

340B Collaborative Program

Hall Render provides Legal, Compliance and Operations support to 340B covered entities, health care systems, retail chain pharmacies and a variety of other health care industry participants in all 50 states.

EXECUTIVE SUMMARY

In order to protect 340B eligible entities from the loss of 340B program discounts due to recent manufacturer actions, Hall Render has formed a collaborative of affected covered entities to protect those discounts. The Collaborative includes over 75 health systems and nearly 400 covered entities from 43 states and is focused on providing efficient group-based legal guidance to our clients, most of whom ask materially similar questions.

DETAILED DISCUSSION

You are likely aware of an increasing number of overreaching drug manufacturer requests and unilateral actions that serve to severely limit 340B Covered Entity access to the 340B Program savings required by law. In response to these efforts, Hall Render has formed a collaborative of 340B Covered Entities whose goal is to protect 340B Program discounts. As of today, we have over 75 health systems participating in this initiative.

There is of course an ongoing robust national dialogue and litigation regarding 340B drug manufacturer refusals to offer 340B contract pharmacy pricing as well as data requests from manufacturers and third parties such as Second Sight/340BESP.com and other for-profit vendors attempting to monetize 340B covered entity data. Looking forward, we are anticipating that additional manufacturers will attempt to restrict or refuse access to 340B pricing.

In an effort to both: i) allow affected covered entities to assert good faith engagement with manufacturers in any potential dispute resolution process with HRSA or otherwise; and ii) avoid unnecessary, burdensome and likely unproductive direct engagement between your team, manufacturers and third party vendors, we have engaged with drug manufacturers, HRSA OPA and third party vendors on behalf of our Collaborative clients to assert our objections to their efforts that we believe are beyond what is permissible under applicable law. Hall Render has successfully utilized this approach with some vendors previously and we believe it is also appropriate in this setting. To date, this approach has had some success with certain manufacturers related to specific implementation actions.

Our first step in this initiative was to send a letter to engage with Second Sight Solutions and drug manufacturers detailing our objections to their approach and informing them that our communication represents a good faith response by and on behalf of each listed collaborative member. This effort has grown to include advising collaborative members regarding how best to preserve dispute/appeal rights to the extent 340B discounts are refused as well as affirmative actions to take to enable access to 340B pricing in the contract pharmacy context wherever possible. Subsequent steps have involved affirmative dispute resolution and litigation efforts and coordination with advocacy team members, though collaborative members would be free to unilaterally opt-out at will and at any time from these efforts. More specifically, to date these efforts have included:

- Strategic guidance and memoranda addressing key 340B issues like Alternative Delivery Models, Child Site Registration issues, DSH percentage optimization, MTM/Pharmacotherapy clinic models and others.
- Preparation of a template state contract pharmacy law statute and related legal feasibility assessment.

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- Access to template contract materials (e.g., contract pharmacy services agreements).
- Operational guidance regarding optimization of manufacturer 340B contract pharmacy restrictions and related PBM pricing discrimination.
- Advocacy guidance letters to, and meetings with, federal legislative stakeholders including the G6.
- Providing guidance and template responses to Government investigatory and informational requests.
- Providing technical assistance to federal legislators and OMB regarding 340B SUSTAIN Act development.
- Monthly webinars on 340B hot topics from a legal perspective.
- Periodic Collaborative status update emails/guidance.
- Template comment letters to federal and state agencies (CMS, HRSA OPA).
- Guidance regarding CMS 340B payment issues.
- Guidance regarding HIPAA and data privacy issues related to 340B ESP.
- Guidance regarding PBM actions related to 340B savings retention.
- Advice regarding ADR dispute resolution processes.
- Filing of an ADR petition and updates related to the revised ADR process recently published.
- Assessment regarding initial appeal rights protection mechanisms.
- Detailed dispute initiation letter to Eli Lilly, AstraZeneca, Sanofi, Novo Nordisk, and other manufacturers.
- Detailed dispute initiation letter to Second Sight Solutions.
- Detailed dispute initiation letter to additional implicated manufacturers.
- Ongoing guidance regarding manufacturer contract pharmacy selection processes (e.g., Eli Lilly, Novartis, AstraZeneca, BMS).
- Advice regarding drug manufacturer contract pharmacy exception implementation.
- Access to a continuously updated manufacturer contract pharmacy guidance document, including proposed language and access enrollment forms modified by Hall Render to address legal considerations.
- Direct engagement with 340B manufacturers to identify a mutually agreeable path forward, subject to individual Collaborative member approval.
- State specific guidance/updates related to 340B issues.

INVESTMENT

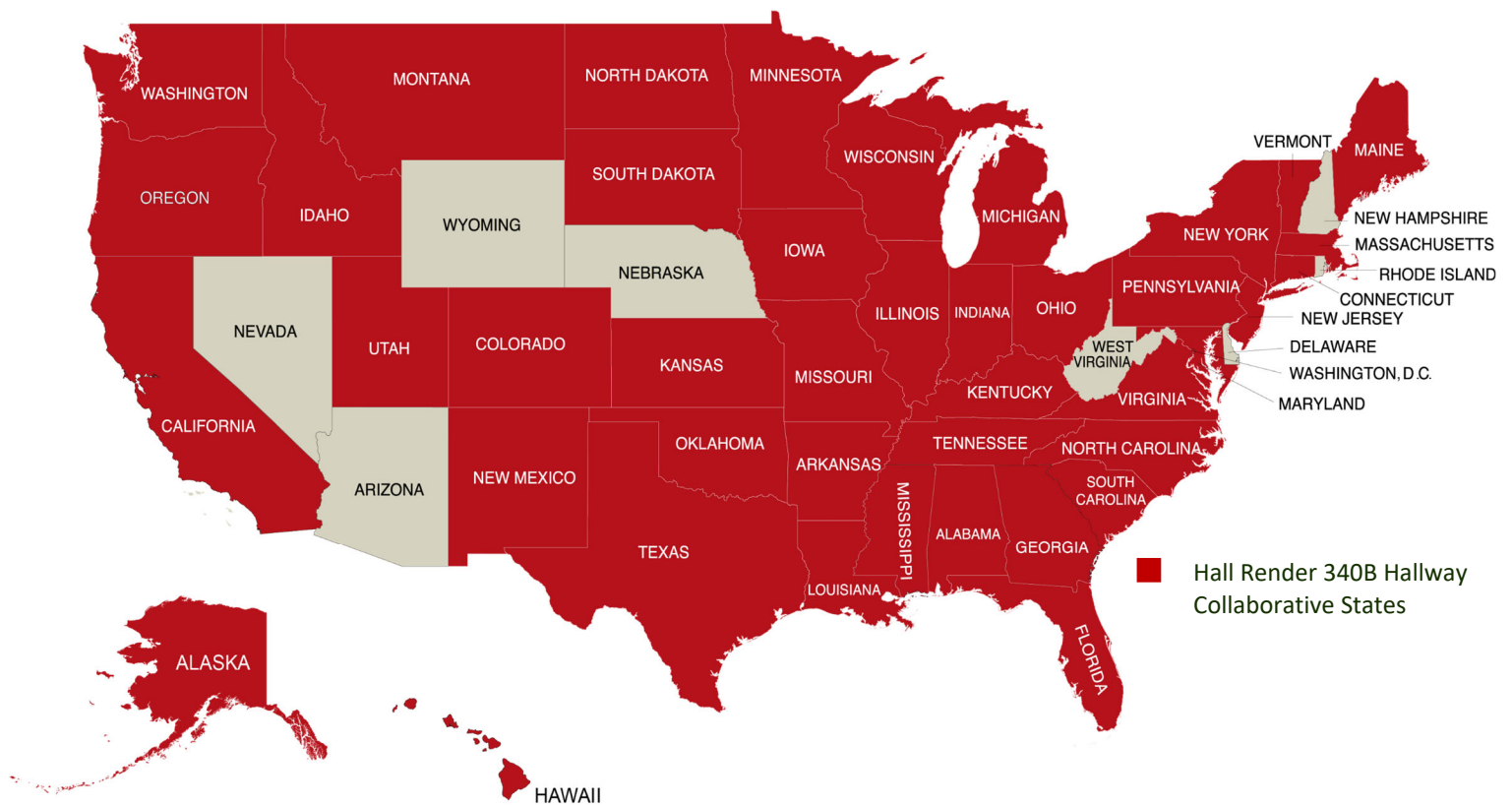
Our goals are to simply represent the shared interest of our clients, minimize their risk and burden, and allow them to share in the costs of our efforts that benefit all of our clients. Regarding cost, we are sharing time and expense equally across all collaborative covered entity members, and there will be no success fee. This should serve the dual purposes of enhancing cost efficiency while also increasing leverage. For new members, there would be a catch-up fee of \$3,500 related to costs incurred that enables access to prior materials. We anticipate subsequent monthly fees of around \$1,000. We have found that these fees are more than offset by the ability to access 340B contract savings to the extent possible.

LET'S GET STARTED

Contact Hall Render to discuss how your organization can benefit from a partnership with our health care attorneys and advisors.



HALL RENDER'S 340B HALLWAY COLLABORATIVE



THE FOLLOWING STATES HAVE MEMBERS OF HALL RENDER'S 340B HALLWAY COLLABORATIVE:

- Alaska
- Alabama
- Arkansas
- California
- Colorado
- Connecticut
- District of Columbia
- Florida
- Georgia
- Hawaii
- Idaho
- Iowa
- Illinois
- Indiana
- Kansas
- Kentucky
- Louisiana
- Maine
- Maryland
- Massachusetts
- Michigan
- Minnesota
- Mississippi
- Missouri
- Montana
- North Carolina
- North Dakota
- New Jersey
- New Mexico
- New York
- Ohio
- Oklahoma
- Oregon
- Pennsylvania
- South Carolina
- South Dakota
- Tennessee
- Texas
- Utah
- Virginia
- Vermont
- Washington
- Wisconsin
- **77 members total as of June 1, 2024**