

recommendations must be received in one of the following ways by January 2, 2014:

1. *Electronically.* You may submit 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) 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 (CMS–10510), Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850 and, OMB Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: 202–395–6974.

Dated: December 17, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013–30434 Filed 12–18–13; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9953–FN]

Health Insurance Exchanges; Approval of an Application by the Accreditation Association for Ambulatory Health Care (AAAHC) To Be a Recognized Accrediting Entity for the Accreditation of Qualified Health Plans

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

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the Accreditation Association for Ambulatory Health Care (AAAHC) for recognition as an accrediting entity for the purposes of fulfilling the accreditation requirement as part of qualified health plan (QHP) certification.

DATE: This notice is effective on December 23, 2013.

FOR FURTHER INFORMATION CONTACT: Rebecca Zimmermann, (301) 492–4396.

SUPPLEMENTARY INFORMATION:

I. Background

Regulations at 45 CFR 156.275(c) require qualified health plan (QHP)

issuers to be accredited on the basis of local performance of its QHPs by an accrediting entity recognized by the Secretary (the Secretary) of the Department of Health and Human Services (HHS). In a final rule published on July 20, 2012 titled, “Data Collection To Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans (77 FR 42658),” we established the first phase of an intended two-phase approach to recognize accrediting entities and proposed both the National Committee for Quality Assurance (NCQA) and URAC as recognized accrediting entities. On November 23, 2012, we notified the public that NCQA and URAC had both met the requirements in the July 2012 final rule to be recognized as accrediting entities (§ 156.275(c)(1)(iv)) and were recognized by the Secretary¹ as accrediting entities for the purposes of QHP certification.

On February 25, 2013, we published a subsequent final rule, titled, “Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation” (78 FR 12834),² which amended § 156.275(c) to establish an application and review process to allow additional accrediting entities to seek recognition. The application submitted by an accrediting entity must include documentation described in § 156.275(c)(4) and demonstrate, in a concise and organized fashion, how the accrediting entity meets the requirements of § 156.275(c)(2) and (3). Specifically, to be recognized, an accrediting entity must provide current accreditation standards and requirements, processes, and measure specifications for performance measures to demonstrate via a crosswalk that it meets the conditions described in § 156.275(c)(2) and (c)(3). Further, once recognized, § 156.275(c)(4)(ii) requires accrediting entities to provide the Secretary with any proposed changes or updates to the accreditation standards and requirements, processes, and measure specifications for performance measures with 60 days’ notice prior to public notification. Lastly, § 156.275(c)(5) requires recognized accrediting entities, when authorized by an accredited QHP issuer, to provide

¹ Certain authority under the Affordable Care Act has been delegated from the Secretary to the Administrator of CMS. 76 FR 53903 through 53906, (August 30, 2011).

² Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation; Final Rule, 78 FR 12834, 12854–12855 (February 25, 2013) (45 CFR 156.275(c)).

specific QHP issuer accreditation survey data elements, other than personally identifiable information, to the Exchange in which the issuer plans to operate one or more QHPs during the annual certification or as changes occur in the data elements throughout the coverage year.

II. Provisions of the Proposed Notice

On September 13, 2013, we published in the **Federal Register** a proposed notice³ announcing the receipt of an application from the Accreditation Association for Ambulatory Health Care (AAAHC) to be a recognized accrediting entity for the purposes of fulfilling the accreditation requirement as part of qualified health plan certification. In the proposed notice, we provided a detailed analysis of whether AAAHC meet the requirements as specified in our regulations at § 156.275. In addition, we solicited public comments on whether it was appropriate to recognize AAAHC as an accrediting entity for the purpose of QHP certification; AAAHC’s accreditation standards for QHP issuers including whether or not AAAHC’s standards meet the requirements in § 156.275; whether AAAHC had any deficiencies in its standards; the content of the proposed clinical quality measures and their appropriateness for use in QHP accreditation; the rigor of the scoring methodology; and if the network adequacy standards will ensure sufficient network of providers for QHP enrollees.

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

We received nine public comments in response to the September 13, 2013 proposed notice. Five commenters supported the recommendation to recognize AAAHC as an accrediting entity for the purposes of QHP accreditation; whereas two commenters did not support the proposal to recognize AAAHC as an accrediting entity. Two commenters provided comments that were outside the scope of the proposed notice.

One commenter questioned the comparability of AAAHC’s standards to other HHS-recognized accrediting entities. Another commenter requested that more child measures be included in the clinical quality metrics. Both of these commenters thought that the accreditation standards were not sufficiently transparent.

³ Health Insurance Exchanges; Application by the Accreditation Association for Ambulatory Health Care To Be a Recognized Accrediting Entity for the Accreditation of Qualified Health Plans; 78 FR 56711–56714 (September 13, 2013).

While there may be some instances where AAAHC's standards differ from other recognized accrediting entities, AAAHC has met the criteria to be recognized by HHS based on our standards in § 156.275(c). We believe there is a sufficient number of measures applicable to children included in the proposed clinical quality metrics and further note that the AAAHC's measure set is identical to the set used by a different HHS-recognized accrediting entity (that is, URAC). Lastly, the accreditation standards are propriety documents and we have not required any of the recognized accrediting entities to make their standards public. Therefore, we cannot require AAAHC to make their standards public.

In addition, we have previously indicated that we may, at a later date, modify the recognition process of accrediting entities and will solicit comments on any proposed future rulemaking that time.

IV. Provisions of the Final Notice

Upon completion of our analysis, including evaluation of comments received as a result of the proposed notice, we have determined that the AAAHC meets the requirements and criteria described in the July 20, 2012 final rule, titled "Data Collection To Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans" (77 FR 42658) to be recognized as an accrediting entity. This final notice acknowledges the approval of AAAHC's application. The AAAHC is now recognized by the Secretary of HHS⁴ as an accrediting entity for the purposes of QHP certification.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

Dated: December 17, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013-30522 Filed 12-20-13; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License for: Convection Enhanced Delivery of a Therapeutic Agent With a Surrogate Tracer for Treating Cancer and Urological Diseases

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404.7, that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive worldwide license to practice the inventions embodied in: HHS Ref. No E-202-2002/0 "Method for Convection Enhanced Delivery of Therapeutic Agents", U.S. Provisional Patent Application 60/413,673 (filed September 24, 2002; expired), International Patent Application No. PCT/US2003/30155 (filed September 24, 2003; nationalized), U.S. Patent Application 7,371,225, European Patent Application 03756863.1, Australian Patent 2003299140, to Medicenna Therapeutics, Inc. having a principle place of business in 1075 West Georgia St., Vancouver, BC, Canada V6E 3C9.

The United States of America is an assignee to the patent rights of these inventions.

The contemplated exclusive license may be in a field of use directed to the treatment of cancers and urological disorders that express IL-4 receptor on their cell surface by administering cpIL4-PE38KDEL by convection enhanced deliver along with a Gd-DTPA surrogate tracer.

DATES: Only written comments and/or applications for a license that are received by the NIH Office of Technology Transfer on or before January 22, 2014 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Michael Shmilovich, Esq., CLP, Senior Licensing and Patent Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5019; Facsimile: (301) 402-0220; Email: shmilovm@mail.nih.gov. A signed confidential disclosure agreement may be required to receive copies of the patent application assuming it has not already been published under either the publication rules of either the U.S.

Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: The invention is a method for monitoring the spatial distribution of therapeutic substances by MRI or CT that have been administered to tissue using convection enhanced delivery, a technique that is the subject of now expired NIH-owned U.S. Patent No. 5,720,720 (HHS Ref. E-173-1992/0). The tracer is a molecule, detectable by MRI or CT, which functions as a surrogate for the motion of the therapeutic agent through the solid tissue. In other particular embodiments, the tracer is the therapeutic agent conjugated to an imaging moiety. The method of this invention uses non-toxic macromolecular MRI contrast agents such as chelated Gd(III). These macromolecular imaging agents have clearance properties that mimic the pharmacokinetic properties of co-administrated drugs, so as to be useful in quantifying the range and dosage level of therapeutic drugs using MR imaging.

The prospective exclusive license will be royalty-bearing and comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within 30 days from the date of this published notice, NIH 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 404.7.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: December 17, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013-30430 Filed 12-20-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Clinical Center; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is

⁴ Delegated to CCIIO, 76 FR 53903 through 53906 (August 30, 2011).