



## AFFORDABLE CARE ACT MASSACHUSETTS IMPLEMENTATION UPDATE

May 04, 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

**Asian Language Tobacco Quitline**, §4002. Announced April 29, 2015.

Funding is available to state and territorial health departments to operate and promote a fully linguistically and culturally appropriate nationwide Quitline service for tobacco users who predominantly speak Chinese, Korean, or Vietnamese languages. The project will also include, as appropriate, the distribution of FDA-approved cessation medications to Quitline callers.

Eligible applicants are limited to states and territories that currently operate a proactive tobacco cessation telephone Quitline that provides counseling in Chinese (Mandarin and Cantonese), Korean or Vietnamese languages. \$3,000,000 in total is available for three awards.

Created through the CDC's first national tobacco education campaign (Tips From Smokers), the Quitline is a free

telephone helpline (1-800-QUIT-NOW) which routes callers to their state Quitlines, offering assistance and treatment for tobacco-related addiction and behavior issues.

Applications are due June 29, 2015

You can learn more about this program by visiting: [CDC.GOV](http://CDC.GOV)

View the announcement at: [GRANTS.GOV](http://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-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

**4/30/15 HHS/CMS issued a correction to Title 45 of the Code of Federal Regulations, Parts 1 to 199, as authorized by the final rule Patient Protection and Affordable Care Act; Annual Eligibility Redeterminations for Exchange Participation and Insurance Affordability Programs; Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges** (which was published in the Federal Register on September 5, 2014). The correction relates to additional standards specific to the Small Business Health Options Program (SHOP).

§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 [final rule](#) called "Patient Protection and Affordable Care Act; Annual Eligibility Redeterminations for Exchange Participation and Insurance Affordability Programs; Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges" (published in the Federal Register on September 2, 2014), specifies options for annual eligibility redeterminations and renewal and re-enrollment notice requirements for qualified health plans (QHPs) offered through the Exchange.

The final rule also amends the requirements for product renewal and re-enrollment (or nonrenewal) notices to be sent by QHP issuers in the Exchanges and specifies content for these notices. According to CMS, states that are enforcing the ACA may develop their own standard notices, for product discontinuances, renewals, or both, provided the State-developed notices are at least as protective as the federal standard notices.

Read the correction at: [www.gpo.gov/fdsys/pkg/FR-2015-04-30/pdf/2015-09681.pdf](http://www.gpo.gov/fdsys/pkg/FR-2015-04-30/pdf/2015-09681.pdf)

**4/30/15 The Food and Drug Administration (FDA)/HHS issued several guidance documents related to the FDA's interpretation of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act).**

**HHS/FDA issued a notice announcing the availability of a guidance document for industry entitled "Biosimilars: 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 BPCI Act. The guidance finalizes several questions and answers (Q&As) from 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 can be submitted at any time.

Read the notice at: [www.gpo.gov/fdsys/pkg/FR-2015-04-30/pdf/2015-10064.pdf](http://www.gpo.gov/fdsys/pkg/FR-2015-04-30/pdf/2015-10064.pdf)

Read the Question and Answer document at:

[www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM444661.pdf](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM444661.pdf)

**HHS/FDA issued a notice announcing the availability of a guidance document for industry called “Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product.”**

According to the FDA, the guidance is intended to provide sponsors with an overview of analytical factors that are relevant to assessing whether a proposed product and the reference product are highly similar for the purpose of submitting a marketing application through an abbreviated licensure pathway. This guidance finalizes the draft guidance issued in February 2012 entitled “Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product.” The guidance addresses the following topics: expression system, manufacturing process, assessment of physicochemical properties, functional activities, receptor binding and immunochemical properties, impurities, reference product and reference standards, finished drug product and stability.

Comments can be submitted at any time.

Read the notice at: [www.gpo.gov/fdsys/pkg/FR-2015-04-30/pdf/2015-10063.pdf](http://www.gpo.gov/fdsys/pkg/FR-2015-04-30/pdf/2015-10063.pdf)

Read the guidance document at: [www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm291134.pdf](http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm291134.pdf)

**HHS/FDA issued a notice announcing the availability of a guidance for industry called “Scientific Considerations in Demonstrating Biosimilarity to a Reference Product.”**

According to the FDA, the guidance is intended to assist sponsors in demonstrating that a proposed therapeutic protein product is biosimilar to a reference product for the purpose of submitting a marketing application through an abbreviated licensure pathway. This guidance finalizes the draft guidance issued in February 2012 entitled “Scientific Considerations in Demonstrating Biosimilarity to a Reference Product.” The guidance addresses the following topics: quality considerations in demonstrating biosimilarity of a therapeutic protein product to a reference product, scientific considerations in demonstrating biosimilarity to a reference product, Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009, formal meetings between the FDA and Biosimilar Biological Product Sponsors or Applicants, and clinical pharmacology data to support a demonstration of biosimilarity to a reference product.

Comments can be submitted at any time.

Read the notice at: [www.gpo.gov/fdsys/pkg/FR-2015-04-30/pdf/2015-10062.pdf](http://www.gpo.gov/fdsys/pkg/FR-2015-04-30/pdf/2015-10062.pdf)

Read the guidance document at: [www.fda.gov/ucm/groups/fdagov-public/documents/document/ucm291128.pdf](http://www.fda.gov/ucm/groups/fdagov-public/documents/document/ucm291128.pdf)

**4/29/15 HHS/CMS issued a correction to a final ruled called "Medicare Program; FY 2015 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements and Process and Appeals for Part D Payment for Drugs for Beneficiaries Enrolled in Hospice."** The document makes corrections to the [final rule](#) which was published in the Federal Register on August 22, 2014. The final rule implements portions of ACA sections 3004, 3132 and 3401.

The rule updates the Medicare hospice payment rates and the wage index for fiscal year 2015 and continues the phase out of the wage index budget neutrality adjustment factor. According to CMS, the final rule reflects the agency's ongoing efforts to protect beneficiary access to patient-centered hospice care. The rule also provides an update on two hospice-related definitions and on a process and appeals for Part D payment for drugs while beneficiaries are under a hospice election.

Read the correction (which was published in the Federal Register on April 30, 2015) at: [www.gpo.gov/fdsys/pkg/FR-2015-04-30/pdf/2015-10169.pdf](http://www.gpo.gov/fdsys/pkg/FR-2015-04-30/pdf/2015-10169.pdf)

**4/28/15 HHS/CMS issued a notice under the Paperwork Reduction Act of 1995 (PRA) seeking comments on the extension of a currently approved information collection activity related to Initial Plan Data Collection to Support Qualified Health Plan (QHP) Certification and Other Financial Management and Exchange Operations.**

As required by the ACA, each Exchange must assume responsibilities related to the certification and offering of Qualified Health Plans (QHPs). In addition to data collection for the certification of QHPs, the reinsurance and risk adjustment programs outlined by the ACA, detailed in the December 7, 2012 [proposed rule](#) regarding Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2014, have general information reporting requirements that apply to issuers, group health plans, third party administrators, and plan offerings outside of the Exchanges. Subsequent regulations for these programs including the [final HHS Notice of Benefit and Payment Parameters for 2014 and the Program Integrity: Exchange, Premium Stabilization Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014](#), and the [final HHS Notice of Benefit and Payment Parameters for 2015](#) provide further reporting requirements.

Comments are due May 28, 2015.

Read the notice at: [www.gpo.gov/fdsys/pkg/FR-2015-04-28/pdf/2015-09849.pdf](http://www.gpo.gov/fdsys/pkg/FR-2015-04-28/pdf/2015-09849.pdf)

**4/28/15 HHS/CMS issued a notice under the Paperwork Reduction Act of 1995 (PRA) seeking comments on the revision of a currently approved information collection activity related to Health Insurance Marketplace Consumer Experience Surveys: Qualified Health Plan Enrollee Experience Surveys.** In order to support the delivery of quality health care coverage offered in the Exchanges, ACA §1311 directs the HHS Secretary to develop a system that rates qualified health plans (QHPs) based on their relative quality and price.

ACA §1311 also directs HHS to develop an enrollee satisfaction survey system that assesses consumer experience with QHPs. For implementation of a Quality Rating System (QRS) and the enrollee surveys, QHP issuers are required to collect and report certain data to HHS.

Additionally, beginning January 1, 2015, QHPs are required to contract with certain hospitals that meet specific patient safety and health care quality standards. QHP issuers must also demonstrate compliance with patient safety standards and the related record keeping and information collection requirements.

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 January 1, 2014. Furthermore, an Exchange makes an advance determination of tax credit eligibility for individuals who enroll in a qualified health plan (QHP) through the Exchange and pursue financial assistance (§1401, 1411, and 1412). QHPs are health plans that have been certified by an Exchange, provide essential health benefits (EHB, §1301) and follow established limits on cost-sharing (such as reduced deductibles, copayments, and out-of-pocket maximum amounts).

Comments are June 29, 2015.

Read the notice at: [www.gpo.gov/fdsys/pkg/FR-2015-04-28/pdf/2015-09850.pdf](http://www.gpo.gov/fdsys/pkg/FR-2015-04-28/pdf/2015-09850.pdf)

**4/24/15 IRS/Treasury issued Notice 2015-37, Eligibility for Minimum Essential Coverage for Purposes of the Premium Tax Credit**, which states that an individual who may enroll in a Children's Health Insurance (CHIP) "buy-in" program that HHS has designated as [minimum essential coverage](#), or MEC, (ACA §1501), is eligible for that coverage under the program for purposes of the premium tax credit only for the period the individual is enrolled.

Beginning in 2014, certain individuals covered under a qualified health plan (QHP) through the Health Insurance Marketplace (Exchange) are allowed a premium tax credit under §36B of the Internal Revenue Code. Under the IRS Code, coverage of an individual (who may be the taxpayer claiming the premium tax credit or a member of the taxpayer's family) may be subsidized by the premium tax credit only for months the individual is not eligible for other MEC, except coverage in the individual market.

Beginning October 1, 2013, qualified individuals and qualified employees could purchase private health insurance coverage through competitive marketplaces called Affordable Insurance Exchanges (also called Health Insurance Marketplaces). 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, where low and moderate income Americans will be eligible for premium tax credits (§1401, §1411) to make purchasing a health plan more affordable by reducing out-of-pocket premium costs.

QHPs are health plans that have been certified by an Exchange, provide essential health benefits (§1301) and follow established limits on cost-sharing (like deductibles, copayments, and out-of-pocket maximum amounts). A QHP must have a certification by each Exchange in which it is sold. ACA §1311 and subsequent regulations provide that, in order to be certified as a QHP and operate in the Exchanges that will be operational in 2014, a health plan must be accredited on the basis of local performance by an accrediting entity recognized by HHS.

The premium tax credit is designed to make purchasing a health plan on the Exchange affordable for low and moderate income Americans by reducing a taxpayer's out-of-pocket premium cost. To be eligible to receive the premium tax credit, individuals and families must have incomes between 100%- 400 % FPL (or between 0% - 400% FPL if lawfully present and ineligible for Medicaid) and be enrolled in a qualified health plan (QHP) through an exchange. The individual must also be ineligible for government sponsored insurance and not have access to employer sponsored insurance that meets definitions of affordability and minimum essential coverage as established by ACA §1401. Advance payments are made monthly under ACA §1412 to the issuer of the QHP in which the individual enrolls. ACA §1402 provides for the reduction of cost sharing for certain individuals enrolled in QHPs offered through the Exchanges and §1412 provides for the advance payment of these reductions to issuers.

For more information on the premium tax credit, visit the IRS at: [www.irs.gov/Affordable-Care-Act/Individuals-and-Families/The-Premium-Tax-Credit](http://www.irs.gov/Affordable-Care-Act/Individuals-and-Families/The-Premium-Tax-Credit)

Read the notice at: [www.irs.gov/pub/irs-drop/n-15-37.pdf](http://www.irs.gov/pub/irs-drop/n-15-37.pdf)

**4/23/15 HHS/CMS issued a proposed rule called "Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2016."**The rule implements portions of ACA §3004 and §3401.

The proposed rule updates the prospective payment rates for inpatient rehabilitation facilities (IRFs) for fiscal year 2016 as required by statute. Under the rule, CMS also proposes an IRF-specific market basket that reflects the cost structures of only IRF providers, phases in the revised wage index changes, and revises and updates quality measures

and reporting requirements under the IRF quality reporting program.

Comments are due June 22, 2015.

Read the rule (which was published in the Federal Register on April 27, 2015) at:

[www.gpo.gov/fdsys/pkg/FR-2015-04-27/pdf/2015-09617.pdf](http://www.gpo.gov/fdsys/pkg/FR-2015-04-27/pdf/2015-09617.pdf)

**4/17/15 HHS/CMS issued a proposed rule called “Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and Fiscal Year 2016 Rates; Revisions of Quality Reporting Requirements for Specific Providers, including Changes Related to the Electronic Health Record Incentive Program.”** The rule implements portions of the following ACA Sections: 1105, 3001, 3003, 3004, 3005, 3008, 3021, 3025, 3106, 3123, 3125, 3133, 3141, 3313, 3401, 10309, 10312, 10313, 10314, 10319 and 10324.

The proposed rule updates fiscal year 2016 Medicare payment policies and rates under the Inpatient Prospective Payment System (IPPS) and the Long-Term Care Hospital (LTCH) Prospective Payment System (PPS). The proposed rule, which applies to approximately 3,400 acute care hospitals and approximately 435 LTCHs, will affect discharges occurring on or after October 1, 2015.

The IPPS pays hospitals for services provided to Medicare beneficiaries using a national base payment rate, adjusted for a number of factors that affect hospitals' costs, including the patient's condition and market conditions to the hospital's geographic area.

According to CMS, the proposed rule proposes policies that continue a commitment to increasingly shift Medicare payments from volume to value. The proposed rule includes policies that focus on paying providers based on quality rather than the quantity of care they give patients and support building a health care system that delivers better care, spends health care dollars more wisely and results in improved health outcomes for individuals.

Comments are due June 16, 2015.

Read the proposed rule (which was published in the Federal Register on April 30, 2015) at:

[www.gpo.gov/fdsys/pkg/FR-2015-04-30/pdf/2015-09245.pdf](http://www.gpo.gov/fdsys/pkg/FR-2015-04-30/pdf/2015-09245.pdf)

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

## 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](http://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](http://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](mailto:Donna.Kymalainen@umassmed.edu) to request accommodations.

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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