2011

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John Aloysius Jr. Cogan, The Affordable Care Act's Preventive Services Mandate: Breaking down the Barriers to Nationwide Access to Preventive Services, 39 J.L. Med. & Ethics 355 (2011)

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Mon Oct 22 16:21:22 2018

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The Affordable Care Act's Preventive Services Mandate: Breaking Down the Barriers to Nationwide Access to Preventive Services

John Aloysius Cogan Jr.

The most prominent — and certainly the most controversial — feature of the Patient Protection and Affordable Care Act (the ACA, or the Act)¹ is the so-called “individual mandate,” which attempts to address the problem of 50 million uninsured by requiring nearly all Americans, beginning in 2014, to obtain health insurance.² While expanded access to health insurance has been both the cornerstone and the lightning rod of the ACA, the Act also contains significant public health provisions focusing on, among other things, promoting the availability of prevention and wellness services. Although these public health provisions have been greeted with mixed reviews,³ there has been very little discussion of what may be the ACA's most significant public health feature: the preventive services mandate. In a bold stroke, the ACA changes the way evidence-based preventive services will be provided and paid for by private health insurance plans, Medicare, and Medicaid. By requiring these health plans to provide evidence-based preventive services with no out-of-pocket costs, the ACA transforms the U.S.'s public and private health care financing systems into vehicles for promoting public health.

The ACA's preventive services mandate accomplishes this transformation by breaking down two barriers that have heretofore precluded the availability of nationwide access to uniform preventive services through individual and group health plans. The first barrier — the public health-health care barrier that has focused our health care system on cure rather than prevention — is both conceptual and functional.⁴ For over 50 years, separate goals, methods, and resources have divided public health and health care. Although “mutually dependent and interactive,”⁵ both fields have operated separately for the last half century, leading to a dominance of individual-based, curative medicine and a lack of population-based preventive health measures. The consequences of this division have been an expensive and poorly performing health care system that shuns preventive care in favor of curative interventions.⁶

The second barrier — the boundaries that keep the health care system too fragmented to allow for uniform availability of preventive services — is legal. The ACA's evidence-based preventive services provisions tear down the jurisdictional divides erected by state lines and the preemption barricade created by the Employee Retirement Income Security Act of 1974

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(ERISA),⁷ which renders impossible the provision of a uniform set of evidence-based preventive services to the U.S. population. The dissolution of these barriers guarantees nearly all Americans access to evidence-based preventive services.

for older individuals;¹³ requires development of criteria for improving access to medical diagnostic equipment for people with disabilities;¹⁴ establishes a public education campaign focused on oral health prevention and education;¹⁵ authorizes the Secretary of the

From a public health standpoint, the most significant provisions of the ACA are those mandating health plan coverage for evidence-based preventive services without cost-sharing. In other words, the ACA mandates that patients have access to preventive health measures without requiring patients to pay for those services when those services are provided.

The ACA's Public Health Provisions

The ACA's public health provisions contain a wide array of promising initiatives, directives, and grant programs. Some of the more notable provisions:

- create a Prevention and Public Health Fund to distribute \$15 billion over 10 years to promote prevention, wellness, and public health activities, including prevention research, health screenings, and immunization programs;⁸
- establish the National Prevention, Health Promotion and Public Health Council, which will, among other things, coordinate and develop a national strategy for prevention, wellness, health promotion, public health, and integrative health care;⁹
- require the Centers for Disease Prevention and Control to convene a Community Preventive Services Task Force (Task Force), require the Task Force to coordinate with the U.S. Preventive Services Task Force (USPSTF), and charge the Task Force with the review of the scientific evidence related to the effectiveness, appropriateness, and cost effectiveness of community preventive interventions;¹⁰
- establish a national public-private partnership to carry out communication activities related to health promotion and disease prevention;¹¹ and
- award grants for the development and implementation of intervention programs to promote good nutrition and physical activity in children and adolescents and establish a program to award grants to support the operation of school-based health centers.¹²

The Act also provides for grants for community-based preventive health activities and intervention programs

Department of Health and Human Services to negotiate prices for vaccines to be purchased by states;¹⁶ requires nutritional labeling for menu items in certain restaurants and vending machines;¹⁷ requires employers to provide reasonable breaks and appropriate spaces for nursing mothers to express breast milk;¹⁸ and provides assistance for employers to evaluate workplace wellness programs,¹⁹ among other things.²⁰ Yet, the most significant public health provisions in the Act are not these initiatives, directives, or grant programs. From a public health standpoint, the most significant provisions of the ACA are those mandating health plan coverage for evidence-based preventive services without cost-sharing. In other words, the ACA mandates that patients have access to preventive health measures without requiring patients to pay for those services when those services are provided.

The ACA's Evidence-Based Preventive Mandates

The ACA requires all group and individual health plans²¹ to cover specific preventive care items and services without patient cost-sharing (i.e., copayments, coinsurance, or deductibles).²² The elimination of cost-sharing is critical to the success of this mandate; while cost-sharing is typically viewed as a cost-saving measure because it reduces consumption and thereby lowers overall health care costs,²³ cost-sharing is actually counter-productive in the context of preventive services. Since cost-sharing creates an economic disincentive to access services, use of preventive services declines when cost-sharing is imposed.²⁴

The ACA's preventive services mandate covers 45 evidence-based preventive services that have been given a rating of "A" or "B" by the USPSTF.²⁵ Services receiving grades of "A" or "B" are recommended because the USPSTF has determined that the net

benefit of the service is moderate or substantial.²⁶ The mandated preventive services address a wide range of potential health problems and conditions, including alcohol abuse, heart disease, obesity, certain types of cancer, osteoporosis, diabetes, HIV infection, and tobacco use. For example, all adults, including pregnant women, will be covered for primary care-based screening and behavioral counseling interventions to reduce alcohol abuse.²⁷ All adults and children aged 6 years and older will be covered for obesity screening and behavioral interventions to promote weight loss if diagnosed as obese.²⁸ The mandate also requires counseling, treatments, and interventions to address heart disease, such as promoting the use of aspirin to reduce heart attacks, high blood pressure and cholesterol screening, and healthy diet counseling.²⁹ Women over 65 years of age will be screened for osteoporosis.³⁰ Men over 65 years of age will be screened for abdominal aortic aneurysm.³¹ Tobacco cessation interventions are also covered.³² In addition, the mandate requires coverage for evidence-based immunizations for children, adolescents, and adults currently recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (Advisory Committee), such as the Diphtheria, Tetanus, and Pertussis vaccine for infants, yearly influenza vaccines for children, and Varicella (Chickenpox) vaccine for adults,³³ and preventive care and screenings for infants, children, adolescents and women contained in comprehensive guidelines supported by the Health Resources and Services Administration.³⁴

Medicare services are also included in the ACA's prevention mandates. The USPSTF's "A" and "B" recommended preventive services, including certain vaccines, wellness visits, and preventive screenings, must all be provided to senior citizens and other Medicare eligible patients with no cost-sharing. The Centers for Medicare and Medicaid Services (CMS) was also given the authority to eliminate Medicare cost-sharing for other preventive services not recommended by the USPSTF.³⁵

Medicaid's preventive requirements under the Act are somewhat different, due mainly to the program's joint state-federal funding and regulation. Unlike Medicare, which is funded completely by the federal government, Medicaid³⁶ is a joint state and federal public health insurance program for the poor. State governments administer the program and provide a range of mandatory and optional services. The federal government provides states the bulk of the funding for Medicaid.³⁷ Starting in 2013, the ACA requires Medicaid programs that cover certain optional diagnostic services to cover "A" and "B" level preventive services recommended by the USPSTF and the immunizations

recommended by the Advisory Committee. The federal government will pay each state an additional 1% in Medicaid matching funds to cover the costs of the preventive services and recommended vaccines if provided with no cost-sharing.³⁸ Thus, while not mandating that preventive services and vaccines be provided to Medicaid enrollees at no cost, the ACA gives the states a strong financial incentive to provide the services without cost-sharing.

The implications of the ACA's preventive mandate are profound. Once the ACA's individual mandate takes effect (assuming it is not overturned by the Supreme Court or repealed by Congress), if every state and the District of Columbia were to include preventive services in their Medicaid programs with no cost-sharing, then 95% of all non-elderly U.S. residents could be covered by a uniform set of evidence-based preventive services with no out-of-pocket-costs by 2016.³⁹

The Barriers to Nationwide Access to Preventive Services

The ACA's preventive services mandate represents a fundamental change to our health care system that is only made possible by the ACA's ability to break down two significant barriers: (1) the public health-health care barrier that has focused our health care system on cure rather than prevention and (2) the legal boundaries imposed by the states and ERISA that keep the health care system too fragmented to allow for a uniform availability of preventive services. In order to fully appreciate the consequences of the first barrier — the public health-health care divide — it is important to understand the divide itself, how it came about, and its repercussions.

Conceptually and functionally, the nation's health care system is viewed as consisting of two distinct components: health care and public health.⁴⁰ The health care component is structured around organizing, financing, and delivering individual-level, curative medical care. To most Americans, "health care" is an amorphous term, encompassing everything from health insurance carriers, to hospitals, physicians, and pharmacies. It also means Medicare, Medicaid, and every other person, place, or thing that provides or pays for curative medical care.⁴¹ Health care in the U.S. is a highly visible enterprise that consumes more than 95% of all U.S. health-related spending.⁴² Its practitioners, most prominently physicians, are highly visible, culturally respected, and generally well-compensated individuals whose heroic feats are covered widely by the press.⁴³

Public health, on the other hand, is "the collective response to the health threats a society faces."⁴⁴ Public health focuses on the health status of entire popula-

tions, not just individuals. In other words, the focus is on everyone at once, not just sick people.⁴⁵ Historically, public health focused on community sanitation and environmental hazards.⁴⁶ But most people no longer die from the spread of communicable diseases and poor sanitation. Now people tend to die from “exposure to the fruits of affluence,” such as poor diets, lack of exercise, easy access to tobacco products, and “the bitter harvest of social stresses,” including violence and drug and alcohol abuse.⁴⁷ The modern role of public health has expanded to include research and efforts to address these problems. In addition, public health is responsible for, among other things, understanding and mitigating the social, behavioral, and environmental factors that contribute to health status, sanitation, clean air and water, vaccination, isolation and quarantine, inspection of food and the food service industry, licensure of medical professionals and facilities, discipline of medical professionals, tracking the spread of disease, and planning and stockpiling of emergency supplies.⁴⁸

Unlike those in health care, public health’s practitioners are less visible, less well-respected, and overall not compensated as well as physicians. They are licensed health professionals, bureaucrats, politicians, and scientists. Although less visible, the public health workforce is vast, spreading across every layer of government and across wide geographic areas.⁴⁹ And, unlike their health care counterparts, public health practitioners receive little attention for their work, perhaps with the exception of recently reported threats of pandemics and bioterrorism.⁵⁰ Yet, despite its expansive nature and critical importance, public health spending comprises only a small part of total U.S. health care spending, generally less than 5%.⁵¹ Put into context, total per capita health spending in the U.S. was \$8,086 per person in 2009. Of that, only about \$251 was spent on public health.⁵²

There are a few possible explanations for this disparity. On the one hand, public health’s diffuse nature tends to give public health an “everywhere and nowhere” quality,⁵³ making it invisible to most Americans.⁵⁴ Another is the so-called “prevention paradox,” the idea that a preventive treatment that offers large benefits to a large population offers only a negligible benefit to each individual in that population. For example, a routine measles vaccination offers only marginal health benefits to any one child because the risk of infection is low. Nevertheless, such vaccines significantly contribute to the health of the

overall population.⁵⁵ The prevention paradox can lead to a lack of interest and compliance problems when population-level public health prevention programs are introduced. The real problem for public health, however, stems from the ascension of health care and the boundary that ascension created between health care and public health. This is the origin of the public health-health care divide.

The Growing Dominance of Health Care over Public Health

In the late 19th century public health and health care were viewed as overlapping endeavors. They had common goals and membership. Physicians participated

Compared to other developed countries, the U.S. spends an enormous amount for its health care. Per capita health expenditures in the U.S. are nearly double the average of 15 Western developed nations. If spending more money produced better outcomes, then the U.S. would certainly be the healthiest country on Earth. Unfortunately, this is not the case.

heavily in public health planning and programs; public health practitioners and physicians were allies in advancing public health reforms.⁵⁶ But the happy marriage of public health and health care would not last. By the mid-20th century, improvements in physician education and skill, better hospital care, advances in medical technology, and the ascendance of the biomedical model greatly improved the quality of individualized, curative medical treatment.⁵⁷

The biomedical model, which focused on biology, physiology, pathology, biochemistry, and other strictly science-based approaches to health care, developed effective responses to disease. Individualized medical treatment, rather than public health, became the dominant mode of health care delivery. As more individuals became patients in an expanding tertiary health care system, the impact of social, economic, behavioral, and environmental factors on health was discounted. They were no longer considered significant contributors to disease and disability. As one history of the public health-health care split noted, “The very nature of the biomedical paradigm was to uncouple disease from its social roots.”⁵⁸ Once removed from health care, public health faded deep into the back-

ground, and to most people, was of little consequence to their personal health.⁵⁹

The result of this focus on curative, individual-based care and its accompanying aversion to prevention is a system that is expensive and performs poorly.⁶⁰ Health care spending in the U.S. is exorbitant and has been rising rapidly for years. In 2009, the U.S. spent \$8,086 per person on health care,⁶¹ and spending has been increasing at a rapid rate over the last several decades.⁶² Compared to other developed countries, the U.S. spends an enormous amount for its health care. Per capita health expenditures in the U.S. are nearly double the average of 15 Western developed nations.⁶³ If spending more money produced better outcomes, then the U.S. would certainly be the healthiest country on Earth. Unfortunately, this is not the case.

Despite its profligate spending, the U.S. remains an international health laggard, consistently underperforming on most quality measures relative to other countries. A Commonwealth Fund report ranked the U.S. last compared to six other comparable nations (Australia, Canada, Germany, the Netherlands, New Zealand, and the United Kingdom).⁶⁴ The World Health Organization ranks the U.S. health care system 37th in the world.⁶⁵ Such rankings are not without their critics.⁶⁶ Other statistics, though, appear to confirm the U.S.'s low health ranking among other comparable nations. For example, the U.S. consistently has had the lowest life expectancy rate and the highest infant mortality rate among G8 countries.⁶⁷ More mothers die in childbirth in the United States per 100,000 births than in other G8 countries, at nearly double the average of other G8 countries. In terms of preventable years of life lost, which is a measure of preventable deaths occurring at younger ages, the U.S. ranks highest among G8 countries.⁶⁸ As one commenter put it, "When it comes to population statistics like these, the U.S. looks absolutely horrible. This leads many to the conclusion that these metrics must all be fatally flawed. I'd be more likely to agree if we weren't dead last in all of them."⁶⁹

Ironically, the U.S.'s high spending and poor health are connected. A large percentage of the increase in U.S. health care spending can be attributed to unhealthy lifestyles and behaviors, including obesity.⁷⁰ Indeed, the top three leading causes of death in the U.S. stem from preventable causes: tobacco use, obesity, and alcohol abuse.⁷¹ The prevalence of obesity is on the rise, progress in reducing tobacco use has slowed,⁷² and the incidence of alcohol dependence or abuse has remained constant.⁷³ Chronic conditions such as heart disease, cancer, and stroke account for more than 50% of all deaths each year. Currently, seven out of ten deaths annually among Americans

result from chronic diseases, and the percentage of Americans with chronic conditions is on the increase. At their current pace, chronic conditions are projected to increase by over 40% by 2023,⁷⁴ despite the vast sums we spend on health care each year.

The ACA is expected to expand coverage by about 30 million and reduce the number of uninsured by more than half.⁷⁵ But given the poor performance of the U.S.'s health care system, expansion of coverage alone does not promise better health outcomes. The most effective way to address preventable disease and chronic conditions is by providing effective and uniform preventive services. Up to now, however, the U.S. health care system was not equipped to do so. The primacy of the biomedical model and curative medicine created a barrier between public health and health care. The result has been escalating health care costs and an explosion of preventable disease. By breaking down this barrier and coupling population-focused, evidence-based preventive services with the insurance plans that finance health care, the U.S., through the Affordable Care Act, finally has the capability to systematically address preventable disease and moderate health care costs.

ERISA and the Legal Barrier to Access to Preventive Services

The second barrier toppled by the ACA's preventive services mandate is the legal framework that fragments the delivery of health care and previously made the possibility of uniform preventive services mandates impossible. This fragmentation has its roots in the health care financing system.

Health care is financed through a mix of public and private health insurance plans regulated by the state and federal governments. In addition to Medicare and Medicaid, there are private health insurance plans, which finance health care for the bulk of the population.⁷⁶ There are also state and local government plans. Since enactment of the McCarran-Ferguson Act in 1944,⁷⁷ primary regulatory authority over these public and private health insurance plans has been distributed horizontally across the states.⁷⁸ Since the mid-1970s, however, with the enactment of ERISA,⁷⁹ the federal government has shared the regulatory role of the states, creating a vertical distribution of authority, but only with respect to employer-based health plans. These horizontal and vertical distributions of authority have produced a highly fragmented health care financing system and a hodgepodge of regulations that has made impossible any attempt to bring nationwide uniformity to the preventive services benefits offered by health plans.

The problem is not with the creation of prevention mandate laws. Many states, in fact, require health insurance plans within their jurisdictions to cover preventive services.⁸⁰ These prevention mandates are part of a larger body of state health insurance benefit mandates that cover preventive care as well as additional services offered by specific providers. In general, state benefit mandates require health insurers and/or health plans to provide coverage for a specific group of people (e.g., dependants), coverage for a specific disease or condition (e.g., Lyme disease or infertility), reimbursement for services provided by specific types of providers (e.g., podiatrists or nurse midwives), reimbursement for certain types of medical devices or pharmaceuticals (e.g., hearing aids or Chantix), or provide reimbursement for a minimum quantity of benefits (e.g., coverage for minimum hospital stay after mastectomy).⁸¹ Since the 1970s, these mandates, the overwhelming majority of which do not cover preventive services, have grown in number, and more are enacted every year.⁸²

Many reasons have been cited to explain the proliferation of state benefit mandates. For example, state benefit mandates have been described as an attempt to correct the market response to the information asymmetry inherent in the private insurance market.⁸³ Individuals typically have more information about their own medical conditions than health insurance companies. This, in turn, creates fear-based incentives for insurers to offer more limited coverage than the public generally desires.⁸⁴ State benefit mandates are also thought to address adverse selection problems. For example, if insurers are allowed to exclude coverage for some high-cost conditions, then persons who need coverage for those conditions will be forced to deal with a limited pool of insurers, who will charge significantly more for coverage.⁸⁵ Mandates have also been justified on that ground that they prevent negative externalities, for example, providing coverage for vaccines from communicable diseases. Such externalities would arise when an individual concludes that her risk of contracting infectious diseases is sufficiently low to justify foregoing health insurance coverage for immunizations. Such a decision would fail to take into account the benefit to society that results from the immunization.⁸⁶ Benefit mandates also operate as cross-subsidization. For example, requiring everyone to purchase coverage for maternity or mental health treatment makes the benefits more affordable for those who will use them.⁸⁷

Despite all these seemingly reasonable bases for mandates, the proliferation of mandates, in many cases, resulted from far less noble reasons. Beneficiaries of state benefit mandates tend to be "concentrated

interests represented by well-organized groups of health care professionals" and "persons or parents of persons with a specific medical condition, who have an intense interest in a particular mandate and its outcome."⁸⁸ Since the costs of state benefit mandates are diffuse and spread over the entire insured population,⁸⁹ the cost of any particular mandate is small, usually less than 1% of the cost of the premium.⁹⁰ State benefit mandates are therefore politically attractive. Enacting a mandate creates the perception that a politician is doing something about health care. But the relatively low cost of a mandate tends to discourage any significant opposition from those who will actually pay for the mandate.⁹¹

Furthermore, political expediency rather than a scientific basis appears to be a central ingredient in the success of many state benefit mandates. Two prominent examples include the adoption benefit mandates covering high-dose chemotherapy with autologous bone marrow transplantation (HDC/ABMT) and minimum length of stay requirements for mothers and newborns. In the late 1980s, some physicians promoted HDC/ABMT as a new form of treatment for breast cancer. The process involved a complicated and highly expensive process whereby a patient's bone marrow was extracted and frozen, the patient was dosed with high levels of chemotherapy, then the marrow was replaced. Although HDC/ABMT had no clinical evidence to support its effectiveness for breast cancer, it was widely used. The treatment was expensive and the insurance industry balked, resulting in widespread litigation.⁹² In response to political pressure and emotional appeals, several states passed laws mandating insurance coverage for HDC/ABMT. Eventually, clinical trials established that HDC/ABMT was not effective. Nevertheless, repeal of existing HDC/ABMT mandates was difficult, despite the contrary clinical evidence.⁹³ By the time HDC/ABMT had been proven ineffective, 30,000 women had received the treatment at a cost of \$3 billion.⁹⁴ Similarly, mother and newborn length-of-stay mandates were enacted despite any evidence that shorter stays were harmful and/or that longer stays improved the health of mother or infants. Ultimately, "the rhetoric of 'drive-through deliveries' was politically compelling and engendered a broad coalition of supporters," resulting in passage.⁹⁵

The problem with state benefit mandate laws, however, is not only that they may not be scientifically based but also that they are expensive. Many states have 40 or more mandates. Although most mandates increase the costs of health insurance by less than 1%, the cumulative effect of 40 or more mandates can impose a significant increase in the cost of coverage.⁹⁶ ERISA, however, gives employers a way out:

as described next, self-funded ERISA health plans are exempt from state coverage mandate laws. This means that employers can opt out of state benefit mandates, including those that mandate preventive services.

ERISA and the Exemption from State Benefit Mandates

Most people get their health insurance through employer-sponsored health benefit plans. Approximately 57% of the civilian population under age 65, or 157 million persons, are covered by employment-based group health insurance. Only about 5% of the civilian population under age 65 gets their coverage through private non-group insurance.⁹⁷ While all private non-group health insurance plans are subject to

the risk of paying the plan's claims and performs all of the plan's administrative functions, such as setting premium rates, maintaining provider networks, processing claims, and adjudicating coverage disputes. In contrast, under a self-insured health plan, the employer assumes the risk of paying the plan's claims. The employer directly funds the health benefits for its covered enrollees and typically contracts out the plan's administrative functions, often to an insurance company. The distinction between fully-insured and self-insured is often lost on employees, their beneficiaries, and health care providers, who typically do not understand the difference between the two types of plans and do not know which kind of plan their employer provides.

The ACA's preventive services mandate represents a major breakthrough for national health reform because it transforms the nation's public and private health care systems into public health delivery vehicles. In doing so, the ACA broke down two significant barriers to meaningful reform: the public health-health care divide, which led to the prevalence of curative rather than preventive medicine, and the legal framework that fragments the financing and delivery of health care, which was perpetuated by ERISA. As a result, prevention measures with proven effectiveness will now be provided on a national and uniform basis, with the potential to improve health outcomes and reduce costs.

state insurance laws, many group plans are not. Most employment-based group health plans are covered by ERISA,⁹⁸ and the majority of employers self-insure.⁹⁹ Although adopted primarily to bring uniformity to pension law and protect multi-state employers from the burden of different state laws,¹⁰⁰ ERISA also regulates employee benefits, such as health insurance. Despite its promise of uniformity, ERISA has produced anything but uniformity with respect to state insurance regulation. ERISA has created confusion and spawned innumerable lawsuits, many of which center on the applicability of state insurance laws to ERISA plans. Put simply, whether an ERISA health plan is subject to state insurance laws depends on one factor: how the ERISA plan is funded.

Employers can fund health benefit plans several ways. One way is to create a so-called fully-insured plan. As the name suggests, a fully-insured health benefit plan is group health insurance coverage purchased from an insurer. In exchange for a premium, which is typically shared by the employer and the employee, the insurer (and not the employer) assumes

Self-insured ERISA plans are not subject to state insurance laws, while fully-insured plans are subject to state laws. The basis for this can be found in ERISA's so-called "conflict preemption" provision and its exceptions.¹⁰¹ This highly confusing and much litigated section of ERISA provides that ERISA "shall supersede any and all State laws" that "relate to any employee benefit plan."¹⁰² This provision was apparently intended to permit multi-state employers to offer benefit plans on a national basis without the burden of having to conform to the laws of every state in which they operate.¹⁰³ However, ERISA's "savings clause"¹⁰⁴ then exempts from preemption state laws that regulate insurers. As a result, states are free to impose a wide range of regulatory requirements, including benefit mandates, on health insurers that sell employer-based benefit plans. There is, however, another exception. The so-called "deemer clause"¹⁰⁵ provides that a self-insured plan shall not be deemed to be engaged in the business of insurance for the purpose of state law regulation.¹⁰⁶ In other words, if an employer obtains health insurance from an insurance company (and is

therefore fully insured), that employer's plan will be subject to state insurance laws, such as mandates. If, on the other hand, an employer's health plan is self-insured, that employer's plan is not subject to state insurance laws, even if an insurance company administers the plan.¹⁰⁷ Essentially, the "deemer clause" prohibits the states from regulating self-insured employer health benefit plans but does not prevent the regulation of fully-insured plans.¹⁰⁸ Thus, by self-insuring, an employer can avoid state insurance mandates. This is an important point because approximately 55% of persons with ERISA health plan coverage are covered by self-insured plans, with fully-insured plans covering the remainder.¹⁰⁹ This means that even if a majority of states banded together to enact a particular prevention mandate, more than half of the group plans would not have to comply. As a result, ERISA has been a major impediment to effective large-scale health care reform at the state level.

The ACA breaks down the ERISA barrier by making the preventive services mandates applicable to all group health plans, including all ERISA plans, regardless of whether they are fully-insured or self-insured.¹¹⁰ This means that, for the first time, a uniform set of evidence-based preventive services is available on a nationwide basis to everyone enrolled in a group health plan. The ACA does not repeal ERISA. State law benefit mandates are still subject to ERISA, and self-insured plans do not have to comply with such laws. Thus, there will still be significant fragmentation in the U.S. health care system; all the problems that fragmentation engenders will remain. However, with the passage of the ACA, the barriers that fragment the health care system no longer apply to a core set of evidence-based preventive services.

Conclusion

The ACA's preventive services mandate represents a major breakthrough for national health reform because it transforms the nation's public and private health care systems into public health delivery vehicles. In doing so, the ACA broke down two significant barriers to meaningful reform: the public health-care divide, which led to the prevalence of curative rather than preventive medicine, and the legal framework that fragments the financing and delivery of health care, which was perpetuated by ERISA. As a result, prevention measures with proven effectiveness will now be provided on a national and uniform basis, with the potential to improve health outcomes and reduce costs.

Nevertheless, questions remain with respect to implementation of the ACA's preventive services mandates. Will the mandates generate unanticipated

negative externalities? For example, will the mandates adversely affect physician workloads, further reducing the availability of primary care physicians? Since cost-sharing is considered by health insurers when physician reimbursement rates are determined, will the prohibition on patient cost-sharing for mandated preventive services lead health insurers to reduce reimbursements to physicians for preventive services (i.e., by not covering the lost copayments)? The implementation of the mandates will no doubt raise many more questions and generate unanticipated outcomes. There are also questions as to whether the preventive mandates will be sufficiently effective to justify their costs, although a recent estimate did hold out the promise of positive gains from the types of preventive services mandated by the ACA.¹¹¹ Regardless of how these questions are answered, the groundwork has been laid for incorporating population-level, evidence-based preventive services into the U.S.'s public and private health care systems. This is a significant step forward for public health and a starting point for further integration of the public health and health care systems.

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7. 29 USC §§ 1132, 1144 (2006) (ERISA's preemption provisions).
8. 42 U.S.C.A. § 300u-11 (2010).
9. *Id.*, June 10, 2010; Exec. Order No. 13,544, 75 *Fed. Reg.* 33983 (June 16, 2010) (establishing the National Prevention, Health Promotion, and Public Health Council).
10. 42 U.S.C.A. § 280g-10 (2010).

11. *Id.*, at § 300u-12.
12. *Id.*, at §§ 280h, 280h-4.
13. *Id.*, at §§ 300u-13, 300u-14.
14. 29 U.S.C.A. § 794f.
15. 42 U.S.C.A. § 280k.
16. *Id.*, at § 247b(1).
17. 21 U.S.C.A. § 343(q)(5).
18. 29 U.S.C.A. § 207(r).
19. 42 U.S.C.A. § 2801.
20. For a more detailed description, see C. S. Davis and S. Somers, "National Health Care Reform and the Public's Health," *Journal of Law, Medicine & Ethics* 39, no. 1, supp. (2011): 65-68, at 65-66; Public Health Law Network, *Public Health Provisions of the Patient Protection and Affordable Care Act*, available at <<http://www.publichealthlawnetwork.org/wp-content/uploads/ACA-chart-formatted-FINAL2.pdf>> (last visited June 15, 2011).
21. New or renewed after September 23, 2010, except for so-called "grandfathered" plans. For a detailed discussion of grandfathered plans, see M. Merlis, "Health Policy Brief: 'Grandfathered' Health Plans," October 29, 2010, available at <http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=29> (last visited June 15, 2011).
22. See generally, Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act, 75 *Fed. Reg.* 41726 (July 19, 2010). The interim final regulations, which became effective on September 17, 2010, clarify the cost-sharing requirements when a recommended preventive service is provided during an office visit. Whether there will be cost sharing depends on the primary purpose of the office visit, whether the preventive service is billed separately from the office visit, and whether the preventive services are provided in-network. For example, if a recommended preventive service is billed separately from an in-network office visit, such as when a patient receives a cholesterol screening test (a recommended preventive service), during a routine office visit, cost-sharing requirements may be imposed for the office visit because the recommended preventive service is billed as a separate charge. *Id.*, at 41728. In other words, if the preventive service is billed separately from the office visit, it is the preventive service that has cost-sharing waived, not the entire office visit. *Id.*, at 41738. If, however, the primary purpose of the in-network office visit is the delivery of the recommended preventive service and the preventive service is not billed separately from the office visit, then cost-sharing may not be imposed for the office visit. Also, if the primary purpose of the office visit is not the delivery of a recommended preventive service, but the preventive service is not billed separately from the office visit, then cost-sharing may be still imposed for the office visit. *Id.*, at 41728. The regulations also make clear that health plans are not required to provide coverage for recommended preventive services delivered by an out-of-network provider and may also impose cost-sharing when recommended preventive services are delivered by an out-of-network provider. *Id.*
23. It is widely recognized that health insurance creates additional demand for health care services. The additional consumption of health care services attributed to health insurance is referred to as "moral hazard." See J. A. Nyman, "American Health Policy: Cracks in the Foundation," *Journal of Health Politics, Policy and Law*, 32, no. 5 (2007): 759-783, at 760. Conventional wisdom posits that moral hazard is responsible for the significant increase in health care expenditures. J. P. Newhouse, "Medical Care Costs: How Much Welfare Loss?" *Journal of Economic Perspectives* 6, no. 3 (1992): 3-21, at 6-7.
24. K. Swartz, *Cost-Sharing: Effects on Spending and Outcomes*, Robert Wood Johnson Foundation, December 2010, at 16, available at <<http://www.rwjf.org/files/research/121710.policy-synthesis.costsharing.rpt.pdf>> (last visited June 15, 2011). Nationally, American adults use preventive services at slightly more than half the recommended rate. See E. A. McGlynn, et al., "The Quality of Health Care Delivered to Adults in the United States," *New England Journal of Medicine* 348, no. 26 (2003): 2635-2645, at 2641.
25. 42 U.S.C.A. § 300gg-13(a)(1). There is, however, an exception for the controversial breast cancer screening, mammography, and prevention recommendations "issued in or around November 2009." 42 U.S.C.A. § 300gg-13(a)(5).
26. U.S. Preventive Services Task Force, "USPSTF A and B Recommendations," available at <<http://www.uspreventiveservicestaskforce.org/uspstf/uspstabrecs.htm>> (last visited June 15, 2011).
27. 75 *Fed. Reg.* at 41741.
28. *Id.*, at 41743.
29. *Id.*, at 41741-42.
30. *Id.*, at 41743.
31. *Id.*, at 41741.
32. *Id.*, at 41741-44.
33. 42 U.S.C.A. § 300gg-13(a)(2); 75 *Fed. Reg.* at 41745-52.
34. 42 U.S.C.A. § 300gg-13(a)(3), (4).
35. 42 U.S.C.A. §§ 1395l, 1395m(n). The ACA does not require Medicare Advantage plans to offer covered preventive services without cost sharing.
36. 42 U.S.C. § 1396 *et seq.*
37. Federal Financial Participation in State Assistance Expenditures, "Federal Matching Shares for Medicaid, the Children's Health Insurance Program, and Aid to Needy Aged, Blind, or Disabled Persons for October 1, 2010 through September 30, 2011," 74 *Fed. Reg.* 62315, 62316 (November 27, 2009).
38. 42 U.S.C.A. § 1396d(a), (b), effective 1/1/2013.
39. Congressional Budget Office, *CBO's March 2011 Estimate of the Effects of the Insurance Coverage Provisions Contained in the Patient Protection and Affordable Care Act (Public Law 111-148) and the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152)*, at 1, available at <<http://www.cbo.gov/budget/factsheets/2011b/HealthInsuranceProvisions.pdf>> (last visited June 21, 2011) (estimating 95% health insurance coverage for all non-elderly U.S. residents by 2016, excluding "unauthorized immigrants").
40. L. O. Gostin and P. D. Jacobson, *Law and the Health System* (New York: Foundation Press, 2006): at 1; see Brandt and Gardner, *supra* note 5, at 707-08.
41. This is the meaning I ascribe to this term throughout this article.
42. Centers for Medicare and Medicaid Services, *The Nation's Health Dollar, Calendar Year 2009: Where It Came From*, available at <<https://www.cms.gov/NationalHealthExpend-Data/downloads/PieChartSourcesExpenditures2009.pdf>> (last visited May 12, 2011).
43. D. Hemenway, "Why We Don't Spend Enough on Public Health," *New England Journal of Medicine* 362, no. 18 (2010): 1657-1658, at 1657. For an example of recent press coverage of a highly visible medical feat, see L. Kowalczyk, "Getting Accustomed to New Face: Burned Patient Adjusting Well," *Boston Globe*, May 10, 2011, available at <http://www.boston.com/lifestyle/health/articles/2011/05/10/face_transplant_patient_adjusting_well/?page=1> (story about U.S.'s first recipient of a full face transplant).
44. S. Burris, "The Invisibility of Public Health: Population-Level Measures in a Politics of Market Individualism," *American Journal of Public Health* 87, no. 10 (1997): 1607-1610, at 1608.
45. A. R. Kovner and J. R. Knickman, eds., *Jonas & Kovner's Health Care Delivery in the United States*, 9th ed. (New York: Springer Publishing Company, 2008): at 92.
46. See P. Starr, *The Social Transformation of American Medicine: The Rise of a Sovereign Profession and the Making of a Vast Industry* (New York: Basic Books, Inc., 1982): at 181 ("In mid-nineteenth-century America, public health was mainly concerned with sanitary reform and affiliated more closely with engineering than with medicine").
47. See Burris, *supra* note 44, at 1608.
48. See Kovner and Knickman, *supra* note 45, at 90-91, 99-101, and 110-111.

49. *Id.*, at 90.
50. See Gostin and Jacobson, *supra* note 40, at 3.
51. See Jacobson and Gostin, *supra* note 3, at 85; see also Centers for Medicare and Medicaid Services, *supra* note 42 (3% public health spending).
52. Centers for Medicare and Medicaid Services, "National Health Expenditures Aggregate, Per Capita Amounts, Percent Distribution, and Average Annual Percent Growth, by Source of Funds: Selected Calendar Years 1960-2009," *available at* <<https://www.cms.gov/NationalHealthExpendData/downloads/tables.pdf>> (last visited June 15, 2011).
53. I. Wylie et al., "Everywhere and Nowhere: a Socratic Dialogue on the New Public Health," *BMJ* 319, no. 7213 (1999): 839-840.
54. See Kovner and Knickman, *supra* note 45, at 87; Burris, *supra* note 44, at 1609.
55. See Burris, *supra* note 44, at 1609.
56. See Brandt and Gardner, *supra* note 5, at 709.
57. See Starr, *supra* note 46.
58. See Brandt and Gardner, *supra* note 5, at 711.
59. See Hemenway, *supra* note 43; Burris, *supra* note 44; Gostin and Jacobson, *supra* note 40, at 3.
60. See Gostin et al., *supra* note 4, at 7-30.
61. See Centers for Medicare and Medicaid Services, *supra* note 52.
62. *Id.*
63. Kaiser Family Foundation, "Health Care Spending in the United States and Selected OECD Countries, April 2011," *available at* <<http://www.kff.org/insurance/snapshot/OECD042111.cfm>> (last visited June 15, 2011).
64. K. Davis et al., *Mirror, Mirror on the Wall: How the Performance of the U.S. Health Care System Compares Internationally, 2010 Update*, June 2010, at 3, *available at* <http://www.commonwealthfund.org/~media/Files/Publications/Fund%20Report/2010/Jun/1400_Davis_Mirror_Mirror_on_the_wall_2010.pdf> (last visited May 12, 2011).
65. World Health Organization, "The World Health Report 2000: Health Systems, Improving Performance," 2000, at 155, *available at* <http://www.who.int/whr/2000/en/whr00_en.pdf> (last visited June 15, 2011).
66. See, e.g., C. Bialik, "Ill-Conceived Ranking Makes for Unhealthy Debate," *Wall Street Journal*, October 21, 2009, at A19, *available at* <<http://online.wsj.com/article/SB125608054324397621.html>> (last visited June 15, 2011).
67. A. Carroll, "How Do We Rate the Quality of the U.S. Health Care System - Population Statistics," *Incidental Economist*, October 19, 2010, *available at* <<http://theincidentaleconomist.com/wordpress/how-do-we-rate-the-quality-of-the-us-health-care-system-%E2%80%93-population-statistics/>> (last visited June 15, 2011) (summarizing OECD data). The data do not include the Russian Federation because it does not submit comparative data. *Id.*
68. *Id.*
69. *Id.*
70. K. E. Thorpe and D. H. Howard, "The Rise in Spending among Medicare Beneficiaries: The Role of Chronic Disease Prevalence and Changes in Treatment Intensity," *Health Affairs* 25, no. 5 (2006): w378-w388.
71. A. H. Mokdad et al., "Actual Causes of Death in the United States, 2000," *JAMA* 291, no. 1 (2004): 1238-1245; A. H. Mokdad et al., "Correction: Actual Causes of Death in the United States, 2000," *JAMA* 293, no. 3 (2005): 293-294.
72. M. French, *Shifting the Course of Our Nation's Health: Prevention and Wellness as National Policy*, American Public Health Association (2009), at 3-4, *available at* <<http://www.apha.org/NR/rdonlyres/0867A2FF-88EE-41CF-97C3-21E79D8C8896/0/FINALPreventionPolicy.pdf>> (last visited June 15, 2011).
73. Substance Abuse and Mental Health Services Administration, "2007 National Survey on Drug Use & Health: Detailed Tables, Tables; Table 8.31B - Substance Dependence or Abuse for Specific Substances in the Past Year among Persons Aged 12 or Older: Percentages, 2002-2007" (percentage of population dependent upon or abusing alcohol is relatively constant, between 7.5% and 7.8%), *available at* <<http://www.oas.samhsa.gov/NSDUH/2k7NSDUH/tabs/Sect8pe1abs1to42.htm#Tab8.31A>> (last visited June 15, 2011).
74. See French, *supra* note 72.
75. M. Buettgens and M. A. Hall, "Who Will Be Uninsured After Health Insurance Reform?" Robert Wood Johnson Foundation, March 2010, at 2, *available at* <<http://www.rwjf.org/files/research/71998.pdf>> (last visited June 15, 2011).
76. Kaiser Family Foundation, *The Uninsured: A Primer*, December 2010, at 1-2, *available at* <<http://www.kff.org/uninsured/upload/7451-06.pdf>> (last visited June 21, 2011).
77. 15 U.S.C. §§ 1011-1015 (2006).
78. *Id.*, at § 1012(a) ("the business of insurance...shall be subject to the laws of the several States").
79. 29 U.S.C. § 1001 *et seq.* Government plans and church plans are not subject to ERISA. 29 U.S.C. § 1003(b).
80. V. C. Bunce, *Health Insurance Mandates in the States 2010*, "Council for Affordable Health Insurance," at 11-34 (listing benefits mandated), *available at* <http://www.cahi.org/cahi_contents/resources/pdf/MandatesintheStates2010.pdf> (last visited June 15, 2011). While the federal government does impose some benefit mandates, such as the Mental Health Parity and Addiction Equity Act of 2008, 29 U.S.C.A. § 1185a(a), which requires group health plans to ensure that financial requirements and treatment limitations applicable to mental health or substance use disorder benefits are no more restrictive than those applied to medical/surgical benefits, benefit mandates have generally left to the states to apply.
81. N. M. Bellows et al., "State-Mandated Benefit Review Laws," *Health Services Research* 41, no. 3, pt. 2 (2006): 1104-1123, at 1105.
82. See Bunce, *supra* note 80, at 7.
83. M. J. Laugesen et al., "A Comparative Analysis of Mandated Benefit Laws, 1949-2002," *Health Services Research* 41, no. 3, pt. 2 (2006): 1081-1103, at 1082, 1083-1084.
84. *Id.*
85. A. B. Monahan, "Federalism, Federal Regulation, or Free Market? An Examination of Mandated Benefit Reform," *University of Illinois Law Review* 2007, no. 5 (2007): 1361-1416, at 1367.
86. *Id.*, at 1365-1366.
87. See *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 731 (1985).
88. See Bellows et al., *supra* note 81, at 1106; Monahan, *supra* note 85, at 1370 n. 45 (mandate laws represent rent seeking by special interests); Laugesen et al., *supra* note 83, at 1094-1095 (noting that mandates were also a way for non-physician providers and alternative medicine providers to command health insurance reimbursement).
89. *Id.*, at 1106.
90. See Bunce, *supra* note 80, at 11-34.
91. See Bellows et al., *supra* note 81, at 1106; Laugesen, *supra* note 83, at 1095; D. Hyman, "Regulating Managed Care: What's Wrong with a Patient Bill of Rights," *Southern California Law Review* 73, no. 2 (2000): 221-275, at 247-249.
92. B. R. Furrow et al., *Health Law, Cases, Material and Problems*, 6th ed. (St. Paul: Thompson/West) at 652.
93. A. B. Monahan, "Value-Based Mandated Health Benefits," *University of Colorado Law Review* 80, no. 1 (2009): 127-200, at 198-199; Laugesen et al., *supra* note 83, at 1096.
94. P. D. Jacobson et al., "Litigating the Science of Breast Cancer Treatment," *Journal of Health Politics, Policy and Law* 32, no. 5 (2007): 785-817, at 790.
95. See Monahan, *supra* note 93; Laugesen et al., *supra* note 83, at 1097; Hyman, *supra* note 91, at 247, 249. This is now a federal coverage mandate. 29 U.S.C. § 1185.
96. See Bunce, *supra* note 80, at 2.
97. Kaiser Family Foundation, *The Uninsured, A Primer*, December 2010, at 2-3, *available at* <<http://www.kff.org/uninsured/upload/7451-06.pdf>> (last visited June 15, 2011) (cited above).

98. Government plans and church plans are not subject to ERISA. 29 U.S.C. § 1003(b).
99. W. Pierron and P. Fronstin, "Erisa Pre-Emption: Implications for Health Reform And Coverage," Employee Benefit Research Institute, February 2008, at 11, *available at* <http://www.ebri.org/pdf/briefspdf/EBRI_IB_02a-20082.pdf> (last visited May 12, 2011).
100. *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 657 (1995) (ERISA pre-emption designed "to avoid a multiplicity of [state and local] regulation in order to permit the nationally uniform administration of employee benefit plans.")
101. 29 U.S.C. § 1144(a).
102. *Id.*
103. *New York State Conference*, 514 U.S. at 657.
104. 29 U.S.C. § 1144(b)(2)(A).
105. *Id.*, at § 1144 (b)(2)(B).
106. *FMC Corp. v. Holliday*, 498 U.S. 52, 61 (1990) (state insurance regulation does "not reach self-funded employee benefits plans because the plans may not be deemed to be insurance companies, other insurers, or engaged in the business of insurance for purposes of such state laws."); see also *Metropolitan Life Ins.*, 471 U.S. at 747 (noting in dicta that insured plans and self-insured plans are treated differently under state mandate laws because the deemer clause prohibits states from applying insurance mandates to self-insured employee health benefit plans).
107. See, e.g., *NGS Am., Inc. v. Barnes*, 805 F. Supp. 462, 473-74 (W.D. Tex. 1992); R. Korobkin, "The Battle over Self-Insured Health Plans, or 'One Good Loophole Deserves Another,'" *Yale Journal of Health Policy, Law, and Ethics* 5, no. 1 (2005): 89-136, at 95.
108. *Id.*, at 105.
109. See Pierron and Fronstin, *supra* note 99.
110. 75 *Fed. Reg.* at 41727 (for the purposes of the ACA, "[t]he term 'group health plan' includes both insured and self-insured group health plans"); R. W. Miller, "The Effect of the Health Reform Act on Self-Insured Employer Health Plans," *Journal of Health & Life Sciences Law* 4, no. 1 (2010): 59-87.
111. See M. V. Maciosek et al., "Greater Use of Preventive Services in U.S. Health Care Could Save Lives at Little or No Cost," *Health Affairs* 29, no. 9 (2010): 1656-1660 (greater use of preventive services could avert the loss of more than two million life-years annually and result in savings of \$3.7 billion).