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December 13, 2019

David Seltz, Executive Director
Health Policy Commission
50 Milk Street, 8th Floor
Boston, Massachusetts 02143

By Electronic Mail

Re: Proposed Drug Pricing Review Regulations (958 CMR 12.00)

Dear Mr. Seltz:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to provide comments on the proposed regulations, 958 CMR 12.00, which implement M.G.L. c. 6D, § 8A and M.G.L. c. 118E, § 12A.

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

PhRMA members have long participated in the Medicaid Drug Rebate Program voluntarily, and PhRMA is supportive of the ability of states to directly negotiate Medicaid supplemental rebate agreements with manufacturers when such negotiations are fair and voluntary. PhRMA is also supportive of working with policymakers on issues of value and cost.

As you know, we are in a new era of medicine where breakthrough science is increasingly transforming patient care and enabling more effective treatment for life-threatening diseases as well as chronic conditions, which are the largest drivers of costs in our health care system. As policymakers consider reforms to control health care costs and improve affordability, it is vital to ensure that the reforms align with and support continued development of emerging, breakthrough medicines, many of which are being developed by biopharmaceutical research companies with operations in Massachusetts.

PhRMA supports the transparent use of rigorous, patient-centered evidence to support decision making. We understand the Health Policy Commission's (HPC's) desire for information about medicines to inform supplemental rebate negotiations. However, PhRMA has several significant concerns with the proposed regulations. Specifically:

- The proposed regulations require manufacturers to disclose trade secrets and other types of highly confidential and proprietary information, far exceeding anything contemplated by the authorizing legislation.

- The proposed regulations do not adequately protect information disclosed by manufacturers from being used for purposes other than what was intended.

- The information required under the proposed regulations is beyond what HPC reasonably needs to understand the value of drugs for purposes of informing Medicaid supplemental rebate negotiations or other related determinations.

- The proposed regulations create a significant risk of improper coercion, which is inconsistent with the objectives of the Medicaid Drug Rebate Program.

- HPC should disclose the methodology it uses to determine value and strengthen standards for using third-party analyses.

PhRMA and its member companies would like to work with HPC to craft an alternative approach to the proposed regulatory scheme, including the current Drug Pricing Review Standard Reporting Form, the process to identify a proposed value for a referred drug, and the process of "determination of unreasonable or excessive pricing." A new approach is needed to provided regulators with relevant, reliable data, consistent with the recommendations described below. Specifically, M.G.L. c. 6D, § 8A(b) clearly contemplates manufacturer input into the reporting process, which is not achieved by a posting of these proposed regulations, reporting form, and associated comment period. Seeking collaborative input from manufacturers could ensure that the information that HPC seeks exists and is useful. HPC should suspend this regulatory process until it meets the criteria of M.G.L. c. 6D, § 8A(b) to seek manufacturer input through an iterative process. We are deeply concerned that the proposed regulations (958 CMR 12.00) could disrupt innovation in the Massachusetts health care ecosystem by imposing unnecessary and irrelevant disclosure requirements that will not promote greater value for MassHealth.

I. Requiring Disclosure of Trade Secrets and Other Confidential and Proprietary Information Is an Overreach of Authority

In enacting M.G.L. c. 6D, § 8A, the legislature struck a balance that ensures that HPC can obtain necessary information to better understand the value of drugs for purposes of Medicaid supplemental rebate negotiation, while also balancing the ongoing need to promote innovation in the health care marketplace. This is why the legislature specifically required manufacturers only to furnish: (1) a schedule of wholesale acquisition cost (WAC) increases over the prior 5 years; (2) information on aggregate, company-level research and development (and other relevant capital expenditures) in the most recent final audited year; and (3) a written, narrative description of factors contributing to WAC changes. *See* M.G.L. c. 6D, § 8A(b).

In stark contrast, the information sought in the regulations and accompanying "Drug Pricing Review Standard Reporting Form" proposed by HPC far exceed the bounds of the statute, which contemplates HPC only requiring "relevant information" that is truly "necessary" for HPC to better understand the value of a drug. *See* M.G.L. c. 6D, § 8A(b). HPC has instead proposed a series of sweeping and vaguely worded requirements that mandate disclosure of significant amounts of trade secrets and other confidential and proprietary information and, as discussed at Section II, is unnecessary for HPC to complete its review. Although HPC may be able to identify reasonable information requirements beyond the three items specifically enumerated in statute, it can only require "objects similar in nature to those objects enumerated by the . . . specific [items] required under the statute."[1] It is thus fundamentally unreasonable and beyond HPC's authority to impose disclosure requirements that bear no resemblance to any of the classes of information enumerated in statute. At bottom, the disclosure requirements in the proposed regulations, and accompanying reporting form, are beyond the bounds of what the legislature intended—or what a reasonable interpretation of the statute permits.

For example, HPC proposes to require manufacturers produce a schedule of *payer-specific* drug prices net of rebates in Massachusetts, nationally and internationally. Such a requirement has the potential to compromise vast troves of highly sensitive and confidential proprietary information. All such information, whether domestic or international, is a closely protected trade secret—and *international* information is often subject to significant confidentiality requirements: Manufacturer agreements with sovereign entities like England, for example, include strict requirements of confidentiality. Further, manufacturers may not track this information in the format contemplated by the proposed regulations. In many cases, manufacturers may not even *possess* this information. Contracts are often executed nationally with pharmacy benefit managers (PBMs), and in most cases, the manufacturer would not know PBMs' contract terms with various in-state insurers.

II. *The Proposed Regulations Do Not Adequately Protect Information from Being Misused*

PhRMA also believes there should be clear standards limiting access to and use of information to ensure that confidential and proprietary information is only used in situations where it is necessary to HPC's review and/or the negotiation of supplemental Medicaid drug rebate agreements. To the extent that HPC (or the Executive Office of Health and Human Services) partners with third parties (e.g., round table members, working groups, etc.) to complete its work, there must also be controls in place to limit access to confidential and proprietary information and to prevent misuse of such information. HPC should limit individuals who can access and review data to a subset of state employees noting relevant departments in the final regulations; expressly limit the use of any manufacturer data only for uses necessary for the negotiation of Medicaid supplemental rebates; and include penalties for inappropriate use and

[1] *Cf. Circuit City Stores, Inc. v. Adams*, 532 U.S. 105, 114 (2001).

unauthorized disclosure of data that are equivalent to those penalties contemplated for manufacturer noncompliance.

Similarly, HPC proposes an open-ended requirement on manufacturers to provide "information to support the Referred Manufacturer's pricing of the Drug, including market analyses, examination of similar drugs, and other analyses." 958 CMR 12.04(3)(d). It is unclear what information HPC is specifically requiring or what constitutes a complete response. The vagueness of HPC's open-ended requirement does not give manufacturers sufficient guidance or notice as to the information subject to required disclosure, which is particularly concerning given that HPC may, in certain instances, impose penalties for submissions that HPC deems "incomplete." *See id.* 12.12(1)(b).

III. The Proposed Regulations Require Disclosure of Information that Is Unnecessary and Irrelevant to the Determination of Value

PhRMA understands and appreciates the desire of HPC to better understand the value of drugs, but HPC is improperly requiring disclosure of significant amounts of information that are not relevant to HPC's review. As mentioned in Section I above, HPC far exceeds the bounds of the statute, which contemplates HPC only requiring "relevant information" that is truly "necessary" for HPC to better understand the value of drug for the purpose of identifying a proposed supplemental rebate. S*ee* M.G.L. c. 6D, § 8A(b). We believe the requests for additional confidential and proprietary information that are dissimilar from what is laid out in the statute constitute an overreach, and much of the information, if it could even be calculated, is not needed to assess value.

For example, HPC demonstrates no need for payer-specific information to understand the value of a drug for Medicaid. Under Medicaid payment rules, the Medicaid rate will ***already*** be lower than commercial payment rates—meaning that it is unclear how such information could be used to inform HPC's analysis. These requirements should be removed.

Also, international pricing information is an inappropriate reference point for policy decisions. The prices set by other countries are influenced by a variety of country-specific factors such as populations, preferences, economic conditions, and cultural norms that may differ markedly from those in the U.S. What is more, using international pricing as a reference ignores the reality that, in many countries, governments are the primary (or only) payer of health care and force companies to accept prices or face restrictions on coverage. Some countries have discriminatory policies or even threaten to break patents on valuable new medicines to force artificially low prices. These regressive and sometimes illegal policies delay patient access to new medicines. Relying on international reference prices to assess value therefore implicitly relies on the harmful and even illegal practices used in other countries to set prices and ultimately harms market-based competition. This competition is needed to expand patient access, improve

affordability, and encourage investment in new treatments and cures.[2] In other words, apples-to-oranges comparisons of prices in countries operating under completely different health care regulatory schemes (and often with markedly lower rates of innovation) will simply result in skewed and inaccurate analyses of proposed value that ignore the myriad factors that influence differences in price and cost across nations.

Similarly, HPC should limit required disclosures of financial information to what is relevant and necessary. In many cases, information like product-level R&D costs; R&D funding sources; and manufacturing, production, and distributing expenditures (and budgets) are not relevant to an assessment of value. A superficial review of various budgetary and expenditure line items could be misleading and result in spurious assessments of value or cost.

In addition to problematic data requests discussed above, the following information requested in the proposed regulations in Section 12.04 is not relevant to a drug's value and may be difficult to calculate or obtain:

- Utilization information of the drug in Massachusetts and nationally;
- Financial information for the referred manufacturer, including but not limited to:
    - The Referred Manufacturer's research and development expenditures specific to the Drug;
    - Funding sources for the Referred Manufacturer's research and development expenditures for the Drug, the Referred Manufacturer's research and development expenditures for the Drug, including identification of any public funding received;
    - The Referred Manufacturer's acquisition cost, because an acquisition may often include other medicines, pipeline medicines, and leadership teams working in other research and business areas;
    - The Referred Manufacturer's marketing expenditures and marketing budget for the Drug and aggregate, company-level marketing expenditures and marketing budget;

Items on the Drug Pricing Review Standard Reporting Form that raise similar concerns include:

- Massachusetts and National Prices, by payer (see above)
- International Prices (see above)

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[2] Research shows that patients in the United States enjoy earlier and less restrictive access to new therapies relative to other countries—whereas access restrictions in many other countries have led to lower survival rates for many of the world's deadliest diseases. *See, e.g.*, IQVIA Institute, Global Oncology Trends 2017, Advances, Complexity and Cost (May 2017); *see also* Allemani C, Weir HK, et al., Global Surveillance of Cancer Survival 1995–2009: Analysis of Individual Data for 25,676,887 Patients from 279 Population-based Registries in 67 countries (CONCORD-2), Lancet (2015), *available at*https://www.ncbi.nlm.nih.gov/pubmed/25467588.

- Information to Support Drug Pricing, including market analyses, examination of similar drugs, and other analyses performed or commissioned by your organization (see above)
- Current and Projected Utilization
- Projected Utilization Supporting Information: utilization can be difficult to predict because population outcomes can differ from clinical trials and utilization may vary significantly with changes to an FDA-approved indication(s) or recognition in national drug compendia. Current and future utilization does not affect the value of a drug.
- Research and Development Expenditures, as indicated above, may not have been tracked as described on this form. For example, facility costs and R&D compensation may not be attributable to or associated with a single compound because many compounds can be under development at one facility and a researcher may be working on several compounds at any given time, some of which may fail before gaining FDA-approval.
- Acquisition Cost (see above)
- Manufacturing, Production, and Distribution Budget and Expenditures and Marketing, as indicated above, companies may not have tracked this information as described with regard to a Drug. Just as is common in other businesses employees, processes, and overhead may not be attributable to one project or drug.

In sum, PhRMA does not believe much of the information being requested is consistent with the clear statutory requirement that HPC-mandated information disclosures be limited exclusively to "relevant" information that is "necessary" to identify a proposed supplemental rebate or proposed value. M.G.L. c. 6D, § 8A(b). Further, stakeholders should have the opportunity to provide input on any proposed changes to a reporting form and should receive clear notice before changes become effective.

IV. The Proposed Regulations Are So Unreasonable that They Are Coercive, which Is Inconsistent with the Objectives of the Medicaid Drug Rebate Program

PhRMA notes that the legislature requires HPC to establish a "reasonable time" to disclose requested information. HPC has proposed a deadline of 30 days to disclose vast amounts of information requested under the proposed regulations, with extensions available only on a purely discretionary basis.

A 30-day time frame is unreasonable. Agencies must develop policies that are based on reasonable consideration of the relevant factors. We urge HPC to consider what is operationally reasonable for manufacturers to satisfy given the breadth of the agency's disclosure requirements. *See generally Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins.* 463 U.S. 29, 43 (1983) (under federal law, agencies must consider all important aspects of the problem under consideration); *see Anarpet Realty Corp. v. Licensing Bd. of Salem*, 85 Mass. App. Ct. 1109, 5 N.E.3d 3 (2014) (importing the same principle into Massachusetts state law).

PhRMA believes that the proposed regulations will have an improper coercive effect if finalized as proposed. Because HPC is requiring more information to be disclosed than is likely to be possible to gather and HPC effectively may have carte blanche to impose civil monetary penalties on manufacturers for failing to make a "timely" or "complete" submission, the regulations have the effect of forcing manufacturers to either agree to additional supplemental rebates in an effort to curtail the review process or potentially be subject to civil penalties. *Cf. id.* § 12.09. PhRMA does not believe that it is appropriate or consistent with basic principles of due process or the objectives of the federal Medicaid Drug Rebate Program for HPC to promulgate requirements that carry a significant risk of improper coercion. HPC should revisit both the scope of the information it is requiring to be disclosed, as well as the timelines for the required disclosure.

In addition, we strongly urge the state to consider whether a state plan amendment is needed given the coercive nature of the proposed regulations, which is in tension with the objectives of the Medicaid Drug Rebate Program.

V. HPC Must Disclose Its Methodology for Determining Value and Enhance Standards for Use of Third-Party Analyses

HPC should describe its methodology for determining value and allow stakeholder input and comment on the proposed methodology. The methodology should provide greater clarity on the types of data that will be considered and standards to ensure scientific and methodological rigor of that data. This is necessary to ensure accuracy in its desired calculations.

In the proposed regulation, HPC also contemplates using analyses from third parties. When soliciting information from third party organizations, it is imperative that such information meets certain standards for methodological rigor, patient-centeredness, and transparency. HPC should clearly note by name any third party that was consulted or whose materials were consulted and disclose the process through which the third party was chosen.

When consulting with third parties or relying upon third-party analyses, HPC should protect against common shortcomings of such analyses, including:

- Cost effectiveness analyses can involve subjective assumptions about the impact of a treatment on different health outcomes and combine them into a single metric. This model has been widely recognized as overlooking significant differences in individual patients. As a result, it has failed to take hold as a basis for decision-making in the U.S.
- Most traditional cost effectiveness assessments ignore outcomes and endpoints that matter to patients. The American Lung Association said in comments to one entity conducting cost effectiveness analyses that "areas important to patient quality of life, including symptom relief, are not considered in the analysis of drug cost effectiveness…[T]argeted therapies, have changed the way we fight and live with serious

diseases. These positive differences on the lives of those living with lung cancer are absent from adequate consideration."

- Cost effectiveness analyses can rely on discriminatory, flawed metrics of value, such as quality adjusted life years, that undervalue the lives of the disabled, elderly and chronically ill. These studies often ignore side effect profiles, ease of use, and whether a physician-administered medicine versus an at home treatment, all of which are valuable to patients but can be especially important in the Medicaid population.

The requirements in the proposed regulations should be enhanced to prevent potential unintended consequences. HPC should require that all third-party materials meet the below standards:

- *Materials developed by third parties should utilize open and transparent processes for developing value assessments and reports.*
    - Third parties providing value assessments should prioritize transparency in report development and disclose how their internal processes meet this goal. This includes, but is not limited to, transparency in the types of data used, economic models and assumptions made. It also includes advance notice of priorities for assessment and scoping documents for planned assessments; opportunity for technical input from organizations with expertise in the items or services being assessed, including manufacturers when relevant; and opportunity for public input on draft reports and public responses to comments received.
- *Materials developed by third parties should incorporate sound, high-quality evidence and expertise from stakeholders.*
    - Value assessments should incorporate a broad range of sound scientific evidence, which should be synthesized using rigorous methods.
    - Practicing physicians and patients bring essential expertise and perspective and should have a central role in the prioritization and development of value assessments to ensure they draw on physicians' clinical expertise, reflect patient values, and respect patient differences.
- *Materials developed by third parties should prioritize patient-focused outcomes.*
    - Value assessments should incorporate a wide range of outcomes that are important to patients and their families – this includes the impact on a patient's productivity, caregiver burden, and their quality of life.
    - Patient sub-populations, who often respond differently to medicines based on factors such as age, genetic variation, and comorbidities, should be considered appropriately in value assessments.

- *Materials developed by third parties should consider the broad range of health interventions.*
    - Consistent with the Patient-Centered Outcomes Research Institute's (PCORI) mandate for its work on comparative effectiveness, value assessments should evaluate the full spectrum of treatments, interventions, and settings of care (e.g., medicines, devices, diagnostics, and surgery), as well as the care management and delivery strategies that influence patient care.
- *Materials developed by third parties should include a full range of study designs and methods.*
    - Value assessments seek to meet the needs of a wide range of decision-makers and involve the evaluation of complex interventions using sophisticated and variable methods and assumptions. Decision-makers should have access to multiple value frameworks, along with other data sources, to support their decisions and ensure the availability of relevant, timely, and high-quality reports.

We would like to work with HPC, EOHHS, and other stakeholders including patients, health care providers, and caregivers to enhance the standards for the use of third-party analyses.

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Beyond the specific recommendations discussed above, PhRMA urges HPC broadly to re-consider its approach to regulations implementing M.G.L. c. 118E, § 12A. We believe a better way to develop the disclosure requirements is an ongoing dialogue between HPC and manufacturers. Such engagement would satisfy the statutory requirement that manufacturers be given meaningful input on the development of the Drug Pricing Review Standard Reporting Form. M.G.L. c. 6D, § 8A(b). Moreover, it would yield more targeted and useful information to HPC, while not exposing manufacturers to potentially improper coercion.

We thank you for your consideration of these comments on the proposed regulations. We look forward to continuing to work with HPC as it considers stakeholder comments and implements the new regulations. Please feel free to contact me if you have any questions regarding these comments at 202-835-3451 or by electronic mail at lwood@phrma.org.

Respectfully submitted,

Leslie Wood

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State Policy