GRADING OBAMACARE, WHILE SPECULATING ABOUT TRUMP

SEPARATING FACT FROM FICTION



Simplicity is about subtracting the obvious and adding the meaningful.

- John Maeda, PhD

Following the unexpected election of Donald Trump, speculation has surged about the fate of the Patient Protection and Affordable Care Act (PPACA), colloquially referred to as "Obamacare." President-elect Trump's "Healthcare Reform [plan] to Make America Great Again" initially focused on a complete repeal of Obamacare, without a specific plan as to what the replacement plan — if any — might be. "Repeal and replace" has also been described as "repeal and delay," implying a timeline of possibly up to three years for a new coverage plan.

INTRODUCTION

Political pundits and health policy experts have stated what might appear to be obvious: eliminating coverage for more than 20 million Americans who have accessed coverage under the ACA without some replacement does not appear to be a tenable political or public health strategy. Several features of Obamacare such as the elimination of preexisting condition denials and household coverage of children under the age of 26 are among the most popular provisions of the PPACA and, according to interview comments by President-elect Trump, are also likely to survive.

The proposed appointment of Congressman Tom Price, M.D., the current Chairman of the House Budget Committee, as Secretary of Health and Human Services (HHS) has raised additional speculation about the future of healthcare policy in a Trump administration based on Congressman Price's prior statements about bureaucratic overreach into the practice of medicine. As Congressman Price re-introduced his own "repeal and replace" legislation in May 2015, it is clear that the new HHS Secretary has his own views about how to address and pay for individual insurance, how to deal with religious freedom issues (e.g., free coverage of birth control), the Children's Health Insurance Program (CHIP), Medicaid expansion and block grants, Medicare comparative effectiveness research and value-based purchasing, and medical malpractice reform.

Changes to the PPACA will not occur overnight. The legislation contains 2,700 pages; associated regulations represent another 20,202 pages.¹ Repeal requires a vote by both houses of Congress. While the Republicans have a clear majority in the House to pass a repeal bill, Democrats can try to use the filibuster rules in the Senate to prevent a vote on a repeal bill, as bringing a full repeal bill to the Senate floor would require 60 votes.² The Republicans could abolish or amend the filibuster or cloture rules in the

new Senate, but that "nuclear option" seems unlikely. An alternative approach would be for Republicans to use the budget reconciliation rules, not subject to filibusters, to eliminate those portions of the ACA that can be eliminated through the reconciliation process. But such a procedure would create a piecemeal "repeal and replace" process that might not immediately eliminate the most unpopular provisions of the PPACA.

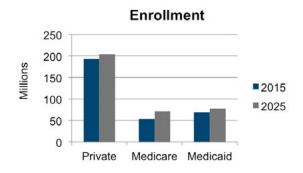
In this article, we evaluate and grade Obamacare, speculate about the emerging Republican replacement plan and provide context to the evolving debate based on data-driven fundamentals of healthcare delivery. Likely "winners and losers" by stakeholder are also identified. Whatever the outcome of PPACA "repeal and replace," Alvarez & Marsal (A&M) believes that another reform debate, focused solely on health insurance coverage and payment for such coverage, will not adequately address the root cause of rising healthcare costs and attendant rises in health insurance premiums, i.e., an inefficient and ineffective care delivery system that on an age-adjusted per capita basis is 50-75 percent more expensive than that of other Organization for Economic Co-operation and Development (OECD) nations.

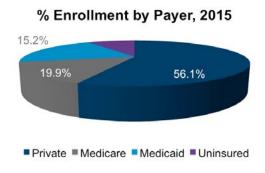
This article is the first of several articles A&M will publish on the prospect of healthcare "re-reform." Our next article will evaluate possible changes to Medicare, Medicaid and commercial insurers and their implications to specific market segments, including hospitals, post-acute care providers and senior living facilities.

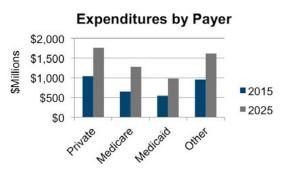
A detailed Appendix is attached to substantiate our hypothesis that the real issues affecting healthcare, inefficiency and ineffectiveness without adequate consumer (patient) engagement are not being adequately addressed by our political elite.

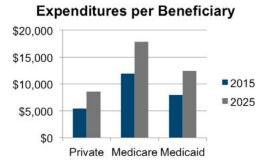


INSURANCE COVERAGE BY PAYER









https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html; Other includes SAMSA, worksite healthcare, workers compensation, Indian Health Service and other federal, state and local programs

In 2016, healthcare expenditures are forecast to approach \$3.4 trillion and represent 18.1 percent of the gross domestic product (GDP). The Centers for Medicare & Medicaid Services (CMS) forecasts spending of \$5.6 trillion by 2025, an increase of \$2.2 trillion within a decade.

The federal government currently spends \$646 billion on Medicare and \$340 billion on its Medicaid contribution; state expenditures on Medicaid represent an additional \$205 billion. The Children's Health Insurance Program (Titles XIX and XXI), Department of Defense, Department of Veterans' Affairs, Indian Health Service, Substance Abuse and Mental Health Services Agency (SAMHSA) and other programs represent another \$400+ billion. In aggregate, \$1.6 trillion or nearly one-half of national health expenditures are funded by federal, state and local governments.⁴

It is important to recognize that government involvement in the large and often dysfunctional U.S. healthcare delivery system has been long-standing since the inception of Medicare and Medicaid in 1965.⁵ The PPACA represents only one step, albeit an important one, in the evolution of care delivery. Any changes to the PPACA by the new Congress and Trump administration will represent the next iteration.

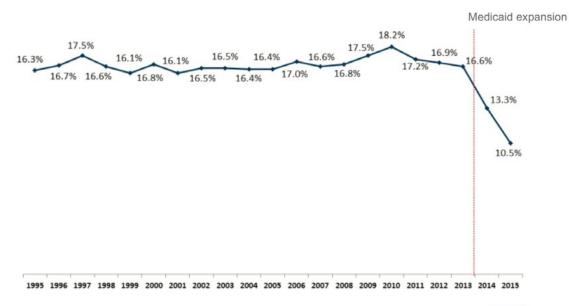
Prudent public policy formation would suggest that any repeal and replacement of the PPACA should take into account those provisions that have succeeded and those that have failed. Below we have attempted to provide a fact-based rationale for grading the impact of the PPACA on expanding healthcare insurance coverage and cost containment. We also grade access and affordability, variables that are intimately related to the implied benefit associated with insurance coverage.

GRADING "OBAMACARE" (1)

	Grade	Rationale
Coverage	А	Increased. Number of uninsured declined from 44.2M in 2013 to 26.8M in 2016. Medicaid enrollment increasing from $58.2M$ to $70.5M^1$
Access	B-	Improving. Increased coverage increases access, though networks remained somewhat constrained to specialists. Medicaid acceptance by physicians at 45.7%; many low-moderate income patients still without primary care ²
Affordability	С	Worsening for many. 25% of Americans, irrespective of income, exceed the Commonwealth Fund Healthcare Affordability Index ³
Cost containment	F	Limited. Re-acceleration of costs post-Great Recession. "Exploding" pharmaceutical prices for specialty drugs. Despite a younger population, U.S. per capita healthcare spending of \$9,990 far exceeds those of OECD nations by 80-140%+4

 $^{{}^1}https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-reports/NationalHealthExpendData/NationalHealthAccountsProjected.html$

UNINSURED RATE AMONG THE NONELDERLY POPULATION, 1995-2015



Source: CDC/NCHS, National Health Interview Survey, reported in http://www.cdc.gov/nchs/health_policy/trends_hc_1968_2011.htm#table01 and http://www.cdc.gov/nchs/data/nhis/earlyrelease/insur201605.pdf.



²http://medicaleconomics.modernmedicine.com/managed-healthcare-executive/news/treating-medicaid-patients?page=full

³http://www.commonwealthfund.org/publications/press-releases/2015/nov/commonwealth-fund-health-care-affordability-index

⁴ OECD http://stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT#

The essence of Obamacare is coverage; the number of uninsured Americans declined by 35 percent from 41.0 to 28.5 million in 2013–2015. This number is forecast to fluctuate no more than +/-2 million by 2025, assuming no legislative or regulatory changes.

As of March 2016, more than 11 million people were enrolled in state or federal Marketplace plans, and as of June 2016, Medicaid enrollment had grown by more than 15 million (27 percent) since the period before open enrollment (which started in October 2013).⁶ Note, however, that the health exchange participation figures are significantly below earlier CMS and Congressional Budget Office

(CBO) expectations, which estimated that by 2016, 33 million Americans would be newly covered, with Medicaid enrollment exceeding expectation by 5 million and health exchange enrollment below expectation by 12 million.⁷

For the entire 2017–2026 period, the incremental federal spending for people who the PPACA made eligible for Medicaid coverage is projected to be \$100 billion per year, whereas the comparable figure for premium exchange subsidies is \$90 billion; in total, this equals \$190 billion in incremental federal healthcare spending per annum.⁶⁷

PATIENT PROTECTION AND THE AFFORDABLE CARE ACT COVERAGE, ACCESS, AND AFFORDABILITY

COVERAGE:

- Medicaid eligibility expansion to those earning 138% of the Federal Poverty Level (FPL), including adults without
 dependents, in participating states. Federal government to pay in 2014-16: 100%, 2017-2019: 95% and 2020+: 90%
 thereafter.
- · Individual mandate; if uninsured, 2016 penalty of \$695 or 2.5% of family income, whichever is greater
- Employer mandate. Employers with >50 full-time (f/t) employees (>30 hours per week) are required to offer health insurance coverage that meet affordability provisions; i.e., no more than 9.5% of gross pay for individual coverage. They will be charged a \$2,000 penalty per full-time employee that lacks health coverage
- Insurers may not deny coverage to individuals for pre-existing conditions; and must offer the same premiums within the same age and geographical group regardless of gender and pre-existing conditions, except tobacco use.
- · Young adult coverage; can remain under parents' health plan through age 26
- Health plans are required to provide essential health benefits (n=10 categories); i.e., ambulatory (outpatient) services, emergency services, hospitalization, pregnancy/newborn, mental health/substance abuse, Rx drugs, rehabilitation, labs, prevention, wellness and chronic disease, pediatric including oral and vision care
- · Elimination of annual and lifetime spending caps

ACCESS:

- Created health exchanges at the Federal and state levels to make "affordable" health plans meeting essential ("basic") health plan requirements available to uninsured and low-to-moderate income individuals and households
- · Employers may not require employees to wait more than 90 days for health insurance eligibility

AFFORDABILITY:

- Subsidies (in the form of refundable tax credits) available on the state health insurance exchanges for individuals with a
 household income up to 400% of the FPL. Note, average premium subsidy \$291/month
- No out-of-pocket costs for preventive services (n=66); e.g., annual primary care visit, screenings (e.g., BP, cholesterol, colorectal cancer, depression, diabetes, hepatitis, HIV) and vaccinations
- · Pretax Health Savings Accounts [HSAs] for enrollees in high deductible health plans
- · Patients are granted the right to appeal whenever an insurer denies payment for health care services.

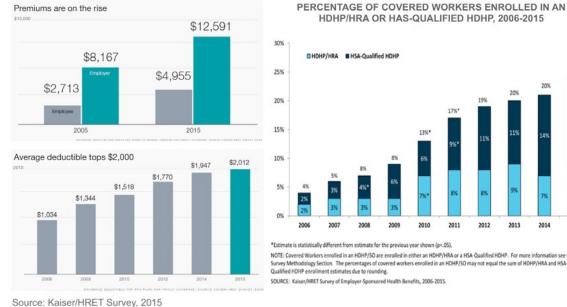
Increased Medicaid and insurance coverage has somewhat increased provider access, especially relative to those who remain uninsured. Increased funding for Federally Qualified Health Centers (FQHC), combined with expanded hours at certain facilities, has helped. However, significant barriers to access to care remain for Medicaid beneficiaries and individuals with health exchange purchased insurance:

- Growing shortage of physicians, estimated by the American Association of Medical Colleges at 46,000–90,000 in 20258
- Inadequate number of network providers, especially specialists in exchange plans and Medicaid
- Limited acceptability of Medicaid by physicians and non-physician providers
- Patients without an identified primary care provider

- Restricted availability of (timely) appointments
- Limited provider proximity and/or excessive transportation costs

Affordability of care is the major barrier to access. Rising out-of-pocket expenses driven by higher premiums, coinsurance, copayments and, especially, deductibles represent financial challenges to many Americans. The PPACA has contributed both to premium increases and higher copayments and coinsurance not only for Americans newly covered under the PPACA who are participating in exchange products, but for Americans who had already been covered by employer-based coverage or by their own individual insurance. Nearly three-quarters of households have income below \$97,000 per annum — the family of four maximum for health exchange subsidies. The average household income was \$55,755 in 2015.9

RISING OUT-OF-POCKET EXPENSES



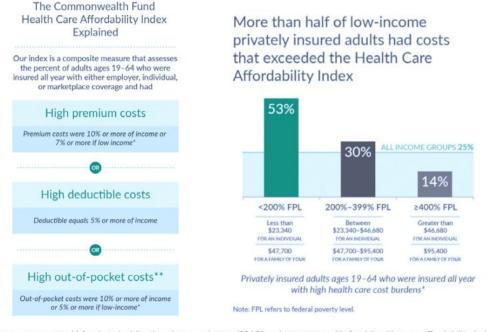
■ HDHP/HRA ■ HSA-Qualified HDHF

imate is statistically different from estimate for the previous year shown (p<.05) NOTE: Covered Workers enrolled in an HDHP/SO are enrolled in either an HDHP/HRA or a HSA-Qualified HDHP. For more inform

Survey Methodology Section. The percentages of covered workers enrolled in an HDHP/SO may not equal the sum of HDHP/HRA and HSA-



HEALTHCARE UNAFFORDABILITY ACCORDING TO THE COMMONWEALTH FUND



http://www.commonwealthfund.org/publications/press-releases/2015/nov/commonwealth-fund-health-care-affordability-index and the commonwealth of t

The Commonwealth Fund has developed a Health Care Affordability Index based on premium, deductible and out-of-pocket costs. One-quarter of all privately insured adults have high healthcare cost burdens. In a 2015 survey, 26 percent of Americans described healthcare costs as causing a serious financial problem during the prior two years, 27 percent describe being unable to pay for basic necessities like food, heat or housing, and 42 percent mention spending all or most of their personal savings. Healthcare costs are a major contributor, if not the leading factor, associated with personal bankruptcy.

The affordability of insurance plans purchased on health exchanges, including those receiving premium subsidies, is also of concern. Premium costs are expected to rise 22 percent in 2017, during a period of declining choice as Aetna, United Health and others have withdrawn from several major markets. Annual out-of-pocket payments of \$7,150 for individuals and \$14,300 are unaffordable for those ineligible for Medicaid and earning 1.4–4.0 times the Federal Poverty Level.

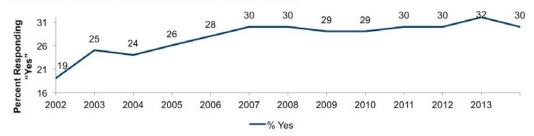
HIGH OUT-OF-POCKET LIMIT IN HEALTH EXCHANGE PLANS

	Bronze	Silver	Gold	Platinum
¹ Actuarial Value	60%	70%	80%	90%
² Specialty Visit Co-pay	\$65	\$56	\$44	\$29
³ Average Preferred Brand Name Drug Copayment	\$56	\$47	\$39	\$31
³ Average Specialty Drug Copayment	\$191	\$166	\$158	\$127
⁴ Annual Out of Pocket	\$7,150 Individual \$14,300 Family	\$7,150 Individual \$14,300 Family	\$7,150 Individual \$14,300 Family	\$7,150 Individual \$14,300 Family

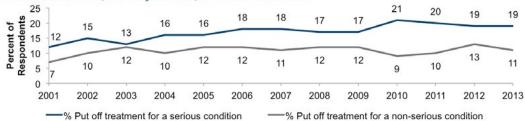
Note: Out-of-pocket maximums only apply to covered essential benefits. So if your plan doesn't cover a service, or the service isn't an essential benefit it may not count toward your maximum. Out of pocket maximums adjusted for income below 250% of the Federal Poverty Level. If household income is 100-200% of FPL, the out-of-pocket limit for an Individual will be no more than \$2,250 or \$4,500 for a family.

HIGHER COSTS AFFECT UTILIZATION OF HEALTH SERVICES

Within the last 12 months, have you or a member of your family put off any sort of medical treatment because of the cost you would have to pay?



When you put off this medical treatment, was it for a condition or illness that was – very serious, somewhat serious, not very serious, or not at all serious?



Source: GALLUP Well-Being. Costs Still Keep 30% of Americans From Getting Treatment. December 9, 2013.

¹http://i.investopedia.com/content/health_insurance_plans.jpg

²Kaiser Family Foundation

 $^{{}^3}http://images.alfresco_advanstar.com/alfresco_images/pharma/2014/12/29/0163c817-3845-45cd-95f4-04d8130b2bb9/NortonBlogImage-800x654.png$

⁴http://obamacarefacts.com/health-insurance/out-of-pocket-maximum/

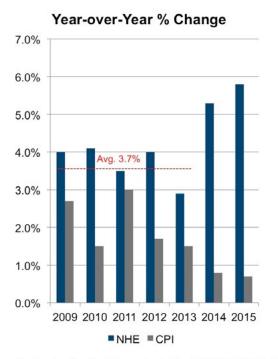
High out-of-pocket costs also adversely affect health outcomes due to the avoidance of necessary care. High deductible plans, in theory, suggest greater selectivity of providers and the site of service. However, limited price and quality transparency, combined with inadequate patient literacy, may not result in the intended consequence. A Gallup Poll from 2013 suggests the possible occurrence of negative healthcare consequences in one-third of avoided visits.

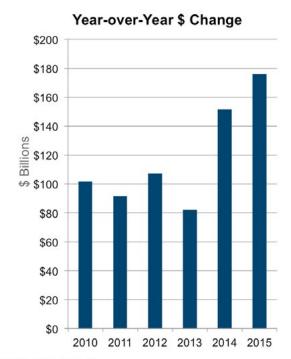
A December 2014 New York Times article entitled "Health Spending Rises Only Modestly" highlighted 2013 as the year with the lowest rate of increase in healthcare spending (3.1 percent) since recording began in 1960.¹¹ One day earlier, the White House published the following statement on its blog: "Today's data make it increasingly clear that the recent slow

growth in the cost of health care reflects more than just the 2007–2009 recession and its aftermath, but also structural changes in our health care system, including reforms made in the Affordable Care Act."¹²

The celebration was premature and factually incorrect. Factors such as the Great Recession, significant cost shifting by employers and continued generic drug penetration led to the slowdown in healthcare spending; net structural changes instituted by the PPACA were inconsequential. In actuality, value-based CMS initiatives were more than offset by increased coverage, provider and insurer consolidation, and explosive growth in specialty and branded drug pharmaceutical pricing, thereby setting the stage for an acceleration of healthcare spending.

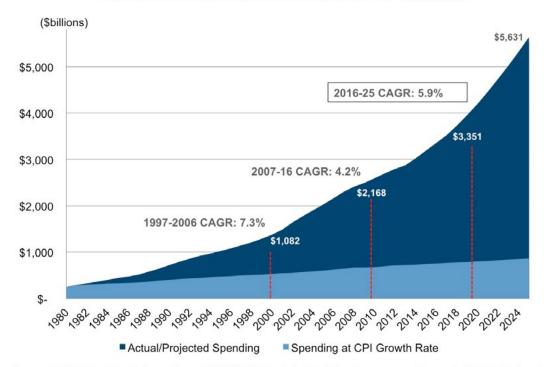
ACCELERATION OF NATIONAL HEALTH EXPENDITURES, 2014-15





http://content.healthaffairs.org/content/early/2016/11/22/hlthaff.2016.1330.full.pdf+html; http://www.usinflationcalculator.com/inflation/current-inflation-rates/

NATIONAL HEALTHCARE EXPENDITURES: 1980-2025



Sources: CMS National Health Expenditures, BLS CPI Inflation Calculator. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html

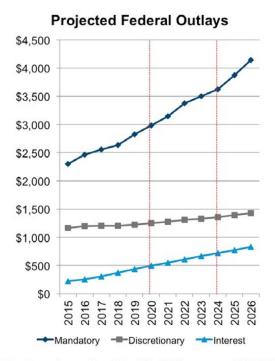
In 2014, overall health spending grew by 5.3 percent, whereas per capita spending increased by 4.4 percent. The comparable figures for 2015 were 5.8 and 5.0 percent, respectively.¹³ The latest projections from CMS forecast even higher growth through 2025.

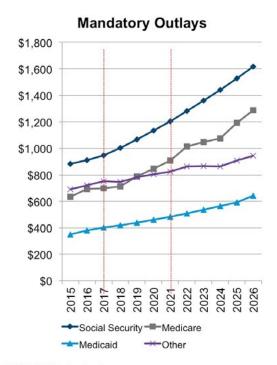
Any discussion about healthcare cost containment is necessarily also a conversation about entitlement reform, the federal budget and the national debt. In 2016–2026, according to the CBO, mandatory federal outlays are forecast to increase from \$2.5 to \$4.1 trillion (CAGR: 5.3 percent), discretionary outlays from \$1.2 to \$1.4 trillion (CAGR: 1.8 percent) and interest from \$255 to \$830 billion (CAGR: 12.5 percent). Medicare (\$596 billion) and Medicaid (\$261 billion) alone account for 51 percent of the federal increase

in mandatory outlays, whereas Social Security accounts for 42 percent. A deficit of -\$544 billion in 2016 is forecast to reach -\$1,366 billion in 2026, leading to an increase in the debt held by the public of \$23.8 trillion.¹⁴ Deficit spending and the subsequent rise in debt are unsustainable.

The CBO projections were generated prior to the November election. A report by the nonpartisan Committee for a Responsible Federal Budget estimates that tax reform plans proposed by candidate and now President-elect Trump would, during the next decade, reduce individual and business taxes by \$4.5 trillion and increase the deficit by \$5.3 trillion; the debt held by the public would reach 105 percent.¹⁵

PROJECTED FEDERAL OUTLAYS, 2016-2026





https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/reports/51129-2016Outlook.pdf

In the Appendix, A&M provides additional fact-based rationale for grading the impact of Obamacare on the following areas:

- Managing competition: Consolidation, as measured by standard measures of competition such as the Herfindahl-Hirschman Index (HHI), leads to higher baseline prices and portends a higher rate of spending growth in the future.
- Increasing clinical effectiveness: Defined as the application of the best knowledge, derived from research, clinical experience and patient preferences to achieve optimum processes and outcomes of care for patients. Systematic reviews — the basis of evidence-based medicine — can show which treatments and prevention methods have been proven to work and what remains unknown.

- Improving efficiency: A measure of the relationship between a specific level of healthcare quality and the resources (intensity) used to provide that care, i.e., the production of the desired effects or results with minimum waste of time, effort or skill.
- Facilitating payment reform: Involves the use of financial incentives and disincentives to facilitate the transition from fee-for-service (FFS) payment models providers receiving a specific amount of compensation in exchange for providing a patient with a specific service — to valuebased payment systems focused on the provision of high-quality, efficient care.

GRADING "OBAMACARE" (2)

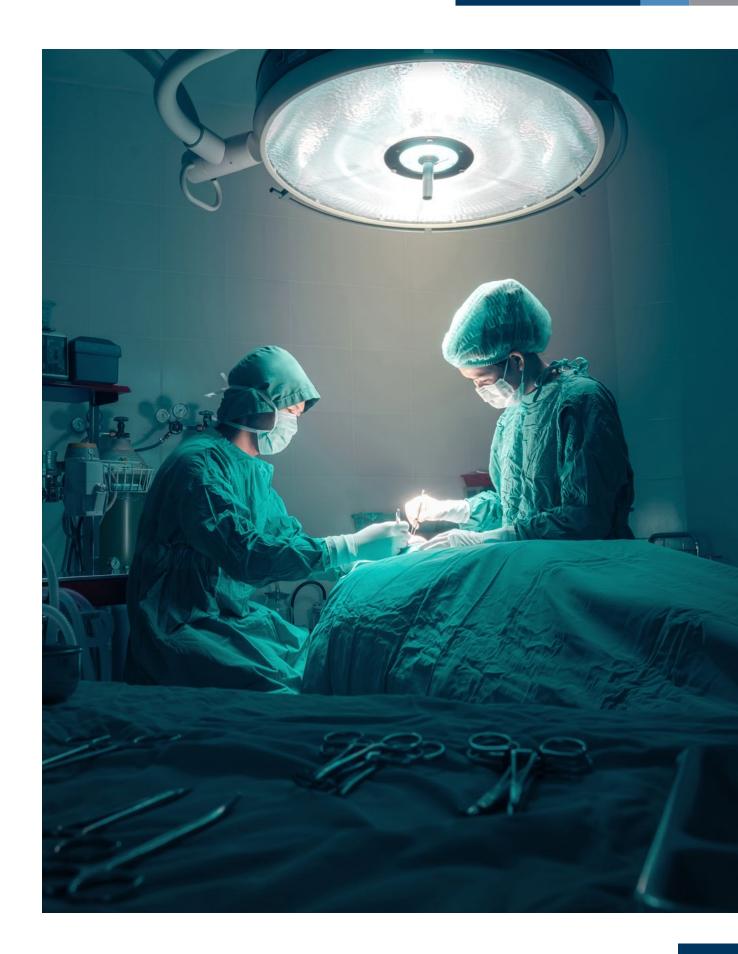
3	Grade	Rationale
Managing competition	C-	Declining. Consolidation of payers, providers and suppliers raising prices
Increasing clinical effectiveness	С	U.S. has a shorter life expectancy; and higher (a) infant mortality (b) maternal mortality © ischemic heart disease mortality (d) lower extremity amputations for diabetes € potential years of life lost and other metrics¹
Improving efficiency	D	Poor. Waste estimated at 10-30% of total spending due to unnecessary procedures, price variation, excessive administration costs, missed prevention opportunities, fraud and other factors ²
Facilitating payment reform	B-	Multiple CMS initiatives "kick-start" shift from fee-for-service to value-based care; episode payment models (e.g., CJR) a major step forward
Enhancing the experience of care	D	Poor. Despite recent efforts at hospital patient satisfaction (HCAHPS), care delivery remains fragmented with limited care coordination, patient/caregiver understanding and engagement; payment (billing) remains confusing.

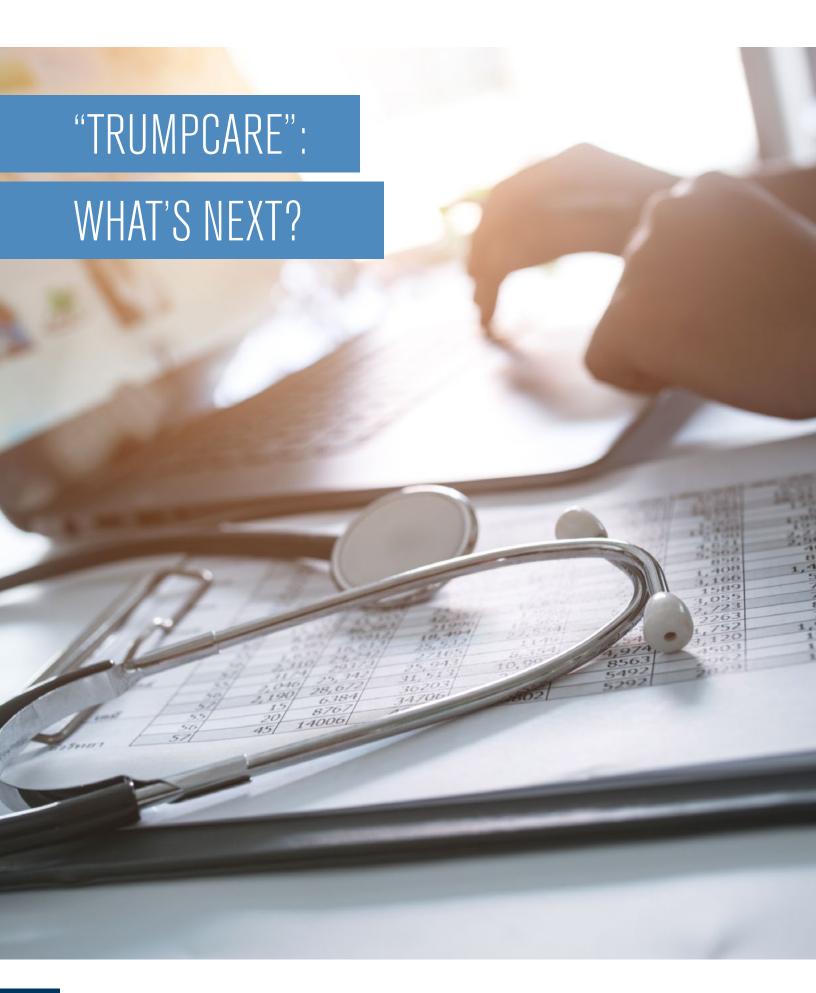
¹ OECD Health Data, 2015 and https://aneconomicsense.files.wordpress.com/2013/11/health-potential-years-of-life-lost-per-100000-males-oecd-2011.png

Enhancing the experience of care: Reflects occurrences and events that happen independently and collectively across the continuum of care. Embedded within patient experience is setting expectations, focusing on the specific needs of individual patients, and engaging patients and their caregivers.

In all of these areas, the record is mixed, if not overall negative. In large part, the PPACA has led to a consolidation of providers and payers, with resultant increased prices. PPACA initiatives have shown only modest impact on clinical outcomes and overall improvements in the health of the general population. Although the PPACA created some new payment models (Accountable Care Organizations) and furthered Medicare's value-based purchasing initiatives, the record on improving efficiency or payment models is negative to mixed. Finally, preliminary data suggests that the PPACA has not increased overall patient / consumer satisfaction with the healthcare delivery system.

²The Healthcare Imperative: Lowering Costs and Improving Outcomes, 2010 Table S-1. Adopted by National Academy of Sciences from IOM Workshop Summary.





Unlike other recent presidential candidates who issued lengthy policy prescriptions, and even published books, as part of their campaigns (e.g., 1992 Bill Clinton "Putting People First," 2000 George W. Bush "A Fresh Start for America," 2008 Barack Obama "The Audacity of Hope," 2016 Hillary Clinton "Stronger Together"), President-elect Trump's campaign provided limited insight into its healthcare policy view, other than sustained promises that Obamacare would be repealed, that any new system for the uninsured would have more flexibility and that the Trump administration would stand by the federal government's historical commitment to Medicare.

Since the election, the Trump transition team has outlined on a single webpage the tenets that will guide its healthcare policy, which in most respects mirror what the candidate said on the campaign trail. The challenge is always to distinguish between campaign trail rhetoric and actual policy position.

One position that has been a constant since the inception of the Trump campaign indeed with the inception of the campaigns of all the Republican candidates - has been an absolute commitment to "repeal and replace" Obamacare. From that perspective, a legislative bill, any bill, must be put forth by the Republican Congress and the Trump administration that is styled as a repeal bill. But on a total repeal of all provisions of Obamacare, already here the president-elect has hedged a bit and has offered that some of the most popular provisions of the PPACA pre-existing condition bans and adult children coverage on a parent's healthcare policy will be maintained; all other provisions (e.g., subsidies, healthcare exchanges, uniform

mandated benefits, Medicare "surtax") are subject to being jettisoned.⁶⁸ Trump administration authorized "replacement bills" might include:

- An increased reliance on Health Savings Accounts (HSAs)
- The elimination of uniform, "minimum" and/or "essential" health insurance benefit provisions required by the federal government, i.e., allowing state insurance commissioners to determine the specific benefits to be included in an individual (not employer sponsored) healthcare plan
- Changes to federal law permitting individual health insurance policies to be sold across state lines.
- Expansion (or establishment) of high-risk pools patients, possibly state-based, to assist individuals with high-cost chronic conditions who otherwise cannot access insurance on an individual market
- Elimination of any mandated benefits (e.g., birth control) that might conflict with beliefs of religious organizations or employers

The Trump transition healthcare position has also called for:

- Additional funding for healthcare research
- Food and Drug Administration (FDA) reforms to speed approval of innovative drugs and medical products

Presumably, a "repeal and replace" bill will eliminate or significantly alter the Medicaid expansion provided under the PPACA. The Trump administration is committed to devolving authority from the federal government to states and allowing individual states to design and administer their own Medicaid programs. Most

TRUMP TRANSITION TEAM WEBSITE: HEALTHCARE POLICY TENETS

Vision for healthcare in Trump Administration laid out in one web page

It is clear to any objective observer that the Affordable Care Act (ACA), which has resulted in rapidly rising premiums and deductibles, narrow networks, and health insurance, has not been a success.

A Trump Administration will work with Congress to repeal the ACA and replace it with a solution that includes Health Savings Accounts (HSAs), and returns the historic role in regulating health insurance to the States.

The Administration's goal will be to create a patient-centered healthcare system that promotes choice, quality and affordability with health insurance and healthcare, and take any needed action to alleviate the burdens imposed on American families and businesses by the law.

To maximize choice and create a dynamic market for health insurance, the Administration will work with Congress to enable people to purchase insurance across state lines.

The Administration also will work with both Congress and the States to re-establish high-risk pools – a proven approach to ensuring access to health insurance coverage for individuals who have significant medical expenses and who have not maintained continuous coverage.

The Administration recognizes that the problems with the U.S. health care system did not begin with – and will not end with the repeal of – the ACA. With the assistance of Congress and working with the States, as appropriate, the Administration will act to:

- Protect individual conscience in healthcare
- Protect innocent human life from conception to natural death, including the most defenseless and those Americans with disabilities
- Advance research and development in healthcare
- Reform the Food and Drug Administration, to put greater focus on the need of patients for new and innovative medical products
- Modernize Medicare, so that it will be ready for the challenges with the coming retirement of the Baby Boom generation – and beyond
- Maximize flexibility for States in administering Medicaid, to enable States to experiment with innovative methods to deliver healthcare to our low-income citizens

Source: https://www.greatagain.gov/policy/healthcare.html

pronounced is the administration's desire to seek more Medicaid waiver programs and, possibly, to exchange Medicaid expansion for block grants. Given Vice President-elect Mike Pence's position on Medicaid, it is highly likely that any Trump administration "replace" plan will include some kind of Medicaid block granting provision.

As a candidate, President-elect Trump frequently announced that the Medicare program was more or less a "sacred promise" to beneficiaries. Although the Trump transition website mentions a desire to "modernize Medicare," any movement from a defined benefit to defined contribution plan, as proposed by House Speaker Paul Ryan, is unlikely to occur, if it is to occur at all, in the

early part of a Trump administration. The Trump administration will, however, likely promote the expansion of market-based solutions such as continuing growth in Medicare Advantage plan enrollment.

The phrase "personnel is policy" was popularized during the Reagan administration.⁶⁹ This maxim is clearly applicable to President-elect Trump, who remains sparing on details around replacement legislation for the PPACA and Medicaid / Medicare reform. Any policy predictions must include consideration of previously advocated healthcare policy positions by Trump appointees and key Republican legislators.

Because President-elect Trump believes himself to be an astute evaluator of talent, history suggests that once he trusts and/or hires a person, that individual will have significant latitude in his or her position. In that respect, every Trump administration appointment appears to have his personal imprimatur.

Four key healthcare-related personnel picks demonstrate the president-elect's intentions:

Foremost is the selection of Mike Pence to be Vice President. Pence, the Governor of Indiana and a former Congressman and leader of the Republican Policy Conference, may emerge as one of the most influential vice presidents in history, even more influential than Vice President Dick Cheney. Pence's influence is particularly noted by his appointment as the chairman of President-elect Trump's transition

team. This transition leadership position means that most, if not all, hires will have his stamp of approval. The first two key healthcare appointments demonstrate Pence's influence, as both appointees have historic relationships with him: Tom Price, M.D., as Secretary of Health and Human Services and Seema Verma, a former healthcare policy consultant and author of the Indiana Medicaid waiver program, as the Administrator of CMS.

The selection of Dr. Price as HHS secretary, a position often given to a governor with executive experience (e.g., Kathleen Sebelius, Michael Leavitt, Tommy Thompson), highlights President-elect Trump's desire for a secretary who literally knows how to write "repeal and replace" legislation for the PPACA and shepherd it through Congress. The president-elect also apparently believes that doctors, not bureaucrats, matter and being an orthopedic surgeon further qualifies Dr. Price as an administrator of healthcare policy.

The appointment of Ms. Verma as Administrator of CMS reflects Vice President-elect Pence's strong preference for the use of innovative Medicaid state waivers and a possible shift to a system of block grants for Medicaid, rather than the traditional federal / state pro rata cost sharing model.

Another significant personnel choice impacting healthcare is Reince Priebus as White House Chief of Staff. Although President-elect Trump campaigned as the consummate Washington "outsider," with Priebus as his Chief of Staff,

he has someone with significant Washington political experience. Mr. Priebus has a close, personal relationship with Speaker Paul Ryan, suggesting that passing legislation is more important to Trump than stoking an internecine party war.

The Price, Ryan and Priebus trio will likely be the primary designers and movers of "repeal and replace" legislation through Congress. Added to this team is Senator Mitch McConnell, Majority Leader of the Senate, considered an expert on the intricacies of Senate rules and procedures, based on more than 32 years of experience. This knowledge will be essential, especially if the Trump administration and the Republican Congressional leadership elect to proceed on "repeal and replace" through the budget reconciliation process, bypassing the Senate's 60 vote or "filibuster" rules.

Lastly, demonstrating that any internecine party wars are over and that "running the trains on time" takes priority, President-elect Trump has reached out to a number of HHS staffers from the George W. Bush administration — Andrew Bremberg, Paula Stannard, Eric Hargan, Scott Gottlieb, M.D., and Nina Owcharenko — to ensure a smooth transition by deputizing former political insiders already familiar with the mechanics necessary to manage the sprawling HHS bureaucracy and its \$1.1 trillion budget.

The First 60 Days to Six Months

How do the general themes outlined by the Trump transition team — most importantly, "repeal and replace" but also Health Savings Accounts, Medicaid block waivers, the sale

of health insurance across state lines and other items – get translated into a robust policy statement and legislative package on a timely basis?

Both HHS Secretary-designate Dr. Price and Speaker Ryan have already generated alternative legislative approaches to "repeal and replace." Dr. Price first introduced HR 2300, also known as the "Empowering Patients First Act," in June 2013 and reintroduced the Act in May 2015 to "fully repeal Obamacare and start[] over with patient-centered solutions."^{70,71}

Speaker Ryan's plan for "repeal and replace" of the PPACA, although not committed to specific legislative language, contains similar provisions to Dr. Price's Empowering Patients First Act, including tax credits, use of HSAs and highrisk pools.

For Republican budget hawks such as Speaker Ryan, a key looming question will be: How much of the federal budget will be committed to subsidies to purchase health insurance, even if the subsidies come by way of a refundable tax credit or voucher from the federal government, rather than a check directly to an insurance company? Since a Republican "repeal and replace" bill may eliminate many of the funding mechanisms of the PPACA — Medicare surtax and the various taxes on employer-based plans — the cost of a repeal and replace with tax credits may add to the federal budget deficit.

ACA REPEAL AND REPLACE: TOM PRICE MODEL

Congressman Tom Price introduced his own "repeal and replace" bill in May 2016 – HR 2300 Empowering Patients First Act -- which could be one model for overhauling the ACA

- Full repeal of the ACA and all healthcare related provisions
- Refundable, age-based "tax credits" for health insurance coverage purchased on the individual market
 - o \$1200 (18 to 35); \$2,100 (35 to 50); \$3000 (50 +); \$900 for each child
 - o No credits available for employer-based insurance or Medicaid / Medicare recipients
- Health Savings Accounts
 - One time \$1,000 tax credit to everyone for an HAS
 - o Increase HSA contribution rate; permit tax-free transfers from 401ks to HSAs
- Employer-based insurance "vouchers": employees permitted to take employer-paid insurer premiums and apply directly to an individually purchased health insurance policy
- Federal grants to States that establish or maintain "high risk" insurance pools
- · Allow small businesses to band together, across State lines, to purchased pooled insurance
- Interstate sales of health insurance permitted
- Medical malpractice reform through establishment of defense "clinical guidelines"
- New claims reporting requirements and penalties on group insurers
- · Repealing several Medicare "comparative effectiveness" payment proposals
- Allow Medicare beneficiaries to seek care from providers not enrolled in Medicare program.
- New antitrust immunities for physicians contracting with health insurance companies

ACA REPEAL AND REPLACE: PAUL RYAN MODEL

Speaker Paul Ryan introduced his own template for ACA repeal and replacement and Medicare and Medicaid reform in June 2016 entitled: "A Better Way"

- Pre-existing condition protection for people who are continuously insured
- Prohibit cancellations and non-renewals based on illness or condition
- · Continue allowing children to remain on parents insurance policy until age 26
- One-time, annual open enrollment
- Refundable "tax credits" for health insurance coverage purchased on the individual market
- Expansion of Health Savings Accounts
- Elimination of the "Cadillac Tax" on employer-sponsored health insurance but a cap on the total deductibility of employer-provided insurance.
- Allow small businesses to band together, across State lines, to purchased pooled insurance
- Federal grants to States that establish or maintain "high risk" insurance pools
- · Medical malpractice reform

Our Prediction:

In some form or fashion, a bill will be enacted by Congress – and signed by President-elect Trump – in 2017 that "repeals" and "replaces" the Affordable Care Act.

- Popular ACA provisions pre-existing condition limitations and children on parents' health plans through age 26 – will likely be maintained
- Health exchange subsidies are likely to be eliminated and replaced by advance, "refundable" tax credits or voucher-like instruments
- Insurers will be allowed to create and sell all types of individual health insurance products, irrespective of a minimum, essential benefits package: high deductible, catastrophic to high-premium, full-coverage plans
- Insurers will be allowed to sell health insurance across state lines
- Use of Health Savings Accounts (HSAs) will be expanded
- High-risk pools will be created or expanded for individuals with high-cost conditions unable to find health insurance
- Medical malpractice reform will only happen if it can get past the 60 vote filibuster threshold in the Senate, a difficult task

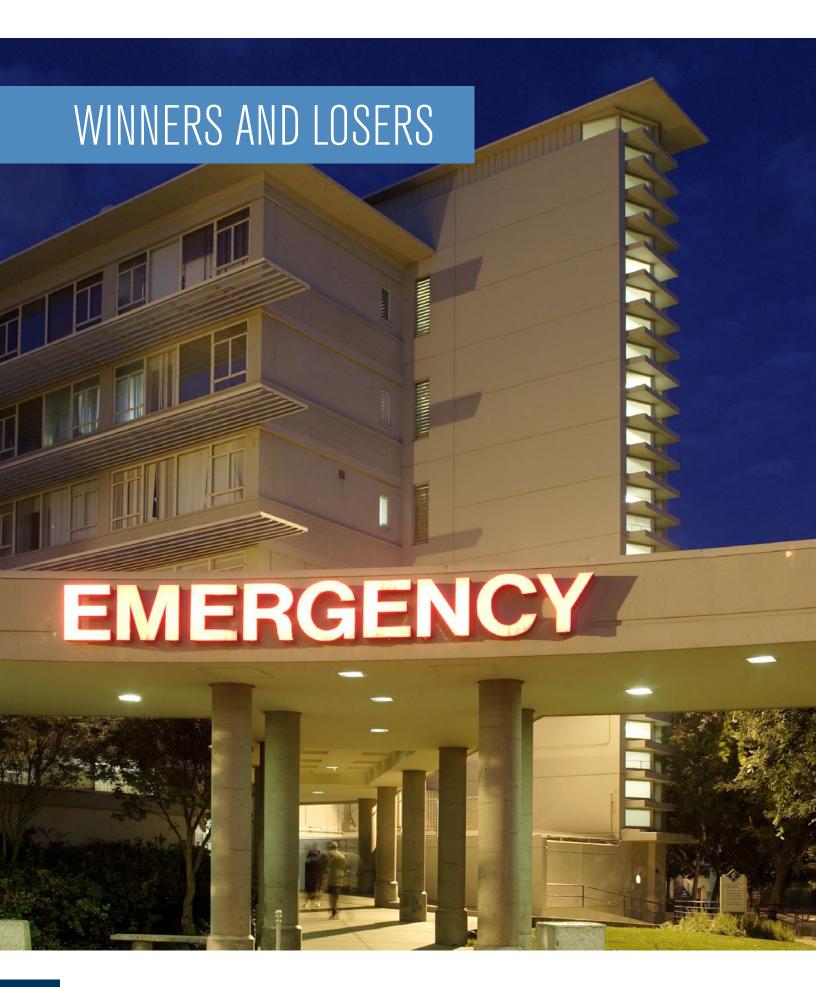
"Repeal and replace" (or "repeal and delay") will occur prior to any legislative changes to Medicare or Medicaid. However, the issue of Medicaid expansion (or block grants) could become part of the budget reconciliation process.

Even without legislative changes to Medicare and Medicaid, however, the Trump administration will have significant regulatory authority at HHS / CMS to:

- Change Medicare provider payments (hospitals, physician, skilled nursing facilities, home health, etc.)
- Eliminate or change CMS quality and payment reform initiatives such as valuebased purchasing, hospital acquired condition, re-admission, episode payment model, Accountable Care Organizations (ACOs) and the Medicare Access and CHIP Reauthorization Act (MACRA)
- Change Medicare Advantage payment rates, oversight, rules, etc.
- Approve new Medicare waiver projects
- Approve new Medicaid waiver projects giving more flexibility to the states

Bottom line: significant activity is likely from CMS if Secretary Price and CMS Administrator Verma are quickly approved by the Senate in January 2017.





The winners and losers are difficult to predict with certainty at this early stage, but broad outlines of "repeal and replace" (i.e., Pricecare, Ryancare) appear to be emerging:

- Federal government: Healthcare spending is forecast by CMS to reach \$5.6 billion by 2026, reflecting a compound growth rate of 5.9%. The forecast incorporates the impact of ongoing value-based payment reform initiatives. Any overall changes to the latter, inclusive of a slowdown in the timing of implementation and/or its financial impact (e.g., penalties) will result in even higher healthcare spending. Improving the efficiency and effectiveness of healthcare delivery must remain a strategic priority. Elimination of the CMS Innovation Center would send a "strong" signal to providers regarding the future of payment reform. Elimination of the ACOs model is not deemed by A&M to be a major loss due to its uncertain value.
- States: 31 states and Washington, D.C., have expanded Medicaid, whereas 19 states have not. The federal government paid 100 percent of the incremental costs associated with expansion in 2014-16, and will pay 95 percent in 2017-19 and 90 percent thereafter. Block grants equivalent to the incremental federal expenditures in states with Medicaid expansion (that contain inflationary increases) will be necessary to remain "whole." States that have not expanded Medicaid will not be significantly affected by the elimination of Medicaid federal subsidies (beyond the average Federal Medical Assistance Match Rate of 57 percent). A change in the Medicaid block grant formula to a federal per capita calculation adjustment would significantly impact states with high level

- of spending and benefit lower spending states. Reducing federal oversight on state Medicaid programs via the elimination and/or reduction in waiver requirements may or may not be beneficial, based on the specifics of the state program.
- Hospitals: Obamacare has clearly benefited hospitals in states with Medicaid expansion due to the increase in coverage and a reduction in charity care. Hospitals have also benefited by the delay in offsetting Medicare and Medicaid DSH reductions. An internal analysis by A&M of safety net hospitals with Low Income Utilization Rates (LIUR) > 25 percent, the threshold for the receipt of Medicaid DSH payments, highlights an average difference in EBITDA of \$61 million (favorable) to hospitals within states that expanded Medicaid. In states without Medicaid expansion, Obamacare will negatively affect operating performance based on the impending reduction in Medicare and Medicaid DSH payments.
- Post-acute care providers: A reduction in Medicare fee-for-service reimbursement, combined with increased Medicare Advantage penetration, has led to lower profit margins for skilled nursing facilities and home health agencies. Any acceleration in Medicare spending is likely to lead to additional reductions in either the rate of reimbursement growth, the absolute level or reimbursement or coverage requirements. Value-based payment initiatives are essential to improve operational efficiency and effectiveness.
- Physicians: The elimination of valuebased physician payments via MACRA would create a real issue with the manner in which Congress tried to fix the annual

Medicare payment update based on the sustainable growth rate (SGR) system. A payment system that promotes significant income disparities between specialists who might earn on average \$750,000 and primary care internists earning \$224,000 will contribute to the growing shortage of the latter despite their far greater contribution to population health and the total cost of care.

- Advantage and Medicaid Managed Care plans will likely be supported by the new administration, a positive for insurance companies focused in those areas. The availability of health plans across state lines is likely to further the competitive position of the largest insurers better able to rapidly form provider networks and price coverage based on actuarial assumptions. The elimination of health exchanges may herald a return of the health insurance broker model.
- Employers: Elimination of the employer insurance mandate for companies with more than 50 employees, minimum coverage requirements and the Cadillac Tax will be welcomed by many businesses.
- Individuals: Despite the likelihood that changes to coverage are unlikely for pre-existing conditions and under 26-year-old population, individuals remained challenged by access and affordability issues. Dr. Price's proposal for "continuous coverage exclusion" might allow insurers to either charge a higher price or exclude coverage based on preexisting conditions for up to 18 months only if a gap in coverage of greater than 63 days exists. Many groups will be concerned if "repeal and replace" results in

discontinuation of mandated reproductive health benefits, a loss of coverage for preventive health services and a reduction and/or loss of health exchange subsidies. High-income households may benefit if the Medicare surtax is eliminated.

• Pharmaceutical companies: Depends on whether drugs can be negotiated by Medicare, shipped cross-border from Canada or elsewhere, and cost-effectiveness data can be required for the reimbursement of newly approved (oncology) drugs by Medicare. Pharmaceutical (and medical product) companies have spent more money on federal lobbying in 1998–2016, \$3.5 billion than any other industry; the 2015 figure is \$241 million.

In summary, as a \$3.4 trillion enterprise with the government funding nearly one-half of total expenditures, healthcare is not amenable to a "deal" that does not consider the underlying inefficiency and ineffectiveness of care delivery. Projected national health expenditures of \$5.4 trillion (\$16,032 per capita) in 2025, representing 20.1 percent of GDP, are a threat to U.S. competitiveness, aging Baby Boomers and the financial security of the middle class. A continued shift from fee-for-service (volume) to value, initiated by President Obama under the PPACA, is a requisite for fundamental change.

Our next article will provide a more detailed analysis of potential "winners and losers" based on a scenario analysis for key provider stakeholders, i.e., hospitals, skilled nursing facilities, home care agencies, senior living operators, physicians and patients. A separate article is also being generated to evaluate the effect of Trump administration healthcare policy on commercial payers, as well as Medicare Advantage and Managed Medicaid plans.



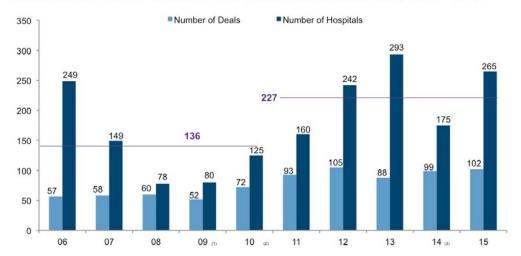
APPENDIX: GRADING OBAMACARE (PART II)

Managing Competition Grade: C-

Healthcare consolidation has increased significantly since passage of the PPACA. The number of hospital deals has increased from an average of 60 (involving 136 hospitals) in 2006–2010 to 97 (involving 227 hospitals) in 2011–2015. Several studies have shown

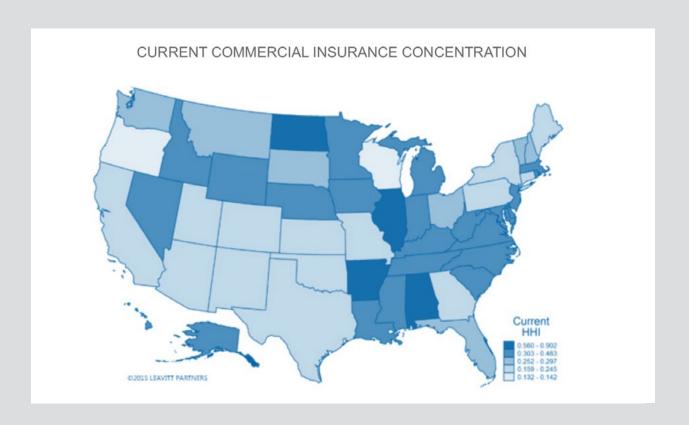
that hospital mergers result in higher prices for employers, consumers and insurance companies.¹⁶ Hospitals are also acquiring physician practices, with nearly one-third of physicians in 2014 either working directly for a hospital or in practices that were at least partially owned by a hospital.¹⁷

PROVIDER CONSOLIDATION ANNOUNCED HOSPITAL MERGERS AND ACQUISITIONS, 1998 – 2015



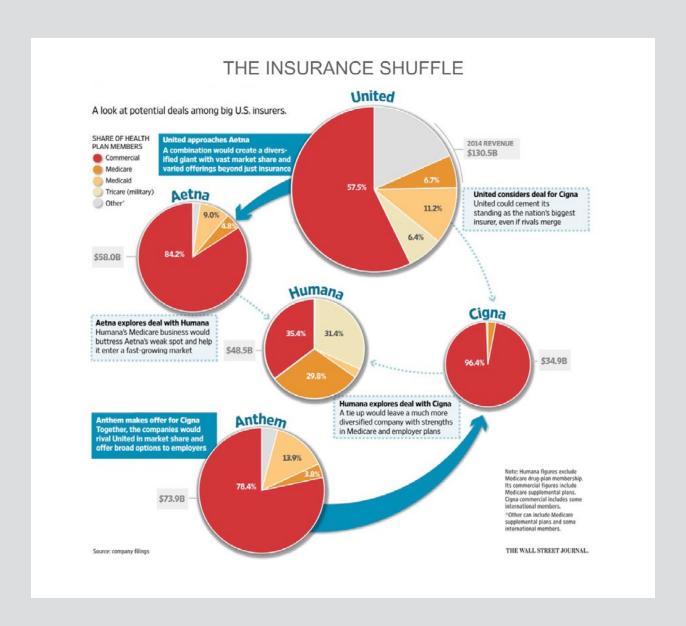
Source: Irving Levin Associates, Inc. (2016). The Health Care Services Acquisition Report, Twenty-Second Edition.

- (1) In 2004, the privatization of Select Medical Corp., an operator of long-term and acute-care hospitals, and divestiture of hospitals by Tenet Healthcare Corporation helped to increase the number of hospitals affected.
- (2) In 2006, the privatization of Hospital Corporation of America, Inc. affected 176 acute-care hospitals. The acquisition was the largest health care transaction ever announced.
- (3) In 2013, consolidation of several investor-owned systems resulted in a large number of hospitals involved in acquisition activity.



Health insurance industry competition has also declined, with fewer companies offering commercial, Medicare Advantage and Medicaid Managed Care plans. According to the National Association of Insurance Commissioners, there are 859 health insurers in the United States; the five largest — United, Anthem, Aetna, Humana and Cigna — generate revenues exceeding \$350 billion. Competition is exceedingly limited in four states — Alabama, Illinois, Arkansas and North Dakota — and limited in many others.





The Herfindahl-Hirschman Index (HHI),

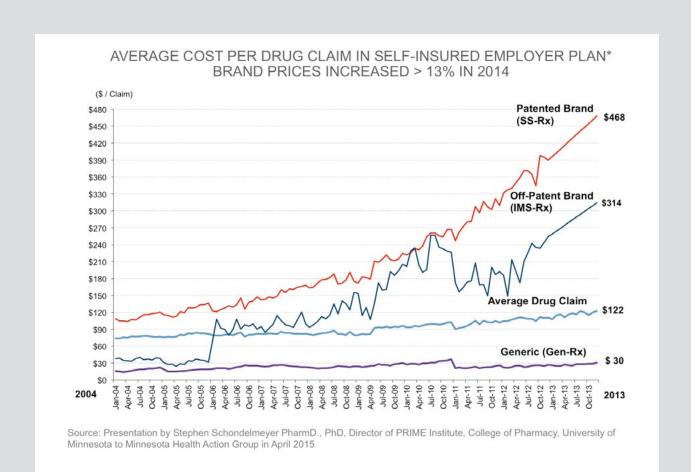
a measure of market share distribution, has values ranging from zero (highly competitive) to 10,000 (non-competitive). According to the Federal Trade Commission (FTC), markets are classified into three categories: non-concentrated (HHI index < 1,500), moderately concentrated (HHI of 1,500–2,500) and concentrated (HHI > 2,500). The median state HHI value for large group health insurance industry HHI has increased from 3,453 in 2011 to 4,256 in 2014 (for large insured groups).

In 2000, the average state HHI approximated 2,000.²¹ According to the Commonwealth Fund, consolidation among private insurers "leads to premium increases, even though insurers with larger market shares generally obtain lower prices from health care providers."²²

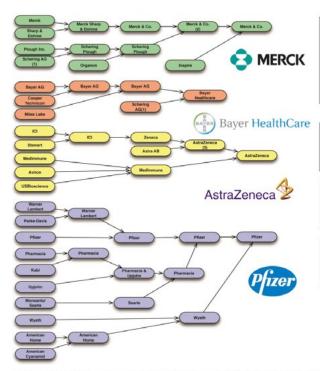
Limited competition has not precluded additional consolidation in the future, particularly among small-to-moderate size commercial and government plans in specific markets.

The pharmaceutical industry has also undergone significant consolidation. Increasing penetration of generic drug prescriptions from 54 percent in 2003 to 88 percent in 2015 has masked an increase in the average price of a patented brand drug prescription from \$110 to \$468 per claim, reflecting a compound annual growth rate of 15.6 percent.^{23,24,25} The end of the generic

"cliff" (i.e., major drug category expirations) has coincided with a shift in pharmaceutical strategy from developing products for population-based unmet needs, such as heartburn, anti-cholesterol and hypertension drugs, to niche, specialty and "orphan" markets with comparatively few patients where competition is somewhat limited and price increase unrestrained.



PHARMACEUTICAL INDUSTRY CONSOLIDATION



- GlaxoSmithKline (9) Glaxo, Welcome, SmithKline Beckman, Beecham Group, Block Drug, Stiefel Labs, Human Genome Sciences, Sterling Health, ID Biomedical
- Novartis (7) Ciba-Geigy, Sandoz, Chiron, Hexal, Eon Labs, Alcon, Fougera
- Roche (6) Syntex, Chugai Pharmaceuticals, Ventana, Genentech, Intermune
- Sanofi-Aventis (6) Synthelabo, Hoechst, Rhone-Poulenc, Zentiva, Chattern, Genzyme

http://www.pm360online.com/wp-content/uploads/2014/05/History-of-BioPharma-Consolidation_1.jphttp://revenuesandprofits.com/wp-content/uploads/2016/02/Merger-and-Acquisition-Analysis-of-Pharma-Industry-1995-2015.png;

Significant industry consolidation has occurred during the past 10–20 years and has more recently affected the generic drug industry. In 2014, a newly introduced medication for hepatitis C reported sales of \$10.3 billion, with a full 12-week course of therapy reaching \$84,000 per patient. U.S. prescription drug spending rose 13 percent in 2014.²⁶ The average price of one type of insulin has increased from \$600 to \$1,200 per vial in less than three years. The cost for the generic antibiotic doxycycline has risen 8,281 percent, asthma treatment albuterol by 4,014 percent and anti-cholesterol medication pravastatin by 573 percent.^{27,28}

CMS does not include hospital and specialty drugs subject to medical claims (J-codes) in gross drug spending calculations. As a result, the vast majority of healthcare professionals are unaware that actual prescription drug spending far exceeds CMS reported expenditures. Also, through 2023, CMS reports drug spending as a percent of National Health Expenditures is forecast to remain relatively constant at 9.4 percent.²⁹ The reality is far different; drug spending is estimated to increase at a greater rate than any other sector within healthcare. Drug spending is also projected to surpass physician service expenditures by 2022 and to represent 20.1 percent of national health expenditures by 2023.30

Increasing Clinical Effectiveness Grade: C

Despite the exceedingly high level of healthcare spending, the United States lags many countries in terms of health outcomes. More specifically, The Conference Board of Canada conducts multi-year research to measure relative health performance on 11 report card indicators among 16 nations: life expectancy, self-reported health status, premature mortality, mortality due to cancer, mortality due to circulatory disease, mortality due to respiratory disease, mortality due to diabetes, mortality due to diseases of the musculoskeletal system, mortality due to mental disorders, infant mortality and mortality due to medical misadventures. The United States is one of only three nations to receive an overall D grade.³¹

U.S. life expectancy ranks only 26th of 36 OECD countries.³² Life expectancy actually declined slightly in 2015 to 78.8 years, driven primarily by obesity-related conditions such as heart and kidney disease, as well as substance abuse and suicide. Age-adjusted death rates increased for non-Hispanic black males and non-Hispanic white males and females. The infant mortality rate also increased, though not in a statistically significant manner.³³

The U.S. health adjusted life expectancy (HALE) at birth, weighted by health status, of 69.1 years is only slightly ahead of Poland (68.7) and China (68.5) and lags the major European Union countries (range: 71.3–72.8) and Japan (74.9).³⁴

11	S	RA	NK	IN	G	ON	N/	10	R	T	ΔΙ	17	ΓV	H	FΔ	IT	ГН	11	V		C	Δ'	TO)F	20	:
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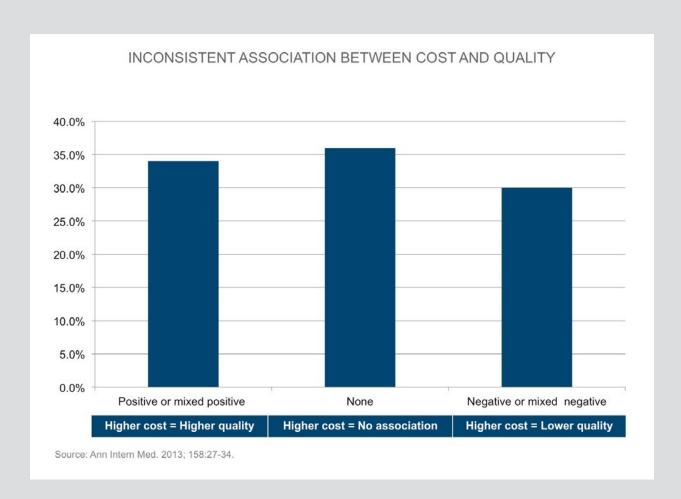
	Life expectancy	Self- reported health status	Premature mortality	Mortality due to cancer	Mortality due to circulatory diseases	Mortality due to respiratory diseases	Mortality due to diabetes	Mortality due to musculo- skeletal system diseases	Mortality due to mental disorders	Infant mortality	Mortality due to medical mis adventures
Australia	B	(A)	A	A	A	A	B	0	B	B	0
Austria	()	•	0	B	0	•	0	0	A	B	0
Belgium	0	(4)	0	0	0	0	0	(3)	0	0	n.a.
Canada	0	0	0	0	0	B	0	0	0	0	0
Denmark	0	A	B	0	0	0	0	0	0	A	A
Finland	0	B	0	(A)	0	(4)	0	(3)	0	0	•
France	(3)	B	B	B	A	(4)	0	0	B	B	0
Germany	0	B	A	B	0	(4)	B	(A)	B	(3)	0
Ireland	0	0	B	0	0	0	0	0	B	•	0
Italy	Ø	B	A	0	0	A	0	(3)	A	(3)	A
Japan	0	0	0	a	A	0	O	0	A	A	A
Netherlands	(3)	(4)	A	0	8	0	0	0	0	B	A
Norway	(3)	(4)	A	B	B	0	0	(3)	0	A	A
Sweden	(3)	A	A	A	0	0	B	(3)	0	(A)	0
Switzerland	•	(1)	•	A	B	•	A	0	0	B	n.a.
U.K.	0	0	B	0	0	0	O	0	0	0	0
U.S.	0	0	0	B	0	0	0	0	0	0	0

The U.S. median for preventable death, measured as the years of potential life lost (YPL) before age 75 per 100,000 population, is 7,700 with a range of 5,700 for the healthiest states (Hawaii, Colorado) to 10,100 for the least healthy state (Mississippi). The YPL, unlike other mortality statistics, emphasizes the impact of poor health on younger populations.³⁵ In comparison, most European nations and Japan have a YPL between 2,413 and 3,124, or 31 to 41 percent of the United States.³⁶

A review of 61 U.S.-based studies published between 1990 and 2012 found

an inconsistent association between cost and quality. Higher cost is not necessarily associated with higher quality.

Clinical effectiveness is "what works" — symptom relief, quicker recovery or longer life while minimizing adverse events.³⁷ Evidence-based medicine has been defined as "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients."³⁸ Evidence-based healthcare broadens the concept to include an "understanding of the patients', families' and doctors' beliefs, values



and attitudes" into their decision-making.³⁹ A significant gap exists between theory and practice, as it applies to clinical effectiveness:

- Healthcare delivery remains focused on acute intervention rather than primary, secondary and tertiary prevention focused on preventing and minimizing the impact of diseases and conditions.
- Despite the increasing focus on population health, and the availability of electronic medical record and claims analytics, significant gaps in care exist.
- Care delivery and, in particular, transition management remain highly fragmented, though efforts to improve care navigation and coordination among acute, post-acute and community providers exist driven by the PPACA.
- Widespread provider variation exists on measures of quality and outcomes as defined by CMS, the Agency for Healthcare Research and Quality (AHRQ), the National Quality Forum (NQF), the Joint Commission, the Leapfrog Group and others.
- Inadequate focus is being given to the social determinants of health including socioeconomic, educational (literacy), psychosocial and environmental factors.
- Patient and caregiver engagement, essential for self-management (treatment adherence, earlier intervention), remains limited.

- Despite the wishes of many patients and their caregivers, end-of-life care, affecting 1.9 million Medicare beneficiaries, continues to be highly invasive for many and is estimated to account for 25–30 percent of total expenditures.
- A shortage of primary care physicians, responsible for patient management across the continuum of services, is worsening due to their relatively low compensation, especially as compared to interventional specialists such as orthopedists, interventional cardiologists and radiation oncologists.

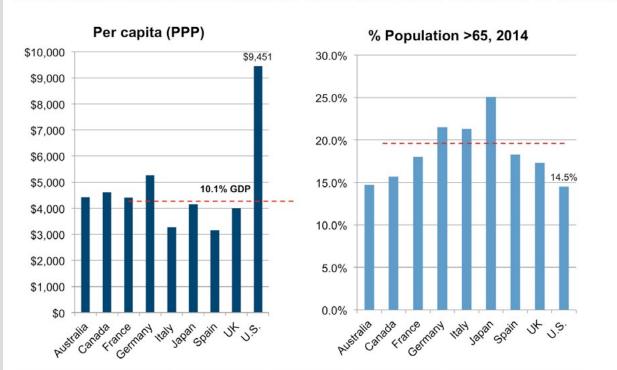
Clinical effectiveness involves the "whole person" inclusive of behavioral health - mood disorders and anxiety affect 9.5 percent to 18.1 percent of the adult population in any given year. 40 Behavioral health disorders have a significant impact on the total cost of care; i.e., those with co-morbid depression have average costs 53 percent higher (range: 34–141 percent depending on the specific condition) than those with a chronic condition or cancer alone due to psychosomatic and/ or treatment adherence issues.41 The underdiagnosis and treatment of behavioral health conditions is common, estimated at 60-80 percent. 42 A recent report from Mental Health America, formerly known as the National Mental Health Association, states "only 41% of individuals with any mental illness report receiving treatment."43

Improving Efficiency Grade: D

Despite our relatively young population, per capita health expenditures in the United States are far higher than those observed in other OECD countries. 44,45 Reduced per capita spending in Europe (and elsewhere) is driven by an increased focus on primary care services, physician salaries (33–50% of those in the United States) and regulatory and reimbursement constraints on new products and procedures. Furthermore, a single-payer system simplifies administration and serves as the backdrop for the lower per capita spending witnessed in these countries. 46

In 2009, the Institute of Medicine (IOM) convened four meetings to identify opportunities to reduce healthcare costs by 10 percent within 10 years without negatively affecting outcomes. Workshops entitled Understanding the Targets, Strategies That Work, The Policy Agenda and Getting to 10 Percent: Opportunities and Requirements were attended by leading experts. 47 Sources of waste totaling \$765 billion or 30.6 percent of total spending were identified: unnecessary services, inefficiencies, excessive administration, price variation, missed prevention opportunities and fraud.

U.S. SPENDING FAR HIGHER THAN OECD MEMBERS DESPITE YOUNGER POPULATION



Sources: OECD http://stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT# and https://data.oecd.org/pop/elderly-population.htm

ESTIMATES OF WASTE IN HEALTHCARE EXPENDITURES OF 10-30%

Category	Cost (\$B)	Sources of Waste
Unnecessary services	\$210	 Overuse — beyond evidence established levels Discretionary use beyond benchmarks Unnecessary choice of higher-cost services
Inefficiently delivered services	130	 Mistakes—errors, preventable complications Care fragmentation Unnecessary use of higher-cost providers Operational inefficiencies at care delivery sites
Excess administrative costs	190	 Insurance paperwork costs beyond benchmarks Insurers' administrative inefficiencies Inefficiencies due to care documentation requirements
Prices that are too high	105	Service prices beyond competitive benchmarksProduct prices beyond competitive benchmarks
Missed prevention opportunities	55	Primary, secondary and tertiary prevention
Fraud	75	All sources—payers, clinicians and patients
Total	\$765	2009 National Health Expenditures: \$2,501B

Source: The Healthcare Imperative: Lowering Costs and Improving Outcomes, 2010 Table S-1. Adopted by National Academy of Sciences from IOM Workshop Summary.

Further quantifying waste in the healthcare system, The Commonwealth Fund estimated \$226 billion for the over-utilization of healthcare services, leading to no patient benefit or even negative outcomes.⁴⁸ In its seminal report entitled "Waste and Inefficiency in the U.S. Healthcare System," the New England Healthcare Institute identified cost savings of \$100 million to \$10 billion associated with inappropriate antibiotic usage for upper respiratory infections, the overuse of back-imaging studies, excessive surgery (hysterectomy, spinal, coronary) and percutaneous coronary interventions.49 A shift from fee-for-service to value-based reimbursement would, at least partially, remediate over-utilization of healthcare services.

Facilitating Payment Reform Grade: B-

The most important fundamental healthcare delivery issue capable of incentivizing behavior change is reimbursement. The current healthcare system is still primarily based on fee-for-service payment system that rewards volume (at the highest possible prices) and not value. This has led to an excess of diagnostic procedures, advanced imaging scans and surgical interventions as well as significant variation in the site of service and procedure costs. Fee-for-service reimbursement has also led to care fragmentation, with poor transition management from hospitals to post-acute care facilities and home.

Obamacare, through the funding of pilot programs and CMS Innovation Center initiatives focused on value-based ("integrative") payment reform, has increased provider focus on quality, the care continuum, transition management, care navigation, post-acute care, the total cost of care and elsewhere. It has also highlighted the importance of IT system interoperability and the role of analytics to better manage the health of populations and individual patients.

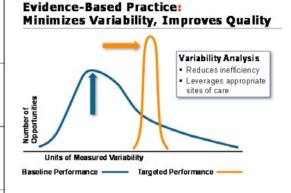
Value is a function of quality and cost. Quality measurements have evolved to include structure, process, outcome, patient experience of care and access. Evidence-based practice requires a reduction in variability toward best practices. CMS has provided incentives to improve care processes and health outcomes,

and reduce hospital readmissions and acquired conditions. Episode payment models (EPMs), especially the recently expanded Comprehensive Care Joint Replacement (CJR) and announced cardiovascular (bypass graft, stenting) initiatives, focus on the total cost of care for a 90-day episode across the continuum (hospital, post-acute and community-based care).

Accountable Care Organizations (ACOs) are intended to "lower healthcare costs, improve quality outcomes and improve the experience of care" by accepting financial responsibility, inclusive of risk management for the health of a targeted Medicare population.⁵⁰ The initial CMS Pioneer ACO Model, launched in 2012 and designed for providers experienced with care coordination across multiple settings

GROWING IMPORTANCE OF QUALITY MEASUREMENT

Table Criteria for Measurement of Health Care Quality Criteria Representative Items Measured What is Evaluated Structure · Licensure (facility and professional) Environment in which Compliance with health and services are provided: safety codes whether there is adequate Medical staff appointment capability to provide the Board certification services offered **Process** Specific ways care is provided: Evaluate against national Laboratory and radiology test criteria and standards for specific diagnostic Diagnostic approaches categories and Drugs prescribed · Therapeutic procedures procedures Outcome Midpoint and end results of the Combine other measures clinical care process: by examining the end Morbidity results of care Mortality Infection rates Complication rates Patient experience of care



Reporting requirements: NCQA, HEDIS, HCAHPS, STAR Ratings, PQRS, Consensus Core Set (CCS), Healthcare Compare, Value-based Purchasing (VBP), Hospital Acquired Conditions (HAC), readmissions, Leapfrog Group, MACRA

http://imaging.ubmmedica.com/CME/pt/content/p981245.gif; http://ajslp.pubs.asha.org/data/Journals/AJSLP/934712/m_AJSLP_24_4_S854fig1.jpeg;

willing to accept bonuses and penalties based on CMS targets of patient spending, has been unsuccessful, with only nine of the original 32 participants still active.⁵¹ The more broadly utilized Medicare Shared Savings Plan initiative has had mixed results.

After several years of evolutionary changes, mostly voluntary but a few mandated, HHS Secretary Sylvia Burwell made the following announcement on January 26, 2015:

"Today, for the first time, we are setting clear goals - and establishing a clear timeline for moving from volume to value in Medicare payments. We will use benchmarks and metrics to measure our progress; and hold ourselves accountable for reaching our goals. Our first goal is for 30 percent of all Medicare provider payments to be in alternative payment models that are tied to how well providers care for their patients, instead of how much care they provide – and to do it by 2016. Our goal would then be to get to 50 percent by 2018. Our second goal is for virtually all Medicare fee-for-service payments to be tied to quality and value; at least 85 percent in 2016 and 90 percent in 2018."52

A full reversal of Ms. Burwell's pronouncement would significantly slow the necessary transition from feefor-service to value-based integrative care. Cost containment driven by an improvement in clinical effectiveness and care delivery efficiency cannot occur without a fundamental change in the reimbursement system.

Enhancing the Experience of Care Grade: D

Obamacare has done little to alter the patient's overall experience of care. The Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient satisfaction survey is now required by CMS for all hospitals in the United States and measures "critical aspects of patients' hospital experiences: communication with nurses and doctors, the responsiveness of hospital staff, the cleanliness and quietness of the hospital environment, pain management, communication about medicines, discharge information, overall rating of hospital, and would they recommend the hospital."⁵³

Since President Obama's inauguration in 2009, the percentage of patients who would rate their experience as a 9 or 10 increased from 64 to 72 percent, and those who would definitely recommend their hospital from 68 to 71 percent. A hospital satisfaction survey represents a snippet of a patient's overall healthcare experience.

In January 2015, CMS began reimbursing clinical staff for monthly 20-minute non-face-to-face interactions to improve care navigation (coordination) among Medicare beneficiaries with at least two chronic conditions; a comprehensive care plan, medication reconciliation 24/7 access and electronic medical record are also required. Despite 35 million potentially eligible patients, enrollment was limited last year.

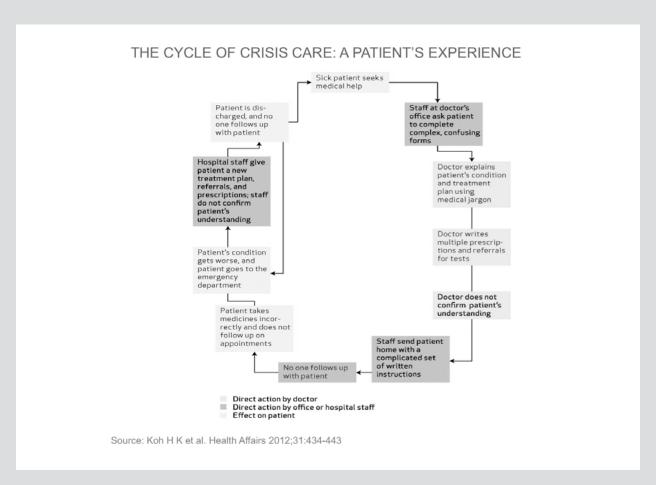
An article entitled "New Federal Policy Initiatives To Boost Health Literacy Can Help The Nation Move Beyond The Cycle Of Costly 'Crisis Care,'" published in Health Affairs, describes a patient's experience as being "regularly confronted with complicated, confusing forms and instructions. As a result, too many people are hospitalized after being given ambiguous instructions about medications or failing to recognize the symptoms of a worsening condition. Effective practices have yet to be developed to assess whether patients properly use medications, complete tests, or receive referrals." 54

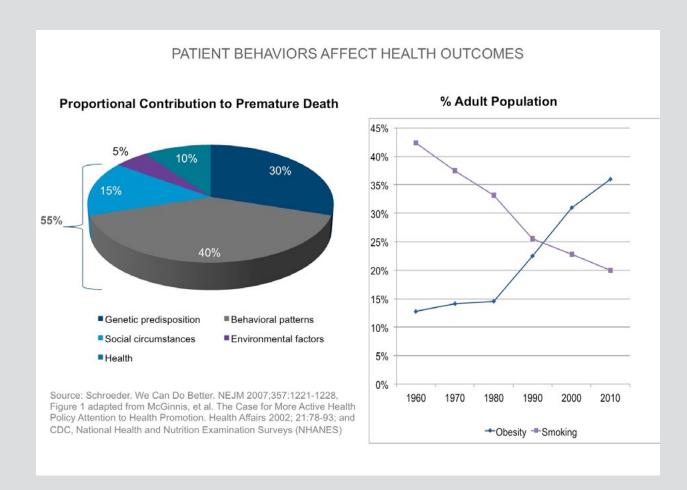
The authors reference the importance of literacy, plain language, provider communications and self-management to health outcomes.

Nearly one-half of the adult U.S. population

has difficulty understanding appointment slips, medical education brochures, physician directions, instructions on prescription drug bottles and consent forms. ⁵⁵ According to the Agency of Healthcare Quality and Research (AHRQ), self-management requires making lifestyle changes; monitoring signs, symptoms and biometric measurements indicative of a potential change in health status; and taking action when warranted (e.g., taking medications, calling a caregiver or physician).

In the current healthcare delivery system, primary care physicians have a limited amount of time to address the chronic care needs of patients, i.e., lifestyle issues, risk factors, co-morbidities and medications. The average face-to-face patient care time measured by direct observation was reported as 10.7 minutes, excluding visit specific work outside





the examination room (2.6 minutes), figures far lower than the self-reported results of the National Ambulatory Medical Care Survey in 2003.⁵⁶ Virtually no time is spent addressing nutrition, exercise, smoking cessation or mental health concerns.^{57,58}

A more recent 2013 study suggests a downside of widespread electronic medical record (EMR) implementation is further erosion of "quality time" with patients.⁵⁹

And, despite public health efforts, the number of Americans with at-risk behaviors is staggering: a poor diet and/or sedentary lifestyle contributing to obesity (72.0 million); cigarette consumption (45.3 million); illicit drug

use excluding marijuana (16.4 million); and "heavy" alcohol ingestion (15.0 million).^{60,61,62} Patient behaviors, particularly lifestyle choices, are the leading contributor to premature mortality, morbidity and disability.⁶³

Behavioral patterns are difficult to change. According to the Prochaska and DiClemente Stages of Change Model, the practice of new behaviors requires a minimum of 3–6 months, whereas to avoid a relapse, a commitment to maintenance of 6–60 months is needed.⁶⁴ Many "programs" for weight loss, substance abuse and other behavior dependent conditions do not meet these time requirements; short-term interventions do not usually address the underlying root cause.^{65,66}

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