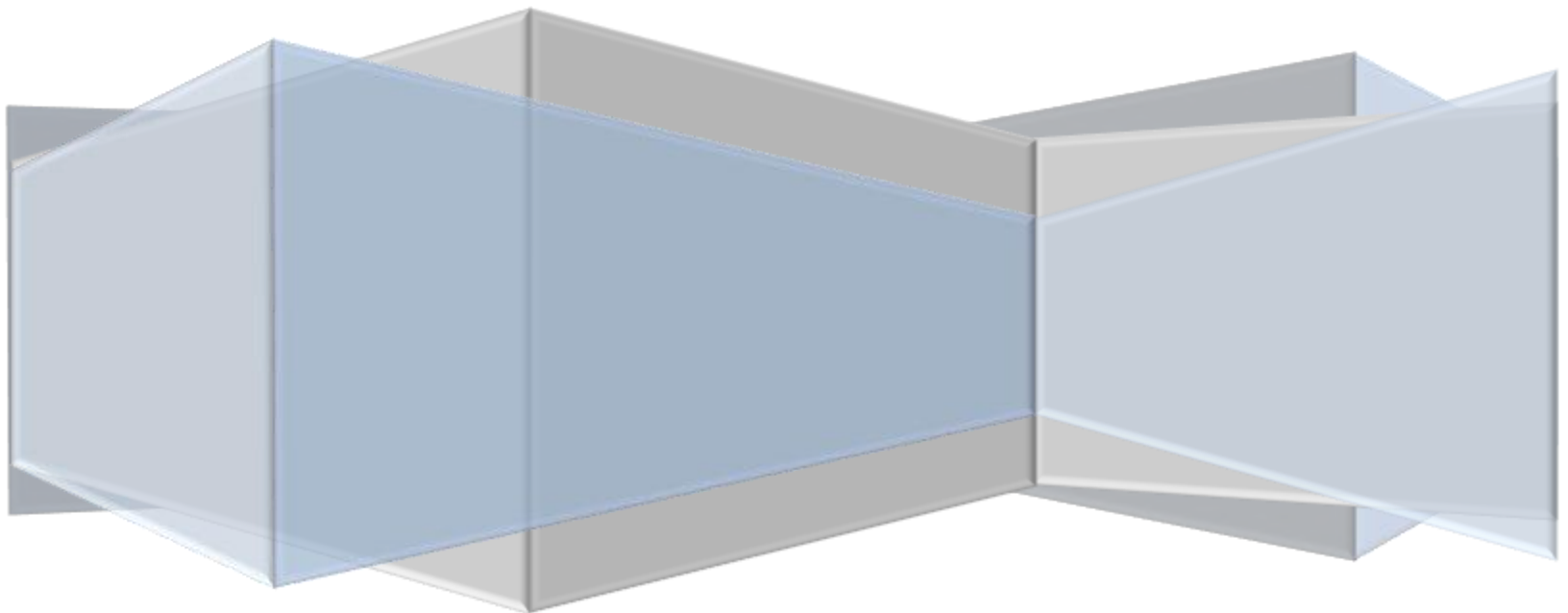


**Frost & Sullivan**

# **The Proposed American Health Care Act – Impact on Medical Device Industry**

*Frost Perspective*

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## Key Takeaways

- The Trump administration's first attempt to repeal and replace the Affordable Care Act (ACA) with the Republican drafted American Health Care Act (AHCA) failed to garner enough support for a vote in the House of Representatives.
- The Speaker of the House and Majority Whip gain support of the Republican Freedom Caucus and moderate Republicans in the House with two amendments to the AHCA and bring it to the House floor for a vote. AHCA passes with 217 YES and 213 NO votes in the House on May 4, 2017.
- AHCA moves to the Senate where an all-male committee is appointed by the Senate Majority Leader to construct legislation sufficient to gather a minimum of 51 votes in the Senate, which will satisfy the budget reconciliation requirement for passage and then move to the president for signature.
- Republican Majority leader in the Senate publicly acknowledges Republicans can only surrender or lose 2 votes to pass a Senate version of the AHCA.
- Senate Democrats vow to block passage of the AHCA.
- Most contentious issues for both political parties preventing a consensus piece of healthcare legislation are Medicaid expansion and maintaining protection from higher premiums provided in the ACA for pre-existing health conditions.
- Despite the political angst in Washington ACA value-based payment models have revolutionized the way healthcare systems are reimbursed for patient care, moving away from a volume driven model.
- As a result, advanced medical technology and medical devices are poised to experience sustainable growth, regardless of the political future of the ACA or AHCA.



### Introduction

On Wednesday, May 3, 2017 the U.S. House of Representatives proposed two amendments to the failed American Health Care Act (AHCA) in hope of dismantling the gridlock among Republicans to enable passage of a Republican healthcare bill to repeal and replace the Affordable Care Act (ACA). Prior to these amendments, the original bill authored in large part by the Speaker of the House (Paul Ryan, R-Wisconsin) the GOP failed to win over the GOP conservative right-wing Freedom Caucus to support Speaker Ryan's AHCA. As a result, Speaker Ryan did not call for an up and down vote on the AHCA in the House and announced that, "Obamacare is the law of the land for the foreseeable future."

Since then, the Republicans introduced the MacArthur-Meadows amendment that persuaded the Freedom Caucus to vote "yes" by offering language that authorizes states to secure waivers (Medicaid 1115) that allow insurance companies to raise premiums for people with preexisting conditions based on their health status for approximately 12 months if these same individuals let their health insurance coverage lapse for more than 63 days.

GOP moderates concerned about maintaining the ACA provision that prevented discrimination against preexisting conditions were reassured with the addition of the Upton amendment. Upton creates an \$8 billion fund for states for the years 2018 to 2023 to reduce premiums and off-set out-of-pocket costs to those who are subjected to inflated premiums as the result of a

Medicaid Waiver. The Upton amendment also allows states to fund high-risk pools which, in concept, will make coverage affordable for persons whose premiums rise as a result of their health status.



With the addition of these two amendments to the AHCA came to a vote on May 4, 2017. The bill narrowly passed in the House with 217 legislators voting yes for the AHCA and 213 opposing. The controversial healthcare

bill now moves to a designated bi-partisan Senate committee where Republicans have stated publicly they are “rewriting the bill.” Democrats assigned to the same committee have vowed along party lines to kill the bill, preventing it from ever becoming law. Republican legislative strategists are most likely to use a process referred to as budget reconciliation to move the bill out of the upper chamber requiring only 51 votes instead of the traditional two-third majority of 60 votes for passage. Even still, the Senate Majority leader (Senator Mitch McConnell) admits publicly he can only afford to lose just two votes from his Republican majority to prevail.

## **Embattled Healthcare Topics Senators Must Solve to Pass AHCA – Is Medical Devices One of Them?**

As it stands now, Frost & Sullivan along with other industry analysts agree there are seminal contentious issues that remain as potential disruptors to the passage of the AHCA bill in the Senate. Medicaid expansion at the top of the list has been a target of conservatives and the AHCA brings this debate to the forefront proposing to dismantle a 60-year old federal entitlement giving states the option to apply for a Medicaid waiver. This, of course, is in bipolar opposition to the ACA vision for Medicaid expansion and Democrats are vehemently opposed to the AHCA’s Medicaid waiver solution which includes a provision for an \$880 billion across the board cut in Medicaid funding over 10 years.

The federal funding mechanism which is currently in place for Medicaid allows for some flexibility based on a state’s variation in funding per enrollee and population demographics, economic strata, and overall health of the Medicaid population. This, in effect, allows for economic elasticity in Medicaid funding from year to year with more federal funding made available if needed. The proposed AHCA Medicaid funding is vastly different and will flow based on a state flat-fee amount per Medicaid enrollee or as a fixed block grant. This means, should states need additional funding to meet the economic burden of paying for healthcare costs for

their Medicaid population, each state will either have to fund it by raising state taxes or curtailing coverage and limiting access to care.

Despite the possibility of Draconian budget cuts to Medicaid, Frost & Sullivan predicts there will be little impact on the economic projections for advanced medical technology and medical devices other than the repeal of the proposed ACA medical device tax (2.3%). This tax has been suspended for 2016 and 2017 and was scheduled to return in January of 2018. The anticipated revenue gained from the proposed medical device tax as proposed by the Obama administration was intended to pay for Medicaid expansion as indicated with the ACA. Amidst the uncertain and political debate surrounding Medicaid as it relates to the AHCA, Frost & Sullivan does not see political impetus from the Democrats or Republicans sufficient to fight for the preservation of the ACA proposed medical device tax. It will be repealed.

The remaining essential debate topics brought to the Senate floor include tax credits, which Frost & Sullivan does not see impacting the medical device healthcare industry vertical. Tax credits are of course of significant importance if the AHCA removes federal subsidies to help draw down health insurance premiums as is the case with coverage sought on the health insurance exchanges. However, in terms of limiting or influencing medical devices other than those who can no longer afford health insurance as a result of no government subsidies are denied access to needed medical devices due to loss of coverage.

One other fundamental element of Obamacare that would be forced to change on a grand scale should the proposed AHCA become law is the current protection the ACA gives people with pre-existing health conditions. The House version of the AHCA would allow states to opt out of protecting the sanctity of pre-existing conditions allowing health insurance carrier actuaries to



price healthcare premiums for people with pre-existing conditions much higher, thus potentially driving up small-business employer based health insurance costs as well.

This combative pre-existing condition topic will draw attention from both sides of the aisle as the debate advances in the Senate with much at stake for those who suffer from chronic

disease or congenital birth defects. Patients who are currently able to receive care including medical devices as part of their care could potentially lose coverage shrinking the medical device market. However, Frost & Sullivan believes both the federal government and states will work to resolve this malady once the existing version of the AHCA before it is signed by the President. The political fallout is too burdensome with Congressional mid-term elections looming in 2018 to ignore.

The hotly contested votes in Congress will decide the future of the ACA and ultimately the House version of the AHCA. A possibility also exists that components of each piece of legislation make its way to a hybrid healthcare reform bill. Yet another variation of the ACA and AHCA may

potentially be the introduction of single payer option, which continues to grow political capital, gathering support from both political parties and their respective constituents.

## **Beyond the Politics of Healthcare – Bundled Payments Fueling Medical Device Economic Growth**

Regardless of the political outcome in Congress with reference to new or old healthcare legislation, the ACA initiated value-based payment models continue to spread. Asking each healthcare asset or resource along the healthcare continuum to amend or replace its current billing and reimbursement methodology prior to ACA would have had little or no chance of finding a champion to carry it forward in hope of amending the current Medicare and Medicaid statutes. With the pronouncement and introduction of the Triple Aim as the basis for health reform (ACA), including the CMS Innovation Center, opportunity presented itself for creative and exploratory value-based payment modeling. Woven tightly with pre-established quality measurements as metrics for improving the quality of, and patient experience for, healthcare



services resonated with providers and patients alike. The intent was imminently clear; healthcare services should no longer be billed for without any relationship to the quality of care delivered.

Value-based payment models will continue to grow, as healthcare organizations implement the Medicare Access and CHIP Reauthorization Act or MACRA. What MACRA will do is to increase incentives for physicians to participate in alternative payment models (APM). With this added encouragement providers are beginning to look to and explore new advanced medical technologies and medical devices to provide better quality outcomes.

Bundled payments may be the best alternative for APMs to create a platform for payors to share financial risk with providers and establish a level playing field for accountability, both clinical and financial. Potentially, medical devices now are logical extensions for both payors and physicians to also share the risk in bundled payment algorithms allowing medical device engineers and scientists to focus their designs and research and development (R&D) on better quality outcomes for adding value to the healthcare continuum by preventing costly readmissions.

The previous volume driven business model for medical devices was a price driven cost-per-unit model with incentives for market share based on volume sales. With the pendulum swing to quality outcomes, a majority of medical device original equipment manufacturers (OEMs) are experiencing positive compound annual growth rates (CAGRs) and year over year (YoY) growth pointing to a sustainable value-driven business model. Moreover, with improved quality

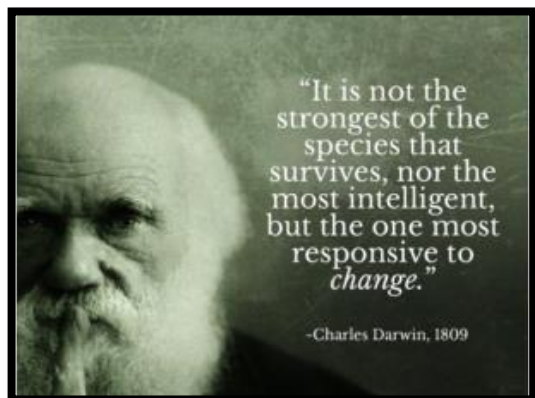
outcomes, costs per capita for healthcare have come down, thus allowing value-based payment medical devices to meet the requirement for achieving the Triple Aim for healthcare.

## **With Mandatory Bundled Payments Comes Horizontal Integration – Including Advanced Medical Technology**

With the signing of the ACA came added new financial and operational impetus for hospitals, providers, and health insurance carriers to remedy existing practices for adopting new revenue cycle management, heightened quality improvement, and most recently, mandatory bundled payments.

This confluence of energy, strategy, and operations forced an organizational restructuring and dismantling of existing healthcare industry verticals. Moreover, what followed became an impacted consolidation of a continuum of integrated services. Historically, all had been independent vendors or billers of Medicare and third party insurers for the same patients.

In 2014 alone, there was a plethora of consolidation and horizontal integration within the expanding healthcare industry. Of particular interest for Capitol Hill and insurance federal regulators was the activity of the “Big 5” commercial health insurance companies<sup>1</sup>. In July 2016, the Justice Department submitted injunctions in court to block the merger of Aetna and Humana and Anthem of Cigna. If allowed to proceed, the Big 5 would have become the



Mammoth 3 controlling some \$91 billion in premiums. This would, in the view of the Justice Department, highly limit competitive forces in the insurance markets across the country. Lesson learned here, if an anticipated healthcare industry vertical consolidation limits fair-market competition, Washington will intervene to prevent any perception of choices and price fixing due to the suggestion of a no competition environment.

Yet, despite strong oversight efforts in the insurance industry, much healthcare industry consolidation and horizontal integration has taken, and continues to take place. In 2014 alone there were a reported 1,299 mergers and acquisitions, up from 1,035 the previous year.<sup>2</sup> Hospital and physician consolidations have increased steadily since the enactment of the tenets of the ACA. In addition, hospitals and provider groups are

<sup>1</sup> “Big 5”; United, Cigna, Humana, Aetna, and Anthem

<sup>2</sup> Bara Vaida, Independent Writer, and Alexander Wess, Alliance for Health Reform, Health Care Consolidation, Alliance for Health Reform, November, 2015.



entering in non-binding agreements along with outright merger and acquisition deals. This is a growing phenomenon which is being categorized as partnerships, collaborations, and/or joint ventures. This flexibility has allowed for a wealth of integration with Accountable Care Organizations (ACOs), bundled payment arrangements, and loosely structured community integrated health networks. These newly formed local healthcare ecosystems can include employers, hospitals, provider groups, medical device OEMs, payers, social service, and spiritual resources. Hospitals are also rapidly and strategically aligning through mergers and acquisitions; specifically larger urban hospitals and health systems have begun a run of acquiring stand-alone rural hospitals to solidify patient referrals from contiguous counties.

## Final Thoughts

All the current consolidation and integration of the healthcare industry vertical eventually will consolidate into a dynamic and symbiotic healthcare ecosystem where hospitals, doctors, and suppliers come together, each sharing risk. Management and operations of this new structure will be a function of another ACA generated term, population health management (PHM), and with each value based payment reform this ecosystem will continue to expand and morph to adapt horizontally with new digital dimensions and healthcare modalities to meet the new requirements for reimbursement in a linear equation where quality outcomes match payment for all consolidated services. As this new healthcare delivery ecosystem matures, its value will eventually be defined from the investments made to prevent chronic disease, monitor patients



in remote locations, replacing cost-saving efficiencies generated in treating these same chronic diseases post-diagnosis.

## Conclusion

Operationally, the paradigm shift to a new healthcare piece of legislation is not yet a reality. However, the seeds for achieving a truly preventive model of healthcare have been planted through bundled payment reform as a direct result of the ACA. What needs to follow now is methodology for arriving at the perceived value the U.S. healthcare delivery system offers society. Presently, this quotient of value is calculated in capital reimbursement for treatment, not prevention. However, current efforts being put forth by the CMS Innovation Center, not Congress, the Supreme Court, or the President is enabling the steady improvement of the overall health of the nation, reduced costs per capita for the consumption of healthcare as a commodity, and vastly improved quality outcomes. In this new advanced medical technology friendly burgeoning ecosystem, medical devices will continue to be in great demand.