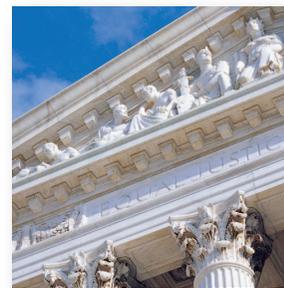


Impact of Federal and State Legal Trends On Health Care Services

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INTRODUCTION

Among the top anticipated legal cases in 2012 is the U.S. Supreme Court's agreement to hear the challenges to the constitutionality of the Patient Protection and Affordable Care Act (ACA) of 2010 emanating from several federal district court rulings (Table 1).^{1,2} Although specific issues deal with various constitutional interpretations, such as the Commerce Clause, real-world repercussions affect clinicians, health care systems, and pharmacies. These implications concern who can provide certain services, which health care organizations or clinicians can cross state lines, and the methods and levels of reimbursement for prod-

ucts and services.

The care of elderly Americans has traditionally involved consideration of the progressive nature of their chronic conditions and evolving treatment strategies that aim to minimize the long-term complications of these conditions. However, today's practitioners must also be attentive to problems involving insurance coverage and payment for each patient—commercial or public sector. Several trends in the nation's health insurance marketplace are dictated by actions at the federal level, especially the legislative branch. In the previous decade, public and private insurers had to continuously adapt to many

overarching federal initiatives, primarily the passage and implementation of the ACA and Centers for Medicare & Medicaid Services (CMS) regulatory initiatives and the efforts to rein in the high federal budget deficit (Table 2).³



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Table 1 Pending Supreme Court Decisions Related to the Affordable Care Act (ACA) in 2012

Issue	Hearing Date	Court Agenda
Anti-injunction Act prohibition on consideration of the individual coverage requirement	March 26, 2012	Determine whether the courts can hear an ACA-related suit brought by the states under the argument that such a hearing is prohibited by the Anti-Injunction Act of 1867 until taxes have actually been collected.
Constitutionality of the individual coverage requirement	March 27, 2012	Review whether Article I of the Constitution allows Congress the power to mandate requirements for individuals to maintain a minimum level of health insurance coverage or pay a penalty.
Severability of the individual coverage requirement	March 28, 2012	Determine whether the entire ACA would be invalidated if the individual coverage mandate is found to be unconstitutional—this provision is non-severable from the entire ACA.
Constitutionality of the federally required Medicaid expansion	March 28, 2012	Examine whether Congress exceeded its authority by mandating that the states expand Medicaid eligibility thresholds in order to receive federal Medicaid matching funds.

Data from the Robert Wood Johnson Foundation.^{1,2}

In addition to dealing with federal and state initiatives, many public and private insurers have been affected by technological advances that have caused the reallocation of fiscal resources in the health insurance marketplace. For example, these resources now fund the application of genomics as part of the movement toward individualized (personalized) medicine.

To provide some insight into current trends in federal and state legal policy, we will look at three key federal trends: health care reform, CMS regulatory initiatives, and deficit-reduction strategies.

HEALTH CARE REFORM

Executive Branch. On March 23, 2010, President Obama signed into law one of the most comprehensive revisions to our nation's health care system in history. The ACA's goals are to increase access, promote quality, and improve the efficiency of our complex and fragmented

patient-care effort. With more than 17.6% of our gross domestic product (GDP) devoted to medical care⁴ and approximately \$1 trillion of that cost borne by taxpayers,⁵ the ACA represents a structural change that will challenge both public and private insurance programs to meet these stated goals. The changes inherent in this reform initiative offer stakeholders numerous opportunities, but they also present challenges to many aspects of their current business model.

Although a number of ACA provisions will not be implemented until 2014, several components of the law that encourage risk sharing among providers and the CMS will become a reality in the next 2 years. Final rules for Accountable Care Organizations (ACOs) were released in October 2011 with the intent of providing guidance for organizations willing to assume financial responsibility for the total care of Medicare beneficiaries.⁶ If the Medicare experiment with ACOs is

successful, a fundamental shift to this form of performance-based care is likely. The ability of pharmacy providers and managers to demonstrate and document value to these ACOs represents a significant opportunity to expand the current scope of practice and to begin formulating models of pharmacist-service reimbursement. The value that medication therapy managers bring to patients in these ACOs could radically transform pharmacy practice from a product-reimbursed profession to a service-reimbursed one.

Medicare's pilot payment program takes a similar approach to coordinated care by bundling payments for all services from 3 days before a patient's hospital admission to 30 days after discharge (Table 3).⁷⁻⁹ Since the CMS's implementation of a panel to address "never events" (preventable medical errors that should never occur in a hospital), as recognized by the National Quality Forum,

Table 2 Key Deficit-Reduction Proposals Related to Public Health Programs

Proposal	Date	Key Provision
National Commission on Fiscal Responsibility and Reform (Bowles-Simpson Plan)	November 7, 2010	Unifies cost sharing for Medicare Parts A and B by creating standard deductibles, co-insurance, and out-of-pocket maximums; requires Medicaid to assume responsibility for "dual-eligibles" and to place them in Medicaid managed care plans; reforms the physician-payment schedules; and expands successful cost-containment provisions of the Affordable Care Act.
House Budget Committee's Budget Resolution, Fiscal Year 2011 (Ryan Plan)	April 15, 2011	Controls federal spending by capping discretionary spending and restricts use of debt limit increases; Medicare would be converted to a premium support program for beneficiaries who are not near retirement age.
Bipartisan Plan to Reduce our Nation's Deficits (Gang of Six Proposal)	July 19, 2011	Requires the Senate to review total health care spending to hold growth to gross domestic product + 1% (starting in 2020); requires all health-related congressional committees to identify system-wide savings; imposes across-the-board cuts if savings are not realized; and requires the Senate Finance Committee to find \$298 billion in savings to replace the physician-payment schedule.
Budget Control Act of 2011 (The Budget Deal)	August 2, 2011	Automatic budget cuts mandated by the Budget Control Act include \$840 billion in savings from discretionary programs; Medicare and Social Security are protected from cuts, but Medicare provider fees might be cut by up to 2%; myriad health programs, medical research, and infrastructure improvements might be affected.
President Obama's Plan for Economic Growth and Deficit Reduction	September 19, 2011	Increases income-related premiums for both Parts B and D; requires drug manufacturers to provide rebates for Part D drugs; reduces payments for a wide variety of medical services; and supports most provisions of the Affordable Care Act.
House Budget Committee's Budget Resolution, Fiscal Year 2012	Spring 2012	Budget proposal announced March 2012

Data from the Office of Management and Budget.³

and physician profiling, proper medication utilization has been essential during the post-discharge period.

The implementation of the policy to address these “never events” will have a negative financial impact on institutions that mismanage patient care. Pharmacists and other clinicians have the opportunity to broaden their roles on health care teams and, potentially, their scope of practice through these various ACA-mandated initiatives.

Changes in Medicare reimbursement are integral parts of both the ACA and several federal deficit-reduction proposals. Many of these proposals reward quality and value over the quantity of services provided. For example, reductions in payments under the ACA to Medicare Advantage plans are tied to quality-driven benchmarks (see Table 3). Similarly, value-based purchasing payment (VBPP) systems are scheduled to be established in late 2012 to pay acute-care hospitals according to their achievement of specific

performance benchmarks (see Table 3). In their infancy, physician payment plans will rely upon attaining defined quality goals. The CMS is required to report to Congress recommendations for implementing VBPPs in other settings, and it can be anticipated that quality-based reimbursement in long-term-care (LTC) facilities, hospice programs, and other environments will be included in these recommendations for implementation in the future.¹⁰

The provisions of the Medicare Modernization Act (MMA) of 2003 that establish medication therapy management (MTM) initiatives in Medicare Part D have been greatly enhanced by ACA regulations (see Table 3).¹¹ Again, a major opportunity for practitioners in a variety of health care settings has been presented, and their success and reimbursement will depend on demonstrated value.

Finally, the ACA provisions will have a spillover effect on the pharmaceutical in-

dustry and on the cost and accessibility of drug products in many ways. In February 2012, the FDA released proposed rules for a comprehensive pathway for the approval of biosimilars (generic biologics) as a result of mandates in the ACA. These provisions ensure an exclusivity period for innovator biologics as well as guidelines for the speedier introduction of biosimilar alternatives.¹²

Legislative and Judicial Branches.

The legislative and judicial branches of the federal government will have a great deal of influence over the final form of our refashioned health care system. In March 2012, the U.S. Supreme Court was scheduled to hear arguments related to two provisions in the ACA (see Table 1, page 218).

A major cornerstone of the ACA is the requirement that almost all Americans have health care insurance. This “individual mandate” ensures greater contributions to the health care system by an

Table 3 Implementation Timetable for Key Provisions of the Affordable Care Act (ACA) In Relation to Public Health Programs (2012–2013)

Provision	Summary	Implementation Date
Medicare Advantage payment reform	Phase-in of rates that more closely track Medicare fee-for-service rates; higher benchmarks are allowed for higher-quality plans.	Phase-in to occur over a period of up to 7 years
Accountable Care Organizations (ACOs)	Allows entities classified as ACOs to share cost savings they achieve with Medicare; organizations are responsible for the overall care of enrolled patients.	CMS final rule established; implementation by January 1, 2013
Value-based purchasing payment system	Establishes incentive-based purchasing program for acute-care hospitals based upon quality measures; mandates CMS plan to move home health care and long-term-care providers to a similar system.	Hospital system by October 1, 2012; long-term-care program plan to Congress by late 2012
Medicare bundled payment program	Establishes bundled payment pilot program for all services extending from 3 days prior to hospital admission to 30 days following discharge.	Pilot project by January 1, 2013
Independence at Home Act (Section 3024 of the ACA)	Demonstration program to provide high-risk patients with comprehensive services in the home; providers are allowed to share savings to Medicare program.	January 1, 2012
Community Living Assistance Services and Supports Act (CLASS Act)	Establishes a voluntary, employer-based, self-funded long-term-care insurance program for all working adults.	Program canceled in 2011 after it could not be proved to be actuarially sound
Part D Medicare changes	Eliminates deduction for employers' subsidy for maintaining prescription drug plan coverage for their retirees; coverage gap phase-out continues.	January 1, 2013

CMS = Centers for Medicare & Medicaid Services.
Data from the CMS;⁷ the Kaiser Family Foundation;⁸ and the Democratic Policy Committee.⁹

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expanded group of citizens and thereby creates a robust insurance pool to support the changes involved in health care reform. The removal of this provision from the ACA would cause major financial disruption to the initiative and perhaps doom efforts to make meaningful change. The Supreme Court will decide whether:

- Congress can require all citizens to purchase health insurance or face financial penalties.
- the entire law is unconstitutional if only the individual mandate provision is determined to be unconstitutional.
- it can actually hear the merits of this case before these penalties (taxes) have been collected.

Certainly, the outcome of the court's decision will have a substantial impact on health care in general and the provision of pharmaceutical products and services in particular.¹³

The ACA also mandates expanding federal and state-funded Medicaid programs to insure a larger population of at-risk citizens. The Court will wrestle with the argument from a majority of the states that the federal government does not have the authority to coerce them into expanding Medicaid eligibility thresholds in order to receive federal matching funds.^{1,2}

CMS REGULATORY INITIATIVES

An often-overlooked driver of the federal direction of the health care system is the fact that the CMS and other agencies are authorized to create rules to implement the programs mandated by Congress. These agencies must also evaluate and grant waivers to these rules. In this era of exceptionally tight state budgets, the CMS has been inundated with requests to allow changes in public health programs, particularly Medicaid.¹⁴ Often these requests for waivers seek to cut spending in this important program for the indigent and elderly. Reductions in prescription reimbursements, restrictions on admissions to LTC facilities, and cuts for numerous ancillary services and programs make for a challenging business climate for the health care industry.

An example of the impact that executive branch agencies have on the health

care industry is the CMS's recent proposed rule regarding the participation of LTC facilities in Medicare's prescription drug benefit program (see Table 3). This rule requires that the LTC facility's consulting pharmacists have no affiliation with the facility's distributing pharmacy or a pharmaceutical manufacturer.¹⁵ Although this requirement has taken hold in several states,¹⁶ the CMS ruling forces a basic restructuring in the LTC pharmacy model, providing some stakeholders with an important professional opportunity while presenting others with a business challenge.

If the ACA survives judicial branch review, some provisions implemented by the CMS will incrementally change Medicare Advantage and Part D programs. Final regulations released on April 15, 2011, codify portions of the ACA pertaining to these programs. The infamous Part D coverage gap ("donut hole") will continue to close, and Part D cost sharing for certain individuals receiving home and community-based services will be eliminated (see Table 3). Low-income-subsidy enrollees will benefit from changes in benchmarks that reduce the number of Part D low-income-subsidy reassignments. The rules pertaining to how certain Part D beneficiaries can be disenrolled from the program have been clarified, and more stringent requirements for Part D plans to address beneficiary complaints will now be required.¹⁵

Reimbursement rules for pharmaceuticals have also changed. The quantity of brand-name drugs that may be dispensed in LTC settings for Part D participants has been modified; allowances are now made for payments for compounded medications if they contain at least one ingredient that is a Part D-covered drug.¹⁵

Finally, Part D plan-sponsored MTM programs will continue to evolve and improve, as the mandated scope of these efforts is driven by quality and outcome measures.¹⁷

Another initiative that was advanced by the ACA was the creation of the Center for Medicare & Medicaid Innovation (CMMI).¹⁸ This division of the CMS is charged with "revitalizing and sustaining Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) and ultimately improving the health care system for all Americans."¹⁸ The CMMI will

be encouraging collaborative initiatives with numerous health care stakeholders that might incorporate MTM strategies, pharmacist involvement, and targeted pharmaceutical care. The goals of these efforts are to achieve better health care, improved health outcomes, and lower costs.¹⁸

In November 2011, the CMMI solicited grant proposals for collaborative programs of health care change through the Health Care Innovation Challenge.¹⁸ This \$1 billion program drew more than a thousand proposals from across the country, many highlighting the inclusion of MTM strategies as part of a wider effort to improve patient health and to lower systemic costs.

Funded proposals are scheduled to be announced in April 2012.¹⁸

FEDERAL DEFICIT-REDUCTION STRATEGIES

It is important to consider how recent federal budget-cutting efforts have affected the health care system overall (see Table 2, page 219).³ Numerous individuals and groups, such as President Obama, the Senate's "Gang of Six" (three Republicans and three Democrats), the House of Representatives Budget Committee, and the National Commission on Fiscal Responsibility and Reform, have presented proposals that would fundamentally alter the way that health care is provided in the U.S. Although these proposals present very divergent, often partisan ideas on how to reduce the deficit, they have many features in common that suggest probable changes in funding public health programs.^{3,13}

In November 2011, the failure of the congressional "supercommittee" to agree on a package of spending cuts and revenue enhancements in an attempt to stabilize the federal budget deficit also suggests probable changes to our public health delivery system. Beginning in 2013, this failure will result in the mandatory sequestration of defense and discretionary funds. Although Medicare and Medicaid were largely spared significant cuts as part of the arrangement, many other health-related agencies and programs are vulnerable to planned budget reductions. These include many federally funded health programs, the public health infrastructure, the FDA, various regulatory agencies, and bio-

medical and translational research programs.

President Obama's \$3.8 trillion federal budget proposal for fiscal year 2013, which was released on February 13, 2012, gives a hint as to the direction of both short-term and long-term federal budget priorities. The goal is to save more than \$364 billion by decreasing health care spending over the next decade, with nearly all of the savings accrued from Medicare and Medicaid reductions. Savings would come from various cost-cutting and efficiency measures, including Medicare drug rebates, reduced payments to doctors and hospitals, higher costs for wealthier retirees, a shift in Medicaid costs to the states, and a continuing crackdown on waste and fraud.

Although Medicare will probably not become a premium-support type of program in the near future, it is conceivable that its beneficiaries will experience fewer covered services, higher copayments and premiums, and reduced access to health care professionals. More affluent beneficiaries are at particular risk for assuming a larger share of their Medicare costs.

As for Part D Medicare, the CMS may be required to negotiate directly with drug companies for prices or to extend current Medicaid rebates to dually eligible beneficiaries.¹⁹ Most of the proposals generally state that the physician payment schedule (the sustainable growth rate) needs to be reformed. Paying for this revision could mean reducing non-physician reimbursements as well as curtailing other public health programs.

With almost 3% to 10% of health care expenditures falling victim to fraud each year, many of the proposals include enhanced efforts to recoup these lost dollars. Indeed, the CMS recovered \$4.1 billion in fiscal year 2011 through a renewed focus on preventing and prosecuting fraud and abuse.²⁰ Congress has also held hearings on the topic and has introduced bills designed to address the problem with a variety of strategies. Public transparency of Medicare and Medicaid payments, along with utilization data, is a common theme in several of these initiatives.

DISCUSSION

The profound effects of implementing health care reform, efforts to rein in the

federal budget deficit, and judicial branch review of these activities cannot be overstated. Pharmacists, physicians, and other clinicians need to be aware of the regulations that Congress and the judicial branch are exploring. The outcome of these decisions will alter the way health care organizations are structured; how individual stakeholders are reimbursed; how the role of practitioners might change; and, ultimately, how patients are treated. Active budget dealings in Congress will have a trickle-down effect on federally funded programs as well as on state funding in general.

This precarious economic and clinical balance faces the stresses of increased costs in medical environments driven by technology and the wide acceptance of genomics and biotechnology solutions, which could have a dramatic effect on patient care as well as on professional clinical practice. Yet this new paradigm, with its emphasis on the value of clinical outcomes, will also offer opportunities for innovative and enterprising health care professionals to improve their business model.

The extent to which clinicians, including pharmacists, engage in activities that support patient care and that are congruent with the aims of the ACA and CMS guidelines will determine the likelihood of success in avoiding regulatory or legal dilemmas regarding reimbursements or standards of practice. In addition, enhanced oversight of fraud and abuse, as promoted by the ACA, will continue to tighten legal-regulatory constraints on clinicians while exposing those outside the system to investigation or legal action earlier.

CONCLUSION

Market forces in the health care delivery system continue to evolve, as do legal and regulatory changes resulting from health reform legislation. Health care organizations need to maintain their diligence in gauging, as well as following, emerging regulatory guidance and rules in addition to federal and state laws. This complexity of the health care regulatory environment is not likely to abate soon; therefore, it is expected that professionals who are responsible for health care administration will need to direct their attention to the legal environment as part of their duties.

As changes occur, this column will keep readers abreast of policy and legal updates that affect health care professionals.

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