

September 8, 2020

Pharma Attacks 340B

340B Health System Coalition

Strategy and Coalition Development

Hospitals and health systems are facing the greatest threat to the future of 340B in many years. In addition to recent HHS regulatory changes that undercut the program and a new Executive Order that targets 340B prices, at least five pharmaceutical manufacturers have taken actions in recent weeks that are designed to dramatically curtail contract pharmacy programs. These unilateral actions threaten funding used by health systems to finance care to the poor and underserved and improve access to health care services for millions of people.

Health System 340B Coalition Conference Call

Please join us for an update on the Coalition and strategies on Friday, September 11 at 1 p.m. ET. Conference number: (872) 240-3311; Access Code 674-589-485 [No Moderator Code].

Advocacy Status

Eli Lilly, AstraZeneca, Novartis, Merck, and Sanofi have all taken various actions that threaten contract pharmacy programs. The most far-reaching actions come from Eli Lilly (click [here](#)) and AstraZeneca (click [here](#).)

The Coalition's immediate objective is to stop these actions by these manufacturers and similar actions that may be taken by other pharma companies.

Short-Term Actions:

- Congressional intervention
 - Members of Congress have already started to challenge the manufacturers' actions.
 - Click [here](#) for the letter from leading House Democrats to Secretary Azar.
 - Click [here](#) for the House bi-partisan sign-on letter.
 - A bipartisan letter in the Senate is under development.
- Regulatory agency intervention
 - HRSA is reportedly investigating the manufacturers.
 - Click [here](#) for the report on HRSA's actions.
- Court action
 - None at this time against the pharmaceutical companies. However, some expert 340B lawyers are questioning the strategy of seeking court intervention at this time, particularly if the action were to fail.
 - Court challenges against the federal regulations are ongoing and under appeal.
- Providers' opposition
 - Provider associations have started pushing back.
 - Click [here](#) for the letter from 7 provider groups.
 - Click [here](#) for the ASHP initiative.

Long-Term Options:

- Congressional legislation
 - Should be developed now and ready for introduction in January 2021.
- Regulatory changes and support
 - This strategy should be fully developed and shaped depending on the outcome of federal elections November 3.
- Hospital and health system action at the state level
 - Enlist support of governors. Work with willing governors on threatening state drug formularies.
 - Research efficacy of unilateral health system action against selected manufacturers, i.e. curtailing drug trials, etc...

Health System Coalition Development

In 2017, Strategic Health Care formed a group of 20 health systems focused on 340B solutions. This Coalition worked closely with Rep. David McKinley (R-WV) to develop a legislative initiative that would have provided a legal framework around 340B, protecting the program for future years. This Coalition is now inviting all health systems to join. Click [here](#) for the 340B Health System Membership Form.

Coalition Overview

- The Coalition is focused exclusively on 340B advocacy for health systems – with an emphasis on Congress and key regulatory agencies.
- Coalition membership is limited to multi-hospital health systems.
 - Why? Not all 340B covered entities have the same policy interests. By limiting membership to multi-hospital health systems, consensus around legislative and regulatory initiatives is more likely.
 - The Coalition will work to broaden the support of its initiatives among all covered entities – to help forge the broadest possible consensus.
- The Coalition will have a Steering Committee comprised of its members. The Steering Committee will meet by phone (and in-person when possible) on a regular basis to review all Coalition activities and provide guidance to government relations professionals retained by Coalition members or who are working for member health systems.
- The Coalition will provide regular written updates and conference calls for all members.
- A small annual fee from each member will finance the activities of the Coalition.
- Strategic Health Care (www.strategichealthcare.net) will manage the Coalition and the Steering Committee. SHC employed and retained government relations and policy professionals will coordinate the strategy and tactics of the Coalition and will rely on information provided by the Steering Committee and membership to guide their activities. This includes meeting with (in person, by phone, email, etc...) Congressional staff and elected officials, agency staff and other government officials. Health systems with its own government relations staff, or retained government relations assistance in Washington, D.C., will be asked to participate in Coalition activities.
- The development of legislation will be guided by a separate legislative policy development committee comprised of Coalition members. It can include members of the Steering Committee.