

healthcare policy & reform

from the FDA & Healthcare Practice

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The Healthcare Sector and the Future of ACA Implementation

Even with the lingering uncertainty over Medicaid program expansion, the High Court's decision brings some certainty and the need to focus on ramifications of ACA implementation.

On June 28, the U.S. Supreme Court held that the Patient Protection and Affordable Care Act of 2010 (P.L. 111-148 or ACA) is constitutional with modifications to the Medicaid expansion provisions. In a 5-4 decision, the Supreme Court (i) upheld the individual mandate as a lawful exercise of Congress's taxing power and (ii) ruled that states could opt out of the ACA's future expansion of the Medicaid program without losing federal funding for their Medicaid programs as they currently exist. The ACA requires states to expand Medicaid coverage to all individuals with an income of up to 133% of the federal poverty level or lose all federal Medicaid matching funds. The Supreme Court held that Congress could not threaten to deny current Medicaid funding if states choose not to go forward with the ACA's expansion of the Medicaid program. The Supreme Court's decision means that states will now have the ability to opt out of this part of the ACA's healthcare reform program.

With the Supreme Court decision behind it, the focus of the healthcare industry has turned from the underlying constitutional rationale to uphold the law to the effects of the decision on the industry. In reaction to the Court's ruling that states could opt out of the Medicaid expansion without loss of current federal funding, several states already have expressed doubts about expanding their Medicaid programs under the ACA, and a few state governors have unequivocally declared that they will not expand their programs. If some states do refuse to expand their Medicaid programs, questions will arise as to the potential impact on various healthcare sectors.

Though the ruling was a victory for supporters of the ACA, the battle over healthcare reform will continue. The future of healthcare reform will depend heavily on which party controls Congress and the White House after the elections in November. While Democrats are calling for continued implementation of the entire ACA, GOP presidential contender Mitt Romney and House and Senate Republican leaders continue to call for a full repeal of the law. Additionally, the Republican Governor's Association has called on GOP governors to delay implementation of key ACA provisions.

Meanwhile, federal implementation of the ACA continues. As the Department of Health and Human Services (HHS) and the Internal Revenue Service (IRS) issue additional regulations and as HHS disperses more money to implement various ACA provisions, repeal may become more challenging.

What does all this mean for the healthcare sector? We have analyzed the ruling for impact on various stakeholders.

Insurers and Medicaid Managed Care

The Supreme Court's decision to uphold the individual mandate provides some welcome clarity for insurers, although other sections of the law remain problematic for the sector. In particular, the industry is feeling the impact of "medical loss ratio" restrictions, which require between 80% and 85% of premiums to go toward medical care or be returned to the customer in the form of rebates. Health insurance exchanges and the continued rollout of ACA consumer protections will also pose new challenges for insurers in the coming years.

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Medicaid managed care plans are likely to gain new customers despite the possibility that some states may choose not to expand their Medicaid programs. The healthcare sector is seeing increased merger and acquisition activity in the Medicaid managed care space. WellPoint's recently announced \$4.5 billion acquisition of Amerigroup is a prominent example. All states are battling rising healthcare costs and are likely to continue to convert more recipients to managed care plans in order to close budget deficits. Additionally, the Medicaid managed care sector could still experience significant growth from the many states that will choose to expand their programs.

Healthcare Providers

The ACA cut billions of dollars in Medicare reimbursements for various healthcare providers and imposed heightened program integrity requirements and consumer protections that providers must navigate. Provider acquiescence on certain payment cuts, particularly those affecting hospitals, was based on the premise that revenue from the newly insured, through both Medicaid and the insurance exchanges, would help offset losses. Up to 17 million newly insured individuals were projected to receive their coverage from state Medicaid programs. With Medicaid expansion in question for some states, provider group support for the ACA could waiver.

In the meantime, new regulations implementing the Medicare cuts, patient protections, and other changes continue to flow out from HHS and IRS. For example, a recently released regulation implements ACA restrictions on the debt collection methods utilized by nonprofit hospitals and their agents.

Many providers are also moving forward on joining the Medicare Shared Savings Program. On July 9, the Centers for Medicare and Medicaid Services (CMS) announced that as of July 1, 89 new accountable care organizations were recognized in the Medicare Shared Savings Program. That brings the total number of program participants to 154.

Pharmaceutical Manufacturers

State refusals to expand Medicaid programs in line with the ACA would also impact the number of Medicaid-covered prescriptions and the size of the Medicaid prescription drug rebate program. Pharmaceutical companies agreed to a number of payment cuts as part of the ACA and had been anticipating additional revenue from the newly insured, including Medicaid recipients, to offset these price concessions.

The approval pathway for biosimilars, a 2.3% tax on medical device manufacturers, and other provisions will also move forward.

Pharmacies

Changes to federal policy on Medicaid prescription drug reimbursement are altering how states reimburse pharmacies for Medicaid prescriptions. Limits on flexible spending accounts and a change that bars their use for over-the-counter medications could reduce pharmacy sales. Integrated care models could utilize pharmacists for medication therapy management, patient education, or other purposes associated with accountable care models. Meanwhile, program integrity oversight of pharmacies appears to be on the upswing as CMS and Medicaid contractors ramp up their activity.

Program Integrity and Transparency Across All Sectors

The Supreme Court's holding left intact all aspects of the ACA dealing with program integrity, transparency, and fraud and abuse—all of which are in various stages of implementation. Providers, manufacturers, and other healthcare stakeholders should closely monitor these program integrity initiatives and changes to avoid increased legal and compliance risk. Morgan Lewis has been following the implementation of such provisions as the Physician Payment Sunshine Act, mandatory compliance programs, return of Medicare overpayments, and new Anti-Kickback Statute and False Claims Act liability.

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Employers

Employers face a number of looming ACA deadlines for group health plan changes and new requirements, including the need to prepare to receive, and properly distribute or apply, any Medical Loss Ratio rebates associated with 2011 insured health coverage; and to complete updates to Summary Plan Descriptions and plan documents to capture and describe the 2011 and 2012 ACA changes to their plan designs.¹

Implications

Healthcare touches nearly every sector of our economy, and the ACA contains changes affecting virtually every player in the healthcare industry. The agencies are issuing new regulations and guidance weekly, and Morgan Lewis is continuously tracking agency efforts to implement the law. Our attorneys not only help clients to adapt, but also connect them with opportunities to shape the healthcare regulatory and legislative process as it happens.

Contacts

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact your Morgan Lewis attorney, or any of the following key members of our cross-practice Healthcare Policy & Reform resource team:

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1. We provided analysis on the issues facing employers in our LawFlash, "Employer Group Health Plans and the Constitutionality of the ACA" (June 28, 2012) available online at http://www.morganlewis.com/pubs/EB_LF_HealthPlansConstitutionalityoftheACA_28june12.pdf.

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