

Summary of Positions on Select Drug Cost Control Proposals

Cost Control Policy	Comments
<i>Drug Industry Participation in HPC Annual Cost Trends Hearings</i>	<p>We support participation by drug manufacturers and PBMs at HPC’s annual cost trends hearings on the important issue of the impact of drug costs on overall healthcare spend in the state and its ability to meet the statutory benchmark. However, we are concerned to the extent that such involvement would unreasonably expose the industry, which unlike most Massachusetts payors and providers currently under HPC oversight are multinational corporations, to potentially arbitrary investigations of drug pricing strategies without protections against the disclosure of confidential and proprietary information. Many aspects of drug development and pricing information can be confidential and proprietary, and unrestricted disclosure requirements, through testimony or otherwise, risks damaging the competitive posture of the disclosing parties, which could hinder their efforts to develop and bring innovative medicines to patients in need. To address this risk, we support the measured approach that would govern industry participation in the HPC cost trends hearing process outlined in H 1178. This proposal contains reasonable protections for drug manufacturers around public testimony and disclosure of confidential and proprietary information, as well as protections against potentially arbitrary investigations.</p>
<i>Drug Price Transparency Authority</i>	<p>We favor targeted and measured price transparency requirements across all entities that impact overall health care cost growth, including payors, providers, PBMs and drug manufacturers. However, drug price transparency disclosure requirements on drug manufacturers should contain clear criteria and limitations in terms of when disclosure is required and what must to be produced. In particular, transparency requirements that grant the state unlimited discretion to compel disclosure from any drug manufacturer of an unlimited range of data without any protections against the disclosure of competitively sensitive, confidential or proprietary information raise significant concerns. As noted, many aspects of drug development and pricing information can be confidential and proprietary, and unrestricted disclosure requirements could have a chilling effect on the pace of development of critically needed therapies. With these principles in mind, we support the drug price transparency provision in H 1178 (Section 22) as applied to both drug manufacturers and PBMs, which appears modeled after recently enacted legislation in Connecticut (see Public Act 18-41). HPC described this legislation as a “robust price transparency law” in its recent Health Care Cost Trends Report (p.16).</p>
<i>HPC Authority to Impose Upper Payment Limit on Certain Drugs</i>	<p>We are concerned that the enactment of upper payment limits on the drug industry by HPC would be an unprecedented intervention in health care pricing that is at odds with how HPC has approached health cost control to date, and may impact patient access to new and innovative therapies. No other health care entity in the Commonwealth’s commercial market confronts reimbursement limits that may be imposed due to affordability concerns, since HPC does not currently regulate reimbursement of prices set by providers. Moreover, since upper payment limits restrict reimbursement levels for certain drug products, they effectively function as price controls on those products. There are significant legal issues raised by state price control policies, including conflicts with the objectives of federal patent law (which is to provide drug</p>

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	<p>patent holders with the economic value of exclusivity during the life of the patent). Given that manufacturers do not set prices on a state by state basis, proposals that restrict pricing in Massachusetts may also unconstitutionally impact a manufacturer’s national pricing strategies. In addition, it is difficult to understand the practical impact of such controls, particularly since they may also conflict with industry’s contractual arrangements with Massachusetts payors and PBMs, which could result in limited access to needed therapies for patients.</p>
<i>HPC Academic Detailing Programs</i>	<p>We support reasonable improvements to the academic detailing program established under current law, including transferring oversight of such programs from DPH to HPC. In particular, we support the academic detailing proposal appearing in Section 13 of H 1178.</p>
<i>Fee Assessments / Penalties on Drug Manufacturers related to New Oversight Responsibilities</i>	<p>New fees imposed on drug manufacturers to account for increased costs incurred by CHIA and HPC due to new oversight responsibilities on the industry should be commensurate with the scope and level of fees imposed on other entities subject to similar oversight by these entities. Fee setting procedures that are not transparent, or otherwise designed to ensure that fees are reasonably and directly related to actual costs incurred, will lead to excessive and unfair fee assessments. Similarly, penalties imposed on manufacturers relative to responses to data requests by CHIA or HPC should not exceed the level of penalties that are imposed on other similarly situated entities under existing law.</p>
<i>Early Notice for Pipeline Drugs</i>	<p>We support early notice for pipeline drugs that may have a significant impact on health care expenditures, with reasonable protections against disclosure of confidential, proprietary or competitively sensitive information. We would support such an early notice proposal appearing in H 1178 (lines 156-189).</p>
<i>Advance Notice of Drug Price Increases</i>	<p>Advance notice of drug price increase requirements can result in the disclosure of confidential, proprietary, and competitively sensitive information that risks damaging the competitive posture of the disclosing manufacturers, which could hinder their efforts to develop and bring innovative medicines to patients in need. It is also unclear how such policies have the effect of driving down drug prices or otherwise benefiting patients. Such advance notification and other disclosure requirements regarding prices could in fact have the opposite of the intended effect of reducing drug costs, and undermine the competitive market. Moreover, advance notification of wholesale acquisition cost (WAC) price increases creates financial incentives for secondary distributors to enter the pharmaceutical supply chain thus creating a “gray” market. As the medicines are sold from one secondary distributor to another, the possibility of counterfeit medicines augmenting the supply of legitimate medicines increases, thereby threatening patient safety.</p>