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340B Prescription Drug Discount Program Reform Legislation Must Preserve Eligible Patient Access to Drug Therapies Through Contracted Pharmacies

Background – Over the last 5 years, there has been growing scrutiny of the 340B prescription drug discount program as hospitals and qualified community health clinics ("340B covered entities") have expanded 340B access for uninsured and underinsured individuals. Under HHS rules, 340B covered entities utilize more than one community pharmacy ("340B contract pharmacies) to fill the prescriptions for these 340B eligible patients.

Federal Law (Section 340B of the U.S. Public Health Services Act) requires drug manufacturers to provide all drugs – including high priced brand drugs and biological products – to 340B covered entities at a deeply discounted price, many manufacturers have legally challenged HHS' Health Resources and Services Administration (HRSA) authority to require that they provide covered entities with these discounted priced drugs to all their contracted pharmacy. And 340B entities have challenged the ability of drug manufacturers to limit them to one contracted pharmacy.

With the federal court cases producing mixed rulings for the manufacturers, HRSA and the 340B covered entities there is growing interest in having Congress develop comprehensive 340B reform legislation to address:

- Requirements for determining and identifying patients who are eligible for 340B drug benefits coverage.
- Requirements for the needs for multiple 340B contract pharmacies for 340B covered entities.
- Accountability and reporting for 340B covered entities to HRSA on program operations.

IPC 340B Reform Principles – With IPC having hundreds of 340B contract pharmacies - especially to clinics in rural and underserved areas, rural hospitals and Disproportionate Share Hospitals (DSH) – we are providing you with the following concepts for a bi-partisan 340B reform bill:

- Have HRSA responsible for a system to identify 340B eligible patients and prescription claims.
- Allow multiple contract pharmacies for community clinics, recognized rural hospitals & DSH facilities.
- Require 340B savings only be used for covering more patients or expanding health care services.
- Require PBMs pay contracted pharmacies the full cost (drug ingredient acquisition cost & professional dispensing cost fee) for 340B prescriptions, with HRSA conducting every 3 years a cost to dispense (COD) survey of 340B contract pharmacies, to maintain a relevant 340B professional dispensing fee.
- Prohibit contract pharmacies preferential treatment terms & payment rates by covered entities & PBMs.
- Prohibit Pharmacy Benefit Managers (PBM) from 340B post claims claw backs from covered entities and contracted pharmacies except in instances where there is written documentation proving fraud.
- Provide covered entities and contract pharmacies with audit rights conducted by PBMs. Require that any 340B audit recoupments funds be returned to: 1) the covered patient for any cost-sharing paid; 2) HRSA and the appropriate State Medicaid agency (since the drug has already been dispensed to the patient).
- Provide "anti-retaliation/anti-gag order" protections to 340B covered entities & contracted pharmacies for notifying HRSA of any violations of the 340B law.

March 2024