

## The US Health Care Law: What's Next for Stakeholders

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*Advisory*

In a widely publicized recent health care ruling, the Supreme Court largely upheld the Patient Protection and Affordable Care Act (ACA). The Court determined that the individual mandate is constitutional. However, the Court also found that states with existing Medicaid programs are not required to adopt the law's expansion to Medicaid eligibility. The rest of the Act remains intact and is the law of the land. The summary below discusses what the decision means for various stakeholders:

- States
- Health insurance plans
- Hospitals and other health care providers
- Massachusetts residents
- Life science companies

### **1. How The Court Ruled**

Chief Justice Roberts, writing for the majority, declined to strike down the ACA's requirement that most Americans buy health insurance by 2014 – its most controversial provision. In short, the Court held that the measure is proper pursuant to Congress's taxation power, but not under its authority to regulate interstate commerce.

As written, the ACA's Medicaid expansion would have added roughly 17 million people to its rolls by increasing the threshold for eligibility to 133% of the federal poverty level. The federal government was empowered to penalize non-participants by withholding all of each state's Medicaid funding. The Court held that such a broad denial is impermissible interference with states' rights.

The Medicaid expansion is still available to any state that wishes to adopt it. Participating states that meet its requirements will receive additional federal funding. However, states that do not wish to join the expansion are free to decline without risking the federal money that they already receive. In practice, it means that the pool of Medicaid-eligible persons will grow, but probably less than it would have if the Court had deemed the expansion mandatory. This significance of this outcome is discussed in more detail below.

### **2. What's Next for States**

#### *Setting Up Exchanges*

Under the Act, states must form exchanges, or marketplaces, where qualifying persons can purchase health insurance that satisfies the individual mandate. On January 1, 2013, the Department of Health and Human Services will decide which states can be ready to run their exchanges by the January 1, 2014, deadline. The federal government will implement an exchange in any state that is deemed unable or unwilling to offer its own by that time.

According to the National Conference of State Legislatures, twelve states (CA, CO, CT, HI, MA, MD, NV, OR, UT, VT, WA, WV) – plus DC – have already enacted laws to create their exchanges. Nine others (IL, LA, MI, NY, OH, OK, PA, RI, SC) have such legislation pending. A few more have set up committees to study the issue but have yet to

advance legislation.

For more information, visit <http://www.ncsl.org/issues-research/health/state-actions-to-implement-the-health-benefit-exch.aspx>.

#### *Decision Point: Medicaid Expansion*

After the ruling, the ACA's Medicaid expansion is optional. Some state leaders will decline to adopt the larger pool. However, because the federal government will pay 100% of the added cost until 2020 (and 90% thereafter), political pressure will probably bring at least a few hesitant states into the fold. This choice appears susceptible to shifting political winds; thus, interested parties should monitor their respective state capitals. Undoubtedly, the 2012 elections will fuel more discourse on this topic.

### **3. What's Next for Health Plans**

#### *The Mandate Survives*

Insurers face a greater degree of certainty going forward. In virtually all relevant respects, the ACA emerged unscathed, and the individual mandate's survival now portends some stability where chaos might have reigned. Plans can no longer deny coverage to persons with preexisting conditions, nor can they charge more to sick people. Parents can cover their children until they turn 26. Without the mandate, these elements of the Act would have incentivized uninsured citizens to delay paying into the system until they needed its benefits. In that scenario, premiums were almost guaranteed to rise.

However, we cannot yet know if the growing pool of customers will be enough to offset insurers' swelling expenses. More people who really need insurance will be able to get it, but fewer individuals may be brought into the market than was anticipated by Act.

#### *The Murky Medicaid Expansion*

The Medicaid expansion remains an area of ambiguity. Many states will eagerly take part, as the federal government pays for it in full until 2020, and picks up 90% of the cost after that. However, insurers cannot count on full realization of the roughly 17 million new Medicaid customers that were originally forecasted, as some states have already voiced relief that they can decline the expansion. But this is the early aftermath of the Court's decision, and leaders are sure to face political pressure from both sides as they contemplate this choice.

#### *Competition in Exchanges*

As exchanges become operational nationwide in 2014, more people will have straightforward access to affordable health care. Those earning between 133% and 400% of the federal poverty line can purchase coverage on the exchanges with the help of subsidies. Insurers should have a clear picture of how their states' exchanges will operate ahead of time, and consider how they will market their plans to this client pool.

Indeed, the exchanges will provide venues for competition between plans to secure customers from amongst the many Americans who will qualify to participate in these new markets.

### **4. What's Next for Hospitals and Health Care Providers**

#### *Increase in Volume of Insured Individuals and Revenue*

The ACA's expansion of health insurance coverage will increase the number of insured residents who can pay for health services, and decrease the number of uninsured residents seeking free care in emergency rooms. As a result, hospitals and health care institutions should see an increase in revenue.

## *Capital Investments and Changes in Health Care Delivery*

Increased revenue will allow hospitals and health care providers to invest in major overhauls in physical infrastructure and technology, clinical capabilities, and quality and performance programs. Furthermore, the ACA will promote changes in the way health care institutions provide care. The Act provides a number of grants and subsidies to encourage health care providers to move away from the traditional fee-for-service payment model, emphasize primary and preventive care, and formulate new ways to provide high-quality care at lower cost. The Act increases funding to community health centers, which provide a variety of services and programs in low-income neighborhoods. It also promotes a global payment model, under which providers are paid a set amount to provide all care for a person for a defined contract period. Global payments will incentivize health care providers to band together in Accountable Care Organizations (ACOs), which take responsibility for meeting the health care needs of a group of patients, with payment tied to achieving health care quality goals and cost savings.

## **5. What's Next for Massachusetts Residents**

### *Increased Access to Health Insurance and Health Care*

Because Massachusetts initiated its own health care reform in 2006, the ACA will affect Massachusetts residents less than residents of other states. However, the Act will still have significant consequences for Massachusetts individuals and families. The Act increases access to health insurance by broadening Medicaid eligibility, extending the Children's Health Insurance Program, and subsidizing premium assistance for lower-income individuals. In addition, the Act protects individuals from a number of insurance practices that have served as barriers to coverage in the past. The Act currently prohibits insurers from denying coverage to children because of pre-existing conditions, bars lifetime dollar limits on coverage, and requires insurers to allow parents to keep young adults under 26 without job-based coverage on family insurance. By 2014, the Act will ban annual limits on coverage and require insurers to accept all applicants, regardless of preexisting conditions.

### *The Individual Mandate*

The Act's "individual mandate" requires that most Americans buy health insurance by 2014 or pay a penalty. Of course, Massachusetts has had a similar requirement in place for years. The Massachusetts penalty for failure to carry health insurance is significantly larger than the federal penalty, and the Act will have no impact on the enforcement of the state penalty.

### *Possible Gaps in Health Insurance Coverage*

The Act is also gradually closing a coverage gap in the Medicare prescription benefit known as the "doughnut hole." The Act has begun to close the gap by providing people with Medicare with a \$250 rebate and a 50% discount on covered brand-name prescription drugs. By 2020, the doughnut hole will be completely eliminated so that seniors do not face a gap in prescription drug coverage.

However, even as the Act closes the gap in the Medicare prescription benefit, states that choose to opt out of the Medicaid expansion may create a new gap in coverage. Individuals with family income at or below the federal poverty level will have some health insurance coverage under current government programs. Individuals with family income at 133% of the poverty level or more will receive subsidies to allow them to purchase coverage in state health insurance exchanges. However, individuals with family income between 100% and 133% of the poverty level will find themselves in a new "doughnut hole," making too much to qualify for Medicaid but not enough to qualify for subsidized coverage through health insurance exchanges.

## **6. What's Next for Life Sciences Companies**

### *Biosimilars*

Though not paid as much media attention, one of the most significant undisturbed parts of the ACA for the biotech industry is the newly established approval pathway for biosimilar products, also known as The Biologics Price Competition and Innovation Act (BPCIA). The Court's decision has removed the looming uncertainty for biosimilar producers who can now proceed with biosimilar products without fear of full legislative overhaul and potential disruption of the abbreviated FDA approval progress. The ruling, however, does not touch on the administration's prior proposals to change the innovator's market exclusivity period from 12 to 7 years and to prohibit "pay-for-delay" settlements. Interested parties should heed the developments in this area closely as it is not likely to garner the high visibility enjoyed by the more controversial ACA provisions.

### *Medicaid Expansion and the Grand Bargain*

Drug manufacturers supported the Act after a prolonged negotiation process with lawmakers and administration officials. Industry members agreed to give up an estimated \$80 billion in rebates and fees over 10 years. Some commentators now project that number to be as high as \$105 billion. The industry has also discounted the cost of drugs for customers that find themselves in the Medicare "doughnut hole," the gap in coverage that had forced many people entirely out of the market.

Drug makers were counting on the mandatory Medicaid expansion to increase the number of persons able to afford prescription drugs. Like insurers, they gained some clarity with the Court's decision to uphold the law, but should monitor how states respond to the optional Medicaid expansion.

### *Medical Device Tax*

Medical device makers must prepare for the application of the APA's 2.3% tax on sales that will take effect in 2013. The House of Representatives, spurred by Republican lawmakers, voted to repeal the tax this June, but the Democrat-controlled Senate – not to mention the White House – rejected such efforts. Prudence suggests that subjects of the tax should plan to be taxed, as the possible political responses after the 2012 elections are tough to predict.

### *Sunshine Reporting*

The ACA's transparency provisions also remain law. Device makers and drug manufacturers have to record and report every instance in which they give something of at least \$10 in value to a provider or a doctor. At the earliest, CMS will begin collecting this data on January 1, 2013.

For more information, visit <http://blog.cms.gov/2012/05/03/information-on-implementation-of-the-physician-payments-sunshine-act/>.

### *PCORI and IPAB*

The ACA creates the Patient-Centered Outcomes Research Institute (PCORI) to evaluate the effectiveness of various medical treatments. PCORI will advise the Independent Payment Advisory Board (IPAB), which is empowered by the ACA to issue binding recommendations to cut costs if Medicare gets too expensive too quickly. The industry has expressed concern that it could be harmed by IPAB's possible cost-cutting measures. However, it is worth noting that IPAB can only act if Medicare costs rise beyond a certain threshold.

**This advisory was prepared by Maria Buckley and Konstantin Linnik, members of the Life Sciences practice group at Nutter McClennen & Fish LLP. They were assisted on the drafting of this advisory by Robin Morse, an associate in the Litigation Department, and summer associate Andrew McArdell. For more information, please contact Maria, Konstantin or your Nutter attorney at 617.439.2000.**

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### **Practice Areas**

Labor, Employment and Benefits

Tax

### **Industries**

Life Sciences: Biotechnology, Pharmaceuticals & Medical Devices

### **Related Professionals**

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