



V E N N
S T R A T E G I E S

Washington Update: The Latest on Health Care Policy

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Speaker Bio

Brian Reardon

- Former senior White House official with 25 years of public policy experience
- Helped enact 2003 Jobs and Growth Act and Medicare Modernization Act as Special Assistant to the President (National Economic Council)
- Veteran of Capitol Hill with senior posts in the Senate and House
- Contributor to the *Wall Street Journal*, *Financial Times*, *Daily Caller*, and others



Agenda

Today, we will cover:

- The Macro Fiscal Outlook
- The Legislative Outlook
- LTC Pharmacies & Their Challenges
- Other Health Care Policies before Congress

Challenges

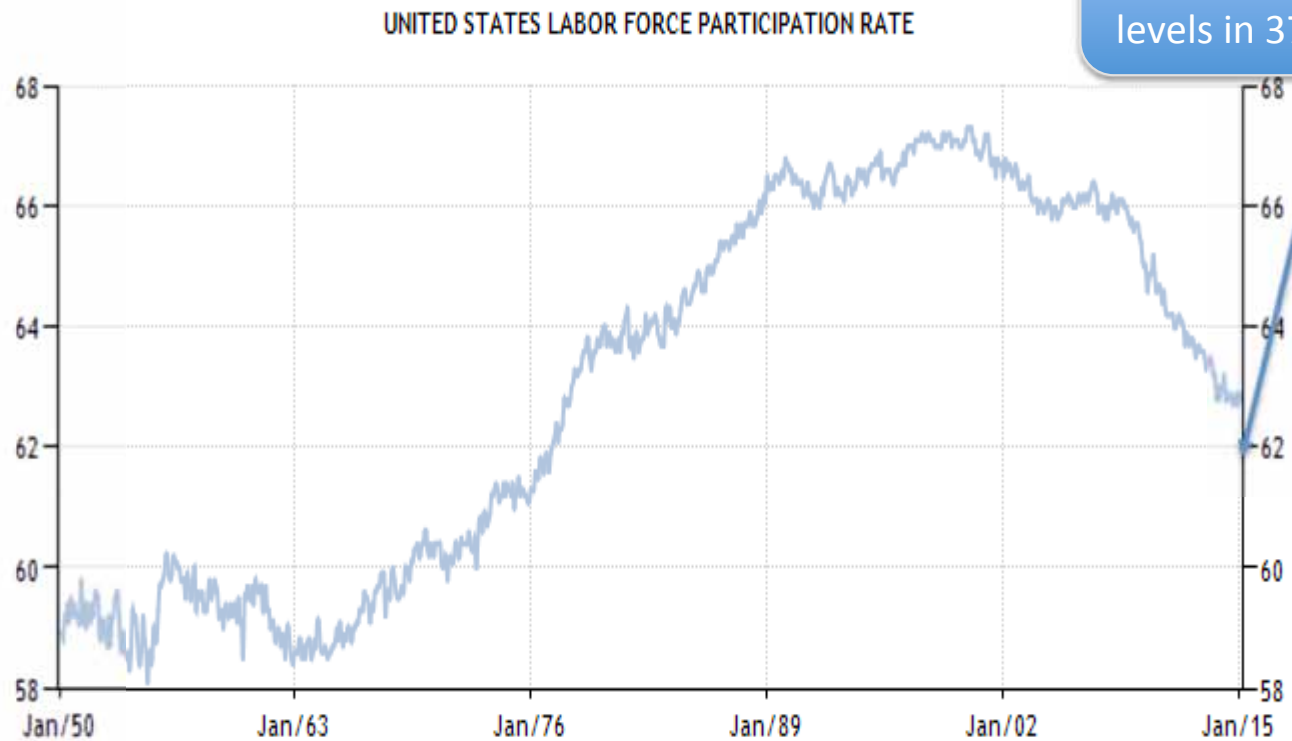
Uncertainty is everywhere

- Take last month's jobs report
- It was terrific!
- 280,000 jobs were added in May
- Unemployment remained low at 5.5 percent
- In a year, we've added 3.3 million jobs and the unemployment rate has declined by 1.3 percent
- But what about this?

Challenges

Labor force participation continues to decline...

62.9 percent —
near its lowest
levels in 37 years!



SOURCE: WWW.TRADINGECONOMICS.COM | U.S. BUREAU OF LABOR STATISTICS

Challenges

Meanwhile, the latest CBO report paints a troubling fiscal picture

- This year, the federal government will collect \$3.2 trillion, spend \$3.7 trillion, and run a deficit of nearly \$500 billion
- Millions, billions, trillions...
- MEGO

Challenges

What if a typical family acted like the federal government in 2014?

- We earned about \$50,000
- We spent \$58,000!
- We added \$8,000 to our credit card debt
- Total credit card debt: Over \$210,000!

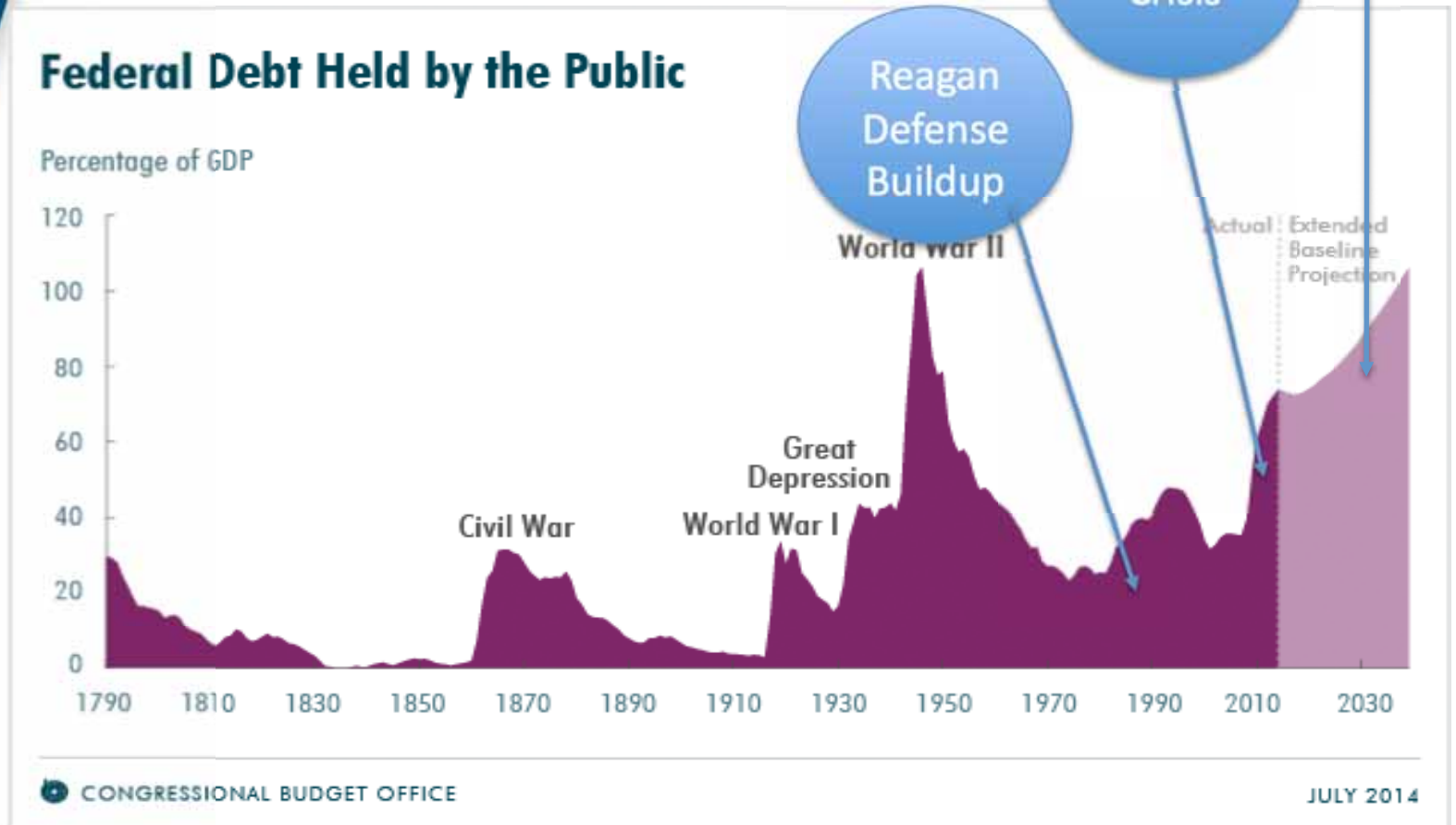
Challenges

So 2014 was a bad year. What about 2015?

- Good news! We got a raise to \$53,000
- Bad News. We plan to spend \$61,000!
- That adds another \$8,000 to our credit card
- Total credit card debt: Over \$220,000!

Challenges

Is this just a short term challenge? No...



Challenges

The implications of rising debt

- Draws money away from private capital, resulting in less investment and lower growth
- Squeezes out spending on other priorities
- Limits policymakers' ability to respond to an economic or financial crisis
- At some point, investors lose confidence in our ability to repay and the real crisis begins

Challenges

The implications for the health care sector

- Historically, the federal government spent one dollar for every five Americans earned
- Over the next decade, this will rise to one in four
- The increase is driven by rising debt and health care costs while defense spending sinks to pre-WWII lows
- Bottom Line: Pressure on health care spending and reimbursement levels is going to continue

Health Care Catalysts

New Congress, New Attitude

Don't look now, but Congress is *legislating!*

- The Senate voted on more amendments in January under McConnell than it did under Reid in all of 2014
- Congressional accomplishments include:
 - First budget resolution adopted in six years!
 - First permanent solution to the SGR formula (Doc Fix) since 1998
 - CHIP funding extended through 2017
- For health care, there are several catalysts and lots of potential policies that could move later this year

Health Policy Catalysts

Debt Limit

- The government ran up against the debt limit on March 15th
- Treasury can use “extraordinary measures” to keep us under the debt limit until September or October
- Unclear how new Republican Leadership will handle this:
 - No one likes to increase the government’s “credit card” limit
 - Only 28 House Republicans joined a majority of Democrats in voting to increase the limit last time
- Stakes are high: This is where sequestration came from!

Health Policy Catalysts

Budget & Reconciliation

- Budgets are important! They force Congress to reconcile anticipated revenues with spending
- They also can include “reconciliation instructions” that allow the Senate to move tax and spending legislation with a simple majority
- The reconciliation instructions in this budget call for Finance and HELP committees to act in July
 - Instructions do not distinguish between taxes and spending
 - Seen as placeholder in case Congress needs to respond to *King*

Health Policy Catalysts

King v. Burwell

- Supreme Court soon will rule on subsidies for federal exchanges
- The law allows subsidies to those enrolled in “an Exchange established by the State under Section 1311...”
- But what about exchanges established by the federal government under Section 1321?
- Lower courts split—DC Court of Appeals ruled against the subsidies, the 4th Circuit for them
- This is a BIG deal! The subsidies of around seven million enrollees rely on the outcome

Health Policy Catalysts

ACA Implementation

- Medicaid expansion continues at a steady rate and appears inevitable—it's hard for states to forego free money
- The exchange future is more troubled, including the fact that exchange insurance continues to be really expensive
 - Nearly 9 out of 10 enrollees receive subsidies
 - Of those, four out of five are below 250 percent of poverty
 - Exchanges look more like “Medicaid Lite”
- Possible ACA-related policy catalysts for this year?
 - SHOP Plans & Employer Mandate Changes
 - Cadillac tax
 - IPAB

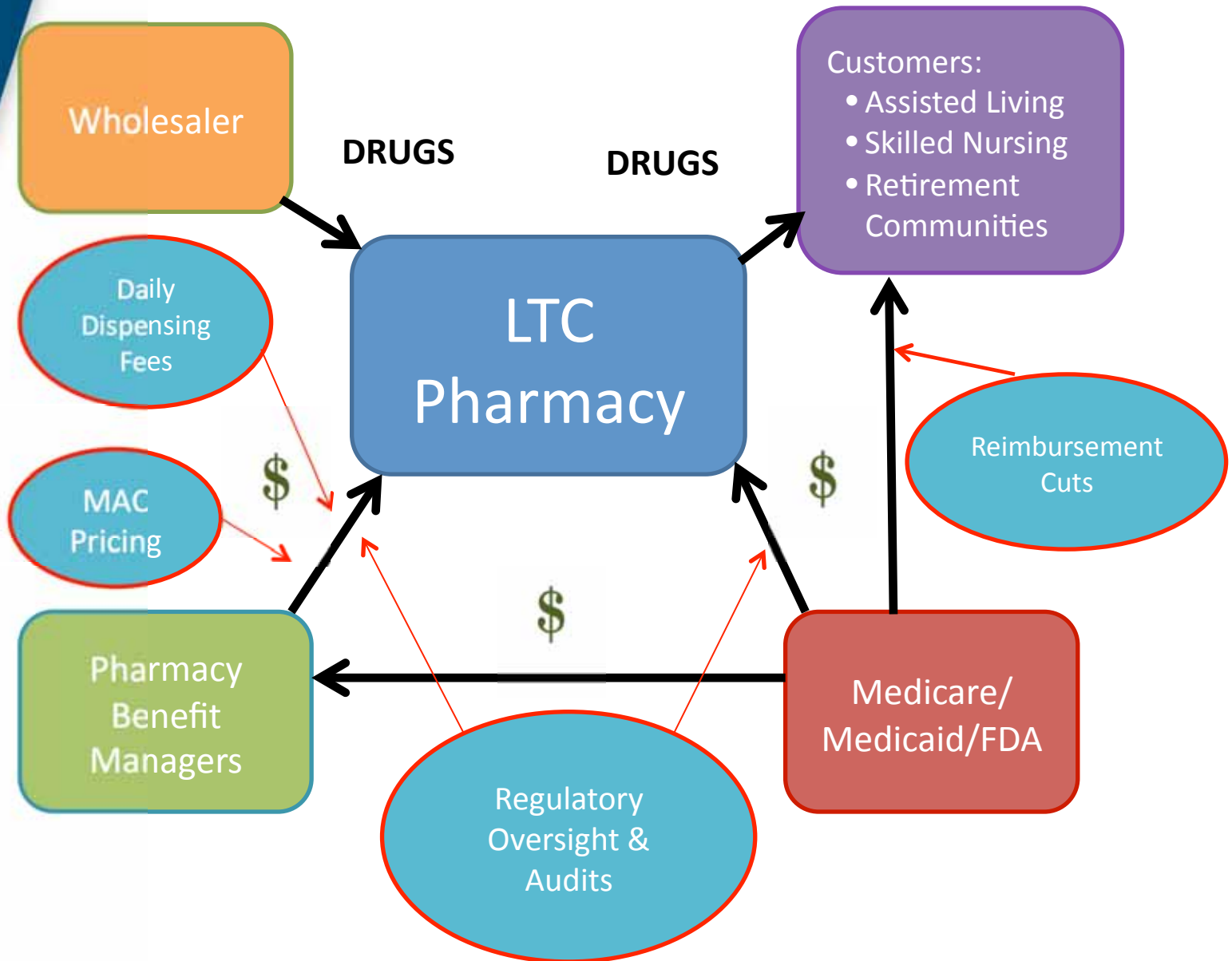
LTC Pharmacy Challenges

LTC Pharmacy Challenges

SCPC

- Established in 2014, the Senior Care Pharmacy Coalition is a new advocacy organization dedicated to representing the interests of independent LTC pharmacies and the patients they serve
- SCPC members operate in 40 states and serve more than 325,000 beds
- So what are the challenges facing LTC pharmacies?

LTC Pharmacy Challenges



LTC Pharmacy Challenges

Daily Dispensing Fees

- In 2013, the two largest PBMs (CVS Caremark and Express Scripts) changed how they compensate LTC pharmacies
 - They moved from a flat, professional dispensing fee to one that is prorated to the days' supply of drug dispensed
- Prorated dispensing fees fail to recognize the professional services involved in filling prescriptions
 - All the services are provided prior to the dispensing event
 - Not dependent on the days' supply of drugs dispensed
- They also threaten continued innovation in our industry by penalizing the move toward more efficient systems

LTC Pharmacy Challenges

Daily Dispensing Fees

- The response:
 - Senators Cardin, Mikulski, Carper, and Wyden wrote CMS asking them to act
 - Senator Cardin introduced S. 1493 to prohibit the proration of dispensing fees
 - 600 pharmacies wrote CMS in support of the Cardin legislation
 - CMS issued proposed rules mirroring the Cardin bill
- Result: Earlier this year, CMS finalized its rule prohibiting dispensing fees that penalize innovation beginning in 2016
- CMS argued that “there is no justifiable rationale for proration, since the cost of dispensing is not directly related to the quantity dispensed.”

LTC Pharmacy Challenges

MAC Pricing

- There is minimal predictability or transparency in reimbursement based on MAC pricing
- PBMs develop and alter their MAC lists without disclosing how they determined those prices, including:
 - How the plan decides which drugs are reimbursed under MAC
 - How the price is set or when it will change
- As a result, LTC pharmacies lack a clear understanding of how they will get paid, even after the fact
 - Reductions to MAC have been significant
 - AWP lag in price increases

LTC Pharmacy Challenges

MAC Pricing

- CMS included favorable language on MAC pricing transparency in its controversial “Mega” rule:
 - Clarifies that MAC pricing should “accurately reflect the market price of acquiring the drug” and should be updated at least every seven days
- Result: CMS finalized its MAC transparency rule with an effective date of January 1, 2016
- Word of caution:
 - There’s no guarantee CMS action will be a complete fix
 - Transparent and low is not an acceptable outcome

LTC Pharmacy Challenges

Lock-In

- Legislation to “lock-in” at-risk patients to specific pharmacies & doctors is moving quickly through Congress:
 - Goal is to reduce substance abuse among seniors
 - Based on Medicaid lock-in programs established by the states
- Challenge: Initial lock-in legislation ignored LTC pharmacies
- SCPC highlighted to members and staff the specific challenge the lock-in policy presents to LTC pharmacies
- Result: Legislation adopted by E&C Committee protects LTC pharmacies and the patients they serve

LTC Pharmacy Challenges

Repackaging

- Draft guidance released by FDA in February limits pharmacies' ability to repackage drugs prior to receiving a prescription
- Challenge: LTC pharmacies repackage many of the drugs they dispense, mostly in anticipation of future scripts
 - Repackaging helps to make med passes more efficient and reduces errors
 - It also results in significant savings to Medicare and Medicaid
- Response: SCPC is working with Congress, CMS, and the FDA to:
 - Highlight the draft guidance's potential negative impact on LTC facilities and federal health programs
 - Convince the FDA to explicitly exclude LTC pharmacies from the new limitations

Other Health Care Policies

Health Care Issues

21st Century Cures

- A compilation of provisions designed to accelerate the pace of “cures” in America
- E&C Chair Fred Upton is moving quickly
 - He released a discussion draft in January, marked it up in May, and is shooting for House consideration in June
- The Senate HELP Committee is moving more deliberately
 - It is just beginning a robust series of roundtables, hearings, and stakeholder communications
- Stakeholders should take this process seriously—fully expect legislation signed into law this Congress

Health Care Issues

The 340B program is under increased scrutiny

- MedPAC debated clawbacks to recapture 340B revenues
- GAO released one critical report with another coming out
- The OIG should have a report out by the end of the year
- *And* we expect so-called “mega guidance” from HRSA sometime this summer. Could address:
 - Patient definition, eligible institutions, and contract pharmacies
- E&C attempted 340B reforms in Cures legislation

Health Care Issues

Generic Price Hikes & Drug Shortages

- Meanwhile, the number of drugs on the drug shortage list continues to be historically high
- November Drug Channels analysis found that 77 generic drugs more than doubled in price the 3rd quarter of 2014
- Rising drugs prices squeeze margins and magnify the impact of lags in MAC pricing updates
- It's been a problem so long, there's an app for that—
<http://1.usa.gov/1DNM5Oh>

Take-Aways

Conclusions

Take-Aways

- Budget deficits and debt will continue to put pressure on federal health care programs and reimbursement levels
- Congress has been more active legislating on health care policies this year and we expect that activity to continue
 - The *King v. Burwell* decision is just one of many catalysts for health care policy out there
- LTC pharmacy community needs to pay attention!
 - Daily dispensing fees, MAC pricing transparency, FDA repackaging rules, and patient lock-in policies are all in play

Thank You!