

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 HHS<sup>4</sup> 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.*

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**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 delivery 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](mailto: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.*

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**BILLING CODE 4140-01-P**

## 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

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