

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2021-03261 Filed 2-17-21; 8:45 am]

**BILLING CODE 4184-45-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10326]

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

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human 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 April 19, 2021.

**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 CMS-10326, 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>.

**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-10326—Electronic Submission of Medicare Graduate Medical Education (GME) Affiliation Agreements**

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:* Reinstatement without change of a currently approved collection; *Title of Information Collection:* Electronic Submission of Medicare Graduate Medical Education (GME) Affiliation Agreements; *Use:* Existing regulations at § 413.75(b) permit hospitals that share residents to elect to form a Medicare GME affiliated group if they are in the same or contiguous urban or rural areas, if they are under common ownership, or if they are jointly listed as program sponsors or major participating institutions in the same program by the accrediting agency. The purpose of a Medicare GME affiliated group is to provide flexibility to hospitals in structuring rotations under an aggregate full time equivalent (FTE) resident cap when they share residents. The existing regulations at § 413.79(f)(1) specify that each hospital in a Medicare GME affiliated group must submit a Medicare GME affiliation agreement (as defined under § 413.75(b)) to the Medicare Administrative Contractor (MAC) servicing the hospital and send a copy to the Centers for Medicare and Medicaid Services' (CMS) Central Office, no later than July 1 of the residency program year during which the Medicare GME affiliation agreement will be in effect.

CMS will use the information contained in electronic affiliation agreements as documentation of the existence of Medicare GME affiliations, and to verify that the affiliations being formed by teaching hospitals for the purposes of sharing their Medicare GME FTE cap slots are valid according to CMS regulations. CMS will also use these affiliation agreements as reference materials when potential issues involving specific affiliations arise. While we have used hard copies of affiliation agreements for those same purposes in the past, we implemented this electronic submission process in order to expedite and ease the process of retrieving, analyzing and evaluating affiliation agreements. *Form Number:* CMS-10326 (OMB control number: 0938-1111); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for profits, Not for profit institutions; *Number of Respondents:* 125; *Total Annual Responses:* 125; *Total*