



AFFORDABLE CARE ACT MASSACHUSETTS IMPLEMENTATION UPDATE

May 18, 2015

Quick Links

[MA-ACA Website](#)



These Updates, published by the Executive Office of Health and Human Services (EOHHS) in consultation with the other state agencies involved in ACA implementation, will bring you news related to the implementation of provisions of the ACA here in Massachusetts.

Grants and Demonstrations

The ACA provides funding opportunities to transform how health care is delivered, expand access to care and support healthcare workforce training.

Grant Announcements

Alzheimer's Disease Initiative - Specialized Supportive Services (ADI-SSS), \$4002. Announced May 6, 2015.

Funding is available to fill gaps in dementia-capable long-term services and supports for persons living with or those at high risk of developing Alzheimer's disease and related dementias and their caregivers by providing quality, person-centered services that help them remain independent and safe in their communities.

Eligible applicants include state, city, township, county and special district governments; public and private institutions of higher education and independent school districts; nonprofit organizations; public and Indian housing authorities; Native American tribal governments and organizations; and small businesses. \$9,825,091 is available for ten awards.

Applications are due July 6, 2015.

View the announcement at: GRANTS.GOV

Grant Activity

For information about ACA grants awarded to and grant proposals submitted by the Commonwealth, visit the Grants page of the **Massachusetts National Health Care Reform website** at: www.mass.gov/eohhs/gov/commissions-

Guidance

5/13/15 The Food and Drug Administration (FDA)/HHS issued a notice announcing the availability of a revised draft guidance document for industry entitled “Biosimilars: Additional Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009.” According to the FDA, the guidance is intended to provide answers to common questions from sponsors interested in developing proposed biosimilar products, biologics license application (BLA) holders, and other interested parties regarding FDA's interpretation of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). The guidance revises the draft guidance entitled “Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009,” issued February 15, 2012. This guidance describes FDA's current interpretation of certain statutory requirements added by the BPCI Act and addresses the following topics: biosimilarity or interchangeability; provisions related to the requirement to submit a BLA for a “biological product” and exclusivity.

ACA §7001-7003 amended the Public Health Service Act to create an abbreviated licensure pathway for biological products that are demonstrated to be “biosimilar” to or “interchangeable” with an FDA-licensed biological product. This pathway is provided in the part of the BPCI Act. Under the BPCI Act, a biological product may be demonstrated to be “biosimilar” if data show that, among other things, the product is “highly similar” to an already-approved biological product. A biosimilar product is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.

Comments are due July 13, 2015.

Read the notice at: www.gpo.gov/fdsys/pkg/FR-2015-05-13/pdf/2015-11528.pdf

Read the Question and Answer document at: www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm273001.pdf

5/11/15 HHS/DOL/Treasury issued FAQ Part XXVI, regarding the implementation of the ACA, specifically regarding coverage of preventive services.

Requirements under ACA §1001(2713) and its implementing regulations relating to coverage of preventive services require non-grandfathered group health plans and health insurance coverage offered in the individual or group market to provide benefits for, and prohibit the imposition of cost-sharing requirements with respect to (among other topics addressed) evidence-informed preventive care and screening provided for in comprehensive guidelines supported by HRSA, to the extent not included in certain recommendations of the U.S. Preventive Services Task Force (USPSTF).

Topics addressed in the FAQ include: coverage of breast cancer susceptibility genes (known as BRCA1 or BRCA2), coverage of Food and Drug Administration (FDA)-approved contraceptives, coverage of well-woman preventive care for dependents and coverage of colonoscopies pursuant to USPSTF recommendations.

Under the ACA, most health plans are required to provide women with coverage for recommended preventive care without charging a co-payment, co-insurance or a deductible. Women's preventive health services include well-woman visits, support for breastfeeding equipment, contraception, and domestic violence screening and counseling.

On July 28, 2014 HHS/Treasury/DOL issued a [final rule](#) called "Coverage of Certain Preventive Services Under the Affordable Care Act" which implements provisions under ACA §1001(2713) that provide women with coverage for

preventive care that includes all-FDA approved contraceptive services without cost sharing, while respecting the concerns of certain religious organizations, including certain non-profit religious organizations. Under the final rule non-exempt, non-grandfathered group health plans are required to provide such coverage. Group health plans of "religious employers" are exempted from the requirement to provide contraceptive coverage if they have religious objections to contraception. In FAQ Part 26, the agencies clarified that issuers must provide no-cost access to at least one version of all 18 FDA-approved contraceptives.

The USPSTF is an independent panel of non-federal government experts that conduct reviews of scientific evidence of preventive health care services. The USPSTF then develops and publishes recommendations for primary care clinicians and health systems in the form of recommendation statements. As part of their recommendations process, the USPSTF will assign definitions to the services they review based on the certainty that a patient will receive a substantial benefit from receiving the benefit. Services that are graded "A" and "B" are highly recommended and the USPSTF believes there is a high certainty that patient will receive a substantial or moderate benefit. Under ACA §1001, all of the recommended services receiving grades of "A" or "B" must be provided without cost-sharing when delivered by an in-network health insurance provider in the plan years (or, in the individual market, policy years) that began on or after September 23, 2010.

Read FAQ Part 26 at: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf

Prior guidance can be found at: www.hhs.gov/healthcare/index.html

News

5/13/15 The Patient-Centered Outcomes Research Institute (PCORI) announced more than \$1.16 million for seven grant awards through the Eugene Washington PCORI Engagement Program.

The Eugene Washington PCORI Engagement Awards encourage active integration of patients, caregivers, clinicians, and other healthcare stakeholders who are part of the medical research process. The program provides a platform to expand the role of these stakeholders in research and to support PCORI engagement strategies that include developing a skilled community of patients and other stakeholders.

The seven awards will be used for studies being conducted at Emory University, the Emory University School of Nursing, the National Alopecia Areata Foundation, the Oregon Health and Science University, the University of Kansas Center for Research, Inc., the Wisconsin Research and Education Network and Yale University.

Created under ACA §6301, PCORI is an independent nonprofit organization, tasked with conducting patient-centered outcomes and studies.

To learn more about these awards, visit: PCORI.ORG

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Upcoming Events

Integrating Medicare and Medicaid for Dual Eligible Individuals (also known as One Care) Implementation Council Meeting

Friday, May 29, 2015
1:00 PM - 3:00 PM
1 Ashburton Place, 21st Floor
Boston, MA

MBTA and driving directions to the Transportation Building are available here: www.mhd.state.ma.us/default.asp?pgid=dist/HQ_directions&sid=about.

MBTA and driving directions to 1 Ashburton Place are located here: www.sec.state.ma.us/secdir.htm.

A meeting agenda and any meeting material will be distributed prior to the meeting. Reasonable accommodations are available upon request. Please contact Donna Kymalainen at Donna.Kymalainen@umassmed.edu to request accommodations.

Integrating Medicare and Medicaid for Dual Eligible Individuals (also known as One Care) Open Meeting

Monday, June 8, 2015
10:00 AM – 12:00 PM
1 Ashburton Place, 21st Floor
Boston, MA

The purpose of this meeting is to continue discussion of key implementation topics for One Care. An agenda will be provided in advance of the meeting.

We welcome attendance from all stakeholders and members of the public with an interest in One Care. Reasonable accommodations will be made for participants who need assistance. Please send your request for accommodations to Donna Kymalainen at Donna.Kymalainen@state.ma.us.

Bookmark the **Massachusetts National Health Care Reform website** at: [National Health Care Reform](#) to read updates on ACA implementation in Massachusetts.

Remember to check the Mass.Gov website at: [Dual Eligibles](#) for information on the "**Integrating Medicare and Medicaid for Dual Eligible Individuals**" initiative.



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