

With so many ups and downs in Washington these days, anticipating what may happen to the 340B Program, its covered entities, contract pharmacies, 340B Administrators and most importantly; **patients** remains to be seen. But, seeing and hearing what has been discussed so far can give us an idea and a preliminary roadmap to help prepare for whatever may lie ahead.

First, take a look back

The 340B Program has grown significantly since its inception in 1992, and by all accounts it is working. Like most federal programs, the 340B Program does encounter opposing arguments, but there is no denying that giving the underserved population access to much needed care and prescription medicine is working and beneficial. The underserved and uninsured population is made of a large variety of people, from veterans to homeless, recently laid-off workers to poverty stricken single mothers; the 340B Program allows healthcare providers the ability to increase access to care and prescription medicine.

In turn, these drastically discounted drugs and services allow qualified Health Centers, Clinics, and Hospitals to increase savings and revenue, this in turn, supports the continuation of providing much needed care, increase access, and invest in healthcare services and equipment.

What has taken place in the first couple months of 2017?

HRSA Audits

In November 2016, HRSA announced it would be subcontracting all of its audits in 2017 to The Blzzell Group. Since then, not only have we seen an increased number of audits being performed in 2017

thus far, 340Basics has witnessed a significant increase in the intricacy of audits, data request turn-around time reducing and digging deeper into 340B focus areas, i.e. eligibility and compliance.

What does this mean for covered entities and contract pharmacies?

340Basics can't stress enough, the importance of instituting and maintaining your 340B program with a day-to-day audit ready approach. This includes, instituting policies and procedures, inventory management, correct OPA database entries, maintaining auditable records, compliance training, internal audits and more.

Mega-Guidance Withdrawn

The Office of Budget and Management (OMB) announced The Department of Health and Human Services (HRSA) withdrew the 340B Program Mega-Guidance from review. This came on the heels of newly elected President Trump freezing all pending regulations and guidance documents.

What does this mean for the program?

With this being put on-hold, all new and pending regulations have been brought to a standstill and HRSA will have to possibly revise and resubmit the regulations to have them reconsidered. It is highly unlikely that they will be published in 2017. For now, it seems that the 340B Program will continue on its current course.

The ACA Draft Legislation Repeal and Replace

On March 6th, the House Republican's submitted draft legislation to Repeal and Replace the Affordable Care Act. The 340B Program saw most of its growth after the ACA was implemented in 2010 under President Obama, it is then that the ACA made the five hospital types, PED, CAN, CAH, RRC and SCH eligible for the 340B Program. Health care organizations participating in the 340B program dramatically increased. These eligible entities are

considered health care safety net providers, they assist a significant portion of rural and underserved populations in the United States.

What does this mean for the program?

The Repeal and Replace Bill that was just submitted for review does not address the eligibility of these safety net providers. If these are not to be included in the new ACA legislation, it could have a serious financial effect on safety net providers utilizing the 340B program. Many of these providers were able to persevere through Medicare and Medicaid funding cuts, rising costs and increased drug prices by instituting the 340B program which helped to meet the volume and maintain the quality of services their communities need.

What's to come?

New 340B Regulation to be Enforced

HRSA is still planning to begin enforcing a final rule entitled "340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation" on April 1, 2017, the first day of the second quarter. HRSA did push back the effective date from March 6th to March 21st in light of the Trump administrations regulatory freeze.

What does this mean for the program?

The regulation is meant to prevent overcharging health care providers. It will specify how 340B ceiling prices will be calculated, this regulation will also fine drug manufacturers that knowingly and intentionally overcharge a 340B provider or a 340B hospital up to \$5,000 for each instance of overcharging. Manufacturers also must ensure that their distributors give providers the 340B ceiling price.

There is no doubt that there is a certain air of uncertainty of how any changes in legislation will affect the 340B Program, but 340Basics recommends business as usual. Continue to conduct your 340B Program in such a manner that you are always HRSA audit ready. Ensure that not only are you compliant, but that your organization is utilizing the program to its fullest potential.

If you have any questions, concerns or would like to learn more about our 340B solutions, please contact us.

Colleen DiClaudio is the President and Co-Founder of 340Basics. She is a thought leader whose entrepreneurial instincts and clarity of vision have carried multiple companies through rapid and continuous growth. Colleen is one of the nation's foremost experts on the Federal 340B program and has over 15 years of experience in the health care industry.



Before launching 340Basics, Colleen was Vice President of Business Operations at CompleteCare Health Network where she provided executive leadership and business operations oversight. She was crucial in the NCQA PCMH certification, acquisition of private group practices, 340B operations, medical billing and collections management and budget preparation as well as overall strategic planning. Colleen holds an MPH from the University of Medicine and Dentistry of New Jersey and a B.S. From Richard Stockton College.

To learn more about the 340B Program and our Solutions please contact:

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