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Client Alert: Chairman Cassidy Releases 340B Discussion Draft Signaling Major Proposed Changes to the 340B Program

Overview

Senate Health, Education, Labor, and Pensions (HELP) Committee Chairman Bill Cassidy (R-LA) has released a discussion draft of the **340B Drug Pricing Integrity and Affordability for Patients Act**, a proposal that would significantly reshape the 340B Drug Pricing Program.

While the proposal has not yet been formally introduced as legislation and is expected to evolve through the legislative process, it represents one of the most comprehensive reform efforts to the 340B Program in recent years. If enacted, the proposal would affect covered entities, hospitals, contract pharmacies, manufacturers, third-party administrators (TPAs), and others participating in the program.

Key Proposed Changes

Among the most notable provisions, the proposal would:

- Permit manufacturers and covered entities to elect a rebate model.
- Establish statutory definitions for key 340B terms, including “patient,” “practitioner,” and “covered entity”
- Impose additional eligibility and certification requirements for certain covered entities
- Significantly reform contract pharmacy arrangements, including limitations on pharmacy relationships and new geographic restrictions
- Create new transparency, reporting, and patient affordability requirements for certain hospitals and covered entities
- Modify requirements for hospital child sites participating in the program
- Restructure compensation models for TPAs and contract pharmacies by requiring flat-fee arrangements and enhanced compliance with federal fraud and abuse laws
- Expand enforcement authority through increased reporting obligations, corrective action requirements, civil monetary penalties, and other compliance measures

What Organizations Should Be Considering

Although the proposal remains in draft form, organizations participating in the 340B Program should begin

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evaluating how the proposed reforms could affect:

- Ongoing financial stability for those whose operations depend on safety net financing established by Congress through the 340B Drug Discount Program
- Contract pharmacy relationships and payment structures
- Third-party administrator agreements and compensation structures
- Patient eligibility and documentation practices
- Hospital child site registration and oversight
- Compliance, reporting, and audit preparedness
- Financial and operational impacts under the proposed pricing models

The breadth of the proposal suggests that many organizations will need to reassess existing policies, contractual relationships, and compliance programs if these reforms advance.

Looking Ahead

As a discussion draft, the proposal is likely to undergo revisions before formal introduction and throughout the legislative process. Nevertheless, it provides important insight into the direction of potential congressional reforms and warrants close attention from all 340B stakeholders.

Our Health Law team is actively monitoring these developments and advising clients on the potential legal, operational, and financial implications of the proposal. If you have questions about how these proposed changes may affect your organization, would like assistance evaluating your current 340B program, or would like to submit comments on the draft, please contact Daphne Kackloudis or a member of our Health Law team.