

THE PATIENT PROTECTION AND AFFORDABLE CARE ACT: WHAT DOES IT REALLY DO?

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*“We have to pass the health care bill so you can find out what’s in it,”
Speaker Nancy Pelosi, March 10, 2010 on the floor of the House
of Representatives urging her colleagues to pass the ACA.*

INTRODUCTION

We are now well into full implementation of the Affordable Care Act and, despite some distinct improvements, the nation is learning to live with reduced expectations about the benefits of that legislation. The exchanges’ initial rollout was chaotic,² deductibles and co-pays are high on the cheaper individual plans sold on the exchanges,³ insurers on the exchanges are seeking rate hikes,⁴ and important state participation has not emerged as anticipated. As of March 2016, only 31 states plus the District of Columbia were participating in the ACA’s Medicaid expansion program

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² See U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-15-238, HEALTHCARE.GOV: CMS HAS TAKEN STEPS TO ADDRESS PROBLEMS, BUT NEEDS TO FURTHER IMPLEMENT SYSTEMS DEVELOPMENT (2014), <http://www.gao.gov/assets/670/668834.pdf>.

³ See Robert Pear et al., *Cost of Coverage Under Affordable Care Act to Increase in 2015*, N.Y. TIMES, Nov. 14, 2014, http://www.nytimes.com/2014/11/15/us/politics/cost-of-coverage-under-affordable-care-act-to-increase-in-2015.html?_r=0. See generally GOV’T ACCOUNTABILITY OFFICE, GAO-15-312, PRIVATE HEALTH INSURANCE: EARLY EVIDENCE FINDS PREMIUM TAX CREDIT LIKELY CONTRIBUTED TO EXPANDED COVERAGE, BUT SOME LACK ACCESS TO AFFORDABLE PLANS (2015).

⁴ See Margot Sanger-Katz, *Get Ready for Higher Obamacare Rates Next Year*, N.Y. TIMES (May 6, 2016), http://www.nytimes.com/2016/05/07/upshot/get-ready-for-higher-obamacare-rates-next-year.html?_r=0.

while 19 states were not.⁵ In 2016, only 12 states and the District of Columbia had their own exchanges; fully 27 states participated in the federal exchange.⁶ Meanwhile, the White House delayed the effective date of the ACA's employer mandates following business community resistance.⁷ Many continue to resent the individual mandate⁸ despite the Supreme Court's decision upholding that mandate in 2012.⁹

Opponents have grown more shrill and much of the rhetoric, including over 50 "ceremonial" repeals of the ACA in the House as of June 2015,¹⁰ were geared towards making ACA's implementation shortfalls and misunderstandings of what the ACA does into a 2016 presidential campaign issue. Not only do many legislators not know or even care what

⁵ See STATUS OF STATE ACTION ON THE MEDICAID EXPANSION DECISION, KAISER FAMILY FOUND. (2016), <http://kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/>.

⁶ See STATE HEALTH INSURANCE MARKETPLACE TYPES, 2016, KAISER FAMILY FOUND. (2016), <http://kff.org/health-reform/state-indicator/state-health-insurance-marketplace-types/>. Four more states have federally supported marketplaces and 7 states have state partnership marketplaces. *Id.*

⁷ See EMPLOYER RESPONSIBILITY UNDER THE AFFORDABLE CARE ACT, KAISER FAMILY FOUND. (2015), <http://kff.org/infographic/employer-responsibility-under-the-affordable-care-act/>. Strictly speaking, the ACA does not require employers to provide their employees with health insurance. However, large employers must pay penalties to the Internal Revenue Service if they do not provide affordable health insurance coverage to their workers. The Obama Administration delayed the original effective date of that employer mandate until January 1, 2015 for employers with at least 100 employees and until January 1, 2016 for employers with at least 50 to 99 employees. *Id.*

⁸ Under the ACA's individual mandate, individuals who can afford minimum essential health insurance but decide not to buy it must either qualify for a health coverage exemption or pay a penalty. The individual mandate went into effect on January 1, 2014. See 26 U.S.C. § 5000A (2015); HealthCare.gov, *The Fee you Pay if you Don't Have Health Coverage*, <https://www.healthcare.gov/fees-exemptions/fee-for-not-being-covered/>. For discussion of the continued resentment in some quarters toward the individual mandate, see Dante Atkins, *King v. Burwell Unpopular, but Anti-ACA Propaganda Having Lasting Effects*, DAILY KOS (Apr. 12, 2015), <http://www.dailykos.com/story/2015/04/12/1376255/-King-v-Burwell-unpopular-but-anti-ACA-propaganda-having-lasting-effects>.

⁹ Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566, 2608 (2012).

¹⁰ See, e.g., Manu Raju & Burgess Everett, *GOP lawmakers: Time to move on from Obamacare repeal*, POLITICO (June 25, 2015, 6:57 PM), <http://www.politico.com/story/2015/06/gop-lawmakers-time-to-move-on-from-obamacare-repeal-119439>.

is in the ACA, much of the public does not understand their options and fears the ACA's potential impact on their choice of care and how it will be paid for.¹¹

To date, most of the commentary and anxiety has centered over the ACA's access provisions and the mandate. Yet there is much more in the ACA that has been largely ignored.

Most believe the ACA was designed only to provide quality healthcare to all Americans through a pluralistic public and private system: private individual and small-employer-sponsored insurance, employer-provided insurance, and several government programs. The private or market component would be realized through centralized insurance marketplaces (known as exchanges), both for individuals and small employers (with less than 50 workers), and eventually through larger employers. The government component would be provided primarily through Medicaid and Medicare.

The ACA sets into motion a number of dynamics that will build upon a number of social and economic forces discussed in Section I and that will eventually realize its goal of universal coverage, but not in the way most anticipated it would do when the legislation was passed in 2010. Instead of a pluralistic public and private system, the final coverage vehicle will eventually become a single government program for everyone administered by private entities that only process enrollment, collect premiums and pay claims – very much like Medicare today. This will occur because the ACA will create an environment where both individual and institutional providers, employers, the general public and the states will become natural allies for a universal health care system much like Medicare. This surprising coalition will overwhelm the “free enterprise” advocates and force Congress to embrace a single payer “not-for-profit” system. The ACA and the emerging social and economic forces propelling it will produce this result in a very chaotic and untidy chain of events over the next decade.

In addition, the ACA will do much more than just expand access to coverage. Over time the ACA will transform not only how one pays for care, but how care is delivered. The ACA will transform today's medical professional paradigm from a fee-for-service entrepreneurial “sickness”

¹¹ See, e.g., KAISER HEALTH POLICY TRACKING POLL: THE PUBLIC'S VIEWS ON THE ACA, KAISER FAMILY FOUND. (2016), <http://kff.org/interactive/kaiser-health-tracking-poll-the-publics-views-on-the-aca/#?response=Favorable--Unfavorable&aRange=twoYear> (last viewed July 10, 2016).

model into a not-for-profit “wellness model” where the medical profession will regain much of the clinical autonomy it lost over the last 30 years. Many also believe that the ACA will result in better quality healthcare at lower cost largely because of concepts that permeate the ACA: value rather than volume purchasing and in particular comparative effectiveness research (CER).¹² This cost reduction may happen, but the experience in other countries makes this outcome indeterminate.

What is more certain is that the ACA will result in a more *efficient* health care system, where decisions in clinical evaluations will balance the incremental benefits of any treatment with its incremental cost and the efficacy of new interventions compared to existing ones. Such a comparison should result in better health outcomes and resource allocation than we have today, viewed from a population perspective. This increased efficiency may even result in a higher rather than a lower or a flatter cost curve relative to gross domestic product because of the transaction costs of moving the system towards “evidence-based medicine” and clinical decision-making that takes into account the marginal cost and benefit of any treatment. Once these initial costs are absorbed, the desired cost impact may be realized.

This Article is divided into four parts.

Section I will start with a brief description of the major social, economic, demographic, technological and political trends within which the ACA will be implemented and evolve over the next decade. This context is essential to understanding how the various ACA provisions will change or influence the direction of major components of the health care system and where things could go wrong. This context is also essential for making reasonable estimates of the political forces affected by the ACA and vice-versa and, therefore, what the U.S. healthcare system will look like in 2025.

Section II will describe how the ACA's provisions attempt to realize a pluralistic private/government access solution and how these efforts will set the stage for eliminating the private institutional sector from financial “risk taking,” diminish private insurers’ role in the delivery of care and hasten the exit of employers from their traditional role of sponsoring coverage.

One of the more significant unintended consequences of the ACA will be public dissatisfaction and jaundice regarding the private sector’s ability to finance and deliver healthcare better than the government. At the

¹² See *infra* Section III.

same time, the high cost for some of mandatory health insurance, rising deductibles and co-pays, and polarization of politics on the state and federal level will increase the public's distrust of government. Yet there are segments within the private sector where public opinion of the ACA is quite favorable and one of those areas involves clinicians delivering medical care. The ACA's structural changes will enhance rather than diminish the role and independence of clinicians regarding medical decisions.

Section III will examine several parts of the ACA that have not received much public attention. These include value-based purchasing, comparative effectiveness research, and several related ACA provisions which will dramatically change how new medical technology and new and existing practices are evaluated and delivered.

CER and these structural changes will reinforce the shift from today's entrepreneurial "for-profit" paradigm to a "not-for-profit" professional paradigm. That, in turn, will change how society and the medical profession view how much autonomy and regulation is proper regarding clinical medical decision-making and how providers should be compensated for such care.

The Article concludes with a prediction of the future evolution of the health care system under several possible scenarios based on different changes in control of the Congress and the White House, as well as other changes in the political landscape.

Interestingly enough, all of the scenarios, when viewed in the changing social and economic environment discussed in Section I, lead towards a common destination: a single government health care system for all that will resemble Medicare in structure and administration.

I. THE CULTURAL, ECONOMIC, POLITICAL, TECHNOLOGICAL AND DEMOGRAPHIC CONTEXT OF THE ACA

There are a number of societal changes underway that help explain the structure of the ACA, the challenges it must overcome and the importance of its dominating philosophies: value-based purchasing and comparative effectiveness research. These societal trends, while different, are very much interrelated and affect one another.

First and foremost, everyone, irrespective of his or her ideological or political bent or economic status, wants the employer out of the middle of the U.S. healthcare finance system. Market-oriented individuals would replace the employer sponsor with the individual worker via co-pays or a voucher-type system. The left would substitute government for the

employer. Employers, both large and small, just want out.¹³ Employers would still be involved via specific or general taxes or possibly some defined contribution type of benefit, but their present role as sponsors of health insurance coverage would be greatly diminished.

Another important influence is that the ACA favors network care control by the medical profession. The ACA does this in a number of ways, but primarily through its endorsement of a new type of network for Medicare called an “Accountable Healthcare Organization” or ACO. The ACO is a clinician-controlled network based on primary care physicians, electronic health records and collaboration between primary care physicians and ancillary and specialist providers participating in the network. The ACO mechanism seeks to make health care providers more accountable for healthcare savings and improved health outcomes through financial carrot and sticks. While originally limited to Medicare, the ACO concept is rapidly spreading throughout other government programs, such as Medicaid, and the private delivery system.¹⁴

Of equal importance is the fact that the ACA’s exchange regulations do not create a favorable environment for a for-profit (public company) insurer. For example, every exchange must have more than one insurer and one of these must be a “not-for-profit” entity.¹⁵ In addition, the ACA requires insurance participants to offer generous coverage (known as “essential health benefits”)¹⁶ with virtually no underwriting,¹⁷ meet

¹³ For some very preliminary estimates of the extent to which the availability of individual insurance on the exchanges encourages employers to refrain from sponsoring health coverage, see U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-12-768, PATIENT PROTECTION AND AFFORDABLE CARE ACT: ESTIMATE OF THE EFFECT ON THE PREVALENCE OF EMPLOYER-SPONSORED HEALTH COVERAGE (2012).

¹⁴ See Atul Gawande, *Overkill*, THE NEW YORKER (May 22, 2015) at 53; Tricia McGinnis, *A Unicorn Realized? Promising Medicaid ACO Programs Really Exist*, THE COMMONWEALTH FUND BLOG (March 11, 2015), <http://www.commonwealthfund.org/publications/blog/2015/mar/unicorn-realized-medicaid-acos> (“hundreds of ACOs [are] now sprouting up in an array of shapes and sizes in Medicare, Medicaid, and the commercial sector”).

¹⁵ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 10104(q), 124 Stat. 902 (2010) (codified at 42 U.S.C. § 18054(a)(1), (a)(3)).

¹⁶ *Id.* § 10104(b), 124 Stat. 896 (2010) (codified at 42 U.S.C. § 18022(a)-(b)). “Essential health benefits must include items and services within at least the following 10 categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use

required loss ratios (*i.e.*, returning between 80% and 85% of premiums collected in the form of insurance benefits),¹⁸ and operate subject to rate regulation¹⁹ and traditional insurance solvency regulation²⁰ that stresses adequate capital.

Competing dynamics inherent in a mixed free market operating under a public utility regulatory structure will force traditional insurance companies to either abstain from participating in many exchanges (many have already) or be selective about where they will participate (a form of underwriting).²¹ These dynamics will force these companies to move even more quickly than they are today towards the administration of premium and claims management rather than assuming risk. Already traditional insurance companies are desperately looking for new missions, such as “case management,” much like the March of Dimes looked for a new disease after tuberculosis was conquered.

disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.” *Essential Health Benefits*, HEALTHCARE.GOV (Sept. 9, 2015), <https://www.healthcare.gov/glossary/essential-health-benefits/> (2015). Minimum essential coverage does not include specialized coverage, such as coverage only for vision care or dental care or workers’ compensation or disability policies. Patient Protection and Affordable Care Act, § 1501(b), 124 Stat. 244 (2010) (codified at 26 U.S.C. § 5000A(f)(3)); *see* 42 U.S.C. § 300gg-91(c).

¹⁷ Patient Protection and Affordable Care Act, § 1201(2)(A), (4), 124 Stat. 154–55 (2010) (codified at 42 U.S.C. §§ 300gg(a), 300gg-3(a)).

¹⁸ *See, e.g., id.* § 9016, 124 Stat. 872 (2010) (codified at 26 U.S.C. § 833(c)(5)).

¹⁹ *See, e.g.,* Ann Mills et al., *Truth and Consequences – Insurance Premium Rate Regulation and the ACA*, 363 NEW ENGLAND J. MED. 899, 899-900 (2010).

²⁰ *See, e.g.,* Patient Protection and Affordable Care Act, § 1322(c)(5), 124 Stat. 190 (2010) (codified at 42 U.S.C. § 18042(c)(5)).

²¹ *See, e.g.,* Reed Abelson & Agustin Armendariz, *In Colorado, Disparity in Health Plan Prices Underscores Ambitions, and Limits, of Affordable Care Act*, N.Y. TIMES, Jan. 19, 2015, http://www.nytimes.com/2015/01/20/business/in-year-2-of-affordable-care-act-premiums-diverge-widely.html?_r=0; U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-14-657, PATIENT PROTECTION AND AFFORDABLE CARE ACT: LARGEST ISSUERS OF HEALTH COVERAGE PARTICIPATED IN MOST EXCHANGES, AND NUMBER OF PLANS AVAILABLE VARIED (2014) (Insurers who pick and choose the geographic areas in which they choose to underwrite often do so to avoid areas with higher proportions of costly high-risk patients.).

One of the more important societal changes over the last 50 years is information technology (IT). IT has transformed virtually every aspect of our lives. Medicine is no exception. As hardware capabilities and processor capacity have grown geometrically, huge datasets have been created that can be updated in real time from many diverse government and private entities.

Just Google and peruse the *Dartmouth Atlas of Health Care*,²² which compiles data on virtually every aspect of medicine – not only with respect to practice variations, but also outcomes of alternative treatments. The *Dartmouth Atlas* is just one of many ongoing analyses taking advantage of this technology. Vast data sets can now be manipulated in an almost infinite number of ways, even down to the zip code level. This new capability will enable government and other healthcare entities to analyze new delivery and financing structures and clinical interventions in terms of outcomes and cost efficiency.

This IT capability makes CER not just a theory but a reality. The ACA also stresses substituting traditional medical charting with electronic records, which will enhance the coordination and continuity of care.²³ Last but not least, the new IT capabilities will facilitate the movement away from fee-for-service reimbursement to bundled payments,²⁴ which will enable enhanced coordination and continuity of care and network accountability.

Another critical dynamic is the significant distrust the public has for many public and private institutions, which influences their comfort

²² DARTMOUTH ATLAS OF HEALTH CARE, <http://www.dartmouthatlas.org/> (last viewed June 28, 2015).

²³ See, e.g., Patient Protection and Affordable Care Act, §§ 1104(b)(2)(C), 3002(d), 124 Stat. 147, 365 (2010) (codified at 42 U.S.C. §§ 1320(i)(4)(B), 1395w-4(m)(7)).

²⁴ Under a bundled payment system, a payer such as Medicare makes one payment for services rendered by two or more providers during a one episode of care or a specified time period. See, e.g., *Bundled Payments*, AMERICAN MEDICAL ASS'N, <http://www.ama-assn.org/ama/pub/advocacy/state-advocacy-arc/state-advocacy-campaigns/private-payer-reform/state-based-payment-reform/evaluating-payment-options/bundled-payments.page> (last viewed July 6, 2015). Bundled payments essentially place the risk of the cost of medical services for a particular episode on healthcare providers. See Suzanne Delbanco, *The Payment Reform Landscape: Bundled Payment*, HEALTH AFFAIRS BLOG (July 2, 2014), <http://healthaffairs.org/blog/2014/07/02/the-payment-reform-landscape-bundled-payment/>.

level regarding with whom, if anyone, they will share their decision making power – especially on a sensitive subject like healthcare. Government is one of the least trusted, while the medical profession is the most trusted. This disparity is clearly reflected in the ACA's provisions regarding the implementation of CER process, with its focus on voluntary adoption of best treatment options, transparency and related measures.²⁵

The ACA's task is a formidable one, fundamentally changing over one-seventh of the U.S. economy.²⁶ Many things will go wrong, especially during the early stages, which will only enhance the public's disenchantment with the private sector's ability and to a lesser degree the government's ability to solve the problem of access and affordability.

Another important trend relates to the median wage in the United States. For a variety of reasons, the median wage has remained relatively stagnant since the 1970s²⁷ and wealth inequality has increased dramatically over that same period.²⁸ At the same time, the cost of medical care grew faster than GDP through 2009 in the United States.²⁹ This combination of

²⁵ See, e.g., Patient Protection and Affordable Care Act, § 1552, 124 Stat. 258 (2010) (codified at 42 U.S.C. § 1396a(a)(1)(A)(i)(VIII)).

²⁶ See CTRS. FOR MEDICAID AND MEDICARE SERVS., NATIONAL HEALTH EXPENDITURE DATA: HISTORICAL, <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html> (last viewed June 28, 2015) (In 2013, healthcare expenditures accounted for 17.4% of the U.S. gross domestic product.).

²⁷ See, e.g., Drew DeSilver, *For Most Workers, Real Wages Have Barely Budgeted for Decades*, PEW RESEARCH CENTER (Oct. 9, 2014), <http://www.pewresearch.org/fact-tank/2014/10/09/for-most-workers-real-wages-have-barely-budgeted-for-decades/>.

²⁸ See, e.g., *Nine Charts About Wealth Inequality in the United States*, URBAN INST. (Feb. 2009), <http://datatools.urban.org/Features/wealth-inequality-charts/>.

²⁹ See Veronique de Rugy, *U.S. Healthcare Spending More Than Twice the Average for Development Countries*, MERCATUS CENTER—GEORGE MASON UNIVERSITY (Sept. 17, 2013), <http://mercatus.org/publication/us-health-care-spending-more-twice-average-developed-countries>. From 2010 through 2013, healthcare expenditures in the U.S. grew at approximately the same rate as GDP. CTRS. FOR MEDICAID AND MEDICARE SERVS., NATIONAL HEALTH EXPENDITURES 2013 HIGHLIGHTS, <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf>. In 2014, healthcare expenditures once again surpassed GDP. CTRS. FOR MEDICAID AND MEDICARE SERVS., NATIONAL HEALTH EXPENDITURES 2014 HIGHLIGHTS, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics->

forces increased the ranks of the uninsured. The ACA's expansion of Medicaid to 133% of the federal poverty level³⁰ and its use of tax credits and subsidies for coverage purchased through the exchanges³¹ attempt to ameliorate the impact of the growing unaffordable cost of health care. The Supreme Court's 2015 decision upholding the payment of subsidies in states with federal exchanges³² removed the legal doubt surrounding the continuation of those subsidies in all fifty states.

Then there is our aging population,³³ which will only bolster the number of Medicare recipients over the next several decades. Entitlement reform, while inevitable, may change eligibility and the generosity of benefits, but it will not alter the basic structure of a government-run safety net for the elderly.

Medicare combined with other government programs paid 43% of the total expenditures on healthcare in 2013.³⁴ Even with entitlement reform, government monies will dominate the healthcare system. Accordingly, virtually all providers, both private and institutional, depend now and will increasingly depend upon government revenues. The entity that controls the purse strings is also in a position to impose conditions for receipt of these monies and influence the contours of the system.

Decisions regarding government programs and in particular Medicare will influence both the private and government health care system. For example, in 1980, Medicare changed hospital reimbursement from fee-for-service to a prospective payment system.³⁵ If a hospital

Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf; Paul Handley, *US economic growth in 2014 fastest in four years*, AFP (Jan. 30, 2015), <https://www.yahoo.com/news/us-economy-grew-2-6-q4-slower-expected-135115848.html?ref=gs>.

³⁰ See, e.g., Patient Protection and Affordable Care Act, § 2001(a)(1), 124 Stat. 271 (2010) (codified at 42 U.S.C. § 1396a(a)(1)(A)(i)(VIII)).

³¹ See, e.g., *id.* §§ 1401-1421, 124 Stat. 213-242 (2010).

³² *King v. Burwell*, No. 14-114, slip op. at 5 (U.S. Jul. 27, 2015).

³³ See *Aging Statistics*, ADMINISTRATION ON AGING, http://www.aoa.acl.gov/Aging_Statistics/index.aspx. (last viewed June 28, 2015).

³⁴ See CTRS. FOR MEDICAID AND MEDICARE SERVS., NATIONAL HEALTH EXPENDITURE DATA: NHE FACT SHEET, <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.html> (last viewed June 28, 2015) (computations by editor).

³⁵ See, e.g., RAND CORP., EFFECTS OF MEDICARE'S PROSPECTIVE PAYMENT SYSTEM ON THE QUALITY OF HOSPITAL CARE,

received just one penny of Medicare funds, it was required to charge that rate to all other Medicare beneficiaries. Shortly thereafter, private payers began to mimic Medicare's prospective payment approach in one form or another.³⁶ The same occurred with respect to the reimbursement of physicians. Today, under the ACA, Medicare hospitals and ACO providers must also participate in a “shared savings” reimbursement system, which is accompanied by many practice and quality standards.³⁷

To summarize, the Affordable Care Act was unveiled amidst an environment where household wages were stagnant, employers wanted to drop health insurance benefits for their workers, the government sought lower health costs and better health outcomes, insurers were already contemplating an exit from underwriting, information technology made it possible to pinpoint more effective treatments, and people placed their trust in their doctors, not in insurers or the government. For the reasons that Section II describes in further detail, the design of the ACA interacts with these dynamics to create an unstable situation where employers, insurers, and the public will increasingly reject the ACA's hybrid private-public model in favor of a single-payer, government system of health insurance coverage.

II. UNINTENDED CONSEQUENCES OF THE ACA'S “BALKANIZED” APPROACH TO THE UNINSURED: DIRECT GOVERNMENT COVERAGE AND ACCESS TO COVERAGE VIA THE PRIVATE SECTOR AND MANDATES

This section describes how the ACA attempts to: 1) extend coverage to the uninsured; 2) preserve a central role for private sector “for-profit” risk-takers, a.k.a. insurance companies; and 3) maintain and even expand employers' historic role as the primary sponsors of health plan benefits. This section will argue that the ACA will only have partial success regarding access to affordable care and will have just the opposite

http://www.rand.org/content/dam/rand/pubs/research_briefs/2006/RAND_RB4519-1.pdf.

³⁶ See Cherie Phillips, *Private Health Insurance*, CASE WESTERN RESERVE UNIVERSITY, http://www.cwru.edu/med/epidbio/mphp439/Private_Insurance.htm (last viewed June 28, 2015).

³⁷ See Patient Protection and Affordable Care Act, § 3022, 124 Stat. 395 (2010) (codified at 42 U.S.C. § 1395jii).

of its intended effect regarding private sector risk-takers and employer participation.

The ACA takes several different approaches to getting health insurance coverage to the uninsured. One approach is to expand Medicaid to more people³⁸ (though the states have to concur in this expansion as a result of a 2012 Supreme Court decision).³⁹ Another is to require all insurance plans -- both insured and self-insured -- to contain certain provisions, such as guaranteed issue, limits on pre-existing conditions, preventive exams, coverage for dependents up to age 26, and no lifetime dollar limits.⁴⁰ Still another is a vehicle for individuals and small groups to purchase coverage in a government-regulated marketplace called an insurance exchange⁴¹ -- this is a guaranteed *access* approach to insurance rather than *direct government* insurance.

Access to coverage is not the same as providing direct or automatic coverage. Instead, individuals and small employers have to be eligible for the coverage and pay for it. When one has access rather than direct coverage, individuals and groups purchase coverage through private for-profit and not-for-profit insurance companies. Individuals and small employers are encouraged to exercise this right to access through penalties for not having minimum coverage⁴² and means testing what one has to pay for coverage through tax credits and subsidies.⁴³

These initiatives will not be successful or at a minimum will fall far short of their intended objectives. In fact, this Article argues that these well-intentioned initiatives will have two unintended opposite effects: 1) the development of a broad public consensus that private “for-profit” enterprises cannot play a constructive role in the financing and delivery of affordable quality healthcare; and 2) facilitating and incentivizing

³⁸ See, e.g., Patient Protection and Affordable Care Act, § 2001(a)(1), 124 Stat. 271 (2010) (codified at 42 U.S.C. § 1396a(a)(1)(A)(i)(VIII)).

³⁹ Nat’l Fed’n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566, 2608 (2012).

⁴⁰ Patient Protection and Affordable Care Act, §§ 1001(5), 1201(2)(A), (4), 10103(a), 10104(b), 124 Stat. 131-32, 154-56, 892, 896 (2010) (codified at 42 U.S.C. §§ 300gg(a), 300gg-1(a), 300gg-2, 300gg-3, 300gg-4, 300gg-11, 300gg-13, 300gg-14, 18022(a)-(b)).

⁴¹ *Id.* § 1311(b)(1), 124 Stat. 173 (2010) (codified at 42 U.S.C. § 18031(b)(1) (2010)); see also King v. Burwell, No. 14-114, slip op. at 5 (U.S. Jul. 27, 2015).

⁴² Patient Protection and Affordable Care Act, § 1501(b), 124 Stat. 244 (2010) (codified at 26 U.S.C. § 5000A).

⁴³ See *id.* §§ 1401-21, 124 Stat. 213-42 (2010).

employers to reduce rather than expand or maintain their operative role in the present system.

Before summarizing the details of the ACA's access components and the challenges the ACA faces in realizing its access objectives, it is useful to examine the demographics of the uninsured population. The demographics explain why the ACA has so many different thresholds regarding and rules for eligibility, mandates, and means-tested ACA tax incentives.

A. THE DEMOGRAPHICS OF THE UNINSURED AND THE DYSFUNCTIONAL “INDIVIDUAL AND SMALL GROUP” PRIVATE INSURANCE MARKET

As of 2010 (when the ACA was enacted), the U.S. had 49.9 million uninsured individuals, comprising 18.4% of the non-elderly population.⁴⁴ Numerous uninsured individuals that year did not have coverage because they were either not working or their employers did not offer coverage.⁴⁵ In addition, many had low motivation to get coverage either because they were young and viewed themselves as invulnerable or coverage was unaffordable in the individual market. Even in the employer-sponsored market, employer and employee contributions were perceived to be too high.⁴⁶ Reduced to essentials, for those individuals, the cost of coverage

⁴⁴ U.S. CENSUS BUREAU, INCOME, POVERTY, AND HEALTH INSURANCE COVERAGE: 2010 - *Tables & Figures*, fig. 7, tbl. 8, <http://www.census.gov/hhes/www/hlthins/data/incpovhlth/2010/tables.html>; DEPARTMENT OF HEALTH AND HUMAN SERVS., OVERVIEW OF THE UNINSURED IN THE UNITED STATES: A SUMMARY OF THE 2011 CURRENT POPULATION SURVEY (Sept. 2011), <http://aspe.hhs.gov/health/reports/2011/cpshealthins2011/ib.shtml> (reporting that the age ranges of the uninsured that year were as follows: 9.8% were below the age of 18; 29.7% were between 19 and 25 years of age; 28.4% were between 25 and 34 years; and 38.1% were between 35 and 64 years of age. In terms of income, 58.7% earned less than \$50,000 a year and 15.4% earned between \$50,000 and \$74,999 a year.).

⁴⁵ DEPARTMENT OF HEALTH AND HUMAN SERVS., OVERVIEW OF THE UNINSURED IN THE UNITED STATES: A SUMMARY OF THE 2011 CURRENT POPULATION SURVEY (Sept. 2011), <http://aspe.hhs.gov/health/reports/2011/cpshealthins2011/ib.shtml>.

⁴⁶ *See Recent Premium Increases Imposed by Insurers Averaged 20% for People Who Buy Their Own Health Insurance, Kaiser Survey Finds*, KAISER FAMILY FOUND. (June 21, 2010), <http://kff.org/private-insurance/press-release/recent-premium-increases-imposed-by-insurers-averaged-20-for-people->

exceeded the perceived value of or need for health insurance coverage relative to other uses of one's money, particularly for people squeezed by flat wages and job instability.

For years the individual and small group markets (defined as employers with less than 50 full-time employees) had been dysfunctional. The pools in this market were spread among many blocks of individuals and small employers. As a result the pools available for distributing risk were much smaller than those available to larger companies or associations to aggregate risk.⁴⁷ In addition, the individuals in these markets were not as healthy as those in the larger group market because of poverty and related reasons.⁴⁸

Affordability was exacerbated in the individual and small group markets because of the small pools, not only because small pools inhibit efficient risk distribution but also because of the increased transaction costs associated with the robust underwriting necessary to minimize adverse selection in an unhealthy population. Affordability was also hampered by the inability of insurance companies to realize economies of scale when setting up and administering many individual and small group policies.⁴⁹

In addition, individuals and employers pre-ACA were not required to buy or provide coverage. Those who sought coverage were often turned down to reduce adverse selection.⁵⁰ Insurers excluded coverage of pre-

who-buy-their-own-health-insurance-kaiser-survey-finds/; see also L. Levitt, G. Claxton & A. Damico, *Measuring the Affordability of Employer Health Coverage*, KAISER FAMILY FOUND. (Aug. 24, 2011), <http://www.kff.org/health-costs/perspective/measuring-the-affordability-of-employer-health-coverage/>; DEPARTMENT OF HEALTH AND HUMAN SERVS., OVERVIEW OF THE UNINSURED IN THE UNITED STATES: A SUMMARY OF THE 2011 CURRENT POPULATION SURVEY (Sept. 2011), <http://aspe.hhs.gov/health/reports/2011/cpshealthins2011/ib.shtml>.

⁴⁷ See Lester Feder & Ellen-Marie Whelan, *An Unhealthy Individual Health Insurance Market*, CTR. FOR AMERICAN PROGRESS (Dec. 23, 2008), <https://www.americanprogress.org/issues/healthcare/news/2008/12/23/5259/an-unhealthy-individual-health-insurance-market/>.

⁴⁸ See Joseph P. Newhouse, *Assessing Health Reform's Impact on Four Key Groups of Americans*, 29 HEALTH AFFAIRS 1714, 1716 (2010).

⁴⁹ See Bernadette Fernandez, *Health Insurance: A Primer*, in HEALTH CARE CRISIS IN AMERICA 84, 90 (Janet B. Prince, ed., 2005).

⁵⁰ See, e.g., Melissa Majerol et al., *The Uninsured: A Primer – Key Facts About Health Insurance and the Uninsured in America*, KAISER FAMILY FOUND. (Jan. 13, 2015), http://kff.org/report-section/the-uninsured-a-primer-what-was-happening-to-insurance-coverage-leading-up-to-the-aca/#endnote_link_136859-8.

existing conditions for those who did qualify for coverage in the individual market to further cut down on adverse selection.⁵¹ Pre-ACA, insurance companies could often also decide what to charge.⁵² “Cherry picking” via the underwriting process and fear of adverse selection from an abnormally poor health population exacerbated the distribution process and incentivized insurance companies to make very conservative actuarial assumptions.⁵³

As a result of all of these factors, the rates for coverage in the individual and small group markets were generally higher than they were in a normal functioning insurance market and the availability of coverage varied greatly between insurance companies.⁵⁴

Much of the ACA’s uninsured initiatives attempt to rationalize the individual and small group market through a number of restrictions on underwriting, the regulation of insurance rates, and a concept that we will explore later called “shared responsibility.”

B. THE ACA’S PRIMARY UNINSURED COMPONENTS: THE INSURANCE EXCHANGE, THE MANDATE AND MEDICAID

The part of the ACA that has received the most coverage and visibility to date is the exchange/mandate concept, which is an effort to ameliorate adverse selection and to bring more competition into the small group/individual market and eventually the entire employer-sponsored market. It is also an effort to make private insurance companies an integral part of the uninsured solution.

Initiatives to make the private health insurance market more competitive have been around in various forms for some time. Previous labels include the “managed competition” that surfaced in the 1980s and was similar to the health insurance purchasing cooperatives in the Clinton Administration plan in the 1990s.

The exchange/mandate concept embraced by the ACA is the latest example of these initiatives. Some believe that competition in healthcare finance via exchanges and mandates coupled with tax subsidies will enable consumers to choose the best coverage for themselves and assure better

⁵¹ See Feder & Whelan, *supra* note 47.

⁵² *Id.*

⁵³ *Id.*

⁵⁴ See, e.g., *id.*; see also Majerol et al., *supra* note 50; Newhouse, *supra* note 48, at 1716.

service than direct government coverage. Many also embrace the exchange concept because of its appeal to the right or middle right of the political spectrum. They believe that private insurers in a free market will result in a more efficient health care system than a system run by the government. Not surprisingly, the mandate/exchange concept was pushed forward in the 1980s by the Heritage Foundation -- a conservative think tank -- as being more in line with our economic market system.⁵⁵ Ironically, it was the Heritage Foundation that decided in 2011 to argue that the mandate was unconstitutional.⁵⁶

1. The Insurance Exchange and Essential Health Benefits

During the debates leading up to the passage of the ACA, many strongly believed that Americans should have the choice of a public health insurance option operating alongside private plans. They believed that having a public option would give them a better range of choices, make the health care market more competitive, and “keep insurance companies honest.” However, the public health insurance option was ultimately dropped from the reform legislation; the insurance sold on the health insurance exchanges in the United States will, therefore, now be exclusively from the private insurers.⁵⁷ Off of the exchanges, Medicare and Medicaid will continue to serve the elderly and the poor. Thus, the ACA rejected a single-payer, social insurance model in favor of a hybrid approach based on a combination of private *and* government financing and guaranteed access to health coverage.

Under this hybrid approach, the ACA requires each state (and in the absence of states doing so, the federal government) to establish an “insurance exchange” -- that is, a government-run, easily accessible, and consumer-friendly market bazaar, where private insurance companies certified by the U.S. Department of Health and Human Services offer

⁵⁵ See Avik Roy, *How the Heritage Foundation, a Conservative Think Tank, Promoted the Individual Mandate*, FORBES (Oct. 20, 2011, 8:26 AM), <http://www.forbes.com/sites/apothecary/2011/10/20/how-a-conservative-think-tank-invented-the-individual-mandate>.

⁵⁶ See Robert E. Moffitt, *Individual Mandate Unconstitutional, Unenforceable*, HERITAGE FOUNDATION (March 23, 2011), <http://www.heritage.org/research/commentary/2011/03/individual-mandate-unconstitutional-unenforceable>.

⁵⁷ See Helen A. Halpin & Peter Harbage, *The Origins and Demise of the Public Option*, 29 HEALTH AFFAIRS 1117, 1117 (2010).

plans.⁵⁸ Individuals can buy health insurance on the exchange and so can small employers, which are entitled to a tax credit of up to 50% of the exchange premium depending on the number of employees and the average salary.⁵⁹ To discourage oligopoly pricing, each exchange must have two or more insurers and at least one must be a “not-for-profit” entity.⁶⁰ As this latter provision suggests, one of the main purposes of the exchanges is to increase price competition among insurers. Another is to assemble larger pools in order to reduce adverse selection and promote economies of scale.

Another way the ACA seeks to increase price competition and coverage is through standardization of benefits. The certified insurance plans participating in an exchange must offer a number of standard health insurance policies with varying co-pays and deductibles and prices that reflect the cost and overhead of providing these coverages.⁶¹ The ACA labels the standard content of each policy “essential health benefits.”⁶² The ACA’s requirement for standard coverages will facilitate price and service comparisons and with it, ideally, price competition.⁶³ That requirement

⁵⁸ Patient Protection and Affordable Care Act, § 1311(b)(1), 124 Stat. 173 (2010) (codified at 42 U.S.C. § 18031(b)(1)); *see also* King v. Burwell, No. 14-114, slip op. at 5 (U.S. Jul. 27, 2015).

⁵⁹ Patient Protection and Affordable Care Act, §§ 1311(b), (d)(2)(A), 1421(a), 124 Stat. 173, 176, 237 (2010) (codified at 42 U.S.C. §§ 18031(b), (d)(2)(A) and 26 U.S.C. § 45R). For tax years 2010 through 2013, the maximum credit was 35% for small business employers and 25% for small tax-exempt employers such as charities. An enhanced version of the credit took effect on January 1, 2014. In general, on January 1, 2014, the rate increased to 50% and 35%, respectively. *See Small Business Health Care Tax Credit Questions and Answers: Calculating the Credit*, INTERNAL REVENUE SERV. (August 11, 2015), <http://www.irs.gov/uac/Small-Business-Health-Care-Tax-Credit-Questions-and-Answers:-Calculating-the-Credit>.

⁶⁰ Patient Protection and Affordable Care Act, § 10104(q), 124 Stat. 902 (2010) (codified at 42 U.S.C. § 18054(a)(1), (a)(3)).

⁶¹ *Id.* §§ 1301(a)(1), 1302, 124 Stat. 162-63 (2010) (codified at 42 U.S.C. §§ 18021(a)(1), 18022).

⁶² *Id.* § 10104(b), 124 Stat. 896 (2010) (codified at 42 U.S.C. § 18022(a)-(b)).

⁶³ To assist in informed comparison-shopping, each exchange must have consumer advisers (either in the form of “navigators,” “in-person assistance personnel,” or “certified application counselors”) to help consumers understand the application process, their eligibility to buy through the exchange, any availability of Medicaid, and their eligibility for tax credits and subsidies. *Id.* § 1311(i); *see also In-Person Assistance in the Health Insurance Marketplaces*, THE CTR. FOR CONSUMER INFO. & INSURANCE OVERSIGHT, <https://www.cms.gov/CCIIO/Programs-and->

will also have the important effect of expanding available coverage (both in the individual market and in employer-sponsored plans).

The ACA also seeks to ensure universal coverage by guaranteeing access, by eliminating exclusions to coverage, and by making coverage affordable. Thus, in order to participate in the exchange, an insurance company plan must be certified as meeting the criteria for a qualified health plan established by the Department of Health and Human Services,⁶⁴ namely:

- o *Guaranteed issue* -- Insurers are not permitted to refuse coverage for any individual or group based on health status and, in particular, pre-existing conditions.⁶⁵
- o *Restrictions on rescission* -- This requirement mirrors the guaranteed issue requirement in that an insurer cannot cancel and must renew coverage irrespective of health status or the experience of the group and in particular pre-existing conditions.⁶⁶
- o *Limits on price variation by class* -- Plans must offer a form of “community rating,” that is, the same rate irrespective of one's health status, age, etc., with two exceptions: use of tobacco and a limited price adjustment for specified age bands. There may be one community rate for individuals and one for families.⁶⁷
- o *Comparable tiers of plans* -- Insurance companies must offer four different versions of the standard coverages differentiated primarily by the dollar level of co-pays and deductibles. These coverages are

Initiatives/Health-Insurance-Marketplaces/assistance.html; Gary Cohen, *Guidance on Certified Application Counselor Program for Federally-Facilitated Marketplace Including State Partnership Marketplaces*, DEP'T OF HEALTH AND HUMAN SERVS. (July 12, 2013), <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/CAC-guidance-7-12-2013.pdf>.

⁶⁴ Patient Protection and Affordable Care Act, §§ 1301, 1311(c), 124 Stat. 162, 174 (2010) (codified at 42 U.S.C. §§ 18021, 18031(c)).

⁶⁵ *Id.* §§ 1101, 1201(2)(A), (4), 124 Stat. 141, 154-56 (2010) (codified at 42 U.S.C. §§ 18001, 300gg-1, 300gg-3, 300gg-4).

⁶⁶ *Id.* § 1201(4), 124 Stat. 156 (2010) (codified at 42 U.S.C. § 300gg-2).

⁶⁷ *Id.* §§ 1101, 1201(4), 124 Stat. 141, 155 (2010) (codified at 42 U.S.C. § 300gg).

labeled Bronze, Silver, Gold and Platinum Plans.⁶⁸ Certified insurers must also offer a catastrophic coverage for individuals under age 30 or with hardship exemptions with a deductible equal to the high deductible plans linked to health savings accounts.⁶⁹ For 2016, the limits on deductibles under catastrophic coverage plans were \$6,850 per year for individuals.⁷⁰

- o *No lifetime limits* -- Insurers are not permitted to engage in the traditional practice of setting an annual or lifetime dollar limits.⁷¹
- o *Availability of subsidies and tax credits* -- Insurers must honor subsidies and credits for those whose annual income is between 138% and 400% of the federal poverty level to help pay for the purchase of insurance coverage on an exchange.⁷²

These provisions are intended to produce universal coverage in three important ways. The guaranteed issue requirement, the limitations on rescission, and the elimination of lifetime limits ensure that individuals will not be denied coverage due to health status or dollar caps.⁷³ The provisions on community rating and tiered plans are both designed to make the menu options on the exchanges more affordable for certain customers. Finally, Congress enacted the subsidies and tax credits because many otherwise would be priced out of health coverage.⁷⁴

Many of these same provisions, however, shift significant and some say unmanageable risks onto insurers. Under the ACA, insurers are deprived of four techniques that they previously used to manage risks and discourage adverse selection: denial of coverage, coverage exclusions, lifetime caps, and individual risk-adjusted pricing. In addition, private insurers on the exchanges face added and unwanted competition, both from

⁶⁸ *Id.* § 1302(d), 124 Stat. 167 (2010) (codified at 42 U.S.C. § 18022(d)).

⁶⁹ *Id.* § 1302(e), 124 Stat. 168 (2010) (codified at 42 U.S.C. § 18022(e)).

⁷⁰ How to pick a health insurance plan, HealthCare.Gov, <https://www.healthcare.gov/choose-a-plan/plans-categories/> (last viewed July 10, 2016).

⁷¹ Patient Protection and Affordable Care Act, § 1001(5), 124 Stat. 131 (2010) (codified at 42 U.S.C. § 300gg-11).

⁷² *Id.* § 1401(a), 124 Stat. 215 (2010) (codified at 26 U.S.C. § 36(c)).

⁷³ *See* King v. Burwell, 135 S. Ct. 2480 (2015).

⁷⁴ *Id.*

one another and from the not-for-profit insurers that the ACA requires and in fact encourages through regulation, grants and loans.⁷⁵ These not-for-profit initiatives focus on the very healthy populations that private insurers are trying to attract.

The ACA also subjects insurers to added rate regulation to help keep policies affordable. In addition to federal review, the states will have the ability to ensure that the policies conform to federal standards and that rates are supported by verifiable data and subject to the medical loss ratios (MLR).⁷⁶ Under the MLR requirement, insurers (both within and outside the exchange) must provide health benefits equaling 80% of the premium dollar for individual coverage and 85% for group coverage. States will review insurance company and self-insured data to verify that MLR standards have been met and to the degree the benefit requirement has not been met, the difference will be rebated to the individual or employer.⁷⁷ States are permitted to disapprove or even set lower health insurance rates.⁷⁸ Special review is provided both at the federal and state level for rate

⁷⁵ The law requires the Comptroller General to establish a 15-member board to make recommendations to the Secretary of Health and Human Services with regard to the award of grants and loans to these not-for-profit plans, known as Consumer Operated and Oriented Plans (CO-OPs). See Patient Protection and Affordable Care Act, § 1322, 124 Stat. 187 (2010) (codified at 42 U.S.C. § 18042). The board appointments were made in 2010. The Center for Consumer Information and Insurance Oversight (CCIIO) within the Department of Health and Human Services works with the advisory board to assist and advise the Secretary and Congress on HHS's strategy to foster the creation of qualified nonprofit health insurance issuers. Specifically, the advisory board provides advice regarding the awarding of grants and loans related to the CO-OP program. In these matters, the Committee shall consult with all components of the Department, other federal entities and non-federal organizations, as appropriate. It will also examine relevant data sources to assess the grant and loan award strategy to provide recommendations to CCIIO. *See id.*

⁷⁶ *Id.* §§ 1331(b), 9016(a), 124 Stat. 200, 872 (2010) (codified at 42 U.S.C. § 18051 and 26 U.S.C. § 833).

⁷⁷ *Id.* § 1001(5), 124 Stat. 137 (2010) (codified at 42 U.S.C. § 300gg-18(b)); *see also* Department of Health and Human Servs., *Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act; Interim Final Rule*, 75 Fed. Reg. 74864, 74865-66 (Dec. 1, 2010).

⁷⁸ *See, e.g.,* Mills et al., *supra* note 19. *See generally* John Aloysius Cogan Jr., *Health Insurance Rate Review*, 88 TEMPLE L. REV. 411 (2016) (arguing that the ACA's expansion of the health insurance rate review process could be a more

increases exceeding 10%.⁷⁹ States are also required to make sure that qualified health plans meet state solvency standards,⁸⁰ such as adequate reserves, quality reserves, and prudent management practices applicable to all insurance companies operating the state.

These requirements all collide with the fact that typically, health insurance providers operate with thin margins.⁸¹ The ACA's MLR and rate review provisions are likely to cut further into those margins and make health insurance carriers more hesitant to continue underwriting risk.

The ACA's new crop of taxes and fees for insurers will only add to that reluctance. Under the ACA, the federal government, state governments, insurers, employers, and individuals have a "shared responsibility to reform and improve the availability, quality and affordability of health insurance coverage in the United States."⁸² This "shared responsibility" is achieved in part through taxes and fees on insurers that not only participate in the exchanges but also those that only provide health coverage administration outside the exchange.

The fees start with the exchange itself. The ACA provides that a state with an exchange must "ensure that [its] Exchange is self-sustaining beginning on January 1, 2015, including allowing the Exchange to charge assessments or user fees to participating health insurance issuers, or to otherwise generate funding, to support its operations."⁸³

effective cost containment tool if updated to address contemporary health insurance market failures).

⁷⁹ 45 C.F.R. § 154.200.

⁸⁰ See, e.g., Patient Protection and Affordable Care Act, § 1322(c)(5), 124 Stat. 190 (2010) (codified at 42 U.S.C. § 18042(c)(5)).

⁸¹ See NATIONAL ASSOCIATION OF INSURANCE COMMISSIONERS & THE CENTER FOR INSURANCE POLICY AND RESEARCH, 2014 HEALTH INSURANCE INDUSTRY ANALYSIS REPORT, at 1 (2014), http://www.naic.org/documents/topic_insurance_industry_snapshots_2014_health_ind_report.pdf (last viewed July 1, 2015); see also Avik Roy, *Private Insurer Profits? \$13 Billion. Medicare Fraud? \$48 Billion. Health Reform? Priceless.*, FORBES, March 4, 2011, <http://www.forbes.com/sites/aroy/2011/03/04/private-insurer-profits-13-billion-medicare-fraud-48-billion-health-reform-priceless/>.

⁸² Internal Revenue Serv., *Questions and Answers on the Individual Shared Responsibility Provision, Question 1*, <http://www.irs.gov/Affordable-Care-Act/Individuals-and-Families/Questions-and-Answers-on-the-Individual-Shared-Responsibility-Provision> (last viewed June 29, 2015).

⁸³ Patient Protection and Affordable Care Act, § 1311(d)(5)(A), 124 Stat. 178 (2010) (codified at 42 U.S.C. § 18031(d)(5)(A)).

There are still other fees or taxes. For example, the ACA imposes a Health Insurance Providers Fee on each health insurance company writing group coverage starting in 2014 equal to \$8 billion allocated among each of the companies based on their national market share. This fee will increase each year to \$14.3 billion by 2018 and will remain in place thereafter adjusted annually for inflation.⁸⁴

Another tax is the so-called “Cadillac” tax. Here, health insurers (and self-funded plans) must pay a 40% tax that applies to workplace plans on any part of monthly premiums paid by employers that exceed defined thresholds for single and family coverage.⁸⁵ Many observers believe the “Cadillac tax” will provide an incentive to health plans to control the cost of health insurance and for individuals and employers to purchase less expensive plans. In 2018, the thresholds will be \$10,200 for single coverage and \$27,500 for family coverage.⁸⁶

These taxes help fund the premium tax subsidies and credits under the ACA. The taxes are also designed to encourage employers to reduce the amount of coverage for their employees, which will increase tax revenues because of the present characterization of healthcare benefits as not being taxable income. This exemption from the income tax laws was a historical accident and has been questioned over the years, but repeal of the exemption never got anywhere because it was politically unpopular. In recent years, however, repeal has been seriously reconsidered since reducing the federal deficit has become a top priority.

In sum, this combination of severe underwriting restrictions, community rating, minimum loss ratios, rate review, required expanded benefits, mandatory competition from not-for-profit insurers, and taxes, some of which are designed in part to reduce employee healthcare benefits sponsored by the employer (even if an employer self-insures and uses a

⁸⁴ *Id.* § 9010, 124 Stat. 865 (2010) (codified at 26 U.S.C. § 4001 note prec.); see Internal Revenue Serv., *Affordable Care Act Provision 9010 --- Health Insurance Providers Fee*, <http://www.irs.gov/Businesses/Corporations/Affordable-Care-Act-Provision-9010> (last viewed June 29, 2015).

⁸⁵ Patient Protection and Affordable Care Act, § 9001(a), 124 Stat. 847 (2010) (codified at 26 U.S.C. § 4980I). The ACA mandates still other taxes on pharmaceuticals, medical device manufacturers, and elective cosmetic medical procedures. *Id.* §§ 9008, 9009, 9017, 124 Stat. 859, 862, 872 (2010) (codified at 26 U.S.C. §§ 4001 note prec., 5000B).

⁸⁶ Internal Revenue Serv., *Section 4980I — Excise Tax on High Cost Employer-Sponsored Health Coverage*, Notice 2015-16, at 3 (2015).

health insurance company only as an administrator), create the perfect storm for a business model based on thin margins and high volume. It is also a business model that runs a high risk of large losses and the unpredictability of such losses. Due to these design features of the ACA, insurers and employers who self-insure will militate more strongly than ever to exit the provision of health coverage.

2. Shared Responsibility for Individuals and Employers: The Mandate

The ACA seeks to cure the small pools and adverse selection that formerly plagued the individual market through a triad of mechanisms. Its guaranteed issue, no-lifetime-cap, and essential minimum benefit provisions give access to universal coverage. The subsidies and tax credits help ensure that access is affordable. Finally, the mandate imposes fines on individuals and large employers who respectively fail to sign up for, or provide their workers with, required coverage.⁸⁷

The individual and employer mandate is a “pay or play” mandate. While the ACA allows individuals to go without coverage and employers not to provide coverage, the ACA imposes a penalty on individuals who choose not to buy minimum essential coverage⁸⁸ and on employers that refuse to provide that coverage.⁸⁹

Acceptable coverage that complies with this mandate includes:⁹⁰

- Employer-sponsored coverage (including COBRA coverage and retiree coverage)
- Coverage purchased in the individual market
- Medicare coverage (including Medicare Advantage)
- Medicaid coverage
- Children's Health Insurance Program (CHIP) coverage
- Certain types of veterans' health coverage
- TRICARE (coverage for members of the military and veterans and their dependents)

⁸⁷ See *King v. Burwell*, 135 S. Ct. 2480 (2015).

⁸⁸ Patient Protection and Affordable Care Act, § 1501(b), 124 Stat. 244 (2010) (codified at 26 U.S.C. § 5000A).

⁸⁹ *Id.* § 1513(a), 124 Stat. 253 (2010) (codified at 26 U.S.C. § 4980H).

⁹⁰ *Id.* § 1501(b), 124 Stat. 244 (2010) (codified at 26 U.S.C. § 5000A(f)).

In 2014, the individual “shared responsibility” penalty was \$95 per person (or \$47.50 per child, capped at \$285 per family or 1% of the family’s yearly income, whichever was greater).⁹¹ The penalty increased each year as follows:

2015: \$325 per adult and \$162.50 per child under 18 (capped at \$975 per family or 2% of the family’s income, whichever was greater).⁹²

2016: \$750 per adult and \$347 per child (capped at \$2000 per family or 2.5% of the family’s income, whichever was greater).⁹³

2017: the same as 2016 adjusted for inflation.⁹⁴ Accordingly, the penalty will increase each year, but will be capped at the bronze level exchange premium for the individual or family.⁹⁵

Individuals subject to this mandate include children, the elderly, citizens living abroad and documented foreign nationals living in this country.⁹⁶ Although the ACA provides for qualified plans and exchanges to have mechanisms to deal with unanticipated risks,⁹⁷ the nature of the ACA mandate creates fertile ground for adverse selection. The key question is whether the ACA’s penalties provide enough incentive for

⁹¹ *Id.* (codified at 26 U.S.C. § 5000A(c)(3)(B)); see *The fee you pay if you don't have health coverage*, HEALTHCARE.GOV, <https://www.healthcare.gov/fees-exemptions/fee-for-not-being-covered/> (last viewed June 30, 2015).

⁹² Patient Protection and Affordable Care Act, § 1501(b), 124 Stat. 244 (2010) (codified at 26 U.S.C. § 5000A(c)(3)(B)); see *The fee you pay if you don't have health coverage*, HEALTHCARE.GOV, <https://www.healthcare.gov/fees-exemptions/fee-for-not-being-covered/> (last viewed July 11, 2015).

⁹³ Patient Protection and Affordable Care Act, § 1501(b), 124 Stat. 244 (2010) (codified at 26 U.S.C. § 5000A(c)(3)(A)).

⁹⁴ *Id.* (codified at 26 U.S.C. § 5000A(c)(3)(D)).

⁹⁵ *Id.* (codified at 26 U.S.C. § 5000A(e)(1)(B)).

⁹⁶ *Id.* (codified at 26 U.S.C. § 5000A(d)).

⁹⁷ *Id.* §§ 1341-1343, 124 Stat. 208-213 (2010) (codified at 42 U.S.C. §§ 18061-18063); see also *Despite Some Delays, CMS Has Made Progress Implementing Programs to Limit Health Insurer Risk*, U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-15-447 (2015).

people to buy through the exchange or elsewhere. The exchange rates for New York for 2014, which many characterized as being much lower than the non-exchange private market, were revealing. The average New York exchange rate for a single individual on a silver plan was \$483 annually before federal subsidies. That same average rate was \$966 for a married couple and \$1377 for family coverage.⁹⁸ That meant that the average premium to buy health coverage through the New York exchange was about 5 times greater than the penalty during the first year.

The ACA also specifies “pay or play” penalties for large employers that do not provide fully insured or self-insurance coverage for their “full-time employees.”⁹⁹ This sharply changes the previous state of affairs where private employers could decline to provide health coverage to their employees free from any penalty. First under the ACA, starting in 2015, large employers had to pay a penalty if they did not offer minimum essential coverage to at least 95% of their full-time employees (and their dependents), and at least one full-time employee received a subsidy or tax credit for purchasing coverage through an exchange. Annually, this penalty is \$2,000 (indexed for future years) for each full-time employee, excluding the first 30 employees.¹⁰⁰ Second, even where large employers offer minimum essential coverage to at least 95% of their full-time employees (and their dependents), they must pay a \$3,000 penalty for any

⁹⁸ See Zane Benefits, *New York Health Insurance Exchange Update – Plan Carriers and Rates* (July 26, 2013), <http://www.zanebenefits.com/blog/bid/306301/New-York-Health-Insurance-Exchange-Update-Plan-Carriers-and-Rates> (last viewed July 11, 2015) (analyzing New York State, *Approved Monthly Premium Rates – Individual Standard Plans*, <http://www.governor.ny.gov/sites/governor.ny.gov/files/archive/assets/documents/Approved2014HealthInsuranceRates.pdf>) (last viewed July 11, 2015) (Computations by Zane Benefits and author).

⁹⁹ Patient Protection and Affordable Care Act, § 1513(a), 124 Stat. 253 (2010) (codified at 26 U.S.C. § 4980H(a), (d)(2)(A)).

¹⁰⁰ Internal Revenue Serv., *Employer Shared Responsibility Provisions*, <http://www.irs.gov/Affordable-Care-Act/Employers/Employer-Shared-Responsibility-Provisions> (last viewed Sept. 14, 2015). A “full-time employee” is defined as one who works at least 30 hours a week. Patient Protection and Affordable Care Act, § 1513(a), 124 Stat. 253 (2010) (codified at 26 U.S.C. § 4980H(d)(4)(A)). Under the transition relief provisions for 2015, the large employer penalty only applied to employers with at least 100 full-time workers. The penalty started to apply to all employers with at least 50 full-time workers in 2016. Internal Revenue Serv., *Transition Relief*, <http://www.irs.gov/Affordable-Care-Act/Employers/Transition-Relief> (last viewed July 1, 2015).

full-time employee who receives the premium tax credit for purchasing coverage through the marketplace.¹⁰¹

There is no penalty for small employers (defined as those with fewer than 50 full-time employees).¹⁰² Nor is there a penalty for employers that have employees making more than 400% of the federal poverty line or \$46,000 per family since those individuals would not be eligible for exchange subsidies in those states that have expanded Medicaid in accordance with the ACA. In states that have not expanded Medicaid to the ACA limits, the threshold would be the threshold amount that the state requires to qualify for Medicaid.

To recap, the ACA depends heavily on the individual mandate to reduce the number of uninsured and eliminate adverse selection in the individual market. Its penalties are too light, however, to drive enough healthy uninsured people to buy coverage. The same problem affects the large employer market, where some employers may find it profitable to treat the penalties as a cost of doing business without providing health coverage. Other medium-sized employers may lay off workers or reduce them to part-time work to come under the 50 full-time employee threshold. Meanwhile, small employers are not subject to a mandate at all.

To the extent that healthy individuals and employers can avoid coverage – either through payment of a penalty or, in the case of small employers, none at all – universal coverage will remain elusive and adverse selection is likely to persist in the individual market. Already, health insurers on the exchanges are seeking significantly higher rates for 2017 compared to 2016, on grounds that the individuals insured through the exchanges are much sicker than anticipated.¹⁰³ While it remains to be seen whether these insurers' claims about the extent of adverse selection are warranted, the weak penalty provisions of the ACA give cause for concern.

¹⁰¹ Internal Revenue Serv., *Employer Shared Responsibility Provisions*, <http://www.irs.gov/Affordable-Care-Act/Employers/Employer-Shared-Responsibility-Provisions> (last viewed Sept. 14, 2015).

¹⁰² *Id.*

¹⁰³ See Margot Sanger-Katz, *Get Ready for Higher Obamacare Rates Next Year*, N.Y. TIMES (May 6, 2016), http://www.nytimes.com/2016/05/07/upshot/get-ready-for-higher-obamacare-rates-next-year.html?_r=0.

C. THE CHALLENGES FACED BY INSURANCE COMPANIES IN THE SMALL GROUP MARKET

Clearly, the exchange marketplace is not a hospitable place for private for-profit and maybe not even for not-for-profit insurers. Due to the guaranteed issue provision, the risk for each insurer is virtually unlimited (though moderated somewhat by the reinsurance and risk adjustment mechanisms of the exchange).¹⁰⁴ Adverse selection is very real because the incentive penalties are so much lower than the premium costs of the broad exchange coverage, even when one considers the federal subsidy. In addition, there is no assurance that the exchange will attract the heterogeneous population, especially the younger healthier population, needed to distribute risk efficiently.

Already many healthy young people have decided to avoid the exchanges and just pay the penalty, arguing that it's a better deal for them financially. In addition, lack of public understanding and knowledge of the existence of the exchange has raised considerable doubt as to whether those who can benefit most from the exchange will apply. Providers of healthcare, and in particular hospitals and health insurers, are actively reaching out to the public because the absence of large pools and people insured by private companies and Medicaid will hurt their bottom line.

Compounding the problem of adequate heterogeneous pools, employers and their advisors are actively looking for ways to avoid the ACA's requirements. Many employers, even small employers, are considering self-insuring or obtaining stop loss to protect themselves from unexpected catastrophic claims.¹⁰⁵ Other employers are redefining their workforces so that they do not meet the full-time employment threshold.¹⁰⁶ Viewed in its totality, the future of private insurance in the exchange

¹⁰⁴ Patient Protection and Affordable Care Act, §§ 1341-1343, 124 Stat. 208-213 (2010) (codified at 42 U.S.C. §§ 18061-18063). For discussion of those reinsurance and risk adjustment mechanisms, *see, e.g.*, GAO, *supra* note 97.

¹⁰⁵ *See, e.g.*, PlanSponsor, *No Rush to Self-Insure Health Benefits Yet*, June 17, 2015, <http://www.plansponsor.com/No-Rush-to-Self-Insure-Health-Benefits-Yet/> (last viewed July 1, 2015).

¹⁰⁶ *See, e.g.*, Karen McVeigh, *US Employers Slashing Worker Hours to Avoid Obamacare Insurance Mandate*, THE GUARDIAN, Sept. 30, 2013, <http://www.theguardian.com/world/2013/sep/30/us-employers-slash-hours-avoid-obamacare>; ObamaCare Facts, *ObamaCare Employer Mandate*, <http://obamacarefacts.com/obamacare-employer-mandate/> (last viewed July 1, 2015).

context is bleak. Publicly traded private insurance companies remain cautious about participation in the exchanges, though they are slowly testing the waters.¹⁰⁷ This reluctance will persist, especially for companies that report quarterly and expect yields competitive with other public stock companies.

In the ACA, Congress assumed that the private insurance sector will continue to underwrite health risks for most of the non-elderly population. But nothing requires private insurers to continue to do so. To the contrary, the burdensome nature of the ACA's provisions is likely to eventually drive private insurers out of the individual health insurance market altogether. Meanwhile, large employers will chafe under their new obligation to provide health coverage under pain of penalty and will align with private insurers to shed their involvement in health insurance. They will be joined by the numerous individuals who discovered to their dismay that many of the subsidized plans that are marketed as affordable come with high deductibles and co-pays. With private insurers heading for the exits, employers following closely behind, and citizens demanding truly affordable health insurance with no costly hidden surprises, an odd coalition of forces will coalesce supporting change to a single-payer, government health insurance system.

III. THE ACA'S MOST ENDURING LEGACIES: FUNDAMENTAL RESTRUCTURING OF THE MEDICAL DELIVERY SYSTEM AND NEW POLITICAL COALITIONS THAT WILL CULMINATE IN TRUE UNIVERSAL HEALTH CARE

During the 20th century, the medical delivery system and third-party payers in the United States “grow’d like Topsy” into a sprawling fragmented universe that more often than not has multiple clinicians treating non-routine maladies with little or no coordination. Today, this fragmented system represents over one-seventh of the total U.S. gross domestic product¹⁰⁸ and is composed of many diverse stakeholders, both with respect to the delivery and payment of care.

¹⁰⁷ See, e.g., GAO, *supra* note 21, at 10-11.

¹⁰⁸ CTRS. FOR MEDICAID AND MEDICARE SERVS., NATIONAL HEALTH EXPENDITURE DATA: HISTORICAL, <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-andReports/NationalHealthExpendData/NationalHealthAccountsHistorical.html> (last viewed June 28, 2015) (computations by editor).

According to recent statistics, there were over 5,600 U.S. hospitals (both profit and not-for-profit), almost 900,000 physicians practicing in many diverse structures in the U.S. (e.g., as sole practitioners, varying types of group practices, and employees of hospitals and other institutional providers, including state and local governments), over 800 third-party payers (a.k.a. insurance companies), and a number of federal and state government programs -- the latter providing over 40% of total medical expenditures.¹⁰⁹ Other stakeholders include pharmaceutical and medical service companies and allied professionals, such as nurse practitioners and chiropractors.

There are many reasons why the rate of rising medical costs threatens to exceed the growth of GDP, including technology, the volume-driven fee-for-service reimbursement methodology, and a professional and societal culture that embraces a “more is better” mentality. One of the most overlooked drivers of medical costs is the transaction cost of dealing with the large and diverse number of payment and delivery components of our balkanized health care system. Estimates vary, but most believe that changing from the current third-payer system to a government-run, single-payer system could reduce the annual cost of health expenditures in the U.S. – currently running at \$2.7 trillion -- by around 16%.¹¹⁰

Most of the stakeholders in the system make more under the fragmented volume-based system and therefore have a vested interest in perpetuating it. This Balkanized system historically deferred to the clinical decisions of professional clinicians (though this deference diminished

¹⁰⁹ *Fast Facts on US Hospitals*, AMERICAN HOSPITAL ASS'N, <http://www.aha.org/research/rc/stat-studies/fast-facts.shtml> (last viewed July 1, 2015); CTRS. FOR MEDICAID AND MEDICARE SERVS., NATIONAL HEALTH EXPENDITURE DATA: NHE FACT SHEET, <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.html> (last viewed June 28, 2015) (computations by editor); *Total Industry Overview*, INS. INFORMATION INST., <http://www.iii.org/fact-statistic/industry-overview> (last viewed July 1, 2015); *Professionally Active Physicians*, KAISER FAMILY FOUND. <http://kff.org/other/state-indicator/total-active-physicians/> (last viewed July 1, 2015).

¹¹⁰ See, e.g., Gerald Friedman, *Universal Health Care: Can We Afford Anything Less?, Dollars and Sense* (July 1, 2011), <http://www.pnhp.org/news/2011/july/universal-health-care-can-we-afford-anything-less>; Elisabeth Rosenthal, *The \$2.7 Trillion Medical Bill*, N.Y. TIMES, (June 1, 2013), http://www.nytimes.com/2013/06/02/health/colonoscopies-explain-why-us-leads-the-world-in-health-expenditures.html?pagewanted=all&_r=0.

significantly over the last 40 years) and displayed a bias towards evaluating the efficacy of a particular product or practice considered alone rather than its effectiveness compared to alternatives. As a result, comparative little attention was paid to the marginal value of a particular intervention compared to its marginal cost.

The ACA changes this historic paradigm in several significant ways and the impact of these ACA changes will be amplified by the economic and demographic trends summarized in Section I of this Article. Many of these ACA initiatives will be more significant and enduring than the much-publicized ACA efforts to cover the uninsured through the exchanges and mandates.

The enduring ACA initiatives are based on several related assumptions: 1) the delivery system must be restructured so that every entity involved in a medical intervention is accountable for its outcome; 2) accountable clinicians should base their decisions on evidence-based medicine – in other words, best practices based on real-world clinical outcomes data and the marginal cost and therapeutic value of any intervention; 3) increased patient satisfaction and participation in the intervention process; and 4) changes in payment methodologies that align clinician reimbursement with the value rather than the volume of such interventions.

These ACA initiatives are intricately related but can be best described by breaking them into three basic categories: 1) value-based purchasing; 2) structural changes to the delivery and financing system; and 3) comparative effectiveness research.

While most of these initiatives focus on Medicare, most believe commercial and other government payers will soon follow suit in one form or another for a number of reasons: 1) Medicare is the largest payer for both institutional and individual providers and these clinicians will gravitate towards its processes; 2) other government payers, such as Medicaid and CHIP, will build on the Medicare initiatives; 3) commercial payers will try and differentiate their value-based purchasing (via branding and somewhat different approaches) and those providing Medicare Advantage will build their value-based purchasing efforts on the Advantage platform. Over time most stakeholders will gradually move towards the Medicare processes because Medicare will provide a “good housekeeping seal of approval” for branding purposes and because insurers, in the process, can reduce the transaction costs otherwise associated with multiple payment systems.

A. VALUE-BASED PURCHASING

Reduced to its essentials, value-based purchasing (VBP) is the restructuring of the historic reimbursement approach for medical care from one based on volume (*i.e.*, the fee-for-service system) to a more efficient healthcare system (in which the marginal therapeutic value of any intervention must exceed its marginal cost) that also pursues other desirable goals. VBP seeks to accomplish these objectives by linking part of healthcare reimbursements to quality measures.¹¹¹

Underlying these objectives is the belief that embracing this methodology will reduce or flatten the rate of rising healthcare costs while improving quality. Over the last 100 years, VBP has raised its head here and there (for example, in the form of the health maintenance organization, case management, and various other prepayment arrangements), but generally the U.S. healthcare payment system has been dominated by fee-for-service reimbursement.

Starting in the early 2000s, VBP received increasing attention, especially at the national level. Congress authorized VBP as a pilot project in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.¹¹² Pursuant to this legislative initiative, the Centers for Medicare and Medicaid Services (CMS) began implementing demonstration programs starting in 2003 that instituted VBP with respect to various healthcare providers, such as group practice physicians, hospitals, nursing homes and home healthcare services.

The ACA centralized oversight for these pilot programs under a new entity located in the Department of Health and Human Services (HHS) called the “Center for Medicare and Medicaid Innovation” (CMMI).¹¹³ The ACA will fund the center with \$10 million annually for 10 years to evaluate and identify new payment methodologies that will result in improved quality and savings.¹¹⁴

¹¹¹ See, e.g., Anita Archer & Judy Monestime, *CMS Value-Based Purchasing Program and ICD-10*, HIMSS NEWS, <http://www.himss.org/News/NewsDetail.aspx?ItemNumber=28816> (last viewed July 1, 2015).

¹¹² Pub. L. No. 108-173, §§ 501(b), 646, 17 Stat. 2289, 2324 (2003); see also Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 5001, 120 Stat. 28 (2006).

¹¹³ Patient Protection and Affordable Care Act, § 3021, 124 Stat. 389 (2010) (codified at 42 U.S.C. § 1315a).

¹¹⁴ *Id.* § 3021, 124 Stat. 394 (2010) (codified at 42 U.S.C. § 1315a(f)).

These VBP pilot projects were and are being primarily carried out in a fee-for-service environment. Their main focus is on data collection, though several do so in the context of programs with real economic consequences for selected stakeholders, primarily hospitals. Among other things, the ACA requires HHS to create comparative websites for hospitals, physicians and other providers providing Medicare services. The initial websites will provide basic data on each provider and include outcomes data as those data become available.

Several recent HHS rulemakings regarding hospitals illustrate the type of programs being developed under the ACA. In 2012 HHS promulgated a rule designed to reduce acute hospital readmission rates. The program initially focuses on selected high-cost or high-volume conditions, such as heart failure and pneumonia. Starting in 2013, hospitals serving Medicare beneficiaries with high volume conditions, such as chronic heart failure, surgeries and infections acquired in hospitals, had to meet certain quality targets and if they did not, CMS would make progressive reductions in their Diagnosis-Related Group (DRG) reimbursement rate.¹¹⁵

In 2013, HHS initiated its hospital VBP program for inpatient stays in approximately 3000 hospitals across the country. Under this program, Medicare will adjust the hospital payment based on either: 1) how well the hospital performs compared to all hospitals in the area; or 2) how much the hospital's performance has improved compared to a defined prior baseline.¹¹⁶

¹¹⁵ Dep't of Health and Human Serv., *Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers – Part II: Final rule*, 77 Fed. Reg. 53258 (Aug. 31, 2012) (codified at 42 C.F.R. pts. 412, 413, et al.); *see also* Dep't of Health and Human Serv., *Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers: Final rule; correction*, 77 Fed. Reg. 60315 (Oct. 3, 2012) (codified at 42 C.F.R. pts. 412, 413, et al.); Patient Protection and Affordable Care Act, §§ 3001(a)(1), 3008, 124 Stat. 353, 376 (2010) (codified at 42 U.S.C. § 1395ww(o), (p)).

¹¹⁶ Dep't of Health and Human Serv., *Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center*

Physicians are already submitting performance data and the ACA mandates a similar program for physicians by 2016.¹¹⁷ More and more of these types of programs will be expanded to other Medicare providers as time data and methodologies are deemed feasible based on the ongoing demonstration projects.

CMS has also established data collection activities in Medicaid and CHIP programs to facilitate the creation of similar projects with reimbursement repercussions for these payers.¹¹⁸ Pursuant to the ACA, other demonstration projects are setting targets for skilled nursing facilities and home health agencies.¹¹⁹ By 2016, targets will be established for psychiatric hospitals, prospective-payment-system (PPS)-exempt cancer hospitals, hospice centers, long-term care hospitals, and rehabilitation hospitals.¹²⁰

At the same time a number of other HHS and commercial entities are experimenting with bundled payments for situations where multiple providers participate in a particular medical intervention.¹²¹ The ACA has taken the bundled approach one step further: the ACO program -- which is not a demonstration pilot but the creation of a new type of entity that will be able to contract directly with Medicare and share in any savings the new entity realizes relative to a predetermined average benchmark

Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals – Part III: Final rule with comment period and final rules, 78 Fed. Reg. 74826 (Dec. 10, 2013) (codified at 42 C.F.R. pts. 405, 410 et al.).

¹¹⁷ Patient Protection and Affordable Care Act, § 3007, 124 Stat. 373 (2010) (codified at 42 U.S.C. § 1395w-4(p)).

¹¹⁸ See Dep't of Health and Human Serv., *Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers – Part II: Final Rule*, 77 Fed. Reg. 53258, 53503-04 (Aug. 31, 2012) (codified at 42 C.F.R. pts. 412, 413, et al.).

¹¹⁹ Patient Protection and Affordable Care Act, § 3006, 124 Stat. 372 (2010).

¹²⁰ *Id.* §§ 3004, 3005, 124 Stat. 368, 371 (2010) (codified at 42 U.S.C. §§ 1395cc, 1395f(i), 1395ww).

¹²¹ See, e.g., CTRS. FOR MEDICAID AND MEDICARE SERVS., BUNDLED PAYMENTS FOR CARE IMPROVEMENT (BPCI) INITIATIVE: GENERAL INFORMATION, <http://innovation.cms.gov/initiatives/bundled-payments/> (last viewed July 6, 2015).

reimbursement under Medicare's fee-for-service and DRG methodology.¹²² The ACO program will be discussed in the next section.

B. MAJOR STRUCTURAL CHANGES IN THE DELIVERY AND REIMBURSEMENT SYSTEM

The ACA contemplates a new type of network of physicians and hospitals called an accountable care organization whose members agree to share responsibility for healthcare provided to patients. Under the ACA, an ACO agrees to manage all of the health care needs of at least 5,000 Medicare beneficiaries for three years or more.¹²³

The ACO structure is voluntary.¹²⁴ It is designed to facilitate seamless quality care and to make all of the clinicians involved collectively accountable for the care each provider provides to an individual patient. Providers are “rewarded” with bonuses for slowing the growth of Medicare healthcare costs while meeting performance standards, including patient satisfaction standards.¹²⁵

Under the final rule defining the contours of ACOs,¹²⁶ there are 33 quality standards that focus on four key areas: patient/caregiver experience, care coordination/patient safety, preventive health, and at-risk populations (people who are frail or elderly).¹²⁷

The ACO structure is available to physicians in group practices, networks of individual physicians, partnerships or joint venture arrangements among hospitals and participating physicians, hospitals employing physicians, and other providers and suppliers determined by the HHS secretary to be eligible for the program.¹²⁸ Notably, non-clinicians

¹²² See Patient Protection and Affordable Care Act, § 3022, 124 Stat. 395 (2010) (codified at 42 U.S.C. § 1395jjj).

¹²³ See *id.*; Jenny Gold, *Accountable Care Organizations Explained*, NAT'L PUBLIC RADIO (Jan. 18, 2011), www.npr.org.

¹²⁴ See, e.g., Dep't of Health and Human Services, *Summary of Final Rule Provisions for Accountable Care Organizations under the Medicare Shared Savings Program* (2015), http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO_Summary_Factsheet_ICN907404.pdf.

¹²⁵ *Id.*; Gold, *supra* note 123.

¹²⁶ Dep't of Health and Human Services, *Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule*, 76 Fed. Reg. 67802 (Nov. 2, 2011).

¹²⁷ *Id.* at 67889-90.

¹²⁸ *Id.* at 67808.

must work through clinicians,¹²⁹ which will enhance physician autonomy vis-à-vis third party payers and other non-clinician “partners.”

An ACO must meet certain criteria and be approved by HHS. Key conditions include: 1) a governing body representing ACO providers and patients; 2) accepting responsibility for at least 5,000 Medicare fee-for-service beneficiaries; and 3) providing a detailed plan acceptable to the secretary regarding how the ACO plans to deliver quality and lower the growth of expenditures, including procedures for routine self-assessment monitoring and the reporting of care it provides plus a process to use the data to continually improve the ACO's quality and cost performance.¹³⁰ This latter provision expects ACOs to be active practitioners of evidence-based medicine.

Once certified, the ACO must participate in the program for at least three years.¹³¹ CMS can terminate the program if the ACO fails to comply with the eligibility and program requirements.¹³²

While certified ACO structures may vary somewhat, each must meet the general requirements listed above. Conceptually the foundation of the ACO will be primary care physicians, responsible for treating groups of patients linked together with participating specialists, hospitals, and electronic records systems.

Any certified ACO that meets the plan quality standards will be eligible to receive a share of the saved earnings relative to a predetermined and updated benchmark. The final rules also provide that an ACO may choose a higher shared savings rate if it agrees to share in any losses.¹³³

Contemporaneous with this ACO “shared savings” rulemaking, CMS’s “innovation center” released a demonstration project for smaller ACO entities that are physician-owned or located in rural locations to receive advance payments (of up to \$250,000) for investments in infrastructure and caregiving staff.¹³⁴ CMS also unveiled a series of demonstration projects providing for provider remuneration based on bundled payments for an episode of care -- where all providers involved in

¹²⁹ *Id.*

¹³⁰ *Id.* at 67807-08, 67816-30.

¹³¹ *Id.* at 67807, 67977.

¹³² *Id.* at 67982-83.

¹³³ *Id.* at 67909-12.

¹³⁴ See CTRS. FOR MEDICAID AND MEDICARE SERVS., ADVANCE PAYMENT ACO MODEL, <http://innovation.cms.gov/initiatives/Advance-Payment-ACO-Model/> (last viewed July 6, 2015).

treating a patient will share in the bundled or single episode payment.¹³⁵ Clearly the end goal of “shared savings” is to align provider incentives with health outcomes – in other words, to create accountability.

Another important Medicare cost containment measure involves the ACA’s changes to the Independent Medicare Advisory Board (IMAB).¹³⁶ IMAB is a 15-member agency¹³⁷ designed to strengthen the Medicare Payment Advisory Commission (MedPAC). MedPAC’s job for many years was to make recommendations to achieve specific savings in Medicare without affecting coverage or quality.¹³⁸ The old MedPAC had no power whatsoever because any of its recommendations had to be approved by Congress.¹³⁹ Of MedPAC’s many recommendations over the years, none was approved by Congress.

The new IMAB has roughly the same charge – to make proposals to Congress to “reduce the per capita rate of growth in Medicare spending”¹⁴⁰ – but its power is enhanced by its structure. First, each member is appointed by the president for staggered terms with advice and consent of the Senate.¹⁴¹ Second, IMAB’s recommendations automatically go into effect unless Congress adopts an equally effective recommendation with approval by both houses, including at least three-fifths of the

¹³⁵ See CTRS. FOR MEDICAID AND MEDICARE SERVS., BUNDLED PAYMENTS FOR CARE IMPROVEMENT (BPCI) INITIATIVE: GENERAL INFORMATION, <http://innovation.cms.gov/initiatives/Bundled-Payments/> (last viewed July 6, 2015).

Other non-Medicare payers are beginning to explore bundling options. See Suzanne Delbanco, *The Payment Reform Landscape: Bundled Payment*, HEALTH AFFAIRS BLOG, (July 2, 2014), <http://healthaffairs.org/blog/2014/07/02/the-payment-reform-landscape-bundled-payment>. Key to organizational decisions to embrace bundled payments are the availability of relevant data, a robust IT system with the analytical ability to evaluate outcomes, and the level and type of risk (operational or insurance) that providers are willing to accept.

¹³⁶ Patient Protection and Affordable Care Act, §§ 3403, 10320, 124 Stat. 489, 949 (2010) (codified in part at 42 U.S.C. § 1899A).

¹³⁷ *Id.* § 3403(a)(1), 124 Stat. 489, 502 (2010) (codified in part at 42 U.S.C. § 1899A(g)(1)(A)(i)).

¹³⁸ See David Newman & Christopher M. Davis, *The Independent Payment Advisory Board*, CONG. RESEARCH SERV. 30 (No. 7-7500, 2010).

¹³⁹ See *id.*

¹⁴⁰ *Id.* at 2.

¹⁴¹ Patient Protection and Affordable Care Act, § 3403(a)(1), 124 Stat. 489, 502-03 (2010) (codified in part at 42 U.S.C. § 1395kkk(g)(1)(A)(i)).

Senate.¹⁴² IMAB's cost control recommendations for Medicare consequently have significantly more teeth.

Still other significant changes, such as the shifting of Medicare funding for residencies in teaching hospitals to community hospitals and clinics,¹⁴³ are designed to reinforce the ACA's structural changes essential to a primary care/CER foundation, including the trend towards evidence-based medicine and advanced continuity and coordination of care.

While there is no "silver bullet" for better individual outcomes, better healthcare for populations, and lower expenditure growth, there is a widespread consensus that the best chance for meeting all three goals requires the alignment of provider treatments with accountability. There is also widespread consensus on the need for more evidence-based medicine and particularly the degree to which new procedures and practices provide better results than existing ones. Realizing evidence-based medicine and best practices is the ultimate goal of another primary ACA objective: comparative effectiveness research.

C. COMPARATIVE EFFECTIVENESS RESEARCH: AN IDEA WHOSE TIME HAS COME

1. What is CER?

Although we have in place a system to test the safety of drugs and medical devices, the Institute of Medicine estimates that over one half of all medical procedures have not been subject to rigorous evaluation.¹⁴⁴ The ACA attempts to change this by expanding the evaluation process to

¹⁴² See Timothy Stolfus Jost, *The Independent Payment Advisory Board*, 363 *NEW ENG. J. MED.* 103, 105 (2010); Newman & Davis, *supra* note 138, at 51. This procedure resembles the successful procedure instituted for recommendations on military base closings in the legislation establishing the Defense Base Closure and Realignment Commission. Topher Spiro, *The Independent Payment Advisory Board*, CENTER FOR AMERICAN PROGRESS (March 5, 2012), <https://www.americanprogress.org/issues/healthcare/report/2012/03/05/11269/the-independent-payment-advisory-board/> (last viewed June 16, 2016).

¹⁴³ Patient Protection and Affordable Care Act, § 5503, 124 Stat. 655 (2010) (codified in part at 42 U.S.C. § 1395ww(h)(8)).

¹⁴⁴ Inst. of Med., *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America* 150-151 (Mark Smith et al. eds., 2012).

encompass all aspects of health care:¹⁴⁵ alternative medical delivery structures, alternative clinical interventions and alternative drugs and medical devices. Not all existing practices can be changed at once. Instead, they will be evaluated in stages in accordance with priorities established by the Institute of Medicine reinforced by an elaborate structure of clinical experts and other stakeholders in the system.

There is no uniform definition of CER, but the definition formulated by the former Federal Coordinating Council for Comparative Effectiveness Research is often used to describe it. CER, according to the Council, is:¹⁴⁶

[...]the conduct and synthesis of research *comparing the benefits and harms* of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in “*real world*” settings. The purpose of this setting is to improve health outcomes by *developing and disseminating evidence-based information* to patients, clinicians, and other decision-makers, responding to their expressed needs, about which interventions *are most effective for which patients under specific circumstances*.

Even this definition does not capture the true significance of CER, which can be best described by articulating how the present evaluation process works and its impact upon the way medical care is delivered and paid for today.

The traditional evaluation approach or clinical trial measures the efficacy of a particular treatment: that is whether the treatment produces or does not produce a marginal benefit in the artificial world of the laboratory measured against a randomized control group. The American Medical Association's characterization is revealing:¹⁴⁷

¹⁴⁵ For the ACA's provisions on comparative effectiveness research, see the Patient Protection and Affordable Care Act, §§ 3011, 3501, 6301(a)-(c), 124 Stat. 378, 507, 707-42 (2010) (codified at 42 U.S.C. §§ 280j, 299b-33, 299b-37, 1320e, 1320e-1).

¹⁴⁶ Federal Coordinating Council for Comparative Effectiveness Research, REPORT TO THE PRESIDENT AND CONGRESS 5 (2009) (emphasis added).

¹⁴⁷ *Advocacy with the Administration: Comparative Effectiveness Research*, AM. MED. ASS'N, <http://www.ama-assn.org/ama/pub/advocacy/federal/advocacy-with-administration.page> (last viewed July 10, 2016).

Most current research on medical treatments compares the benefits of a specific treatment to no treatment, but little information is available to physicians to help them determine if new treatments outperform existing options.

The differences between traditional evaluation and CER will have a profound effect upon the delivery and financial structure of medical care. More often than not, the traditional clinical trial focuses on comparing the “efficacy” of a given treatment to no treatment (via a “control group”), rather than also comparing the new intervention’s cost and outcome to existing alternative treatments. In addition, this traditional focus more often than not concentrates on new technology and whether a new procedure or product is safe “on average,” which dilutes or avoids ascertaining whether there would be similar or different outcomes for subpopulations based on age, gender, health status and other relevant factors.

The traditional evaluation process fits into the prevailing medical paradigm, *i.e.*, that something new is always better across-the-board. It fits into the prevailing reimbursement paradigm of fee-for-service -- the more you do, the more money you make. Both reinforce “for-profit” as opposed to “not-for-profit” medicine.

Of even greater importance, the traditional evaluation process does not measure whether the incremental benefit of a new intervention outweighs its incremental cost. This is a highly relevant indicator, along with how the new technology’s outcomes compare with existing alternatives, of the *efficiency* of the new medical intervention.

CER’s potential for cost-benefit analysis is greatly feared by many stakeholders in the present system, especially drug and medical device manufacturers. Another controversial aspect of CER is that its findings of best practices could be used to mandate a particular treatment under particular circumstances. Although the American Medical Association (AMA) has strongly endorsed CER, its focus has been on clinical outcomes and it is very explicit regarding the use to which CER findings could be put to use.¹⁴⁸

¹⁴⁸ *Principles for Comparative Effectiveness Research*, AM. MED. ASS’N, <http://www.ama-assn.org/ama/pub/advocacy/federal/advocacy-with-administration.page> (last viewed July 10, 2016) (emphasis added).

The highest priority should be placed on targeting health care professionals and their organizations to ensure rapid dissemination to those who develop diagnostic and treatment plans.

The CER entity must not have a role in making or recommending coverage or payment decisions for payers.

Physician discretion in the treatment of individual patients remains central to the practice of medicine. CER evidence cannot adequately address the wide array of patients with their unique clinical characteristics, co-morbidities and certain genetic characteristics. . . . [S]ufficient information should be made available on the limitations and exceptions of CER studies so that physicians who are making individualized treatment plans will be able to differentiate patients to whom the study findings apply from those for whom the study is not representative.

It is noteworthy that while the AMA strongly embraces evidence-based medicine and comparative effectiveness research, it makes it very clear that professional autonomy regarding the use of CER findings is of key importance to clinicians. This theme permeates the ACA. For example, ACO governance is heavily dominated by clinicians.¹⁴⁹ Funds for building infrastructure emanate from the government for direct distribution to clinicians,¹⁵⁰ which reduce the dependence of clinicians upon non-clinician “deep pockets” for infrastructure capital. In addition, the ACA's bias

¹⁴⁹ Department of Health and Human Services, *Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule*, 76 Fed. Reg. 67802, 67816-22 (Nov. 2, 2011).

¹⁵⁰ CTRS. FOR MEDICAID AND MEDICARE SERVS., ADVANCE PAYMENT ACO MODEL, <http://innovation.cms.gov/initiatives/Advance-Payment-ACO-Model/> (last viewed July 6, 2015).

towards “not-for-profit delivery systems”¹⁵¹ strengthens the leverage of the profession regarding clinical decision-making.

Because many in the public equate limits of any kind as “rationing,” in view of the importance of clinical autonomy for the medical profession and the concerns of all stakeholders regarding the economic impact of CER, it is not surprising that a large part of the ACA's CER provisions deal with how CER is implemented.

2. Implementation of CER

Most agree that CER, if implemented to its full potential, will transform the medical professional paradigm.¹⁵² Many, however, are skeptical that CER will realize its potential, primarily for three reasons: 1) the restrictions the ACA places on the use of CER findings and evidence for Medicare and to a more limited degree recommendations to Congress by IMAB;¹⁵³ 2) the inclusion of non-clinician stakeholders in the governing mechanisms of CER; and 3) the historic reticence of clinicians to abdicate their autonomy regarding clinical decisions.

To be sure all three present challenges. However, these challenges are overstated and the way CER implementation is structured not only ameliorates these concerns by accident or elegant design but actually creates a structure that is best suited to realize CER's potential for clinicians and other stakeholders to adopt voluntarily identified and documented best practices and increased reliance upon evidence-based medicine. The following will first summarize the governing structure of CER and then describe how the structure overcomes the major concerns of skeptics.

CER is not a new concept and has been around for some time although its implementation has been fragmented in the U.S. It first became centralized with the American Recovery and Reinvestment Act of

¹⁵¹ See, e.g., Patient Protection and Affordable Care Act, §§ 1322, 10104(q), 124 Stat. 187, 903 (2010) (codified at 42 U.S.C. §§ 18042, 18054(a)(3)).

¹⁵² See, e.g., John Aloysius Cogan Jr., *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) (arguing that the ACA's requirement that public and private health plans provide evidence-based preventive services with no out-of-pocket costs effectively transforms those plans into vehicles for promoting public health).

¹⁵³ See Patient Protection and Affordable Care Act, §§ 3403(a)(1), 6301(c), 124 Stat. 490, 740 (2010) (codified at 42 U.S.C. §§ 1320e-1(a), (c)(1), 1395kkk(c)(2)(A)(ii)).

2009 (ARRA), which appropriated \$1.1 billion to fund CER among three agencies: the Department of Health and Human Services, the NIH and the Agency for Healthcare Research and Quality (AHRQ).¹⁵⁴

ARRA also created a public entity, the Federal Coordinating Council for Comparative Effectiveness Research, to coordinate CER efforts at the federal level.¹⁵⁵ The Institute of Medicine (IOM) also was given the responsibility to establish national priorities for CER¹⁵⁶ and IOM recommended 100 critically important initial topics for CER research.¹⁵⁷

The ACA builds upon these concepts and creates a new not-for-profit corporation that the ACA stresses is “neither an agency nor establishment of the United States government.”¹⁵⁸ The new entity is named the “Patient-Centered Outcomes Research Institute” (PCORI), which replaces its predecessor, the Federal Coordinating Council for Comparative Effectiveness Research.¹⁵⁹

PCORI is directed by a board of governors composed of the heads of NIH and AHRQ and 17 other members selected by the General Comptroller. Three board members represent patient and consumer interests. In addition, there must be five physicians and provider representatives, including at least one surgeon, nurse, integrative healthcare practitioner, and hospital representative. Other representatives must include three private payers, including at least one to represent self-funded employers. Pharmaceutical, medical device, and diagnostic firms have three representatives. Finally one board member must be an independent health service researcher and the two remaining members must represent state and federal health agencies.¹⁶⁰

PCORI’s mission is to advance the “quality and relevance of evidence” available to patients, physicians, payers, and policymakers.¹⁶¹ Its

¹⁵⁴ American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, tit. VIII, 123 Stat. 177 (2009).

¹⁵⁵ *Id.* § 299b-8.

¹⁵⁶ *Id.* § 3.

¹⁵⁷ See Inst. of Med., *100 Initial Priority Topics for Comparative Effectiveness Research*, <http://iom.nationalacademies.org/~media/Files/Report%20Files/2009/ComparativeEffectivenessResearchPriorities%20Stand%20Alone%20List%20of%20100%20CER%20Priorities%20-%20for%20web.ashx> (last viewed July 7, 2015).

¹⁵⁸ Patient Protection and Affordable Care Act, § 6301(a), 124 Stat. 728 (2010) (codified at 42 U.S.C. § 1320e(b)(1)).

¹⁵⁹ *Id.* §§ 1320e(b)(1), 2996-8.

¹⁶⁰ *Id.* § 1320e(f)(1).

¹⁶¹ *Id.* § 1320e(c).

responsibilities are to identify research priorities, analyze evidence identifying the relevance of current evidence and economic effects, and advance broad dissemination of research findings.¹⁶²

The ACA specifically directs PCORI to pursue “comparative clinical effectiveness research,”¹⁶³ which the ACA describes as head-to-head comparisons of “health care interventions, protocols for treatment, care management and delivery procedures, medical devices, diagnostic tools, pharmaceuticals . . . , integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, individuals.”¹⁶⁴

Part and parcel of PCORI’s efforts is to provide information to educate patients so that patients will play a more pivotal role in treatment decisions and their relationship with their physicians.¹⁶⁵ Whether or not PCORI will be able to ameliorate the asymmetry of information between doctor and patient and the cultural dominance of clinicians in the doctor-patient relationship remains to be seen.

PCORI has considerable human and dollar resources at its disposal.¹⁶⁶ Among other things, it has a nationally recognized Executive Director and a large staff of experts to evaluate research proposals and make decisions regarding these proposals.¹⁶⁷

Transparency and checks and balances are to be assured by a requirement that PCORI submit a draft of research priorities for public comment prior to formal adoption.¹⁶⁸ The ACA further limits the use of PCORI’s conclusions for purposes of Medicare.¹⁶⁹

The Secretary may only use evidence and findings from research conducted under section 1181 to make a determination regarding coverage under title XVIII [Medicare] if such use is through an iterative and transparent process which includes public comment and considers the effect on subpopulations.

¹⁶² *Id.* §§ 299b-37, 1320e(c), (d)(1)-(d)(2).

¹⁶³ *Id.* § 1320e(b)(3), (d)(6)(C).

¹⁶⁴ *Id.* § 1320e(a)(2)(B).

¹⁶⁵ *Id.* §§ 299b-37, 1320e(c).

¹⁶⁶ *See id.* §§ 1320e(b)(3), (d), 1320e-2.

¹⁶⁷ *Id.* § 1320e(d)(6), (f)(1)-(f)(2), (f)(6).

¹⁶⁸ *See id.* § 1320e(d)(6)(C)(i), (h)(1).

¹⁶⁹ *See id.* § 1320e-1(a).

In addition, PCORI is specifically prohibited from adopting “QALY” or similar thresholds for establishing what types of care are cost-effective.¹⁷⁰ Medicare decisions cannot be made “in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than” an individual who is not.¹⁷¹ Similarly, the Secretary of HHS is specifically prohibited from adopting a QALY or similar metric for establishing what types of care are cost-effective.¹⁷²

These ACA limitations conclude by saying “nothing in . . . [the ACA should] be construed as superseding or modifying the coverage of items or services . . . that the Secretary [of HHS] determines are reasonable and necessary under” existing law.¹⁷³

- (b) Nothing in section 1181 shall be construed as –
 - (1) Superseding or modifying the coverage of items or services under title XVIII that the Secretary determines are reasonable and necessary under section 1162(l)(1); or
 - (2) authorizing the Secretary to deny coverage of items or services under such title solely on the basis of comparative clinical effectiveness research.

Though these limitations appear severe and far-reaching, they do not apply to voluntary professional clinical decisions under Title XVIII. Nor do these limits apply beyond HHS Medicare regulations. The new IMAB is subject to roughly the same restrictions although the language is different and appears somewhat narrower in scope.¹⁷⁴

¹⁷⁰ “QALY” is a metric consisting of a “quality-adjusted life year.” QALY adjusts the value of a year of added life by the quality of life that year. See Nat’l Inst. for Health and Clinical Excellence, *Measuring Effectiveness and Cost Effectiveness: The QALY* (Apr. 20, 2010), <https://www.nice.org.uk/proxy/?sourceurl=http://www.nice.org.uk/newsroom/features/measuringeffectivenessandcosteffectivenessstheqaly.jsp>.

¹⁷¹ Patient Protection and Affordable Care Act, § 6301(c), 124 Stat. 740 (2010) (codified at 42 U.S.C. § 1320e-1(c)(1)).

¹⁷² See *id.* § 1320e-1(d)(1).

¹⁷³ *Id.* § 1320e-1(b).

¹⁷⁴ *Id.* § 1395kkk(c)(2)(A)(ii).

[An IMAB] proposal shall not include any recommendation to ration health care, raise revenues or Medicare beneficiary premiums under section 1818, 1818A, or 1839, increase Medicare beneficiary cost-sharing (including deductibles, coinsurance, and copayments), or otherwise restrict benefits or modify eligibility criteria.

Consequently, despite the vagaries of these statutory limitations, it is clear that Congress preferred that PCORI's findings and evidence and IMAB's recommendations be implemented "voluntarily" by clinicians.

3. Potential obstacles to the implementation of CER

Most skeptics emphasize the ACA's CER Medicare restrictions as the main impediment to successful implementation of CER. To be sure, the process restrictions on the use of PCORI findings and research are significant, but they are not as onerous as the skeptics claim.

First, the restrictions are limited to decisions within Medicare coverage, and to a more limited degree to cost control recommendations by IMAB. The restrictions do not limit the use of PCORI findings for other government programs and private sector coverage. Second, the transparency process, which is much like federal rulemaking, will often result in a better product if the old adage "more heads are better than one" has any efficacy. Many regulators have found that stakeholders -- even those opposed to a proposed regulation -- often come up with better ideas or find mistakes that the regulators overlooked. When these deficiencies are identified in the public comment process, regulators have a chance of correcting them. Even if there are no deficiencies and stakeholders are adamant in their opposition, the regulator gets the additional advantage of knowing what issues will be opposed, the arguments for those positions and the opportunity to develop counter-arguments. A PCORI finding or evidence that successfully runs the required ACA procedural gauntlet will only have its legitimacy and credibility enhanced, which will greatly increase the chances of acceptance by clinicians.

Skeptics also believe that non-clinician stakeholders participating in PCORI governance will greatly increase the danger of regulatory capture. For the very same reasons articulated above, the ACA process mitigates this danger and in fact may reduce the risk of such capture considerably.

The third major concern articulated by skeptics relates to the absence of a mandate for clinicians to accept PCORI findings. Skeptics point to the historic reticence of clinicians to give up any autonomy and in particular to give it up to the government. This argument overlooks the fact that the polestar of PCORI is *voluntary* acceptance of its findings and/or evidence. Whether or not clinicians will accept or reject PCORI findings and/or evidence remains to be seen. Clinicians will certainly prefer the PCORI process to the restrictions imposed by the insurance industry over the last 40 years. In addition, odds are that credible PCORI findings and/or evidence will be accepted by clinicians, especially if PCORI is viewed as “a trusted source.” Although it has been amply documented (including through John Wennberg's small practice variations studies¹⁷⁵ and initiatives such as the Dartmouth Atlas of Medicine¹⁷⁶) that clinician decision-making has an aspect of “herd” autonomy -- that is, clinicians, at least to date, have been influenced more by the professional socialization process, *i.e.*, where they went to school and what their peers do, than by evidence when making clinical care decisions – there is growing evidence in recent years that clinicians are increasingly embracing evidence-based medicine.¹⁷⁷

In sum, either because of political necessity, accident or elegant design, PCORI's focus on transparency and voluntary adoption by clinicians appears to be the optimal route to the implementation of CER and evidence-based medicine for clinicians.

IV. PROGNOSIS (OR A BETTER TITLE ANYONE? SUCH AS “PULLING IT ALL TOGETHER.”)

Despite the bungled rollout of the ACA and resulting public confusion over the ACA's access options, exchanges, mandates and subsidies, the ACA has resulted in expanded coverage for some 16.4

¹⁷⁵ See, *e.g.*, Klim McPherson, John E. Wennberg, Ole B. Hovind & Peter Clifford, *Small-Area Variations in the Use of Common Surgical Procedures: An International Comparison of New England, England, and Norway*, 307 NEW ENG. J. MED. 1310 (1982).

¹⁷⁶ *Dartmouth Atlas of Health Care*, <http://www.dartmouthatlas.org/> (last viewed June 28, 2015).

¹⁷⁷ See, *e.g.*, Atul Gawande, *Overkill*, NEW YORKER, May 22, 2015, at 42, 52-53; Earl P. Steinberg & Bryan R. Luce, *Evidence Based? Caveat Emptor!*, 24 HEALTH AFFAIRS 80 (2005).

million uninsured¹⁷⁸ through the prohibition of pre-existing exclusions, expanded age participation for dependents on parents' policies, and Medicaid expansion in those 29 states plus the District of Columbia that opted for expansion under the ACA. Now that the "glitches" that manifested themselves during the rollout are being remedied, more will be covered not only through the exchange market but also by Medicaid since one of the functions of the exchanges is to refer Medicaid eligibles to the government program.

Even so, public opinion regarding the ACA and the President remains sharply divided and repeal or substantial change is not beyond the realm of possibility if the Republican Party captures the White House and both houses of Congress in 2016.

However, any change will not be quite as expected largely because of benefits from the ACA itself and the societal changes described in Section I of this Article. Even if those favoring repeal come into ascendancy, their options will be severely limited due to the millions of newly covered uninsureds. Even those who were already insured when the ACA went into effect are weary of change and uncertainty and these uncertainties and anxiety will force those that advocate change to be very cautious -- especially as the employer's role diminishes.

Any new changes will create turmoil and shift public opinion from the existing distrust of ACA's real or perceived coercion regarding the individual mandate to an environment that underscores the absolute need for and practicality of having coverage. This need has been embraced by most of the stakeholders and is of particular importance to institutional providers and large portions of the individual medical community. While some elements of the population and clinicians are still holding out, in the end practicality will trump the historic infatuation with free choice.

The changes that do occur or have the most likelihood of occurring will be limited to ACA's "free-market" access programs discussed in Section II. The lasting and enduring legacies of the ACA discussed in Section III of this Article will remain in place for several reasons.

¹⁷⁸ Department of Health and Human Services, *Health Insurance Coverage and the Affordable Care Act* 1 (May 5, 2015), http://aspe.hhs.gov/health/reports/2015/uninsured_change/ib_uninsured_change.pdf (last viewed July 8, 2015). That represents a 35% reduction in the number of uninsured individuals from 2013 (the final year before the ACA fully went into effect) through first quarter 2015. *See id.*

First and foremost will be the new and expanded political constituencies favoring direct coverage rather than guaranteed access accompanied by evidence-based medicine and greater clinical autonomy that exists today over clinical decisions. For example, between 2014 and 2020, the Medicare population is projected to increase by 21% to 54.8 million beneficiaries¹⁷⁹ due to the onset of retirement for the baby boomers. Over the same period, the Medicaid population is projected to increase by 12%, to 65 million,¹⁸⁰ due to the 29 states and the District of Columbia that have opted into the program and the likelihood that other states will change their mind and will welcome at least 10 years of fiscal relief from Medicaid liabilities.¹⁸¹ Many also believe the Medicaid population will increase also because the gap between the have and have-nots will increase rather than decrease. Institutional providers and individual clinicians will support this increase in Medicare and Medicaid participation to ensure cash flow for their operations.

The medical clinicians will consolidate for the same reasons. The growth of ACOs will accelerate for similar reasons as well as for another very important one: the ACO structure leverages clinician power vis-à-vis other stakeholders and restores to them a fair amount of the autonomy they had lost to third-party payers over the last 40 years.

¹⁷⁹ CTRS. FOR MEDICAID AND MEDICARE SERVS., NATIONAL HEALTH EXPENDITURE DATA: PROJECTED, NHE PROJECTIONS, 2013-2023 – TABLES, tbl. 1, <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html> (last viewed July 9, 2015) (computations by editor).

¹⁸⁰ Robin Rudowitz, *A Look At CBO Projections For Medicaid and CHIP*, KAISER FAMILY FOUND. (June 5, 2014), <http://kff.org/medicaid/issue-brief/how-much-will-medicare-cost-in-the-future-and-why-a-look-at-federal-projections/> (last viewed July 8, 2015) (computations by editor).

¹⁸¹ To encourage states to sign up for Medicaid expansion, the ACA stipulated that the federal government would pay for 100% of that expansion through 2016. Starting in 2017, the federal contribution will drop slowly every year and then plateau at 90% in 2020 (and for all subsequent years). See Matt Broaddus & January Angeles, *Federal Government Will Pick Up Nearly All Costs of Health Reform's Medicaid Expansion* (Center on Budget and Policy Priorities, March 28, 2012), <http://www.cbpp.org/research/federal-government-will-pick-up-nearly-all-costs-of-health-reforms-medicare-expansion> (last viewed July 8, 2015); Patient Protection and Affordable Care Act, § 2001(a)(3)(B), 124 Stat. 272 (2010) (codified at 42 U.S.C. § 3696d(y)).

Last but not least, the employer community (both large and small) is eager to move rapidly away from employers' traditional role as sponsors of health plans either by no longer providing such plans, encouraging employees to move to the exchanges, or shifting to a defined contribution rather than defined benefit environment. New employers in particular will be loath to go back to the system of the last 60 years.

All of these constituencies have a similar agenda: 1) shifting actual or moral responsibility for healthcare plan formation and administration from the private sector to the government; 2) a belief that healthcare efficiencies will only be realized through universal participation (a large diversified group with resulting cross subsidies and uniform procedures); and 3) a consensus that healthcare efficiencies can be best realized through "evidence-based medicine" and best practices. This latter consensus is even embraced by the medical community as long as clinical autonomy is restored and best practice findings are "voluntary" and considered by clinicians as emanating from a "trusted source."

For these reasons the enduring legacies described in Section III of this Article will remain in place as long as the VBP/CER protocols are maintained. Diverse participation in decision-making, transparency and voluntary acceptance are essential to CER being a "trusted source."

The ACA may also have another benefit though this in my mind is more of an aspirational than a likely result. Maybe stated a better way is that these aspirational hopes will be the most difficult to overcome.

The ongoing dialogue regarding the flawed ACA rollout hopefully will educate the public that the private model is not sustainable, equitable or workable. Hopefully the dialogue will educate the public that we are all in this together. Hopefully the young invincibles will realize that the need for medical care for them is not an option or in the "if" category -- instead it is just a matter of "when" -- which can happen at any time whether by sickness or accident.

The ACA debate will also hopefully educate the body politic that there is no benefit or plan known to man that does not have limits, because we do not have infinite resources. In addition, life itself has limits and this may be the most difficult concept for any of us to accept. Hopefully the ACA will help by giving all of us the grace to accept that fact.

