Claims Clearinghouse, Strengthening HRSA Among Few Consensus Areas in Responses to Senate 340B Overhaul Effort

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The creation of a claims clearinghouse and increasing both the funding and authority of the federal agency overseeing the 340B program were among the only areas of common ground in widely divergent feedback provided to a bipartisan group of U.S. senators expected to craft a legislative overhaul of the program.

The large variety of views on ways the program should be overhauled came in response to the request of three Democratic and three Republican senators for ideas from 340B program stakeholders on changes needed to "ensure the program has stability and oversight to continue to achieve its original intention of serving eligible patients." Comments to the six lawmakers, led by Sen. John Thune (R-S.D.), the Senate's second ranking Republican, are not expected to be posted publicly, but many stakeholders shared their comments with 340B Report or made them available.

Stark Differences Even in Common Ground Areas

Even in the few consensus areas, there was wide divergence on how to implement the proposed changes. For instance, the American Hospital Association (AHA) wrote that any national data claims clearinghouse should limit data collection to Medicaid claims to prevent duplicative 340B discounts and Medicaid drug rebates.

In contrast, Pharmaceutical Researchers and Manufacturers of America (PhRMA) wrote that the clearinghouse also needs to collect Medicare claims to address 340B provisions of the Inflation Reduction Act.

Similarly, both 340B providers and drug makers urged expanded HRSA funding, while seeking expanded activity by the agency in very different directions.

The National Rural Health Association, which includes hospitals and other covered entities (CEs) in 340B, urged authorizing the Health Resources & Services Administration (HRSA) to impose civil monetary penalties on drug makers that violate proposed new protective language on contract pharmacy arrangements, patient definition and child site arrangements. NRHA also called on Congress to enact legislation allowing orphan drug discounts for rural hospitals.

In contrast, the Biotechnology Innovation Organization (BIO) urged HRSA to expand its provider audits to include covered entity child sites, contract pharmacies, and "any other entities with a formal relationship with the covered entity related to the 340B program, including software vendors and third party administrators."

Broad Changes Sought

Advocates for providers, pharmaceutical firms and other healthcare entities sought extensive legislative changes to the 340B program.

Changes sought by advocates for 340B hospitals included:

- Protecting the 340B benefit for drugs dispensed through contract pharmacies
- Prohibiting drug companies' restrictive conditions on access to 340B discounts
- Allowing CEs to directly challenge drug company 340B restrictions or conditions in federal court

- Preventing additional 340B hospital reporting requirements, especially outpatient department-level reporting or a focus on uncompensated or charity care
- Prohibiting 340B-specific discriminatory policies by payers and pharmacy benefit managers
- Operationalizing the 340B administrative dispute resolution process
- Eliminating the orphan drug loophole and group purchasing organization prohibition
- Prohibiting states from mandating that providers use or not use 340B for Medicaid patients

“We recommend that Congress pass legislation to protect 340B hospitals from drug companies’ harmful 340B restrictions and conditions,” 340B Health, which represents 340B hospitals, wrote in its letter to the senators.

Changes sought by drug makers included:

- Clarifying who qualifies as an eligible “patient” of a covered entity to whom benefits must be delivered
- Requiring covered entities (including child sites) and contract pharmacies to pass through 340B discounts to reduce out-of-pocket costs to patients based on their ability to pay
- Establishing contract pharmacy limits, including how much profit they can generate from the program
- Establishing minimum amounts of charity care 340B hospitals must provide to uninsured, low-income, and other patients
- Prohibiting 340B hospitals from engaging in aggressive medical debt collection on 340B patients
- Applying the same eligibility requirements to hospital child sites as the parent site

- Limiting fees pharmacies and other for-profit entities can charge to perform 340B-related services
- Requiring public reporting of information by CEs
- Updating manufacturer audit guidelines
- Increasing financial penalties on CEs for non-compliance

“We strongly encourage Congress to carefully consider the full range of policy shortcomings that have taken the 340B program off course,” PhRMA wrote. “It is time for Congress to enact comprehensive legislative reforms to realign the 340B program to support vulnerable patients and true safety-net providers and ensure appropriate oversight and accountability.”

Changes sought by grantees included:

- Increasing the standards before a pharmaceutical manufacturer could audit a CE
- Allowing phased compliance by CEs through corrective action
- Allowing CEs providing more transparency and accountability to use an unlimited number of contract pharmacies
- Capping the percentage of 340B savings contract pharmacies can receive
- Barring PBM and insurer policies that cut health centers’ 340B reimbursement
- Prohibiting state actions that cut Medicaid reimbursement for 340B drugs below wholesale acquisition cost
- Establishing a reasonable cap on the administrative fees TPAs can charge
- Requiring annual reports to HRSA that include community benefit as reported on the health center’s IRS form 990 and evidence of tangible benefit to patients

“The 340B program is being steadily eroded by the actions of state policymakers, pharmaceutical companies, and pharmacy benefit managers, to the detriment of the nation’s safety net providers,” wrote Advocates for Community Health, which represents federally qualified community health centers.

Others Seeking 340B Changes

Many groups outside of the central struggle within the program between pharmaceutical firms and providers also sought to influence the anticipated legislation. One group, ASAP 340B, which was formed earlier this year by the National Association of Community Health Centers and PhRMA, offered its own slate of changes, which included:

- Requiring locating contract pharmacies near the CE’s service area and to honor any applicable sliding fee scale or other patient affordability benefits
- Requiring CEs to meet basic standards to increase access to affordable medications for low income patients
- Increasing specificity of the 340B “patient” definition
- Ensuring child sites serve a safety net mission
- Limiting fees pharmacies and other for-profit third parties can charge for 340B-related services
- Tightening CE eligibility definition
- Requiring CEs to offer prescription discount programs through contract pharmacy arrangements
- Requiring CEs to report information, including total acquisition cost and reimbursement for 340B discounted medicines, payer mix, and the total amount spent subsidizing out-of-pocket costs for patients receiving 340B discounted medicines

“In general, our coalition supports an approach, consistent with our principles, that includes reforms across a range of policy areas to increase program integrity, with statutory changes that codify critical provisions necessary to better tailor the program to benefit rural and safety-net providers and their patients and curb abuse,” ASAP 340B wrote.