campaign. CDC will carefully consider all comments submitted into the docket.

Written Public Comment: Written comments must be received on or before May 5, 2021.

Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children Program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment at the May ACIP meeting must submit a request at *http://www.cdc.gov/vaccines/acip/meetings/* no later than 11:59 p.m., EDT, April 30, 2021, according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email by May 3, 2021. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to 3 minutes, and each speaker may only speak once per meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–05216 Filed 3–12–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4195–FN]

Medicare Program; Approved Renewal of Deeming Authority of the National Committee for Quality Assurance for Medicare Advantage Health Maintenance Organizations and Preferred Provider Organizations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to renew the Medicare Advantage ''deeming authority'' of the National Committee for Quality Assurance (NCQA) for health maintenance organizations and preferred provider organizations for a term of 6 years.

DATES: The decision announced in this final notice is effective December 30, 2020 through December 30, 2026.

FOR FURTHER INFORMATION CONTACT: Greg McDonald, (410) 786–8941.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services through a Medicare Advantage (MA) organization that contracts with CMS. The regulations specifying the Medicare requirements that must be met for a Medicare Advantage Organization (MAO) to enter into a contract with CMS are located at 42 CFR part 422.These regulations implement Part C of Title XVIII of the Social Security Act (the Act), which specifies the services that an MAO must provide and the requirements that the organization must meet to be an MA contractor. Other relevant sections of the Act are Parts A and B of Title XVIII and Part A of Title XI pertaining to the provision of services by Medicare certified providers and suppliers. Generally, for an entity to be an MA organization, the organization must be licensed by the state as a risk bearing organization, as set forth in 42 CFR part 422.

As a method of assuring compliance with certain Medicare requirements, an MA organization may choose to become accredited by a CMS-approved accrediting organization (AO). By virtue of its accreditation by a CMS-approved AO, the MA organization may be ''deemed'' compliant in one or more requirements set forth in section 1852(e)(4)(B) of the Act. For CMS to recognize an AO's accreditation program as establishing an MA plan's compliance with our requirements, the AO must prove to CMS that its standards are at least as stringent as Medicare requirements for MA organizations. MA organizations that are licensed as health maintenance organizations (HMOs) or preferred provider organizations (PPOs) and are accredited by an approved accrediting organization may receive, at their request, deemed status for CMS requirements with respect to the deemable areas. At this time, recognition of accreditation does not include the Part D areas of review set out at 42 CFR 423.165(b). AOs that apply for MA deeming authority are generally recognized by the health care industry as entities that accredit HMOs and PPOs. As we specify at § 422.157(b)(2)(ii), the term for which an AO may be approved by CMS may not exceed 6 years. For continuing approval, the AO must apply to CMS to renew their deeming authority for a subsequent approval period.

The National Committee for Quality Assurance (NCQA) was last approved as a CMS-approved accreditation organization for MA deeming of HMOs and PPOs for a 6-year term beginning on October 19, 2014, and that term lapsed on October 18, 2020, prior to our decision on its renewal application. NCQA did not accredit or re-accredit any HMOs or PPOs for MA deeming between that date and December 30, 2020, the effective date of its re-approval. On May 22, 2020, NCQA submitted an application to renew its deeming authority. On that same date, NCQA submitted materials requested by CMS that included information intended to address the requirements set out at § 422.158(a) and (b) that are prerequisites for receiving approval of its accreditation program from CMS. CMS subsequently requested that additional materials and revisions be submitted by NCQA to satisfy these requirements. NCQA submitted all the necessary materials to enable us to make a determination concerning its request for approval as an accreditation organization, and the renewal application was determined to be complete on August 28, 2020.

II. Provisions of the Proposed Notice

In the November 9, 2020 **Federal Register** (85 FR 71346), we published a proposed notice announcing NCQA's request to renew its Medicare Advantage deeming authority for HMOs and PPOs. In the November 9, 2020 proposed notice, we detailed our evaluation criteria. Under section

1852(e)(4) of the Act and § 422.158 (Federal review of accrediting organizations), we conducted a review of NCQA's application in accordance with the criteria specified by our regulations which include, but are not limited to the following:

- The types of MA plans that it would review as part of its accreditation process.
- A detailed comparison of the AO's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk) in the following 5 areas: Quality Improvement, Anti-Discrimination, Confidentiality and Accuracy of Enrollee Records, Information on Advance Directives, and Provider Participation Rules.
- Detailed information about the organization's survey process, including—

++ Frequency of surveys and whether surveys are announced or unannounced.

++ Copies of survey forms, and guidelines and instructions to surveyors.

++ Descriptions of—

— The survey review process and the accreditation status decision making process;

— The procedures used to notify accredited MA organizations of deficiencies and to monitor the correction of those deficiencies; and

— The procedures used to enforce compliance with accreditation requirements.

- Detailed information about the individuals who perform surveys for the accreditation organization, including—

++ The size and composition of accreditation survey teams for each type of plan reviewed as part of the accreditation process;

++ The education and experience requirements surveyors must meet;

++ The content and frequency of the in-service training provided to survey personnel;

++ The evaluation systems used to monitor the performance of individual surveyors and survey teams; and

++ The organization's policies and practice with respect to the participation, in surveys or in the accreditation decision process, by an individual who is professionally or financially affiliated with the entity being surveyed.

- A description of the organization's data management and analysis system with respect to its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.
- A description of the organization's procedures for responding to and investigating complaints against accredited organizations, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs.
- A description of the organization's policies and procedures with respect to the withholding or removal of accreditation for failure to meet the accreditation organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.
- A description of all types (for example, full, partial) and categories (for example, provisional, conditional, temporary) of accreditation offered by the organization, the duration of each type and category of accreditation and a statement identifying the types and categories that would serve as a basis for accreditation if CMS approves the accreditation organization.
- A list of all currently accredited MA organizations and the type, category, and expiration date of the accreditation held by each of them.
- A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization.
- The name and address of each person with an ownership or control interest in the accreditation organization.
- CMS also considers NCQA's past performance in the deeming program and results of recent deeming validation reviews or look-behind audits conducted as part of continuing federal oversight of the deeming program under § 422.157(d).

In accordance with section 1865(a)(3)(A) of the Act, the November 9, 2020 proposed notice (85 FR 71346) also solicited public comments regarding whether NCQA's requirements met or exceeded the Medicare conditions of participation as an accrediting organization for MA HMOs and PPOs.

III. Analysis of and Responses to Public Comments on the Proposed Notice

We received one public comment which is outside the scope of the MA deeming application renewal process.

IV. Provisions of the Final Notice

A. Differences Between NCQA's Standards and Requirements for Accreditation and Medicare's Conditions and Survey Requirements

We compared the standards and survey process contained in NCQA's application with the Medicare conditions for accreditation. Our review and evaluation of NCQA's application for continued CMS approval were conducted as described in section II. of this final notice, and yielded the following:

- Pursuant to § 422.158(a)(2), NCQA amended its crosswalk and standards to ensure current NCQA standards are clearly cross-walked to our regulations in each of five deemable areas: Quality Improvement, Anti-discrimination, Confidentiality and Accuracy of Enrollee Records, Information on Advance Directives, and Provider Participation Rules.
- NCQA submitted additional information and/or documentation regarding its survey process that was intended to address our regulations at §§ 422.158(a)(1), (a)(3)(i), (a)(3)(ii), (a)(3)(iii)(A) through (C), (a)(4)(iii), (a)(6) through (11), and (b)(1) and (2).

B. Term of Approval

Based on the review and observations described in section II. of this final notice, we have determined that NCQA's accreditation program requirements meet or exceed our requirements. Therefore, we approved NCQA as a national accreditation organization with deeming authority for MA HMOs and PPOs on December 30, 2020 for a term of approval to continue through December 30, 2026. We informed NCQA of their renewal via a letter from CMS dated December 30, 2020.

V. Collection of Information Requirements

This notice announces the new term of approval for NCQA. Since it does not impose information collection requirements, that is, reporting, recordkeeping or third party disclosure requirements, 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.*).

VI. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

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: March 10, 2021.

Lynette Wilson,

Federal Register Liaison, Department of Health and Human Services.

[FR Doc. 2021–05322 Filed 3–12–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Engineered Tumor Infiltrating Lymphocytes for Cancer Therapy; Correction

AGENCY: National Institutes of Health, HHS.

ACTION: Notice; correction.

SUMMARY: The Department of Health and Human Services, National Institutes of Health published a Notice in the **Federal Register** on February 25, 2021. That Notice requires a correction in the **SUPPLEMENTARY INFORMATION** section.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of February 25, 2021, in FR Doc. 2021–03873, on page 11548, as found within the **SUPPLEMENTARY INFORMATION** section, correct to read:

The use of the Licensed Patent Rights to develop, manufacture, distribute, sell, and use autologous tumor infiltrating lymphocyte (TIL) adoptive cell therapy products for the treatment of metastatic melanoma, lung, breast, bladder, and HPV-positive cancers. Specifically excluded from this Agreement are cell therapy products involving TIL genetically modified for reactivity against cancer-specific mutations or TIL selected for reactivity against cancer-specific mutations, unless such cell therapy products are a combination of unselected, unmodified TIL therapy with the Licensee's proprietary technologies or the Licensee's in-licensed technologies.

The field of use described in the Notice was found to be incorrect. The correction addresses this discrepancy by accurately stating the field of use which the NIH intends to grant to Iovance Biotherapeutics, Inc for the disclosed federally owned invention.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Andrew Burke, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240)–276–5484; Email: *andy.burke@nih.gov.*

Dated: March 9, 2021.

Daniel R Hernandez,

Federal Register Officer, National Institutes of Health.

[FR Doc. 2021–05272 Filed 3–12–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development, Production, and Commercialization of Ebola Neutralizing Single Monoclonal Antibody for the Treatment of Ebola Virus Disease in Humans

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the U.S. and European Patents and Patent Applications listed in the Supplementary Information section of this Notice to Ridgeback Biotherapeutics, L.P., located in Miami, Florida.

DATES: Only written comments and/or applications for a license which are received by the National Institute of Allergy and Infectious Diseases' Technology Transfer and Intellectual Property Office on or before March 30, 2021 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Daniel Lee, J.D., Technology Transfer and Patent Specialist, National Institute of Allergy and Infectious Diseases Technology Transfer and Intellectual Property Office by email (*daniel.lee5@nih.gov*) or phone (301–761–6327).

SUPPLEMENTARY INFORMATION:

Intellectual Property

E–045–2015: Neutralizing Antibodies to Ebolavirus Glycoprotein and Their Use

1. United States Provisional Patent Application No. 62/087,087, filed 3 December 2014 (HHS Reference No. E–045–2015–0–US–01);

2. International Patent Application No. PCT/US2015/060733, filed 13 November 2015 (HHS Reference No. E–045–2015–0–PCT–02);

3. European Patent Application No. 15797815.6, filed 13 November 2015 (HHS Reference No. E–045–2015–0–EP–03); and

4. United States Patent No. 10,273,288, issued 30 April 2019 (HHS Reference No. E–045–2015–0–US–05).

The patent and patent application 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 fields of use may be limited to the following: Development, production, and commercialization of Ebola neutralizing monoclonal antibody mAb114, as a single antibody not in combination with other monoclonal antibodies, for the treatment of Ebola virus disease in humans.

This technology discloses the discovery, isolation, production, and advancement in the development of recombinant neutralizing antibodies specific to the Ebola virus glycoprotein, varying Ebola virus glycoprotein recognition profiles, and increasing neutralization potency for a therapeutic in a patient diagnosed with Ebola virus.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR 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 Institute of Allergy and Infectious Diseases 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 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent commercialization license. In response to this notice, the public may file comments or objections. Comments and objections, other than those in the form of a 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 from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.