



## AFFORDABLE CARE ACT MASSACHUSETTS IMPLEMENTATION UPDATE

July 28, 2014

### 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

**Eugene Washington Patient-Centered Outcomes Research Institute (PCORI) Engagement Awards, §6301.** Announced July 22, 2014. Funding is available to develop projects that will foster active integration of patients, caregivers, clinicians, and other healthcare stakeholders as integral members of PCORI's work. Funded projects will promote training of patients and other stakeholders and encourage participation with PCOR; create methods to connect patients and other stakeholders with the research community; and/or facilitate patient and other stakeholder engagement in PCOR.

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. Only eligible applicants that receive an invitation from PCORI will be allowed to apply. \$15.5 million in awards is available.

Required Letters of Intent are accepted on a rolling basis.  
Application deadline (by invitation only) is within 60 days of invitation receipt.

The announcement may be viewed at: [PCORI.ORG](http://PCORI.ORG)

The Patient Centered Outcomes Research Institute (PCORI), created under ACA §6301, PCORI is an independent nonprofit organization, tasked with conducting patient-centered outcomes research and studies.

For more information about PCORI, visit [PCORI](http://PCORI)

For more information about PCORI funding opportunities, visit: [www.pcori.org/funding-opportunities](http://www.pcori.org/funding-opportunities).

## 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](http://www.mass.gov/eohhs/gov/commissions-and-initiatives/healthcare-reform/national-health-care-reform-plan/grants-and-demonstrations.html)

## Guidance

**7/23/14 HHS issued a correction to the final rule called "Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond."** The correction fixes technical errors that appeared in the [final rule](#) (which was published in the Federal Register on May 27, 2014).

The final rule clarifies key policies applicable to Health Insurance Exchanges and the insurance market reforms under Title I of the ACA relating to: qualified health plan (QHP) quality reporting and enrollee satisfaction surveys; standards for consumer notices related to plan policy coverage changes; modifications in the Small Business Health Options Program (SHOP); standards for Navigators and other consumer assisters and modified premium stabilization policies for 2015 and beyond.

Although HHS has previously outlined many of the major provisions in the rule, the rule further addresses various requirements applicable to health insurance issuers in order to improve consumer protections and stabilize premiums. Under the rule, HHS requires that insurers provide clear information to consumers when they make changes to their policies, such as discontinuing or renewing plans. The rule provides additional guidance to Navigator, non-Navigator and certified application counselors to protect consumers and prohibit assisters from specific solicitation activities.

Building upon the existing QHP certification requirements related to quality reporting and implementation of quality improvement strategies, under the rule HHS requires insurers to submit data to support the calculation of quality ratings which Exchanges will be required to display. Beginning in 2016, Exchanges will be required to present the HHS-calculated quality ratings and enrollee satisfaction survey results in a standardized method designed to help consumers compare and chose health plans.

Beginning October 1, 2013, qualified individuals and qualified employees could purchase private health insurance coverage through Exchanges (Marketplaces) 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 in 2014, where low and moderate income Americans may be eligible for premium tax credits (§1401, §1411) to make purchasing a health plan more affordable by reducing out-of-pocket premium costs. §1311(b)(1)(B) also requires that the Small Business Health Options Program (SHOP) assist qualified small employers in facilitating the enrollment of their employees in qualified health programs (QHPs) offered in the small group market. QHPs are health plans that have been certified by an Exchange, provide essential health benefits ("EHB", §1301) and follow established limits on cost-sharing (like deductibles, copayments, and out-of-pocket maximum amounts).

The ACA established three risk-mitigation programs, which HHS began operationalizing in 2014, to stabilize premiums in the individual insurance market and minimize the effects of adverse selection that may occur as

insurance reforms and the Exchanges launch in 2014. These programs include transitional reinsurance (§1341), temporary risk corridors programs (§1342), and a permanent risk adjustment program (§1343) to provide payments to health insurance issuers that cover higher-risk populations and to more evenly spread the financial risk borne by issuers. The transitional reinsurance program and the temporary risk corridors program, which begin in 2014, are designed to provide issuers with greater payment stability as insurance market reforms are implemented. The reinsurance program will reduce the uncertainty of insurance risk in the individual market by partially offsetting risk of high-cost enrollees. The risk corridors program, which is a federally administered program, will protect against uncertainty in rates for qualified health plans by limiting the extent of issuer losses and gains.

Read the correction (which was published in the Federal Register on July 24, 2014) at:  
[www.gpo.gov/fdsys/pkg/FR-2014-07-24/pdf/2014-17403.pdf](http://www.gpo.gov/fdsys/pkg/FR-2014-07-24/pdf/2014-17403.pdf)

**7/21/14 HRSA issued an interpretive rule called “Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program.”** An interpretive rule is used by HRSA to explain how the agency interprets a statute. According to the agency’s summary, the interpretive rule intends to: (1) provide clarity in the marketplace; (2) maintain the 340B Program savings for newly-eligible entities; and (3) protect the financial incentives for manufacturing orphan drugs designated for a rare disease or condition, as indicated in the ACA and intended by Congress.

The 340B Drug Pricing Program, administered by HRSA, requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices. The 340B drug discount program allows certain hospitals, and federally qualified health centers and other specified federal grantee clinics to purchase covered outpatient drugs at discounts.

The interpretive rule restates HRSA’s earlier guidance in a [final rule](#) called “Exclusion of Orphan Drugs for Certain Covered Entities Under 340B Program,” (which was issued on July 23, 2013) and states that section 340B(e) of the PHSA excludes drugs with an orphan designation only when those drugs are transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the drug has been designated.

On May 23, 2014, the U.S. District Court for the District of Columbia issued a [ruling](#) in *Pharmaceutical Research and Manufacturers of America v. US Department of Health and Human Services* that vacated the orphan drug regulation on the grounds that HHS does not have the statutory authority to engage in such rulemaking and issue a substantive rule. However, according to the agency, the decision did not invalidate HHS’s interpretation of the orphan drug exclusion and HRSA continues to stand by the interpretation described in its published final rule.

The final rule provides clarity on orphan drug exclusions for covered entities under the 340B Drug Pricing Program. ACA §7101 expands the covered entities eligible under 340B to include: children’s hospitals and free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals. §7101 also excluded these additional covered entities, except children’s hospitals, from access to 340B drug pricing for an orphan drug when it is used for a rare disease or condition. Orphan status designation by the FDA indicates that the drug has been found promising for treating a rare disease.

The final rule implements §7101 and further provides for 340B discount pricing for orphan drugs that are used to treat non-orphan conditions. According to HHS, the final rule protects the financial incentives for manufacturing orphan drugs designated for a rare disease or condition as indicated in the ACA.

More information on the 340B Drug Pricing Program is available at: [www.hrsa.gov/opa/](http://www.hrsa.gov/opa/)

Read the interpretive rule (which was published in the Federal Register on July 23, 2014) at:  
[www.gpo.gov/fdsys/pkg/FR-2014-07-23/pdf/2014-17409.pdf](http://www.gpo.gov/fdsys/pkg/FR-2014-07-23/pdf/2014-17409.pdf)

**7/17/14 DOL/HHS/Treasury issued FAQ Part XX regarding the implementation of the ACA, specifically employer disclosure requirements with respect to coverage of preventive services under ACA §1001 (2713).** According to the FAQ, employers who opt of the requirement to provide contraception under the ACA must follow policies pursuant to the Employee Retirement Income Security Act

of 1974 (ERISA) and notify their employees about the lack of coverage. [ERISA](#) is a federal law that sets minimum standards for pension plans in private industry.

The FAQ applies to “closely-held for-profit corporations” and clarifies what the disclosure requirements are for employers who opt-out of providing coverage, including specific requirements for changes made during a plan year. The guidance follows the June 30, 2014 Supreme Court [decision](#) to allow closely-held for-profit corporations to use the accommodation previously outlined by HHS for companies who object to providing contraceptive services as part of the benefits under the ACA-required women’s preventive services. The FAQ provides clarification on the actions required of such employers who decide not to offer such coverage and states that if they decide to stop covering contraceptive services they must notify their workers about the reduction in benefits.

The ruling issued earlier this summer by the Supreme Court in the *Burwell v. Hobby Lobby Stores, Inc.* case allows certain employers to withhold contraceptive care from their employees' health coverage based on their own religious beliefs.

On July 28, 2014 the agencies 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.

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. The rule ensures that such non-profit organizations with religious objections won't have to contract, arrange, pay, or refer for insurance coverage for these services to their employees.

Women's preventive health services include well-woman visits, support for breastfeeding equipment, contraception, and domestic violence screening and counseling.

For more information on women's preventive services coverage, visit: [HHS.Gov](#)

Read the FAQ Part XX at: [www.dol.gov/ebsa/faqs/faq-aca20.html](http://www.dol.gov/ebsa/faqs/faq-aca20.html)

Prior guidance can be found at: [www.hhs.gov/healthcare/index.html](http://www.hhs.gov/healthcare/index.html)

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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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