

# The 2016 November Elections

Now is time for all Covered Entities participating in the 340B Drug Pricing Program – the key stakeholders – to pay close attention to the November elections. Collectively, the White House, Senate and House of Representatives have the power to make legislative changes to the Program, as well as influence the responsible government agency, the Health Resources and Services Administration (HRSA), and its Office of Pharmacy Affairs (OPA).

Elevating the importance of the November elections, the White House Office of Management and Budget (OMB) reported online that it received 340B Program Omnibus Guidelines (“the Guidelines”) from HRSA on September 1. Whatever direction HRSA, with OMB input take the Guidelines there is potential for legislative actions.

Should the Guidelines maintain the status quo or offer opportunities to expand the Program, it is logical to expect a legislative assault on the program fueled by the drug manufacturers stated dissatisfaction with the Program. Should the Guidelines cause the program to contract, Covered Entities and their 340B partners will need to actively engage both the Senate and the House of Representatives to get the legislation needed to optimize the Program.

With respect to Federal regulations, including the Guidelines, OMB’s core mission is to serve the President in implementing their vision across the Executive Branch. To accomplish this, OMB evaluates the economic and broader potential impacts of regulations, as part of the regulatory decision-making process. Typically, OMB reviews result in either approving the proposed rules, in which case they are published in the Federal Register and become effective; or sending them back to the agency that promulgated them, for further consideration. Reviews are normally completed in 90 days. If OMB follows its normal course, and does not ask HRSA to make any major changes, the Guidelines should be released in the late November/early December time-frame, after the elections.

Separately, we note that there is already one Congressman, Christopher Collins (R-NY), who serves on the House of Representatives Energy and Commerce Committee’s health sub-committee, who is on record stating that 340B legislation could surface in early 2017. At an August industry conference, Congressman Collins suggested that reforms to the Program could parallel future efforts to renew Medicare extenders, which end in 2017, or the reauthorization of funding for the Children’s Health Insurance Program.

## Presidential Race

Neither candidate has articulated, nor is expected to articulate a view on the 340B Program. However, the candidates' divergent views on the Affordable Care Act (ACA) may provide a roadmap for their potential actions. Clinton's view that the ACA should be defended and expanded appears to align with a positive view of protecting the Program. Trump's view that the ACA needs to be completely repealed appears to align with a negative view of protecting the Program. A repeal process would provide numerous opportunities to introduce legislation negative to the Program

## The Senate Races

Currently, the United States Senate consists of 54 Republicans, 44 Democrats and 2 Independents. Twenty-four of the Republican Senators, 10 of the Democratic Senators, and none of the Independent Senators are up for election. Democrats are expected to make a significant gain in this election cycle, and are likely to regain the majority. This change would be accompanied by gaining control of the highly influential Health, Education, Labor and Pensions (HELP) Committee. Under Republican control for the last 2 years, the Committee has been attempting to take a critical look at the Program through studies conducted by the General Accountability Office and the Office of the Inspector General. See Table 1 for information on all 34 Senate races.

2016 UNITED STATE SENATE RACES			
State	Incumbent	Challenger	Challenger
Alabama	Richard Shelby	Ron Crumpton	
Alaska	Lisa Murkowski	Ray Metcalfe	
Arizona	John McCain	Ann Kirkpatrick	
Arkansas	John Boozman	Conner Eldridge	
California	Retiring	Kamala Harris	Loretta Sanchez
Colorado	Michael Bennet	Daryl Glenn	
Connecticut	Richard Blumenthal	Dan Carter	
Florida	Marco Rubio	Patrick Murphy	
Georgia	Johnny Isakson	Jim Barksdale	
Hawaii	Brian Schatz	John Carroll	
Idaho	Mike Crapo	Jerry Sturgill	
Illinois	Mark Kirk	Tammy Duckworth	
Indiana	Retiring	Todd Young	Evan Bayh
Iowa	Chuck Grassley	Patty Judge	
Kansas	Jerry Moran	Patrick Wiesner	
Kentucky	Rand Paul	Jim Gray	
Louisiana	Retiring	Party Nominees	Party Nominees
Maryland	Retiring	Chris Van Hollen	Kathy Szeliga

■ Dem.    ■ Rep.

Table 1 (Source: [www.electionprojection.com](http://www.electionprojection.com), Sept. 15, 2016)

2016 UNITED STATE SENATE RACES (Continued)			
State	Incumbent	Challenger	Challenger
Missouri	Roy Blunt	Jason Kander	
Nevada	Retiring	Catherine Masto	Joe Heck
New Hampshire	Kelly Ayotte	Maggie Hassan	
New York	Chuck Schumer	Wendy Long	
North Carolina	Richard Burr	Deborah Ross	
North Dakota	John Hoeven	Eliot Glassheim	
Ohio	Rob Portman	Ted Strickland	
Oklahoma	James Lankford	Mike Workman	
Oregon	Ron Wyden	Mark Callahan	
Pennsylvania	Pat Toomey	Katie McGinty	
South Carolina	Tim Scott	Thomas Dixon	
South Dakota	John Thune	Jay Williams	
Utah	Mike Lee	Misty Snow	
Vermont	Patrick Leahy	Scott Milne	
Washington	Patty Murray	Chris Vance	
Wisconsin	Ron Johnson	Russ Feingold	

■ Dem.    ■ Rep.

Table 1 (Source: [www.electionprojection.com](http://www.electionprojection.com), Sept. 15, 2016)

## The House Races

The House of Representatives consists of 435 members who are elected biennially. The current make-up of the House is 247 Republicans, 187 Democrats, 0 Independents and 2 vacancies. All seats are up for election in November. Current predictions indicate that the Democrats will pick up a significant number of seats, but have only an outside chance of gaining the majority. Control of the critically important Energy and Commerce (E&C) Committee is expected to remain in Republican hands. See Tables 2 and 3 for information on the House of Representative races.

### 2016 HOUSE OF REPRESENTATIVES RACES: Current Best Guess Election Summary

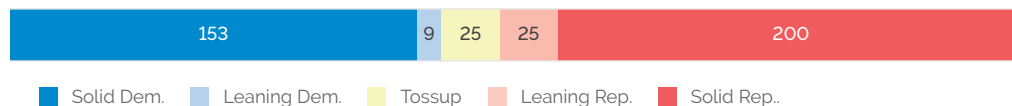


Table 2 (Source: [www.270towin.com](http://www.270towin.com), Sept. 15, 2016)

COMPETITIVE HOUSE OF REPRESENTATIVE RACES			
District	Incumbent	Elected	Term
AK-AL	Don Young	1973	22th
AZ-01	Incumbent Not Running	-	-
AZ-02	Martha McSally	2015	1st
CA-07	Ami Bera	2013	2nd
CA-10	Jeff Denham	2011	3rd
CA-21	David Valadao	2013	2nd
CA-24	Incumbent Not Running	-	-
CA-25	Steve Knight	2015	1st
CA-31	Pete Aguilar	2015	1st
CA-36	Raul Ruiz	2013	2nd
CA-49	Darrell Issa	2001	8th
CA-52	Scott Peters	2013	2nd
CO-03	Scott Tipton	2011	3rd
CO-06	Mike Coffman	2009	4th
FL-07	John Mica	1993	12th
FL-13	David Jolly	2014	2nd
FL-18	Incumbent Not Running	-	-
FL-26	Carlos Curbelo	2015	1st
IA-01	Rod Blum	2015	1st
IA-03	David Young	2015	1st
IL-10	Robert Dold	2015	1st
IL-12	Mike Bost	2015	1st
IN-09	Incumbent Not Running	-	-
KS-03	Kevin Yoder	2011	3rd
MD-06	John Delaney	2013	2nd
ME-02	Bruce Poliquin	2015	1st
MI-01	Incumbent Not Running	-	-

COMPETITIVE HOUSE OF REPRESENTATIVE RACES			
District	Incumbent	Elected	Term
MI-07	Tim Walberg	2011	3rd
MN-02	Incumbent Not Running	-	-
MN-03	Erik Paulsen	2009	4th
MN-08	Rick Nolan	2013	2nd
MT-AL	Ryan Zinke	2015	1st
NE-02	Brad Ashford	2015	1st
NH-01	Frank Guinta	2015	1st
NJ-05	Scott Garrett	2003	7th
NV-03	Incumbent Not Running	-	-
NV-04	Crescent Hardy	2015	1st
NY-01	Lee Zeldin	2015	1st
NY-03	Incumbent Not Running	-	-
NY-18	Sean P. Maloney	2013	2nd
NY-19	Incumbent Not Running	-	-
NY-21	Elise Stefanik	2015	1st
NY-22	Incumbent Not Running	-	-
NY-23	Tom Reed	2010	4th
NY-24	John Katko	2015	1st
PA-08	Incumbent Not Running	-	-
PA-16	Incumbent Not Running	-	-
TX-23	Will Hurd	2015	1st
UT-04	Mia Love	2015	1st
VA-02	Incumbent Not Running	-	-
VA-05	Incumbent Not Running	-	-
VA-10	Barbara Comstock	2015	1st
WI-08	Incumbent Not Running	-	-

■ Dem. ■ Rep.

Table 3 (Source: [www.270towin.com](http://www.270towin.com), Sept. 15, 2016)

## Bipartisanship

It is important to note that views of the Program do not align 100% by either political party. Many Republican members of Congress have been supportive of the Program. Evidence of this bipartisan support is best seen in the July 25, 2014 letter to the House's E&C Committee, which was signed by 76 Congressmen, and the July 28, 2014 letter to the Senate's HELP Committee, which was signed by 31 Senators. Senators and Congressmen interested in the Program tend to focus on whether or not "it is working." Typically, support for the Program comes when a Senator/Congressman sees real-life examples of the Program working as planned – Covered Entities enabled to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.

## Covered Entities

How can Covered Entities make sure that the Program remains intact and that changes focus on expansion and optimization, not contraction? **We urge you to follow the following four simple steps: We are confident they will be highly effective.**

1

### Get the facts.

Know where the candidates stand on healthcare issues, in general, and the 340B program specifically.

2

### Give them the facts.

Make sure the candidates know how important your work is to their state and/or district. Support your statements with facts, including how many people you employ and how many patients you treat. Discuss how critical your Covered entity is to their constituency.

3

### Let them know the Program is working.

All elected officials want to know if the Program is working as it should. Give them your success story – discuss gains in treating more patients, creating innovative programs to improve health and opening new clinics to serve more patients. The most efficient way to let candidates know about your Program is through opinion/editorial pieces placed in local newspapers.

4

### Set the record straight.

Opponents to the Program have been very effective in "changing the facts." Let the candidates know the following.

- ◆ The program was not established to exclusively benefit the uninsured. The program was enacted to eliminate a loophole in the 1990 Medicaid Drug Rebate Program that resulted in Covered Entities experiencing significant increases in the cost of pharmaceuticals for their outpatients. As stated by HRSA, "The 340B Program enables covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

- ◆ Drug manufacturers are not mandated to participate in the Program. They are only required to participate, if they elect to make their drugs eligible for purchase by State Medicaid Agencies.
- ◆ The size of the 340B discount is determined by the drug manufacturers' actions not the regulator's. The initial 340B discount is statutory and nearly equal to the discount that State Medicaid agencies receive. However, the discount increases if the manufacturer increases the price of its drug at a rate above the increase of the Consumer Price Index for inner cities. Rapid or prolonged increases in prices by a manufacturer are the only pathway to the 340B price of a drug declining. The fact that many drugs have a \$0.01 340B price is testament to drug manufacturers' decisions to increase prices both rapidly and consistently.
- ◆ The size and the "cost" of the program to the drug manufacturers are two different calculations. Drug manufacturers often combine the two, making it appear that the size of the Program is equal to the amount of dollars they are contributing to the Program. This is incorrect. Current industry estimates indicate that \$10-\$12 billion worth of drugs were purchased from drug manufacturers at 340B prices in 2015. That is \$10-\$12 billion of cash paid to the drug manufacturers by Covered Entities. Assuming a 340B discount was not available, Covered Entities would have paid \$12 to \$15 billion for these same drugs. The net cost to the drug manufacturers, therefore, ranges somewhere between \$2-\$5 billion. This represents a very small percentage of the HHS' estimated \$457 billion spent on drugs in 2015.

The entire Wellpartner Team is here to serve as an information source for 340B-related news and analysis, and to partner with you to advocate on behalf of the lives and communities serviced. Please call or email us, if we can assist you.

**Wellpartner – Sharing Insights When it Matters Most.**



## About the Author

**James R. Love**

*President and Chief Executive Officer*

Jim Love joined Wellpartner as President in December 2011 and was named Chief Executive Officer in April 2012. Prior to joining Wellpartner, Mr. Love had significant healthcare experience in both operations and investment banking. He spent the early part of his career in the investment banking division of Merrill Lynch & Company where he led the healthcare group and provided both strategic and financing advice to a wide range of companies including Johnson & Johnson, Hospital Corporation of America, Medco, and Biogen Idec. Mr. Love left Merrill Lynch to serve as Executive Vice President of Syntec Inc. (and its successor company Medical Manager, Inc.) a publicly traded healthcare information technology company, where he was responsible for all finance and administrative functions. During his tenure at Syntec, Mr. Love led the efforts to raise both debt and equity capital, acquire several business, and ultimately merge the company with WebMD. After the merger with WebMD, Mr. Love returned to the investment banking business, at the Bank of Montreal, where he rebuilt the firm's commercial and investment banking healthcare effort, and at Madison Williams and Company, where he was a senior investment banker.

Mr. Love received an A.B. degree from Brown University, and a M.B.A degree from New York University.

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### Wellpartner: Who We Are

Wellpartner is a leading provider of 340B Drug Pricing Program services. We also offer provider and patient centric specialty pharmacy services via our URAC accredited pharmacies. Our services are finely tuned toward optimizing our clients' programs through; industry leading compliance, the unique ability to unlock specialty prescriptions from exclusive networks, access to over 60,000 pharmacies, and easy to implement data interfaces. Our goals align with our clients', as we work together to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. Today, hundreds of covered entities, ranging from large disproportionate share hospitals to small clinics, trust Wellpartner to optimize their 340B programs and serve their patients.

**Wellpartner** | When it matters most

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