

subject to final approval, an agreement containing a consent order from Focus Education, LLC (“Focus Education”), Chief Executive Officer, Michael Apstein, and Chief Financial Officer, John Able (“Respondents”).

The proposed consent order (“proposed order”) has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement’s proposed order.

This matter involves Focus Education’s advertising for the ifocus System, which included the Jungle Rangers computer game and comic book, and information on children’s behavior, exercise, and diet. The Commission’s complaint alleges that the Respondents violated Sections 5(a) and 12 of the Federal Trade Commission Act by making false or unsubstantiated representations that playing the ifocus System’s Jungle Rangers computer game improves children’s focus, memory, attention, behavior, and/or school performance, including in children with ADHD, and that these improvements were permanent. The complaint also alleges that Respondents violated Sections 5(a) and 12 by making false representations that scientific studies prove these claims.

The proposed order includes injunctive relief that prohibits these alleged violations and fences in similar and related violations. For purposes of the order, “Covered Product” means any product, program, device, or service that purports to alter the brain’s structure or function, improve cognitive abilities, behavior, or academic performance, or treat or lessen the symptoms of cognitive abnormalities or disorders, including ADHD.

Part I of the Order prohibits the Respondents from making any representation that the ifocus System or any substantially similar product improves children’s cognitive abilities, behavior, or academic performance, including in children with ADHD unless any such representation is non-misleading and the Respondents possess and rely upon competent and reliable scientific evidence. For purposes of this Part, competent and reliable scientific evidence is defined as “human clinical testing of such product that is sufficient in quality and quantity, based on standards generally accepted by experts in the relevant field, when considered in light of the entire body of relevant

and reliable scientific evidence, to substantiate that the representation is true. Such testing shall be (1) randomized, double-blind, and adequately controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing.” In addition, competent and reliable scientific evidence is subject to the preservation requirements set forth in Part IV.

Part II is a fencing-in provision. It prohibits the Respondents from making any claim about the benefits, performance, or efficacy of any Covered Product unless the claim is non-misleading and the Respondents possess competent and reliable scientific evidence that is sufficient in quality and quantity, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of this Part, Covered Product is defined as any product, program, device, or service that purports to alter the brain’s structure or function, improve cognitive abilities, behavior, or academic performance, or treat or lessen the symptoms of cognitive abnormalities or disorders, including ADHD. Competent and reliable scientific evidence means “tests, analyses, research, or studies (1) that have been conducted and evaluated in an objective manner by qualified persons; (2) that are generally accepted in the profession to yield accurate and reliable results; and (3) as to which, when they are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as set forth Part IV are available for inspection and production to the Commission.”

Part III prohibits the Respondents from misrepresenting, in relation to the advertising of any Covered Product, (1) the results of any test, study, or research; or (2) that the benefits of any such Covered Product are scientifically proven.

Part IV requires the Respondents, for human clinical tests or studies, to secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test. There is an exception for a “Reliably Reported” test, defined as a test published in a peer-reviewed journal that was not conducted, controlled, or sponsored by Respondents, affiliates, or others in the manufacturing and supply chain. Also, the published report must provide sufficient information about the test for experts in the relevant field to assess the reliability of the results.

Part V contains recordkeeping requirements for advertisements and substantiation relevant to representations covered by Parts I through III of the order.

Parts VI through IX of the proposed order require Respondents to: Deliver a copy of the order to principals, officers, directors, managers, employees, agents, and representatives having responsibilities with respect to the subject matter of the order; notify the Commission of changes in corporate structure, discontinuance of current business or employment, or affiliation with any new business or employment that might affect compliance obligations under the order; and file compliance reports with the Commission.

Part X provides that the order will terminate after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the complaint or proposed order, or to modify the proposed order’s terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2015–01516 Filed 1–27–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Full Committee Meeting.

Time and Date:

February 24, 2015 9:00 a.m.–5:30 p.m. EST
February 25, 2015 8:30 a.m.–12:00 p.m. EST

Place: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, 3311 Toledo Road, Auditorium A and B, Hyattsville, Maryland 20782, (301) 458–4524.

Status: Open.

Purpose: The purpose of this meeting is to review the status of current NCVHS activities and to strategically plan for 2015 NCVHS objectives and deliverables. The Committee will review its ongoing efforts in coordinating Subcommittee projects. Additional topics will include implementation plans for the ACA Review Committee process and reviewing the summary from the Roundtable on Supporting

Community Data Engagement. The Working Group on HHS Data Access and Use will continue strategic discussions on Building a Framework for Guiding Principles for Data Access and Use.

The times shown above are for the full Committee meeting. Subcommittee issues will be included as part of the Full Committee schedule.

Contact Person for More Information: Substantive program information may be obtained from Debbie M. Jackson, Acting Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2339, Hyattsville, Maryland 20782, telephone (301) 458-4614. Summaries of meetings and a roster of committee members are available on the NCVHS home page of the HHS Web site: <http://www.ncvhs.hhs.gov/>, where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458-4EEO (4336) as soon as possible.

Dated: January 22, 2015.

James Scanlon,

Deputy Assistant Secretary for Planning and Evaluation (Science and Data Policy), Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2015-01536 Filed 1-27-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics; Meeting Standards Subcommittee

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards

Time and Date: February 26, 2015, 8:30 a.m.–5:00 p.m. EST

Place: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, 3311 Toledo Road, Auditorium A and B, Hyattsville, Maryland 20782, (301) 458-4524.

Status: Open.

Purpose: The purpose of this hearing is to review and discuss the current status of selected administrative simplification topics of interest to the National Committee on Vital and Health Statistics.

The objectives of this hearing will be to (1) review, discuss and consider for recommendations the operating rules presented for adoption for four HIPAA transactions—Health Care Claims, Enrollment/Disenrollment, Premium Payment, and Prior Authorization; and (2) discuss and consider suggestions of the Review Committee evaluation criteria for

existing standards, code sets, identifiers, and operating rules.

Contact Person for More Information: Debbie M. Jackson, Acting Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2339, Hyattsville, Maryland 20782, telephone (301) 458-4614 or Terri Deutsch, Centers for Medicare and Medicaid Services, Office of E-Health Standards and Services, 7500 Security Boulevard, Baltimore, Maryland 21244, telephone (410) 786-9462. Program information as well as summaries of meetings and a roster of committee members are available on the NCVHS home page of the HHS Web site:

<http://www.ncvhs.hhs.gov/>, where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458-4EEO (4336) as soon as possible.

Dated: January 22, 2015.

James Scanlon,

Deputy Assistant Secretary for Planning and Evaluation (Science and Data Policy), Office of the Assistant Secretary for Planning and Evaluation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Availability: Test Tools and Test Procedures Approved by the National Coordinator for the ONC HIT Certification Program

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice announces the availability of test tools and test procedures approved by the National Coordinator for Health Information Technology (the National Coordinator) for the testing of EHR technology to the 2014 Edition Release 2 EHR certification criteria under the ONC HIT Certification Program. The approved test tools and test procedures are identified on the ONC Web site at: <http://healthit.gov/policy-researchers-implementers/testing-and-test-methods>. The test tools and test procedures for the “optional—transitions of care” certification criterion (§ 170.314(b)(8)) and the optional testing and certification for the “view, download, and transmit to 3rd party” certification criterion (§ 170.314(e)(1)) have not yet been approved.

FOR FURTHER INFORMATION CONTACT: Alicia Morton, Director, Office of

Certification, Office of the National Coordinator for Health Information Technology, 202-549-7851.

SUPPLEMENTARY INFORMATION: On January 7, 2011, the Department of Health and Human Services issued a final rule establishing a permanent certification program for the purposes of testing and certifying health information technology (“Establishment of the Permanent Certification Program for Health Information Technology,” 76 FR 1262) (Permanent Certification Program final rule). The permanent certification program was renamed the “ONC HIT Certification Program” in a final rule published on September 4, 2012 (77 FR 54163) (“2014 Edition EHR Certification Criteria final rule”). In the preamble of the Permanent Certification Program final rule, we stated that when the National Coordinator had approved test tools and test procedures for certification criteria adopted by the Secretary ONC would publish a notice of availability in the **Federal Register** and identify the approved test tools and test procedures on the ONC Web site.

In the 2014 Edition Release 2 EHR Certification Criteria final rule the Secretary adopted additional and revised certification criteria as part of the 2014 Edition EHR certification criteria (79 FR 54430). The National Coordinator has approved test tools and test procedures for testing EHR technology to most of these additional and revised certification criteria under the ONC HIT Certification Program.¹ These approved test tools and test procedures are identified on the ONC Web site at: <http://healthit.gov/policy-researchers-implementers/testing-and-test-methods>. The test tools and test procedures for the “optional—transitions of care” certification criterion (§ 170.314(b)(8)) and the optional testing and certification for the “view, download, and transmit to 3rd party” certification criterion (§ 170.314(e)(1)) have not yet been approved. Draft test procedures for § 170.314(b)(8) and the optional testing and certification for § 170.314(e)(1) are available on the Web site listed above.

Authority: 42 U.S.C. 300jj-11.

Dated: January 21, 2015.

Lisa Lewis,

Acting National Coordinator for Health Information Technology.

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¹ These certification criteria are: § 170.314(a)(18), (a)(19), (a)(20), (b)(9), (f)(7), (g)(1), (g)(3), (h)(1), (h)(2), and (h)(3).