

SUMMARY OF AN ACT RELATIVE TO PROMOTING COMPREHENSIVE TRANSPARENCY IN THE PHARMACEUTICAL INDUSTRY

A. Drug Industry/PBM Transparency (Sections 17-29)

- CHIA develops list of up to 10 outpatient drugs that account for a significant share of state spending in prior year **and** increased WAC price by 25% or more in that prior year.
- Companies on list shall disclose reason for WAC increase as well as company level R&D for most recent year that final audited data are available.
- CHIA authorized to analyze trends in PBM formulary design, specialty product lists, aggregate information regarding rebates and discounts, amounts owed to pharmacies, additional information deemed reasonable and necessary by CHIA.
- No data subject to public records law
- CHIA can assess fees on drug industry and PBMs not to exceed \$2000 per entity

B. Industry Appearance at HPC Cost Trends Hearings (Sections 5-12, 14, 16)

- Requires drug companies (1 publicly held company; 1 generic drug company; 1 company in existence < 10 yrs) and 2 PBMs to appear at HPC cost trends hearing
- Testimony includes impact of rebates, discounts and other price concessions on net pricing
- HPC can assess fees on drug industry and PBMs not to exceed \$2000 per entity

C. Horizon Scanning for Pipeline Drugs (Section 15)

- Manufacturers provide early notice for review by HPC of submitted new drug or biologics license applications, abbreviated new drug applications for generic drugs, and all new biosimilar biologics license applications
- Submitted information includes primary disease being studied and indication; routes of administration being studied, clinical trial competitors, and estimated year of market entry or applicable FDA user fee action date at the manufacturer's discretion
- Manufacturers must report orphan, fast track, breakthrough, accelerated approval, or priority review for new molecular entity designations
- Data submissions due no later than 60 days after receipt of FDA user fee action date
- Submitted information is confidential and not subject to disclosure under the public records law

D. Clarifying HPC's Drug Pricing Review Authority (Section 13)

- Preserves substantially all of HPC's drug pricing review authority under GL c. 6D, Section 8A but limits HPC's transparency authority to certain categories of publicly available information.
- Requires HPC to consult outside experts if the drug referred by EOHHS treats a rare disease or is a first-in-class treatment.