HFMA Mid-South Conference Washington Legislative and Regulatory Outlook

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Agenda

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- **Health Care Reform – Where are We? What Happens Next?**
- **Upcoming Legislative Issues**
- **Health Care Regulatory Issues**
- **Pharma Issues & Proposals**

2 Source: BofA Merrill Lynch Global Research

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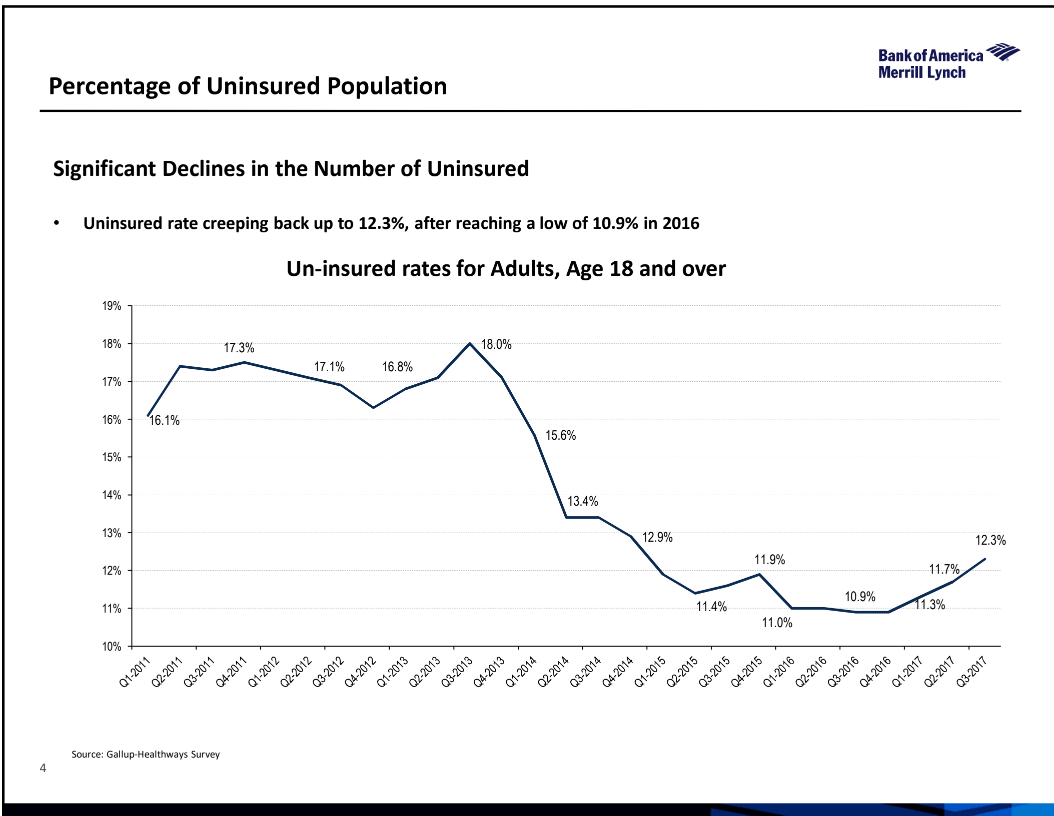
Affordable Care Act – Outlook



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Affordable Care Act Coverage Expansion – Roughly 20 Million

Medicaid Expansion Coverage

- Total Increase in Medicaid = 16.5 million (since 4th Q 2013)
- **Estimated roughly 13 million newly covered individuals –** through Medicaid expansion
- 32 States plus District of Columbia
- Maine Ballot Initiative Passed Approving Expansion – Still issues to be worked out on implementation
- Although other states have interest (KS, TN, SD, VA, NC, etc.)
- However, several key states remain staunch opponents (TX, FL)

Health Insurance Exchange Coverage

- 12.2 million signed up for Coverage for 2017, while
- However, 10.2 million were enrolled (and paid) as of March 2017
- Estimated roughly 11-12 million coverage for 2018 (8.7 million signed up on Federal Exchanges as of Dec. 2017)
- **Estimated that roughly 50-60% on exchanges are newly covered individuals (roughly 6 million out of 10 million on exchange)**

Health Coverage for Dependents up to age 26

- **CMS estimates roughly 3 million additional coverage for children up to age 26 on parents health plan**

Source: HHS, BofA Merrill Lynch Global Research

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Status of Health Insurance Exchanges – 2018

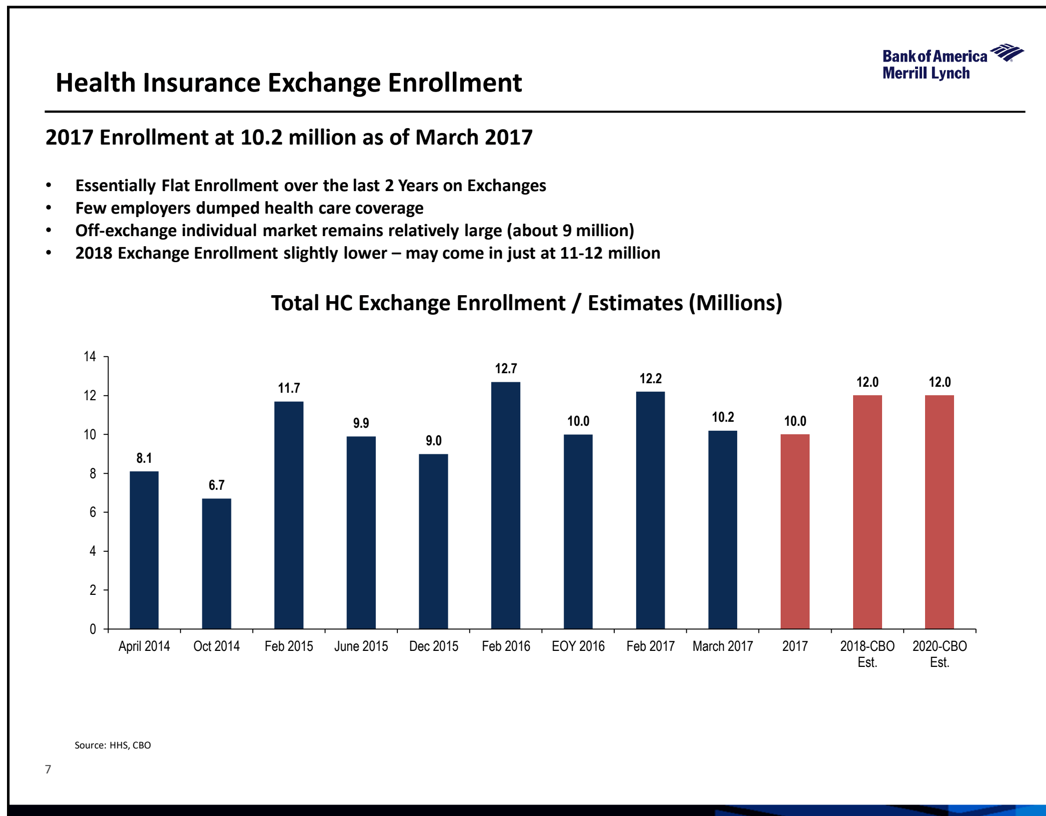
Significant Premium Increases

- On Average, 37% premium increases for 2nd Lowest Silver Plan in 2018
- With wide variation across states
  - Many states with significant increases:
  - Kentucky (+50%); Iowa (+88%); Maine (+53%); Mississippi (+64%); New Mexico (+52%); Utah (+77%); Virginia (66%)
  - And, several with stable or declining premiums:
  - Alaska (-22%); Arizona (0%); North Dakota (7%); Montana (13%); South Dakota (14%)
- However, note, that these increases assume no CSR payments are paid out

Fewer Health Plans available in most States

- Total number of plans declined to 132, down from 167 in 2017. Eight states in PY18 will have only one issuer: Alaska, Delaware, Iowa, Mississippi, Nebraska, Oklahoma, South Carolina, and Wyoming.
- Eight states now only have 1 participating health plan: AK, DE,IA, MS, NE, OK, SC, WY
- Average number of plans available per state has declined over last 4 years
  - 2014: 4.5 plans per state
  - 2015: 5.9 plans per state
  - 2016: 5.4 plans per state
  - 2017: 3.9 plans per state
  - 2018: 3 plans per state

Source: HHS, BofA Merrill Lynch Global Research


Health Insurance Exchange Enrollment
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2017 Enrollment at 10.2 million as of March 2017
• Essentially Flat Enrollment over the last 2 Years on Exchanges
• Few employers dumped health care coverage
• Off-exchange individual market remains relatively large (about 9 million)
• 2018 Exchange Enrollment slightly lower – may come in just at 11-12 million
Total HC Exchange Enrollment / Estimates (Millions)
14
12
10
8
6
4
2
0
8.1
6.7
11.7
9.9
9.0
12.7
10.0
12.2
10.2
10.0
12.0
12.0
April 2014
Oct 2014
Feb 2015
June 2015
Dec 2015
Feb 2016
EOY 2016
Feb 2017
March 2017
2017
2018-CBO Est.
2020-CBO Est.
Source: HHS, CBO
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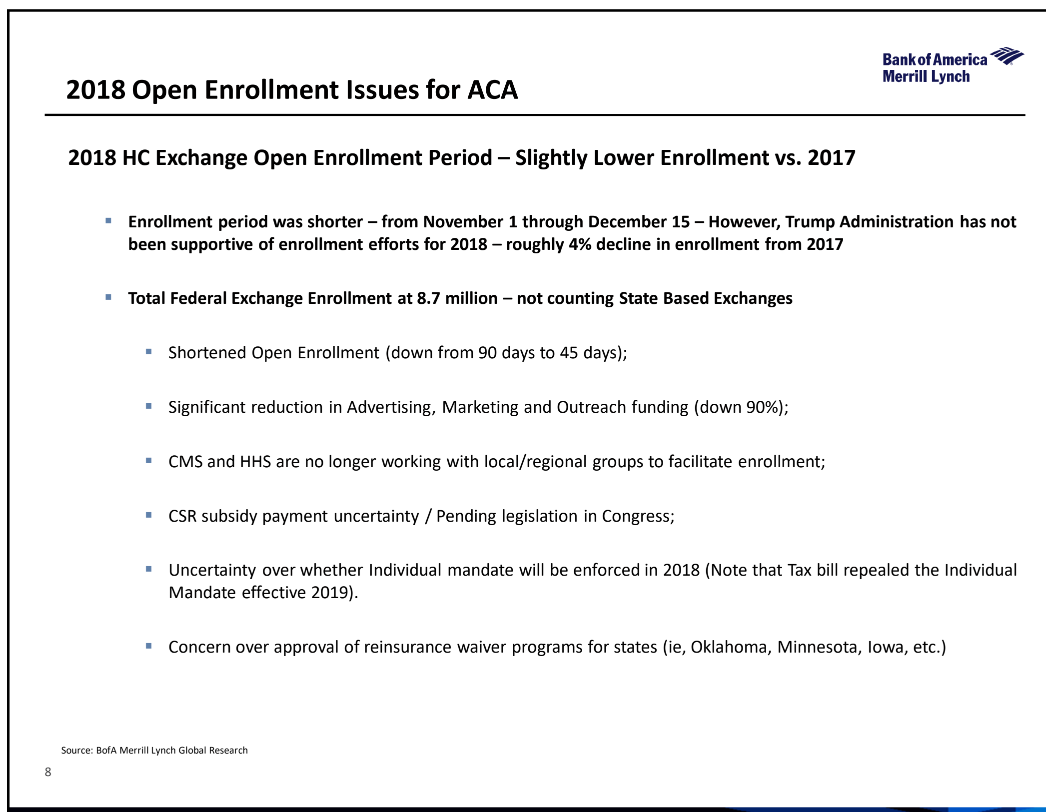
2018 Open Enrollment Issues for ACA
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2018 HC Exchange Open Enrollment Period – Slightly Lower Enrollment vs. 2017
Enrollment period was shorter – from November 1 through December 15 – However, Trump Administration has not been supportive of enrollment efforts for 2018 – roughly 4% decline in enrollment from 2017
Total Federal Exchange Enrollment at 8.7 million – not counting State Based Exchanges
Shortened Open Enrollment (down from 90 days to 45 days);
Significant reduction in Advertising, Marketing and Outreach funding (down 90%);
CMS and HHS are no longer working with local/regional groups to facilitate enrollment;
CSR subsidy payment uncertainty / Pending legislation in Congress;
Uncertainty over whether Individual mandate will be enforced in 2018 (Note that Tax bill repealed the Individual Mandate effective 2019).
Concern over approval of reinsurance waiver programs for states (ie, Oklahoma, Minnesota, Iowa, etc.)
Source: BofA Merrill Lynch Global Research
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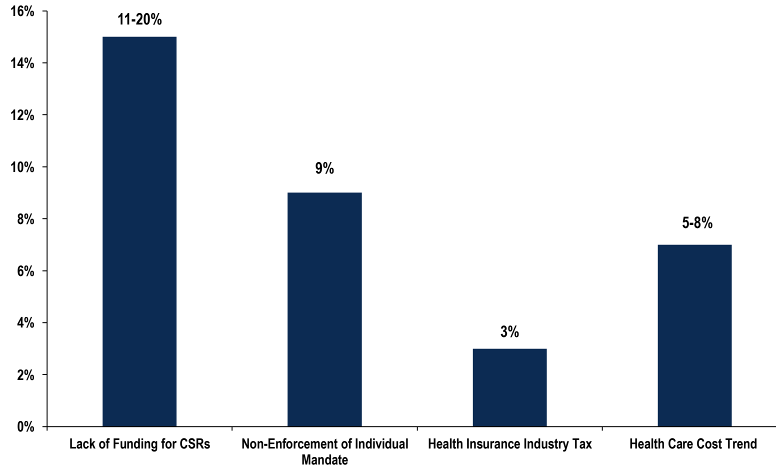
Key Issues for Health Insurance Exchanges for 2018 Plan Year

Contributing Factors to 2018 Exchange Plan Premium Increases

- **Overall, while State Increases will Vary Dramatically, expecting 28-40% Increases – Due to Uncertainty**



Source: Oliver Wyman, BofA Merrill Lynch Global Research

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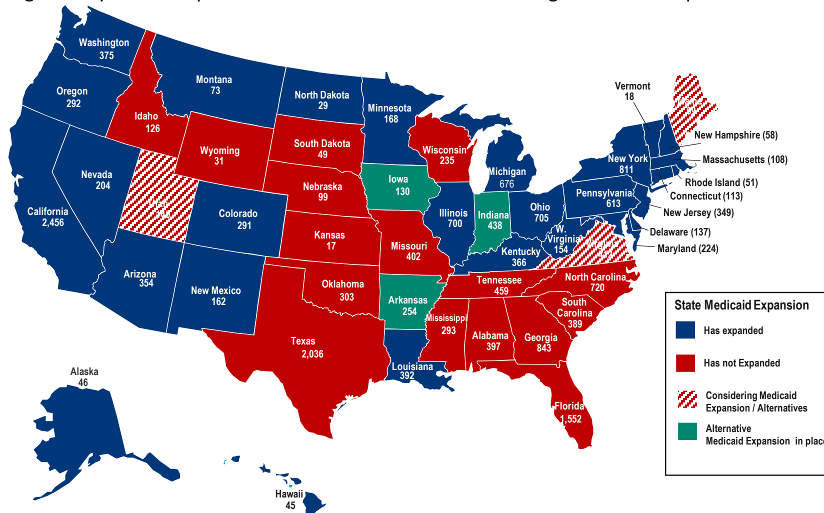
State Medicaid Expansion Plans

Medicaid Eligible Uninsured Adults with income below 133% of FPL (Thousands)

- HHS estimates expansion has increased Medicaid Enrollment by 16.5 million– Roughly 13 Million Newly Eligible
- 32 States have expanded Medicaid – Several additional states are still attempting to expand – but, have faced opposition with legislatures, or Governors – while other states have no interest in expanding
- Virginia may look to expand Medicaid in 2018 with new State legislature makeup



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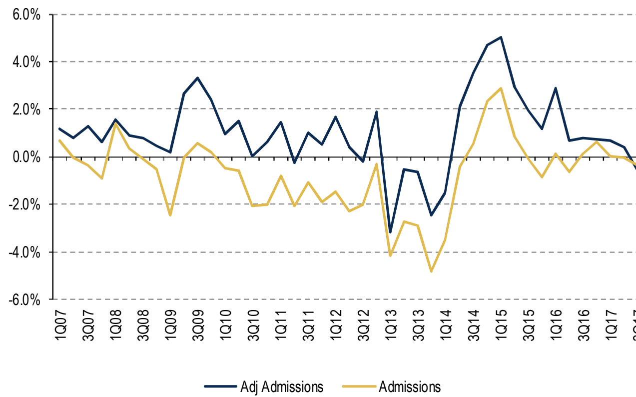
Source: AP, Urban Institute, BofA Merrill Lynch Global Research

Impact on Hospital Admissions

Overall, Admissions Saw a Significant Boost in 2014-2015 – But, now back to negative growth

Overall Industry Adjusted Admissions & Inpatient Admissions, 2007-2017

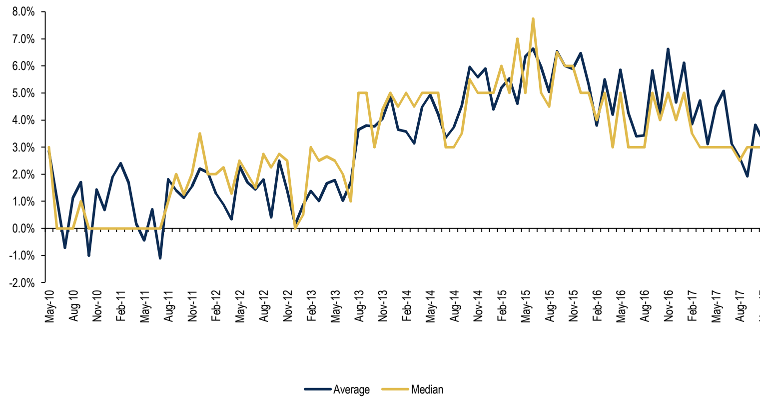


Source: BofA Merrill Lynch Global Research

Impact on Hospital Admissions

Outpatient Volume Growth Remains Relatively Strong

Hospital Survey – Outpatient Volume Growth, 2010-2017

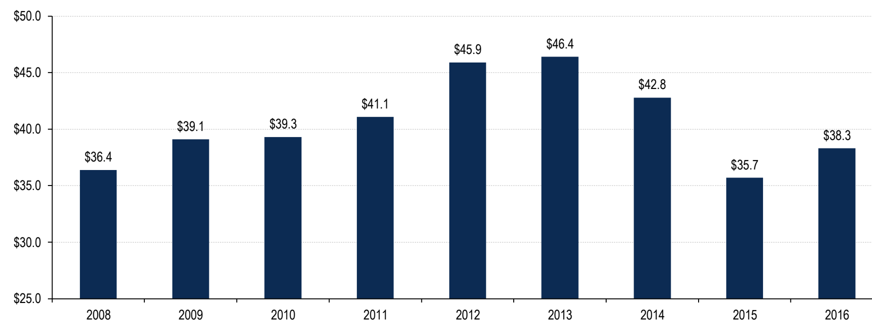


Source: BofA Merrill Lynch Global Research

Impact on Hospital Uncompensated Care

Hospital Uncompensated Care Costs are Rising Again After 2 Years of Decline

Hospital Uncompensated Care Costs, 2008-2016



Source: American Hospital Association

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Senate Action on Repeal & Replace Legislation

Final Efforts at Repeal Failed to Pass the Full Senate

- **Revised BCRA Senate Repeal and Replace bill failed to gain 60 votes (only received 43 votes),** included Senator Cruz' Consumer Freedom Amendment, and Senator Portman Amendment with $100 billion in additional funding. Bill needed 60 votes to waive budget point of order, since it had not been scored by CBO, and would violate Budget Act.

- **Obamacare Repeal Reconciliation Act of 2017 (ORRA) also Failed** – Repeal of many portions of ACA, however, does not include a Replacement. Would phase-out ACA Exchange subsidies and Medicaid Expansion in 2 years. CBO estimates 32 million fewer people covered by 2026.

- **"Skinny" Reconciliation bill Fell One Vote Short –** Republican Senators McCain (R-AZ); Collins (R-ME); and Murkowski (R-AK) sided with all Democrats to Defeat this last effort. Bill would included repeal of Individual and Employer mandate, as well as revisions to the Section 1332 waiver flexibility for states, HSA revisions, medical device tax moratorium through 2020, additional funding for health centers, and prohibit funding for Planned Parenthood

- **Graham-Cassidy bill** – Also fell at least 1 vote short, as Senators McCain (R-AZ); Collins (R-ME); and Paul (R-KY) voiced opposition – other Senators (Murkowski, R-AK) also voiced concerns over the bill. Bill was ultimately pulled from consideration before a vote. Senators Graham (R-SC) and Cassidy (R-LA) both expect to renew their repeal effort in 2018.

Source: BofA Merrill Lynch Global Research

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Executive Order on Health Insurance

With Failure of Congress to Enact Major Health Care Reform / Repeal – President Trump sought to move forward with an Executive Order on Health Insurance

- **On October 21, President Trump stated signed an Executive Order addressing some health insurance regulatory issues:**
- **Association Health Plans –** We note that Association Health Plans (AHPs) are an idea that has been around for some time, but, has generally been opposed by the insurance industry, as it could lead to splintering the risk pool for small group plans. AHPs are currently regulated by both States and Federal requirements – Proposal may exempt AHPs from state oversight, using ERISA regulations. Concerns include:
  - Exemptions from state insurance regulations could lead to market instability and higher premiums in the traditional small-group market;
  - Exemptions could eliminate consumer and patient protections;
- **Short-term health plans -** currently limited to a maximum of 3-months of coverage as the Obama Administration sought to limit these plans that are not subject to any of the ACA regulatory requirements. Now, these short-term health plans may be available for coverage up to 1-year, and be renewable**.**
- **Changes to Health Reimbursement Accounts –** May allow employers' contributions on a pre-tax basis that an employee could use to purchase individual insurance. This could lead employers to potentially drop coverage and instead provide an HRA contribution.

Source: BofA Merrill Lynch Global Research

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Upcoming Legislative Issues / Tax Reform

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Efforts on Repeal & Replace Legislation in 2017

Final Efforts at Repeal Failed to Pass the Full Senate

- **House Passed Repeal and Replaces legislation in May 2017 (217-213 vote) –** Replaced ACA with a new tax credit proposal effective in 2020
- **Revised BCRA Senate Repeal and Replace bill failed to gain 60 votes (only received 43 votes),** included Senator Cruz' Consumer Freedom Amendment, and Senator Portman Amendment with $100 billion in additional funding. Bill needed 60 votes to waive budget point of order, since it had not been scored by CBO, and would violate Budget Act.
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Source: BofA Merrill Lynch Global Research

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CBO Score Comparison of House & Senate HC Repeal Bills

Metric	House Passed (AHCA)	Senate Proposed (BCRA)	Graham-Cassidy Proposal
Reduced HC Coverage (2018) **Reduced HC Coverage (2026)**	14 million 23 million	15 million 22 million	Est. 15 million Est. 20 million +
Deficit Reduction (over 10 years)	$119 billion	$321 billion	$133 billion
Medicaid Spending Reductions	$834 billion	$772 billion	$772 billion
Premium Effect in 2018 **Premium Effect in 2026**	20% increase 4% reduction (on average)	20% increase 20% decrease	Est. 20% increase N/A
Impact on Net Premiums **Below 100% of FPL** **Younger & low-income (175% FPL)** **Older & low-income (175% FPL)**	 Reduction Modest Reduction Significant increase	 Reduction Modest increase Significant increase	 Reduction Modest increase Significant increase
Impact on Deductibles/Actuarial Value	Eliminates AV requirements / Promotes HSAs and High Deductible Plans	Sets Benchmark at 58% AV (vs. 70%) Increase in Deductibles	Likely Increase in Deductibles
Tax Repeal Provisions (Non-Coverage related)	$664 billion	$541 billion	$41 billion – Includes repeal of Med Device Tax; HSA provisions, and repeal of tax on OTC drugs (FSA)

Source: BofA Merrill Lynch Global Research

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  - Exemptions from state insurance regulations could lead to market instability and higher premiums in the traditional small-group market;
  - Exemptions could eliminate consumer and patient protections;
  - Proposed Regulations issued on January 4
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Source: BofA Merrill Lynch Global Research

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Key Legislative Issues Remain for 2018

Key Legislative Issues that Must be Addressed in December – A lot on Congress' Plate!

- **Children's Health Insurance Program (CHIP) Extension / Community Health Center Funding**
  - Funding expired September 30 – CHIP agreement on 5-year extension; CHC funding agreement on 2 year extension
  - Current CR extended funding theoretically until March 31, 2018 – But, some states may still run short sooner
  - Medicaid DSH Cuts delayed for 2 years as part of CHIP bill
- **Health Care Exchange / Individual Market Stabilization Legislation**
  - Alexander-Murray bill has Support, and Senator Collins has also pushed for it as a requirement to gain her support on tax reform, but, House may not support
  - Collins-Nelson bill would provide $10 billion over 2 years for State based High-Risk Pool and Reinsurance programs
  - Republicans may try to use FY2019 Budget Reconciliation for another attempt at HC Repeal/Replace in 2018
- **FY2018 Omnibus Appropriations**
  - Continuing Resolution expires on January 19 – May see a CR into February;
  - Congress still must agree on full year FY2018 Omnibus appropriations
- **Debt Ceiling**
  - Debt Ceiling Extension tied to Disaster relief – extended through December 8
  - Treasury now using extraordinary measures, and, may have liquidity under Debt Ceiling through February/March 2018
- **Another Effort at Repealing/Replacing the ACA**
  - Graham-Cassidy still looking to pursue proposal that calls for Block-granting funds to States / Medicaid per-capita caps
- **Effort at Entitlement Reforms**
  - Not likely to see push for Medicare reforms, but, Medicaid reforms remain an area of focus

Source: BofA Merrill Lynch Global Research

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Tax Reform – Key Health Policy Provisions

- **Repeal of Individual Mandate – effective in 2019**
  - CBO estimates reduced coverage of 4 million in 2019; and 13 million by 2027; Savings of $318 billion over 10 years
  - Impact estimated to increase premiums by 10%
- **Orphan Drug Tax Credit Reductions**
  - Final bill includes a reduction in the Orphan Drug Research Tax Credit down from 50% down 25% credit
- **Deductibility of Medical Expenses (currently for expenses over 10% of AGI)**
  - Final bill appears to leave deduction for medical expenses in place
  - Lowers threshold to 7.5% of AGI for 2 years, then back to 10% of AGI
- **Not-for-profit Hospitals – Elimination of Tax-exempt Private Activity Bonds / Advance Refunding Bonds**
  - Final bill would retain tax-exempt status for private active bonds
  - Advance refunding bonds would no longer have tax-exempt status

However --

- **Future potential action on Entitlement Reforms** – with increased deficits of over $1 trillion over 10 years, Republican leaders are already discussing potential pivot to Medicare and Medicaid entitlement reforms and cuts beginning in 2018
  - We would expect more focus on Medicaid reforms than Medicare reforms in 2018 – given the upcoming elections.

Source: BofA Merrill Lynch Global Research

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Separate Effort to Delay Several ACA Tax Provisions

House Ways and Means Committee has Offered a Package of Bills to Delay Several ACA Taxes

However, not clear how/if these bills would be paid for; and Senate has not weighed in

- **Medical Device Tax**
  - 5-year further suspension (2018-2022)
- **Health Insurance Industry Fee**
  - Tax is set at $14.3 billion in 2018 (roughly 2-3% of premiums)
  - Partial relief in 2018 – reducing tax by 2% for most health plans if they provide premium rebates to beneficiaries
  - Full repeal in 2019
  - Full 2-year repeal (2018-2019) for plans in Puerto Rico
- **Employer Mandate**
  - Suspension of Employer mandate – retroactive from 2015 through 2018
- **Cadillac Tax**
  - Delays implementation of excise tax on high cost health plans for 1 year (until 2021)
  - 40% Excise tax would apply to health plans with premiums over $10,800 for single coverage and $29,050 for family coverage
- **OTC Drugs in FSAs/HRAs/HSAs**
  - Allows for OTC drugs to be deductible as part of spending accounts for 2 years (2018-2019)

Source: BofA Merrill Lynch Global Research

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Remaining Key Health Care Legislative Issues

Other Key Healthcare Legislative Issues to be Addressed

- **FY2018 Appropriations / Continuing Resolution**
  - Continuing Resolution expires on January 19;
  - Negotiations continue on budget caps, and could see an additional CR into January
  - NIH Funds are likely to see an increase of $1-$2 billion in FY2018
- **Medicare Extenders Package (2 - 5 year extensions)**
  - **Includes a range of provisions:**
    - Ambulance add-ons – 5 year extension
    - Extension of Home Health Rural Add-On – 5 year extension
    - Part B Therapy Caps exceptions (permanent);
    - Medicare Dependent Hospital Program extension – 2 year extension
    - Extension of Work Geographic Practice Cost Indices Floor – 2 year extension
    - Extension of Increased Inpatient Hospital Payment Adjustment for Certain Low-Volume Hospitals – 2 years
    - Extension for Specialized Medicare Advantage Plans for Special Needs Individuals – 5 years
  - **Payfors include (~$18 billion)**:
    - Payment reforms for SNFs & Home Health;
    - Extension of mis-valued coding initiative;
    - Non-emergency transports for ESRD patients;
    - Reduction in Prevention and Public Health Fund, and Medicaid Third Party Liability

Source: BofA Merrill Lynch Global Research

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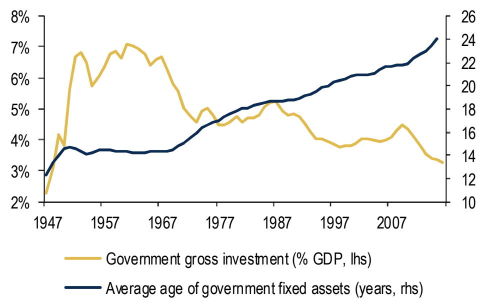
Infrastructure Spending – Not on Congress' Radar – But, May be for 2018

- ***Big under-investment***
  - ***Low share of GDP, aging fast***
  - ***ASCE grade: "D+"***
  - ***Both repair and big projects***
- ***Prospects***
  - ***House Republicans did not run on***
  - ***Trump budget cuts spending overall***
  - ***Private-public partnership?***

Infrastructure share of GDP and average age



Source: BofA Merrill Lynch Global Research, Bureau of Economic Analysis

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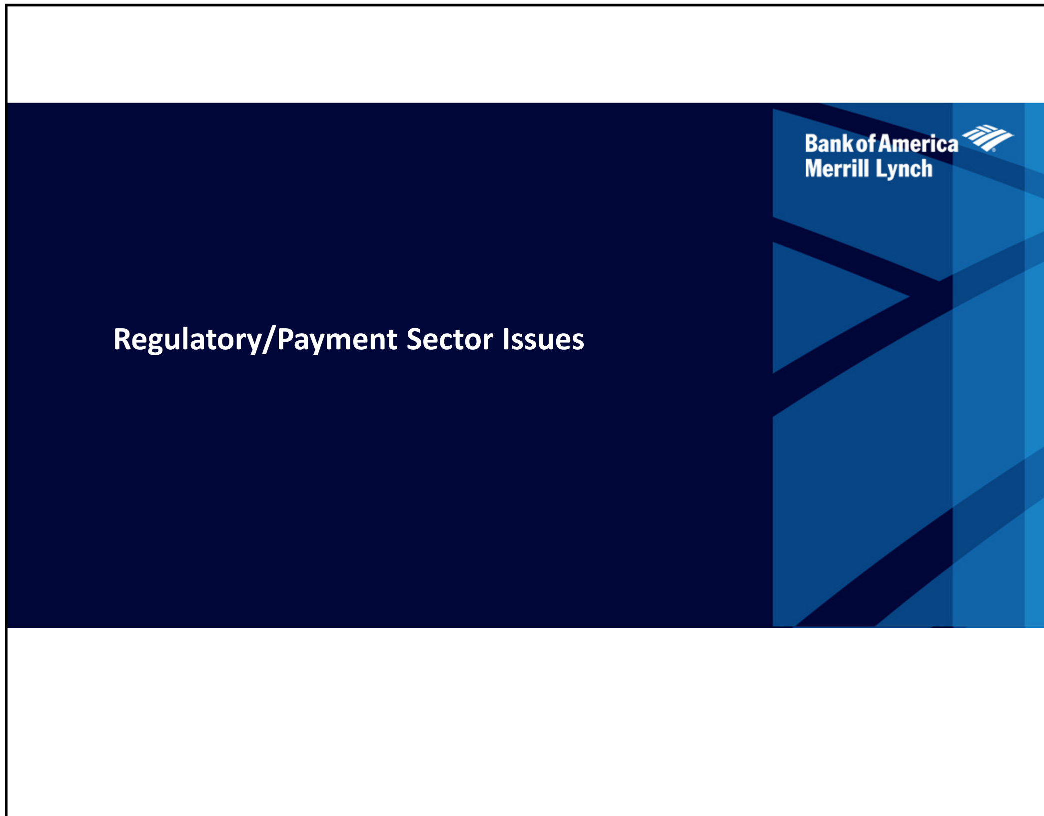

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Hospital Regulatory Issues

Rate / Regulatory issues

- **Inpatient Hospitals:** CMS finalized a net Inpatient Hospital Medicare payment increase of +2.3% for FY2018 –in line with expectations – Overall, the final payment increase of 2.3% came in below the proposed payment increase of 2.9%, but still a fairly solid overall increase in payments for hospitals, given previous year increases of less than 1%.
- **Outpatient Hospital Payments:** CMS finalized a net **1.4% payment increase for HOPD rates for 2018** – in-line with expectations.
- **However, we note that the final reduction in payments for 340B Drugs ($1.6 billion)** is a significant issue for safety net facilities.
- **MedPAC FY2019 Recommendation:** Increase the 2019 Medicare Inpatient and outpatient payment rates for acute care hospitals by 1.25%. This is the estimated update called for under current law, including an estimated 2.8% MB update less 0.8% productivity factor reduction, and less 0.75% ACA reduction.
- **MedPAC notes that overall Hospital Medicare Margins are expected to decline from -9.6% in 2016 to -11% in 2018**; In 2016, there were 21 hospital closures (mostly small, rural facilities), and 11 hospital openings.
- **MedPAC reports that Medicare inpatient utilization declined by 2.8% in 2016, with a decrease of 5.2% in medical cases, while surgical cases increased by 4.3%** (attributed to increase in hip/knee procedures, GI procedures, and Sepsis procedures. Outpatient services continued to see growth as per beneficiary outpatient utilization increased by 1.1% per beneficiary in 2016. However, chemotherapy administration increased by 7.3%, while clinic visits increased by 3.9%, and ER department visits increased by 1.9% in 2016.

Roll-Back on Payment Reform Efforts: Bundled Payments / ACO Models

- **CMS has now Scaling back the CJR Bundled Payment Demonstration & cancelled the expansion of the bundled payment program for Cardiac procedures (AMI & CABG) & Hip/Femur Surgeries** – was to take effect on July 1, 2017 in 98 markets for Cardiac, and 67 markets for Hip/Femur (same 67 as CCJR demo)
- **MedPAC has also called for Repealing Physician MIPS program** (VBP that was part of MACRA legislation)

26 Source: BofA Merrill Lynch Global Research

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Inpatient Psychiatric Hospital Payment Issues

Inpatient Psychiatric Hospital Payment Issues:

- **Final FY2018 Medicare Inpatient Psych Facility payment update included a net 0.99% increase.** Overall, CMS estimates total Inpatient Psych Medicare payments will increase by $45 million in FY2018.
- CMS Continues to Analyze Possible Future Refinements to the IPF Payment System
- CMS once again stated that they "will continue to collect data and analyze them for both timeliness and accuracy with the expectation that these data will be used in a future refinement." We note that CMS has continued to analyze IPF PPS data for possibly payment refinement for several years, without any action.
- CMS again noted that its preliminary analysis of 2012 and 2013 data found that over 20% of IPF stays reported no ancillary costs, such as laboratory and drug costs in their claims. CMS notes that they would expect that most patients requiring inpatient hospitalization would need drugs and laboratory services, and consequently, CMS plans to share its findings regarding these claims with no ancillary services to the Center for Program Integrity for further investigation.

 Source: BofA Merrill Lynch Global Research

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Post-Acute Sector Regulatory Issues

Rate / Regulatory issues

- **Post-Acute Payments – for 2018 mandated at 1% update;** However, Long-Term Acute Care hospitals still working through shift to site-neutral payment reforms;
- **SNFs & Home Health** - CMS has proposed significant payment refinements for Skilled Nursing Facilities for 2019, but has delayed proposed payment reforms for Home Health that were to take effect in 2019, that may have included 4.3% cuts.
- **MedPAC Post-Acute PPS Payment Recommendation:** MedPAC recommends that Congress should direct the Secretary to begin to base Medicare payments to Post-Acute Care (PAC) providers on a blend of the setting specific relative weights and unified PAC prospective payment system (PPS) relative weights in FY2019.
  - **Home Health Agencies:** MedPAC estimates that Medicare Home Health margins will decline from 15.5% in 2016 to 14.4% in 2018. MedPAC recommends that Congress should: Reduce Medicare payment for home health agencies by 5% in 2019; Implement a 2-year rebasing of the payment system beginning in 2020; Direct the Secretary to revise the PPS to eliminate the use of therapy visits as a factor in payment determinations, concurrent with rebasing
  - **Skilled Nursing Facilities:** MedPAC noted that Medicare Advantage plans typically pay 15-20% less than Medicare FFS for per diem SNF rates. MedPAC recommends that Congress should: Eliminate MB update for SNFs in FY2019 and FY2020; Implement a redesigned PPS system for FY2019; and HHS/CMS should report to Congress on the impacts of the revised PPS and make any additional adjustments to payments needed to more closely align SNF payments with costs in FY2021.
  - **Inpatient Rehab Facilities:** MedPAC notes that IRF Medicare margins remain high, but, will decline from 13.0% in 2016 to 11.9% in 2018. MedPAC recommends Congress should: Reduce the FY2019 Medicare payment rates for inpatient rehab facilities by 5% (same as last year's recommendation)
  - **Long-Term Acute Care Hospitals:** MedPAC notes that LTCH margins for qualifying cases are expected to decline from 6.3% in 2016 down to 4.7% in 2018. MedPAC notes that since 2012, the number of LTCH cases per beneficiary has declined each year, with a drop in 2016 of 4.2% in LTCH cases per 10,000 FFS beneficiaries. MedPAC recommends that the Secretary should: Eliminate the FY2019 Medicare payment update for LTCHs.

 Source: BofA Merrill Lynch Global Research

Physician Payment Reforms - MACRA

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Payment Reforms for Physicians

- **Final 2018 Medicare Physician Payment Update calls for essentially flat payments in 2018 (+0.3%),** however, freestanding imaging centers remain under pressure:
  - Independent Pathology Labs: -4% (better than the -6% proposed)
- **Annual Updates:**
  - **2016 through 2019:** +0.5% per year
  - **2020 through 2025:** No update
  - **2026 and Beyond:** 0.75% Update for physicians in APM; 0.25% Update for all other physicians
- **Alternative Payment Models:** 5% bonus payment to all physicians who quality beginning in 2019, through 2024
- **Merit Based Incentive Payment System –** Value based purchasing program for physicians:
  - **2019:** +/- 4%
  - **2020:** +/- 5%
  - **2021:** +/- 7%
  - **2022 and beyond** **+/-9%**
- **However, MedPAC recommends** scrapping the MIPS program, and replace with Establish a new Voluntary Value Program (VVP) and increase Medicare payment rates for physicians by the amount specified under current law (0.5%) for 2019.

29 Source: BofA Merrill Lynch Global Research

Other Provider Sector Regulatory Issues

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Rate / Regulatory issues

- **ASC Payments:** CMS finalized an increase of +1.2% in ASC payment rates for 2018. CMS estimates that total Medicare ASC payments will increase by $130 million in 2018 to $4.6 billion, after incorporating utilization, enrollment, and case-mix changes.
  - **MedPAC recommends** eliminating the payment update for ASCs in 2019 and require ASCs to report cost data to CMS.
- **Clinical Lab Payment Reforms (PAMA)** – CMS finalized PAMA lab payment reforms/cuts for 2018, with net 4-5% cuts in 2018, and larger cuts of 8-9% in 2019 and 2020.
  - Industry is pursuing both regulatory and legislative relief – but, we do not expect to see much traction for changes
  - Drugs of Abuse testing did receive a reprieve on its payment cuts for 2018, as payments for these tests will decline by 2.75% in 2018 (vs. original 10% proposed cut)
- **Dialysis Payments:** CMS released its final 2018 Medicare dialysis payment regulation including a net 0.5% payment increase. CMS estimates total Medicare payments for ESRD facilities will increase $60 million to $9.8 billion in 2018 with FFS dialysis enrollment increasing by 1.6% in 2018.
  - **MedPAC recommends** increasing dialysis payment update by 1.3% in 2019 - which is the same as current law, which includes a MB update less productivity factor
- **Hospice Payments:** CMS finalized FY2018 hospice payments including a net payment increase of 1.0%, or $180 million. CMS notes that total Medicare hospice spending has grown from $2.8 billion in 2000 to $16.8 billion in 2016, and expects growth of 7% per year going forward.
  - MedPAC projects that Hospice Medicare margins will decline from 10% in 2015 down to 8.7% in 2018. Medicare spending on hospice rose from $15.9 billion in 2015 to $16.8 billion in 2016.
  - Another concern in Medicare hospice has been the growing percentage of live discharges, which moved up from 16.7% in 2015 to 16.9% in 2016.
  - **MedPAC recommends** eliminating the Medicare payment update for Hospice providers in FY2019.

30 Source: BofA Merrill Lynch Global Research

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Medicare Margins – By Sector

Medicare margins by sub-sector

	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016*	2017*	Medicare exposure
IRFs	16.7%	13.4%	12.4%	11.8%	9.3%	8.4%	8.7%	9.9%	11.2%	11.6%	12.5%	13.9%	13.9%	14.3%	61%
SNFs	13.8%	13.1%	12.8%	14.7%	16.7%	18.0%	19.4%	21.3%	14.1%	13.2%	12.5%	12.6%	10.5%	10.6%	40%
Home Health	16.0%	17.4%	15.8%	16.6%	17.4%	17.7%	19.1%	14.8%	14.5%	12.7%	10.8%	15.6%	8.8%	11.1%	80%
LTACs	9.0%	11.9%	9.7%	4.7%	3.7%	5.7%	6.8%	6.9%	7.5%	6.8%	4.9%	5.4%	3.3-5.9%	3.2-5.4%	66%
Outpatient Dialysis	3.9%	5.8%	5.9%	4.8%	3.2%	3.1%	2.3%	2.5%	3.9%	4.3%	2.1%	0.4%	0.8%	-1.0%	60%
Total Hospital	-3.0%	-3.0%	-4.7%	-6.0%	-7.3%	-5.3%	-4.8%	-5.4%	-5.4%	-5.4%	-5.8%	-7.1%	-9.0%	-10.0%	30-35%

*MedPAC projections.

Source: MedPAC Data Book March 2010, 2011, 2012, 2013, 2014, 2015, June 2015, MedPAC meetings Dec 2014, Jan 2016.

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Medicaid Waiver/Flexibility Activity

Revise Medicaid Expansion Eligibility Down to 100% of FPL – From 138%

- Several states have been interested in revising its Medicaid expansion down from 138% of FPL

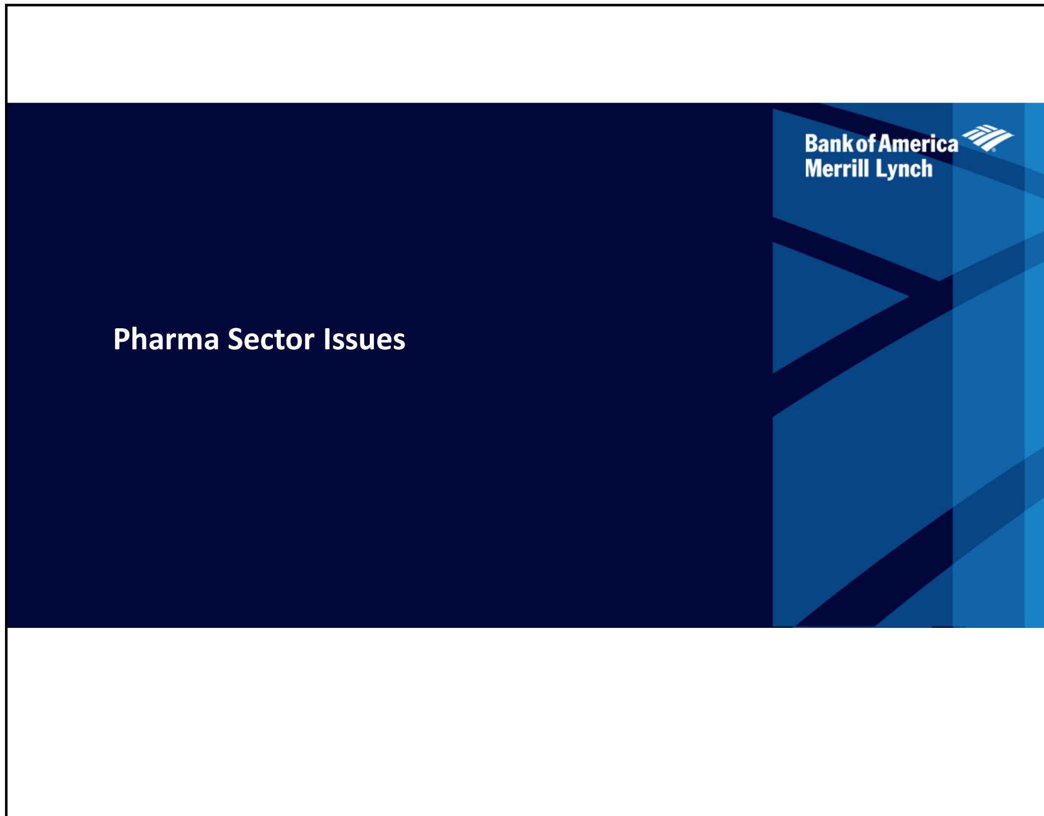
State Medicaid Waivers/Flexibility are Likely to Accelerate, with HHS/CMS letter to Governors

- Wisconsin waiver request: to include work requirements, drug testing, premiums, cost-sharing, etc.
- Kentucky, Maine, Massachusetts, Florida among first states to push forward on Waiver requests
  - Health Savings Accounts (based on Indiana model)
  - Work requirements
  - Cost sharing increases
  - Premium contributions
  - Drug testing
  - Benefit re-design – reduced benefits
  - Medicaid drug formularies
  - Time limits on benefits
  - Open enrollment periods

Uncompensated Care Pool Funding / Provider Taxes

- Florida received approval for $1.5 billion in supplemental "low-income pool" funding next year, up from $600 million
- Texas already received approval to maintain its funding
- California awaiting approval of its Hospital provider fee

Source: HHS, BofA Merrill Lynch Global Research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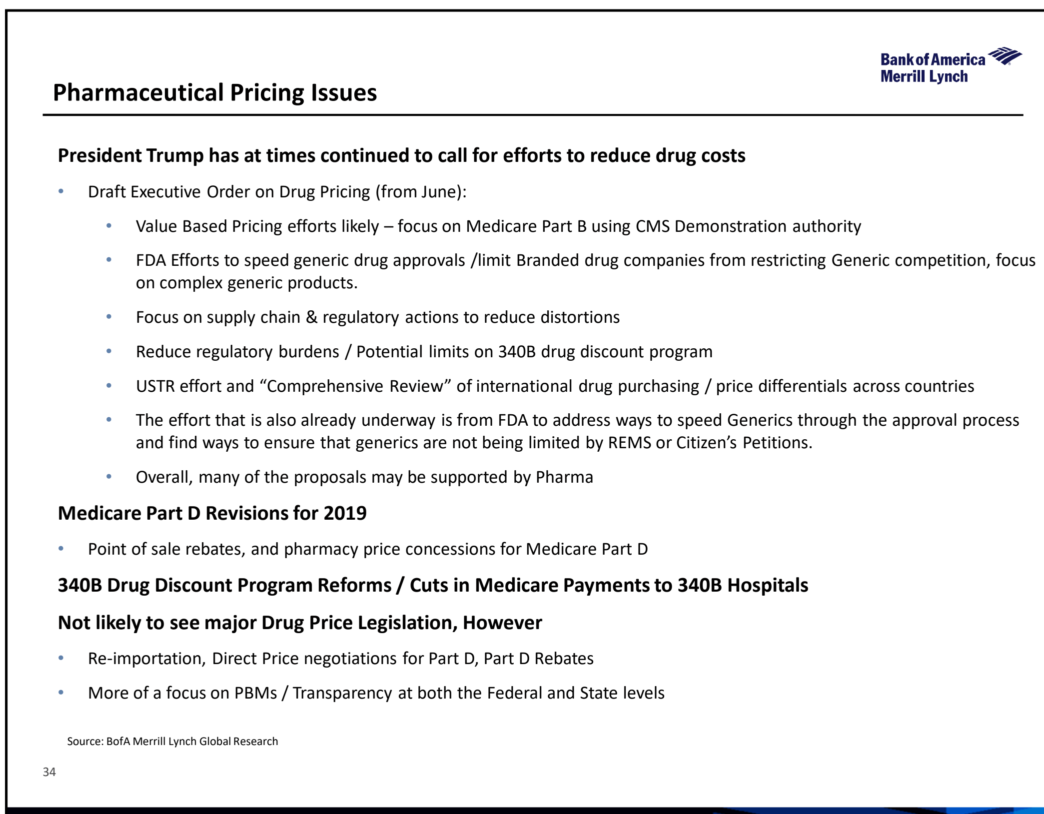
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Pharmaceutical Pricing Issues
President Trump has at times continued to call for efforts to reduce drug costs
Draft Executive Order on Drug Pricing (from June):
Value Based Pricing efforts likely – focus on Medicare Part B using CMS Demonstration authority
FDA Efforts to speed generic drug approvals /limit Branded drug companies from restricting Generic competition, focus on complex generic products.
Focus on supply chain & regulatory actions to reduce distortions
Reduce regulatory burdens / Potential limits on 340B drug discount program
USTR effort and “Comprehensive Review” of international drug purchasing / price differentials across countries
The effort that is also already underway is from FDA to address ways to speed Generics through the approval process and find ways to ensure that generics are not being limited by REMS or Citizen’s Petitions.
Overall, many of the proposals may be supported by Pharma
Medicare Part D Revisions for 2019
Point of sale rebates, and pharmacy price concessions for Medicare Part D
340B Drug Discount Program Reforms / Cuts in Medicare Payments to 340B Hospitals
Not likely to see major Drug Price Legislation, However
Re-importation, Direct Price negotiations for Part D, Part D Rebates
More of a focus on PBMs / Transparency at both the Federal and State levels
Source: BofA Merrill Lynch Global Research
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Key Issue – Revisions to 340B Drug Payments under Medicare HOPD

CMS Finalized Revisions to payments for Medicare Part B drugs acquired with 340B Drug Discounts

- Would reduce Medicare payment for non-pass-through, separately payable drugs (other than vaccines) acquired under the 340B Program (by $1.6 billion)
- Reduces Medicare Part B drug payments down from ASP+6% down to ASP minus 22.5%.
- CMS would require hospitals to report a modifier with separately payable drugs that were NOT purchased under the 340B program
- CMS estimates proposal would cut Part B drug payments by $1.6 billion, but, CMS would implement on a budget neutral basis, including a 3.2% payment increase for other HOPD services
- **Significant negative for safety net hospitals that rely on 340B Drug Discounts, while a significant boost for non-340B drug discount hospitals**

35 Source: BofA Merrill Lynch Global Research

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Pharmaceutical Pricing Issues

Other Federal Legislation – Still not likely to see much movement

- Speeding approval of Generic drugs / increase incentives for generic drug entry – FDA is moving on some efforts already
- PBM Transparency legislation (Senator Wyden) – would require disclosure of PBM rebates
- CREATES Act – would limit branded drug companies from using REMS process to limit generic access to drugs
- FAIR Drug pricing Act – Would require notice of drug price increases (of 10% or more in 1 year; or 25% over 3 years)
- Improving Access to Affordable Prescription Drugs Act – Includes a wide range of proposals:
  - Drug price transparency;
  - Examination of copay coupons / patient assistance programs;
  - Direct price negotiations;
  - Accelerate closure of Medicare Part D donut hole in coverage;
  - Reimportation;
  - Medicare Part D rebates;
  - Cap on prescription drug cost-sharing;
  - Innovation prizes for development of more effective anti-biotics;
  - Limit branded-generic drug settlements;
  - Generic drug incentives;
  - Disallow tax deduction for prescription drug advertising

Source: BofA Merrill Lynch Global Research

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Pharmaceutical Pricing Issues – State Level Issues

States Stepping up on Drug Pricing Proposals - 30 states proposed more than 60 drug price transparency bills targeting disclosure of costs, prices, profits of drug manufacturers, and disclose PBM rebates

- **Vermont (2016) –** Drug pricing transparency law - requires the state to identify up to 15 drugs that account for significant state spending and which have seen price increases of either 50 percent over five years or 15 percent over one year. Manufacturers of those products have to submit price justifications to the Attorney General;
- **California (2016) / Ohio (2017)** – Ballot initiative to limit state drug payments (Medicaid) to VA / Federal Supply Schedule payment rates. Effort failed in California in 2016, and failed in Ohio in 2017.
- **California (2017)** – Drug price transparency proposal requires a 60-day notification of price increases over a specified pricing threshold and mandates that health plans report the percentage of premiums spent on prescription drugs / Ban use of Coupons for Copayments.
- **Nevada (2017) -** Drug pricing transparency law (signed in June) - Requires drug companies to annually disclose the list prices for insulin, their profits on the diabetes drug and the discounts they provide to pharmaceutical benefit managers. Drug industry is challenging the law in Court, claims the law interferes with federal patent law, and violates the Commerce Clause.
- **Maryland (2017) –** Drug pricing transparency law - State Attorney General and Circuit Courts authority to penalize the makers of essential generic and essential off-patent medications for excessive price increases. Due to take effect on October 1, Generic drug industry is challenging the law in court.
- **Utah / Montana / New Mexico / Massachusetts –** All have implemented task forces or working groups to address different drug pricing transparency efforts, or re-importation proposals.
- **New York (2017) –** Legislation includes a Medicaid prescription drug spending growth cap, includes referral to a state Drug Utilization Review Board (DURB) for recommendations on potential supplemental rebates, or apply Medicaid prior authorization.
- **Pennsylvania (2017) –** Effort to document drug price increases, and potential alternative payment models

Source: BofA Merrill Lynch Global Research

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Pharmaceutical Issues – Opioid Abuse

Focus on Opioids

- FDA focus on opioid abuse and prescribing issues
- CDC guidelines for prescribing and distribution of opioids
- State Attorney Generals seeking to recoup costs for improper promotion / prescribing of opioids
- Additional funding for state and federal treatment programs
- Other investigations ongoing into Opioid manufacturers, Distributors, and Pharmacies:
  - Senate report on opioid sales and marketing tactics and the promotion of pain drugs
  - Potential new authority for DEA

Source: BofA Merrill Lynch Global Research

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