given day by using the traditional alcoholism therapy based on clinical experience and intuition, with little rigorous validation of their effectiveness (*http://health.nih.gov/topic/Alcoholism/SubstanceAbuse*). About 18% of American adults have anxiety disorders (www.nimh.nih.gov). More than 40 million Americans suffer from chronic, long-term sleep disorders, and an additional 20 million report sleeping problems occasionally (*http://www.adaa.org*).

*Inventors:* Juan J. Marugan, Ke Liu, Samarjit Patnaik, Noel T. Southall, Wei Zheng (all with NHGRI); Markus Heilig (NIAAA).

*Related Publication:* N Cannella *et al.* Persistent increase of alcohol-seeking evoked by neuropeptide S: An effect mediated by the hypothalamic hypocretin system. Neuropsychopharmacology. 2009 Aug; 34(9): 2125–2134. [PubMed: 19322167].

*Patent Status:* U.S. Provisional Application No. 61/328,900 filed 28 Apr 2010 (HHS Reference No. E–041–2010/0–US–01).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Steve Standley, PhD; 301–435–4074; *sstand@mail.nih.gov*.

*Collaborative Research Opportunity:* The NIH Chemical Genomics Center (NCGC), NHGRI, NIH is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize these NPSR antagonist small molecule compounds for various therapeutic uses including treatment of neuropsychiatric disorders and alcohol and drug addiction. Please contact Dr. Juan J. Marugan at *maruganj@mail.nih.gov* for more information.

**A Rapid, Peripheral Blood Gene Expression Biomarker Panel for Diagnosis of Acute Ischemic Stroke**

*Description of Invention:* There are presently no rapid, accurate diagnostic procedures or methods that can be used to determine whether a patient has suffered an acute ischemic stroke (AIS). Current technologies for diagnosis of AIS are limited by speed and resources as well as inaccuracy and generally require a high level of training to interpret the results for medical technicians. In contrast, this invention may lead to the development of a rapid and accurate clinical diagnostic kit that would require very little training for proper use and could be used in the field or the emergency room setting.

Scientists at the National Institutes of Health have discovered that expression levels of a set of nine genes may be used as biomarkers for diagnosis of AIS as well as outcome prediction. These biomarkers may be rapidly identified using peripheral whole blood and may form the basis of a rapid and accurate clinical point of care diagnostic kit.

Further, if validation is positive, this technology may enable rapid differential diagnosis between acute ischemic stroke and hemorrhagic stroke, transient ischemic attack, or any pathology mimicking a stroke. Not only can this be used to identify stroke earlier in the course of treatment, this panel may also help to better characterize stroke subtype, and identify new pathways for stroke treatment. This is important as the only FDA approved treatment for acute ischemic stroke is tissue plasminogen activator (tPA) and tPA must not be given to hemorrhagic stroke patients since it could increase intracranial bleeding. To effectively treat AIS, tPA must be administered intravenously within 3–4 hours of known stroke onset. Because the differential diagnosis of AIS versus hemorrhagic stroke is difficult without specialized imaging equipment such as a CT scan with contrast or an MRI image, only a small percentage of stroke patients (3–5%) are ever given tPA. So, a rapid and accurate clinical diagnostic kit based on this invention would have a profound public health benefit and likely a large commercial potential.

*Applications:*

- A rapid and accurate clinical diagnostic kit for acute ischemic stroke.
- Differentiation between acute ischemic stroke and a hemorrhagic stroke, transient ischemic attack, or any pathology mimicking a stroke.
- Aid in the prediction of outcome and identify new pathways for ischemic stroke treatment.

*Advantages:* Faster, more accurate, and requires less training than currently available diagnostic procedures.

*Development Status:* Clinical Validation Pilot Study: Whole blood was collected in a clinical setting and gene expressions were subsequently profiled.

*Market:* Every year, about 795,000 people in the United States have a stroke, and about 675,000 of those strokes are ischemic. In 2006, 137,000 people in the United States died of stroke (*http://www.cdc.gov/stroke/*).

*Inventors:* Taura L. Barr (NINR), Maria Del Mar Matarin Jimenez (NIA), Steven J. Warach (NINDS), Andrew B. Singleton (NIA), Jinhui Ding (NIA), Allissa A. Dillman (NIA), Mark P. Cookson (NIA), Yvette Conley (University of Pittsburgh).

*Publication:* Barr, T.L.; Conley, Y.; Ding, J.; Dillman, A.; Warach, S.; Singleton, A.; Matarin, M. Genomic biomarkers and cellular pathways of ischemic stroke by RNA gene expression profiling; *Neurology,* Volume 75(11), 14 September 2010, pp 1009–1014.

*Patent Status:* U.S. Provisional Application No. 61/307,233 filed 23 Feb 2010 (HHS Reference No. E–023–2010/0–US–01).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Jeffrey Clark Klein, PhD; 301–594–4697; *kleinjc@mail.nih.gov*.

*Collaborative Research Opportunity:* The NINR is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize a point of care test for ischemic stroke diagnostics and outcome prediction. Please contact Dr. Taura Barr at 304–293–0503 or *barrt@mail.nih.gov* for more information.

Dated: September 20, 2010.

**Richard U. Rodriguez,**

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

[FR Doc. 2010–23957 Filed 9–23–10; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[CMS–7019–N]**

### Medicare Program; Meeting of the Advisory Panel on Medicare Education, October 13, 2010

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

**ACTION:** Notice of meeting.

**SUMMARY:** This notice announces a meeting of the Advisory Panel on Medicare Education (the Panel) in accordance with the Federal Advisory Committee Act. The Panel advises and makes recommendations to the Secretary of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program. This meeting is open to the public.

**DATES:** *Meeting Date:* Wednesday, October 13, 2010 from 1 p.m. to 4 p.m., eastern daylight time (e.d.t.).

*Deadline for Meeting Registration and Comments:* Wednesday, October 6, 2010, 5 p.m., e.d.t.

*Deadline for Requesting Special Accommodations:* Wednesday, October 6, 2010, 5 p.m., e.d.t.

**ADDRESSES:** *Meeting Location:* The October 13, 2010 meeting will be a "virtual meeting" using Adobe Acrobat Connect Pro Meeting, a Web conferencing product that allows users to conduct live meetings and presentations over the Internet. The audio portion is also available via telephone conferencing.

*Meeting Registration:* The meeting is open to the public, but attendance is limited to the telephone lines available. Persons wishing to attend this meeting must register at *http://www.blsmeetings.net/H1714-4.*

*Meeting Presentations, Written Comments, and Special Accommodations:* Jennifer Kordonski, Designated Federal Official (DFO), Division of Forum and Conference Development, Office of External Affairs, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mailstop S1–13–05, Baltimore, MD 21244–1850 or contact Ms. Kordonski via e-mail at *Jennifer.Kordonski@cms.hhs.gov.*

**FOR FURTHER INFORMATION CONTACT:** Jennifer Kordonski, (410) 786–1840. Please refer to the CMS Advisory Committees' Information Line (1–877–449–5659 toll free)/(410–786–9379 local) or the Internet (*http://www.cms.hhs.gov/FACA/04_APME.asp*) for additional information and updates on committee activities. Press inquiries are handled through the CMS Press Office at (202) 690–6145.

**SUPPLEMENTARY INFORMATION:**

## I. Background and Meeting Agenda

Section 9(a)(2) of the Federal Advisory Committee Act authorizes the Secretary of Health and Human Services (the Secretary) to establish an advisory panel if the Secretary determines that the panel is "in the public interest in connection with the performance of duties imposed * * * by law." Such duties are imposed by section 1804 of the Social Security Act (the Act), requiring the Secretary to provide informational materials to Medicare beneficiaries about the Medicare program, and section 1851(d) of the Act, requiring the Secretary to provide for "activities * * * to broadly disseminate information to [M]edicare beneficiaries * * * on the coverage options provided under [Medicare Advantage] in order to promote an active, informed selection among such options."

The Panel is also authorized by section 1114(f) of the Act (42 U.S.C. 1311(f)) and section 222 of the Public Health Service Act (42 U.S.C. 217a). The Secretary signed the charter establishing this Panel on January 21, 1999 (64 FR 7899, February 17, 1999) and approved the renewal of the charter on January 21, 2009 (74 FR 13442, March 27, 2009). The Panel advises and makes recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program.

The goals of the Panel are as follows:

- To provide recommendations on the development and implementation of a national Medicare education program that describes benefit options under Medicare.
- To enhance the Federal government's effectiveness in informing the Medicare consumer.
- To make recommendations on how to expand outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of a national Medicare education program.
- To assemble an information base of best practices for helping consumers evaluate benefit options and build a community infrastructure for information, counseling, and assistance.

The current members of the Panel are: Stephen P. Fera, M.B.A., Vice President, Social Mission Programs, Independence Blue Cross; Richard C. Frank, M.D., Director, Cancer Research, Whittingham Cancer Center; Cathy C. Graeff, R.Ph., M.B.A., Partner, Sonora Advisory Group; Carmen R. Green, M.D., Professor, Anesthesiology and Associate Professor, Health, Management, and Policy, University of Michigan; Cindy Hounsell, J.D., President, Women's Institute for a Secure Retirement; Kathy Hughes, Vice Chairwoman, Oneida Nation; Gail Hunt, President and Chief Executive Officer, National Alliance for Caregiving; Warren Jones, M.D., F.A.A.F.P., Executive Director, Mississippi Institute for Improvement of Geographic Minority Health; Sandy Markwood, Chief Executive Officer, National Association of Area Agencies on Aging; David W. Roberts, M.P.A.,Vice President, Government Relations, Healthcare Information and Management System Society; Julie Boden Schmidt, M.S., Associate Vice President, Training and Technical Assistance, National Association of Community Health Centers; Rebecca P. Snead, Chief Executive Officer and Executive Vice President, National Alliance of State Pharmacy Associations and APME Chair; Donna Yee, PhD, Chief Executive Officer, Asian Community Center of Sacramento Valley; Deeanna Jang, Policy Director, Asian and Pacific Islander American Health Forum; Andrew Kramer, M.D., Professor of Medicine, Division of Health Care Policy and Research, University of Colorado, Denver; and John Lui, PhD, M.B.A., Executive Director, Stout Vocational Rehabilitation Institute.

The agenda for the October 13, 2010 meeting will include the following:

- Recap of the previous (June 22, 2010) meeting.
- Subgroup Committee Work Summary.
- Medicare Outreach and Education Strategies.
- Public Comment.
- Listening Session with CMS Leadership.
- Next Steps.

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should submit a written copy of the oral presentation to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. The number of oral presentations may be limited by the time available. Individuals not wishing to make a presentation may submit written comments to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

## II. Virtual Meeting Participation Information and Instructions

### *A. Software Requirements*

Software to participate in a Connect Pro meeting only requires that you have an Internet connection, a Web browser, and Adobe Flash Player Version 8 or later to attend a Web conference. Connect Pro supports nearly any operating system including Windows, Macintosh, Linux, and Solaris, as well as the most widely used browsers including Internet Explorer, Firefox, and Safari.

### *B. Participation in an Acrobat Connect Pro Meeting*

1. Pre-Meeting Computer Testing

It is recommended that you test your computer prior to attending a meeting. You can do this by going to: *https://admin.adobe.acrobat.com/common/help/en/support/meeting_test.htm.* The connection test checks your computer to make sure all system requirements are met. If you pass the first three steps of the test, then you are ready to

participate in a meeting. If you do not pass the connection test, perform the suggested actions and run the test again.

2. Joining the Meeting

Registrants will receive an e-mail invitation with meeting access information prior to meeting. When the meeting date and time arrive, click on the link or enter the URL into your Web browser. The meeting login screen appears. Select "Enter as a Guest," type in your first and last name, and click "Enter Room." The meeting launches in your browser.

To access the audio portion of the meeting please dial 1–888–469–0694 and enter passcode 1995616. If you should have difficulties accessing the meeting please contact Syreeta Jones via phone at 1–301–577–0244 ext. 4900 or via e-mail at *sjones@blseamon.com.*

**Authority:** Sec. 222 of the Public Health Service Act (42 U.S.C. 217a) and sec. 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, sec. 10(a) and 41 CFR 102–3).

(Catalog of Federal Domestic Assistance Program No. 93.733, Medicare—Hospital Insurance Program; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 9, 2010.

**Donald M. Berwick,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2010–23312 Filed 9–23–10; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Centers for Medicare & Medicaid Services

**[CMS–4143–N]**

## Medicare Program; Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2011

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the annual adjustment in the amount in controversy (AIC) threshold amounts for Administrative Law Judge (ALJ) hearings and judicial review under the Medicare appeals process. The adjustment to the AIC threshold amounts will be effective for requests for ALJ hearings and judicial review filed on or after January 1, 2011. The 2011 AIC threshold amounts are $130 for ALJ hearings and $1,300 for judicial review.

**DATES:** *Effective Date:* This notice is effective on January 1, 2011.

**FOR FURTHER INFORMATION CONTACT:** Liz Hosna (*Katherine.Hosna@cms.hhs.gov*), (410) 786–4993.

**SUPPLEMENTARY INFORMATION:**

### I. Background

Section 1869(b)(1)(E) of the Social Security Act (the Act), as amended by section 521 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), established the AIC threshold amounts for ALJ hearing requests and judicial review at $100 and $1,000, respectively, for Medicare Part A and Part B appeals. Section 940 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), amended section 1869(b)(1)(E) of the Act to require the AIC threshold amounts for ALJ hearings and judicial review to be adjusted annually. The AIC threshold amounts are to be adjusted, as of January 2005, by the percentage increase in the medical care component of the consumer price index for all urban consumers (U.S. city average) for July 2003 to July of the year preceding the year involved and rounded to the nearest multiple of $10. Section 940(b)(2) of the MMA provided conforming amendments to apply the AIC adjustment requirement to Medicare Part C (Medicare Advantage "MA") appeals and certain health maintenance organization and competitive health plan appeals. Health care prepayment plans are also subject to MA appeals rules, including the AIC adjustment requirement. Section 101 of the MMA provides for the application of the AIC adjustment requirement to Medicare Part D appeals.

*A. Medicare Part A and Part B Appeals*

The statutory formula for the annual adjustment to the AIC threshold amounts for ALJ hearings and judicial review of Medicare Part A and Part B appeals, set forth at section 1869(b)(1)(E) of the Act, is included in the applicable implementing regulations, 42 CFR Part 405, Subpart I, at § 405.1006(b). The regulations require the Secretary of the Department of Health and Human Services (the Secretary) to publish changes to the AIC threshold amounts in the **Federal Register** (§ 405.1006(b)(2)). In order to be entitled to a hearing before an ALJ, a party to a proceeding must meet the AIC requirements at § 405.1006(b). Similarly, a party must meet the AIC requirements at § 405.1006(c) at the time judicial review is requested for the court to have jurisdiction over the appeal (§ 405.1136(a)).

*B. Medicare Part C (Medicare Advantage) Appeals*

Section 940(b)(2) of the MMA applies the AIC adjustment requirement to Part C (MA) appeals by amending section 1852(g)(5) of the Act. The implementing regulations for Medicare Part C appeals are found at 42 CFR Part 422, Subpart M. Specifically, § 422.600 and § 422.612 discuss the AIC threshold amounts for ALJ hearings and judicial review. Section 422.600 grants any party to the reconsideration, except the MA organization, who is dissatisfied with the reconsideration determination, a right to an ALJ hearing as long as the amount remaining in controversy after reconsideration meets the threshold requirement established annually by the Secretary. Section 422.612 states that any party, including the MA organization, may request judicial review if, in part, the AIC meets the threshold requirement established annually by the Secretary.

*C. Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans*

Section 1876(c)(5)(B) of the Act states that the annual adjustment to the AIC dollar amounts set forth in section 1869(b)(1)(E) of the Act applies to certain beneficiary appeals within the context of health maintenance organizations and competitive medical plans. The applicable implementing regulations for Medicare Part C appeals are set forth in 42 CFR Part 422, Subpart M, and as discussed above, apply to these appeals. The Medicare Part C appeals rules also apply to health care prepayment plan appeals.

*D. Medicare Part D (Prescription Drug Plan) Appeals*

The annually adjusted AIC threshold amounts for ALJ hearings and judicial review that apply to Medicare Parts A, B, and C appeals also apply to Medicare Part D appeals. Section 101 of the MMA added section 1860D–4(h)(1) of the Act regarding Part D appeals. This statutory provision requires a prescription drug plan sponsor to meet the requirements set forth in sections 1852(g)(4) and (g)(5) of the Act, in a similar manner as MA organizations. As noted above, the annually adjusted AIC threshold requirement was added to section 1852(g)(5) of the Act by section 940(b)(2)(A) of the MMA. The implementing regulations for Medicare Part D appeals can be found at 42 CFR Part 423, Subpart M and Subpart U. The regulations impart at § 423.562(c) that,