# Health Reform Implementation Tracking Update (Sept. ed.)

*October 3, 2016*

Please find below all key developments in implementation of the Affordable Care Act (ACA) during the month of September. These updates are being posted to our online catalogue of ACA implementation here, which is indexed by title and section of the law. We hope you find this to be a helpful recap and reminder of the broad range of regulations, guidance, grants, demonstrations and nomination opportunities released under the ACA.

**Title I – Insurance Market Reforms**

- **PHSA Section 2713 (Section 1001) – Preventive Services** – Key developments include:
  - On Sept. 6, the USPSTF released a final recommendation statement on screening for latent tuberculosis infection in adults. The Task Force issued a grade "B" recommendation on screening among asymptomatic adults who are at increased risk of infection with tuberculosis.
  - On Sept. 28, the USPSTF issued a request for public comments on a draft recommendation statement and draft evidence review on screening for preeclampsia. In the statement, the Task Force issues a grade B recommendation in support of screening for preeclampsia in pregnant women with blood pressure measurements throughout pregnancy. Comments are due by Oct. 24.
- **PHSA 2794 (Section 1003) – Rate Review** – On Sept. 26, CCIIO posted guidance on the "manner in which an issuer must "prominently post" the required rate filing information and its Final Justification for implementing a rate increase deemed to be "unreasonable" and clarifies the type of information that an issuer must include in its Final Justification."
- **PHSA Section 2703 (Section 1201), Sections 1311, 1321 – Guaranteed Renewability, Exchanges** – Key developments include:
  - On Sept. 2, CCIIO posted updated federal standard renewal and product discontinuation notices based on enrollees' movement out of the service areas. They are generally for use beginning in 2018 policy years.
  - On Sept. 16, CMS released an information collection notice addressing 2017 annual redeterminations and reenrollments, as well as specified discontinuation notices (see above). Comments are due by Oct. 17.
- **Sections 1302, 1311, 1321 – Essential Health Benefits, Exchanges** – On Aug. 31, CMS released details on the process through which providers may petition for inclusion – or correct their existing status – as Essential Community Providers (ECPs) under the ACA requirements for QHPs. Data corrections and suggested additions for the 2018 list are due via petition by Oct. 15, 2016.
- **Sections 1311, 1321 – Exchanges** – Key developments include:
  - In an Aug. 29 FAQ, CMS outlined the Medicaid and CHIP Periodic Data Matching Process, through which its cross-references Marketplace enrollees who receive premium subsidies with Medicaid and CHIP beneficiaries whose coverage is minimum essential coverage. Additional slides on final notices are posted here. Also see slides on Medicare-Marketplace Periodic Data Matching.

1720 Eye St. NW – Ste. 400 | Washington D.C. 20006 | (202) 309-0796 | bwynne@thornrun.com

- On Aug. 30, CMS addressed questions on its follow-up on QHPs' quality improvement strategy implementation plan and progress report forms (here) and process for notifying issuers of evaluation results, including deficiencies or concerns (here).
- In an Aug. 31 FAQ, CMS explained the portions of its enrollment manual that address Federally Facilitated Marketplace QHP reenrollment binder payments and effectuation confirmation.
- On Sept. 6, CMS announced the award of $63 million in Navigator grants to help consumers determine their eligibility and enroll in Federally-facilitated (FFM) or State Partnership Marketplaces (SPMs).
- In a Sept. 6 FAQ, CCIIO explained its flexibility to adjust Marketplace enrollments based on QHP issuers' capability to absorb enrollments, among other considerations. States had to submit their alternate enrollment plans by Sept. 13, 2016, if applicable.
- On Sept. 6, noting a decline in recent special enrollment period (SEP) activity, CCIIO contemplated a 2017 pilot through which it would continue to verify Marketplace SEPs. The agency sought feedback on whether the pilot should be geographically defined or should involve a subset of Healthcare.gov enrollees (due: Sept. 20).
- On Sept. 12, the GAO released three reports, two addressing undercover testing of the Marketplaces for Coverage Year 2015 and 2016, and the other about consumer satisfaction with plans on the market. See here, here, and here.
- On Sept. 14, the House Oversight and Government Reform Committee held a hearing examining ACA premiums at which several state Insurance Commissioners testified, among others.
- On Sept. 14, the House E&C Subcommittees on Health and Oversight and Investigations held a joint hearing to examine Exchanges' stability and outlook.
- On Sept. 16, CMS outlined a safe harbor from specified Federally Facilitated Marketplace requirements for issuers experiencing a significant enrollment increase in 2017. Affected standards include health insurance case work and customer service for issuers that "have experienced a substantial increase in enrollment make reasonable efforts to address concerns in an appropriate time frame."
- On Sept. 26, Senate HELP Chairman Lamar Alexander (R-TN) released a statement on BlueCross BlueShield of Tennessee's decision to only offer individual and Marketplace plans in five of eight regions statewide for 2017.
- On Sept. 27, the Alliance for Health Reform held a congressional briefing on the decisions of several large insurers to scale back their 2017 Marketplace participation.
- On Sept. 27, CMS announced a new campaign intended to enroll young adults during the upcoming Open Enrollment period for Marketplace coverage. The announcement was made in conjunction with the White House Millennial Outreach and Enrollment Summit convened that today.
- On Sept. 29, the HHS OIG released a report, "Vermont Did Not Properly Allocate Millions to Establishment Grants for a Health Insurance Exchange" (see here).

- **Sections 1311, 1321, 1402 – Exchanges, Premium Tax Credit** – On Sept. 1, the IRS posted a "tax tip" for Marketplace enrollees regarding reporting changes in circumstances, "Moving in 2016? Notify Your Marketplace about Your New Address."
- **Sections 1322 – CO-OPs** – Key developments include:
  - On Sept. 6, the GAO issued an ACA-required report finding market concentration in the private insurance market of many states in 2014, including Exchanges.

- On Sept. 12, Health Republic Insurance of New Jersey announced that it would close, bringing the remaining CO-OPs to six, according to a House E&C Committee Republican release.
- On Sept. 15, the House E&C Committee Republicans released a staff report on the CO-OP program, including policy recommendations for CMS oversight and risk adjustment modifications, among other ideas.

- **Sections 1322, 1501 – CO-OPs, Individual Mandate** – On Sept. 27, the White House issued a Statement of Administration Policy opposing H.R. 954, the CO-OP Consumer Protection Act of 2016, which passed the House. It would temporarily exempt individuals from tax penalties if his or her insurance coverage ended mid-year because of a CO-OP closure.
- **Section 1341 – Reinsurance** – Key developments included:
  - On Sept. 20, CMS posted slides addressing ACA reinsurance supporting documentation as well as slides on counting methods.
  - On Sept. 21, CMS issued an FAQ recapping the steps that contributing entities follow as part of the ACA reinsurance collections process.
  - On Sept. 29, the GAO released a decision concluding that "HHS lacks authority to ignore the statute's directive to deposit amounts from collections under the transitional reinsurance program in the Treasury and instead make deposits to the Treasury only if its collections reach the amounts for reinsurance payments specified in section 1341."
- **Sections 1341, 1343 – Reinsurance, Risk Adjustment** – On Aug. 30, CMS released slides describing its web-based process for QHPs "reporting on the status of their EDGE servers for 2016 benefit year data submission.
- **Section 1342 – Risk Corridors** – Key developments include:
  - On Sept. 9, CCIIO announced that based on preliminary estimates, no funding will be available at this time for 2015 benefit year ACA risk corridor payments because all 2015 collections will be used for outstanding 2014 risk corridor payments. The agency also recognizes the litigation brought by some QHP issuers based on risk corridor payments that have not been fully received. CCIIO says while the DOJ is defending those claims, "as in all cases where there is litigation risk, we are open to discussing resolution of those claims." CCIIO says it is "willing to begin discussions at any time."
  - On Sept. 20, House E&C Republicans wrote to Secretary Burwell seeking details on risk corridor settlement plans. They ask whether HHS believes it is legal to use the DOJ Judgement Fund for such purposes and request additional information they had asked that Administrator Slavitt provide in follow up during a recent hearing.
  - On Sept. 27, Sens. Mike Lee (R-UT), John Barrasso (R-WY), Marco Rubio (R-FL), and Ben Sasse (R-NE) wrote to HHS inquiring about risk corridor settlement plans.
- **Sections 1502, 1512 – Information Reporting** – On Sept. 29, the IRS announced that software developers and transmitters may access recent webinars on ACA Information Return processes (Aug. 23 slides; Aug. 20 slides; July 19 slides; July 14 slides).

**Title II – Medicaid & CHIP**

- **Section 2001 – Medicaid Coverage for the Lowest Income Populations** – On Sept. 27, CMS released state-reported Medicaid and CHIP eligibility and enrollment data for July 2016. According to the latest report, an additional 134,541 people were enrolled in Medicaid or CHIP during the month of July, as compared to June data, amounting to more than 72.8 million total enrollees. Within the 48 states that reported child enrollment figures for the month of July, total Medicaid child and CHIP enrollment reached nearly 35.4 million.

- **Section 2201 – Enrollment Simplification and Coordination with State Health Insurance Exchanges** – On Sept. 30, CMS issued an informational bulletin, offering ways that states utilizing the federally-facilitated marketplace (FFM) can assist in enrollment for individuals when their eligibility is denied under Medicaid or CHIP. The bulletin also provides information to help state-based marketplaces improve their eligibility and enrollment coordination with Medicaid and CHIP programs.
- **Sections 2501 and 2503 – Prescription Drug Rebates; and Providing Adequate Pharmacy Reimbursement** – On Sept. 29, CMS released the latest FULs for multi-source Medicaid drugs, which are calculated according to the methodology finalized in the Medicaid outpatient drug rule. CMS continues to also post National Average Drug Acquisition Cost (NADAC) weekly and the weekly comparison data.
- **Section 2602 – Providing Federal Coverage and Payment Coordination for Dual Eligible Beneficiaries (Including Financial Alignment Initiative Update)]** – Key updates include CMS posting here and/or here of the updated National Enrollment/Disenrollment Guidance for States and MMPs; the PowerPoint slides for the MMP Provider Pharmacy Directory (PPD) Technical Assistance Call that was held on Sept. 8, 2016; the CY 2017 MMP Drug Only and Integrated EOB Models; and the CY 2016 Reporting Requirements Core Measure 2.1 FAQs. State-specific postings include: (1) California – CY 2017 Member ID Card and DN; (2) New York – CY 2017 MMP Delegated Notices (P1, P2, P3, P4 & P5) for the New York FIDA IDD model, as well as the final State-Specific Reporting Requirements Appendix and Workbook for the FIDA IDD model; (3) Rhode Island – CY 2017 MMP Handbook/Evidence of Coverage (EOC) (Chapters 5-12); and (4) Texas – CY 2017 MMP Marketing Guidance and Marketing Guidance Memo. Also, on a related note, CMS seeks comments on long-term services and supports (LTSS) measures and those related to dual-eligibles. Comments are due Oct. 7
- **Section 10201(i) of the Senate Manager's Amendment – Section 1115 Waiver Amendments** – Key developments include:
    - On Aug. 24, Kentucky submitted a section 1115 demonstration titled, Kentucky Health, which seeks to leverage a managed care delivery system (via a high deductible health plan with two health care spending accounts) to serve all non-disabled individuals under age 65. Comments are due Oct. 8.
    - On Sept. 1, California submitted an amendment to its section 1115 waiver in which it sought to revise the incentive payment methodology under its Dental Transformation Initiative (DTI) program, among other purposes. Comments were due Oct. 1.
    - On Sept. 1, Oregon submitted an extension of its section 115 demonstration, outlining a number of Medicaid delivery system reforms, including those focused on addressing the social determinants of health to improve health equity. Comments were due Oct. 1.

**Title III – Medicare**

- **Section 3002 – Improvements to the Physician Quality Reporting System** – On Sept. 27, CMS posted key updates regarding the PQRS program.
- **Section 3004 – Quality Reporting for Long-Term Care Hospitals, Inpatient Rehabilitation Hospitals, and Hospice Programs** – On Sept. 2, CMS announced that the IRF and LTCH Quality Reporting Program (QRP) Provider Preview Reports would be made available until September 30, 2016. During that period, providers could review their performance data on each quality measure prior to public display on the IRF Compare or LTCH Compare websites.
- **Section 3006 – Plans for a Value-Based Purchasing Program for Skilled Nursing Facilities and Home Health Agencies** – On Sept. 15, CMS posted an article that provides

information on the SNF VBP program, including information on program measures, performance scoring, and on quarterly quality feedback reports.

- **Section 3008 – Payment Adjustment for Conditions Acquired in Hospitals** – On Sept. 7, the House Ways and Means Subcommittee on Health convened a hearing to examine the status of various quality programs in place in Medicare Part A.
- **Section 3021 – Establishment of Center for Medicare and Medicaid Innovation within CMS** – Key updates include:
    - In a Sept. 7 blog post, CMS touted both "progress" and "value" under Round 1 of the State Innovation Model (SIM) initiative Model Test Awards (Round 1 Test Awards).
    - On Sept. 8, the House Budget Committee held a hearing, "Center for Medicare and Medicaid Innovation (CMMI): Scoring Assumptions and Real-World Implications." The hearing was scheduled to examine how the CBO's scoring of CMMI is affecting the ability of Congress to perform its duties.
    - On Sept. 8, CMS announced a Track 1 funding opportunity and an overview webinar for the Accountable Health Communities (AHC) model. Applications are due by 3pm ET on Nov. 3 (including from applicants that previously applied to Track 1 under the original AHC FOA that must reapply).
    - On Sept. 9, CMS issued a RFI related to its State Innovation Mode (SIM) initiative.
    - On Sept. 12, CMS posted for review potential ICD-10 episode exclusion categories and fracture codes for FY 2017 for its Comprehensive Joint Replacement model.
    - On Sep 13, CMS held a webinar to provide an overview of the new funding opportunity and application requirements specific to Track One of the AHC innovation model.
    - On Sept. 13, CMS posted the Health IT vendor list for its Comprehensive Primary Care Plus model.
    - On Sept. 14, CMS posted slides from a webinar explaining how a recent proposed rule impacts the Comprehensive Joint Replacement model's ability to qualify as an advanced APM under MACRA.
    - On Sept. 19, CMS released the second annual evaluation report for Models 2-4 of the voluntary Bundled Payments for Care Improvement (BPCI) initiative.
    - On Sept. 29, CMS today announced the award of $347 million in Hospital Improvement and Innovation Network (HIIN) contracts to continue efforts in reducing hospital-acquired conditions and readmissions in the Medicare program.
    - On Sept. 29, CMS announced the second round awardees for the Support and Alignment Network under the Transforming Clinical Practice Initiative.
- **Section 3134 – Misvalued Codes under the Physician Fee Schedule** – The Medicare Payment Advisory Commission (MedPAC) held a session on misvalued clinician services in the Medicare PFS during their September meeting.
- **Section 3201 – Medicare Advantage Payment** – On Sept. 22, CMS announced that Part D premiums will remain stable for CY 2017, partially in part due to payment reforms established under the ACA. See here.

## Title V – Workforce

- **Section 5311 – Nurse Faculty Loan Program** – On Sept. 15, HHS announced a $24.6 million grant opportunity. Eligible applicants are public or private nonprofit accredited schools of nursing offering educator coursework as part of an advanced education nursing degree program(s) that prepares students to serve as nurse faculty. Applications are due on Nov. 14.

- **Section 10503 of the Senate Manager's Amendment – Community Health Centers and the National Health Service Corps Fund** – Key developments include:
    - On a related note, on Sept. 15, HHS awarded more than $87 million in health centers' IT enhancements to 1,310 health centers in all 50 states and U.S. Territories. A full list of awardees is available here.
    - Also on a related note, on Sept. 16, HRSA issued two funding opportunities (details here and here) totaling over $362 million under its Health Center Program 2017 Service Area Competition. For additional details, please also refer to HRSA's Service Area Competition (SAC) funding opportunities landing page (filtering by "open opportunities"). Applications are due Oct. 17 (HRSA-17-053) and Nov. 7 (HRSA-17-054).

**Title VI – Transparency**

- **Section 6301 – Patient-Centered Outcomes Research** – Key updates include:
    - On Sept. 6, PCORI joined with the American Heart Association (AHA) to announce a "crowdsourcing challenge" for clinicians and researchers across the country to find the best ideas for new research questions that deal with problematic challenges identified by patients with cardiovascular diseases.
    - On Sept. 22, the GAO announced the appointment of two new members to the Governing Board of PCORI: Russell Howerton, MD, Chief Medical Officer and Vice President of Clinical Operations at Wake Forest Baptist Medical Center and Kathleen Troeger, MPH, Director of Outcomes Research at Hologic, Inc. in Massachusetts. In addition, Grayson Norquist, MD, was named to a second three-year term as chair.
    - On Sept. 27, the PCORI Board of Governors approved $14.8 million to fund a study of two newer blood-thinning medications. The study will compare the two drugs against each other and against an older drug to see which works best in preventing the recurrence of blood clots in the veins and lungs.
- **Section 6409 – Medicare Self-Referral Disclosure Protocol** – On Sept. 9, CMS published a notice seeking approval to revise its currently approved information collection request regarding the Medicare SRDP. The new request includes a required form for SRDP submissions. Comments are due Oct. 11.

**Title VII – 340B and Biosimilars Pathway**

- **Section 7002 – Biosimilars** – Key updates include:
    - On Aug. 30, the FDA announced the approval of Erelzi, (etanercept-szzs) as a biosimilar to Amgen's Enbrel for multiple inflammatory diseases. Erelzi, which is manufactured by Sandoz, is approved as a biosimilar to Enbrel (etanercept) but was not deemed an interchangeable product.
    - On Sept. 16, the FDA announced a public meeting to discuss proposed recommendations for the reauthorization of the Biosimilar User Fee Act for FYs 2018-2022. The public meeting will be held on Oct. 20.
    - On Sept. 19, the FDA published a notice that an applicant for a proposed biosimilar product notified FDA that a patent infringement action was filed in connection with the applicant's biologics license application. The case is *Amgen v. Sandoz*.
    - On Sept. 23, the FDA announced the approval of Amjevita (adalimumab-atto) as biosimilar to AbbVie's Humira for multiple inflammatory diseases. Amjevita, which is manufactured by Amgen, is approved as a biosimilar to Humira but not as interchangeable. This is the fourth biosimilar to be approved by the FDA.
- **Section 7101 – 340B** – Key updates include:

- On Sept. 1, HRSA sent the final 340B Drug Discount Program Omnibus Guidelines to the OMB for regulatory clearance.
- In early September, HRSA's OPA distributed a notice from the manufacturer, Pharmacyclics, regarding the limited distribution plan for the drug Imbruvica (*ibrutinib*).
- On Sept. 27, HRSA's OPA announced that it is extending the upcoming quarterly 340B program registration window to span Oct. 1-17, 2016. Details are available here.