



AFFORDABLE CARE ACT MASSACHUSETTS IMPLEMENTATION UPDATE

April 11, 2016

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

4/5/16 The Patient Centered Outcomes Research Institute (PCORI) announced three grant opportunities. Created under ACA §6301, PCORI is an independent nonprofit organization, tasked with conducting patient-centered outcomes research and studies.

For all three opportunities, mandatory Letters of Intent (LOI) are due May 4, 2016 and applications are due August 8, 2016.

For more information about PCORI, visit: PCORI.ORG

For more information about PCORI funding opportunities, visit: PCORI.ORG

Pragmatic Clinical Studies to Evaluate Patient-Centered Outcomes: Funding is available to address prevention, diagnosis, treatment, or management of a disease or symptom to improve healthcare system-level approaches to managing care; communicating or disseminating research results to patients, caregivers, or clinicians; or eliminating health or healthcare disparities.

Eligible applicants include: private or public research organizations; nonprofit or for-profit organizations; university or college hospitals or healthcare systems; or local, state, or federal government agencies. \$90 million is available for studies.

An announcement for this opportunity can be viewed at: PCORI.ORG

Dissemination and Implementation of PCORI Funded Patient-Centered Outcomes Research

Results and Products in Real World Settings: Funding is available to support the dissemination and implementation of patient-centered outcomes research results and products attained from PCORI-funded studies. This opportunity is designed to give PCORI awardees and their patient and stakeholder partners the opportunity to help close the gap between evidence development and implementation of that evidence in practice.

Eligible applicants include: private or public research organizations; nonprofit or for-profit organizations; university or college hospitals or healthcare systems; or local, state, or federal government agencies. \$2 million is available for these studies.

An announcement for this opportunity can be viewed at: PCORI.ORG

Comparison of Surgical and Nonsurgical Options for Management of Nonspecific Chronic Low Back Pain: Funding is available to study ways to improve treatment of chronic lower back pain- a leading cause of disability and one of the most frequent reasons adults seek medical care. Studies should compare optimal clinical strategies that both do and don't include spinal fusion surgery.

Eligible applicants include: private or public research organizations; nonprofit or for-profit organizations; university or college hospitals or healthcare systems; or local, state, or federal government agencies. \$22 million is available for these studies.

An announcement for this opportunity can be viewed at: PCORI.ORG

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-and-initiatives/healthcare-reform/national-health-care-reform-plan/grants-and-demonstrations.html

Guidance

4/4/16 HHS/FDA released a Notice of Availability of a draft guidance for industry entitled "Labeling for Biosimilar Products."

The draft guidance is intended to assist applicants in developing draft prescription drug labeling for proposed biosimilar products. The recommendations for prescription drug labeling in this guidance pertain only to the prescribing information (commonly referred to as the package insert). The draft guidance provides an overview of FDA's recommendations for labeling for biosimilar products licensed under the Public Health Service Act (PHS Act).

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 Biologics Price Competition and Innovation Act of 2009 (BCPI 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.

In the draft guidance, FDA outlines its recommendations for biosimilar product labeling. A demonstration of biosimilarity means, among other things, that FDA has determined that there are no clinically meaningful differences between the proposed product and the reference product in terms of safety, purity and potency. Accordingly, biosimilar applicants should incorporate relevant data and information from the reference product labeling, with appropriate product specific modifications as described in the draft guidance.

FDA invites comment on the draft guidance, including whether patient labeling (*e.g.*, Patient Information, Medication Guide, and Instructions for Use) should include a biosimilarity statement similar to the statement described in section IV.C.1 of the draft guidance.

Comments should be submitted by June 3, 2016.

Read the draft guidance at: www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM493439.pdf

Read the notice at: <https://www.gpo.gov/fdsys/pkg/FR-2016-04-04/pdf/2016-07611.pdf>

4/1/16 HHS/CMS issued a notice under the Paperwork Reduction Act of 1995 (PRA) seeking comments on the extension of a currently approved collection activity related to Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment.

Beginning October 1, 2013, qualified individuals and qualified employees could purchase private health insurance coverage through Exchanges for January 1, 2014 effective dates. The ACA established Affordable Insurance Exchanges (§1311(b)) to provide individuals and small business employees with access to health insurance coverage beginning January 1, 2014. The Exchanges, which became operational on January 1, 2014, enhanced competition in the health insurance market, expanded access to affordable health insurance

for millions of Americans, and provided consumers with a place to easily compare and shop for health insurance coverage. §1311(b)(1)(B) also requires that Small Business Health Options Program (SHOP) assist qualified small employers in facilitating the enrollment of their employees in qualified health plans offered in the small group market. QHPs are health plans that have been certified by an Exchange, provide EHB, and follow established limits on cost-sharing (like deductibles, copayments, and out-of-pocket maximum amounts).

The reporting requirements and data collection in Medicaid, Children's Health Insurance Programs (CHIP), and Exchanges: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment [final rule](#) (which was published in the Federal Register on July 15, 2013) addresses: (1) standards related to member notices, (2) procedures for the verification of enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan; and (3) other eligibility and enrollment provisions to provide detail necessary for state implementation.

Comments are due May 31, 2016.

Read the notice at: <https://www.gpo.gov/fdsys/pkg/FR-2016-04-01/pdf/2016-07423.pdf> (see item #4)

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

News

4/5/16 The U.S. Preventive Services Task Force (USPSTF) issued a final recommendation statement on screening for chronic obstructive pulmonary disorder (COPD) in asymptomatic adults. The Task Force recommends against such screening for COPD and assigned a "D" grade to the recommendation.

According to the USPSTF, COPD is a serious, chronic condition that affects a person's ability to breathe. It is the third leading cause of death in the United States. The most common symptoms of COPD are difficulty breathing, chronic cough, phlegm production, and wheezing. Smoking is the main risk factor for COPD; more than 70% of people with COPD are current or former smokers.

The Task Force's review concluded that there is no evidence that screening for COPD in adults without symptoms

results in improved health outcomes. The USPSTF stated that avoiding smoking is the most important step a person can take to prevent COPD.

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. Since the recommendation on screening for COPD in asymptomatic adults was finalized with a "D" rating, then such screening will not be required to be provided without cost sharing.

Read the final recommendation statement at: www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/chronic-obstructive-pulmonary-disease-screening

Learn more about preventive services covered under the ACA at: HHS.Gov

Learn more about the USPSTF at: www.uspreventiveservicestaskforce.org

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

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



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