SENATE DOCKET, NO. 1992 FILED ON: 2/18/2021

SENATE . . . . . No. 736

The Commonwealth of Massachusetts

PRESENTED BY:

Joseph A. Boncore

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act relative to promoting comprehensive transparency in the pharmaceutical industry.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Joseph A. Boncore	*First Suffolk and Middlesex*

SENATE DOCKET, NO. 1992 FILED ON: 2/18/2021

SENATE . . . . . No. 736

By Mr. Boncore, a petition (accompanied by bill, Senate, No. 736) of Joseph A. Boncore for legislation to promote comprehensive transparency in the pharmaceutical industry. Health Care Financing.

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Second General Court
(2021-2022)

An Act relative to promoting comprehensive transparency in the pharmaceutical industry.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. Section 1 of chapter 6D, as appearing in the 2016 Official Edition, is hereby amended by inserting after the definition of "Disproportionate share hospital" the following definition:-

"Early notice", advanced notification by a pharmaceutical manufacturing company of a new drug, device or other development coming to market.

SECTION 2. Said section 1 of said chapter 6D, as so appearing, is hereby further amended by inserting after the definition of "Performance penalty" the following 3 definitions:-

"Pharmaceutical manufacturing company", any entity engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drugs, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs;

provided however, that “pharmaceutical manufacturing company” shall not include a wholesale drug distributor licensed pursuant to section 36A of chapter 112 or a retail pharmacist registered pursuant to section 38 of said chapter 112.

“Pharmacy benefit manager”, any person, business or entity, however organized, that administers, either directly or through its subsidiaries, pharmacy benefit services for prescription drugs and devices on behalf of health benefit plan sponsors, including, but not limited to, self-insured employers, insurance companies and labor unions.

“Pharmacy benefit services” shall include, but not be limited to: formulary administration; drug benefit design; pharmacy network contracting; pharmacy claims processing; mail and specialty drug pharmacy services; and cost containment, clinical, safety, adherence programs for pharmacy services. For the purposes of the chapter, a health benefit plan that does not contract with a pharmacy benefit manager shall be a pharmacy benefit manager.

SECTION 3. Said section 1 of said chapter 6D, as so appearing, is hereby further amended by inserting after the definition of “Physician” the following definition:-

“Pipeline drugs”, which are defined as those drugs that contain a new molecular entity (“NME”) for which the sponsor has submitted a new drug application or biologics license application (“BLA”).

SECTION 4. Said section 1 of said chapter 6D, as so appearing, is hereby further amended by inserting after the definition of “State Institution” the following definition:-

“Sponsor”, any person who submits an NDA (including a 505(b)(2) application), ANDA, BLA or an amendment or supplement to an NDA, ANDA, or BLA to obtain FDA approval of a

new drug or FDA licensure of a biological product application and any person who owns an approved NDA (including a 505(b)(2) application), ANDA, or BLA.

SECTION 5. Section 4 of said chapter 6D, as so appearing, is hereby amended by striking out, in lines 6 and 7, the word “manufacturers” and inserting in place thereof the following words:- manufacturing companies, pharmacy benefit managers.

SECTION 6. Section 6 of said chapter 6D, as so appearing, is hereby amended by adding the following paragraph:-

To the extent that the analysis of spending trends with respect to pharmaceutical or biopharmaceutical products increases the expenses of the commission, such expenses shall be fully assessed to pharmaceutical manufacturing companies and pharmacy benefit managers. Any fees assessed by the commission under this section, when paid by every pharmaceutical manufacturing company and pharmacy benefit manager, shall not exceed the commission’s reasonable regulatory costs to analyze such spending trends, and in no event shall exceed $2000 annually as assessed against each such pharmaceutical manufacturing company and pharmacy benefit manager. A pharmacy benefit manager that is a surcharge payor subject to the preceding paragraph and administers its own prescription drug, prescription device or pharmacist services or prescription drug and device and pharmacist services portion shall not be subject to additional assessment under this paragraph.

SECTION 7. Section 8 of said chapter 6D, as so appearing, is hereby amended by inserting after the word “organization” , in lines 6 and 7, the following words:- , pharmacy benefit manager, pharmaceutical manufacturing company.

SECTION 8. Said section 8 of said chapter 6D, as so appearing, is hereby further amended by inserting after the word “organizations”, in line 14, the following words:- , pharmacy benefit managers, pharmaceutical manufacturing companies.

SECTION 9. Said section 8 of said chapter 6D, as so appearing, is hereby further amended by striking out, in lines 32 and 33 , the words “and (xi) any witness identified by the attorney general or the center” and inserting in place thereof the following words:- (xi) 2 pharmacy benefit managers; (xii) 3 pharmaceutical manufacturing companies, 1 of which shall be representative of a publicly traded company that manufactures specialty drugs, 1 of which shall be representative of and doing business in generic drug manufacturing and 1 of which shall have been in existence for fewer than 10 years; and (xiii) any witness identified by the attorney general or the center.

SECTION 10. Said section 8 of said chapter 6D, as so appearing, is hereby further amended by striking out, in line 48, the first time it appears, the word “and”.

SECTION 11. Said section 8 of said chapter 6D, as so appearing, is hereby further amended by inserting after the word “commission”, in line 59, the first time it appears, the following words:- ; and (iii) in the case of pharmacy benefit managers and pharmaceutical manufacturing companies, testimony that is suitable for public release and that is not likely to compromise the financial, competitive or proprietary nature of any information and data concerning factors underlying prescription drug costs and price increases; the impact of aggregate manufacturer rebates, discounts and other price concessions on net pricing; and any other matters as determined by the commission. No pharmaceutical manufacturing company

identified as a witness under this section, or any testimony by any such company, shall be subject to the provisions of section 17 of chapter 12C.

SECTION 12. Subsection (g) of said section 8 of said chapter 6D, as so appearing, is hereby amended by striking out the second sentence and inserting in place thereof the following sentence:-

The report shall be based on the commission's analysis of information provided at the hearings by witnesses, providers, provider organizations, insurers, pharmaceutical manufacturing companies and pharmacy benefit managers, registration data collected pursuant to section 11, data collected or analyzed by the center pursuant to sections 8, 9, 10,10A and 10B of chapter 12C and any other available information that the commission considers necessary to fulfill its duties in this section, as defined in regulations promulgated by the commission.

SECTION 13. Section 8A of chapter 6D is hereby deleted and replaced in its entirety with the following new section:-

Section 8A. (a) As used in this section, the following words shall, unless the context clearly requires otherwise, have the following meaning:

“Manufacturer”, an entity that manufactures a pharmaceutical drug covered by MassHealth.

“Rare disease”, any disease that affects fewer than 200,000 people in the United States, which has status as an "orphan" disease for research purposes, or is known to be substantially under diagnosed and unrecognized as a result of lack of adequate diagnostic and research information.

"Wholesale acquisition cost", the cost of a prescription drug as defined in 42 U.S.C. §1395w-3a(c)(6)(B).

(b) The commission may require a manufacturer specified in subsection (c) to disclose to the commission within a reasonable time the following information relating to the manufacturer's pricing of that drug, as applicable, on a standard reporting form developed by the commission with the input of the manufacturers:

(1) A schedule of the drug's wholesale acquisition cost increases over the previous five calendar years if the drug was manufactured by the company;

(2) A written description suitable for public release of the specific financial and nonfinancial factors used to make the decision to increase the wholesale acquisition cost of the drug over the previous five calendar years including, but not limited to, an explanation of how these factors explain the increase in the wholesale acquisition cost;

(3) The manufacturer's aggregate, company-level research and development and other relevant capital expenditures, including facility construction, for the most recent year for which final audited data are available;

(4) If the drug was acquired by the manufacturer within the previous 5 years, all of the following information:

(A) The wholesale acquisition cost at the time of acquisition and in the calendar year prior to acquisition.

(B) The name of the company from which the drug was acquired, the date acquired, and the purchase price.

(C) The year the drug was introduced to market and the wholesale acquisition cost at the time of introduction.

(5) The patent expiration date of the drug if it is under patent.

(6) If the drug is a multiple source drug, an innovator multiple source drug, a noninnovator multiple source drug, or a single source drug, as defined in subparagraph (A) of paragraph (7) of subdivision (k) of Section 1396r–8 of Title 42 of the United States Code.

(7) A description of the change or improvement in the drug, if any, that necessitates the price increase.

(8) Volume of sales of the drug in the US for the previous year.

(9) If the drug was approved during the preceding 5 calendar years, and the wholesale acquisition cost of the drug exceeded a current average annual gross cost per utilizer for public and private health care payers in Massachusetts of greater than $50,000 during the immediately preceding calendar year, all of the following information:

(A) A description of the marketing and pricing plans used in the launch of the drug in the US and internationally.

(B) The estimated volume of patients that are prescribed the drug.

(C) If the drug was granted breakthrough therapy designation or priority review by the Federal Food and Drug Administration prior to final approval.

(D) The date and price of acquisition if the drug was not developed by the manufacturer.

(10) Any other information that the manufacturer wishes to provide to the commission.

The manufacturer may limit the information reported pursuant to this section to that which is otherwise in the public domain or publicly available. Based on the records furnished, as well as any records relied upon by the executive office of health and human services in connection with the procedures under section 12A of chapter 118E and any other publicly available records, the commission may identify a proposed supplemental rebate, in consultation with the executive office, for a prescribed drug specified in subsection (c); provided that the proposed supplemental rebate may be based on a proposed value of the drug; and provided further, that the commission shall consider any proposed supplemental rebate framework or other information provided to the commission under subsection (g) of section 12A of chapter 118E.

(c) A manufacturer of the following prescribed drugs shall comply with the requirements set forth in this section: a drug for which the executive office was unable to successfully conclude supplemental rebate negotiations with the manufacturer under subsections (b) and (c) of section 12A of chapter 118E, and for which the commission has received notice from the executive office under subsection (g) of said section 12A of said chapter 118E.

(d) Records disclosed by a manufacturer under this section shall: (i) be accompanied by an attestation that all information provided is true and correct; (ii) not be public records under section 7 of chapter 4 or chapter 66; and (iii) remain confidential; provided, however, that the commission may produce reports summarizing any findings; provided that any such report shall not be in a form that identifies specific prices charged for or rebate amounts associated with drugs by a manufacturer, or in a manner that is likely to compromise the financial, competitive or proprietary nature of any information.

(e) If, after review of any records furnished to the commission under subsection (b), the commission determines that the manufacturer's pricing of the drug is potentially unreasonable or excessive in relation to the commission's proposed value under subsection (b), the commission shall, with 30 days' advance notice to the manufacturer, request that the manufacturer provide, at the manufacturer's discretion, further information related to the pricing of the prescribed drug and the manufacturer's justification for the pricing. In addition to the manufacturer, the commission may identify other relevant parties including but not limited to patients, providers, provider organizations, external experts and payers who may provide information to the commission.

(f) Any information, analyses or reports regarding a particular drug reviewed or used in identifying the supplemental rebate or assessing the proposed value of the drug shall be provided to the manufacturer for review and input. The commission shall consider any clarifications or data provided by the manufacturer with respect to its drug. The commission may not base its determination on the supplemental rebate, the proposed value or the reasonableness of the drug pricing, solely on the analysis or research of an outside third party.

(g) If the commission relies upon a third party to provide cost-effectiveness analysis or research related to the proposed value, such analysis or research shall also provide, but not be limited in scope to, (i) a description of the methodologies and models used in its analysis; (ii) any assumptions and potential limitations of research findings in the context of the results; and (iii) outcomes for affected subpopulations that utilize the drug.

(h) (1) In connection with the identification of a proposed supplemental rebate or a proposed value for a drug that is approved for the treatment of a rare disease or that is otherwise

identified as first-in-class, including without limitation any consultation with a third party to provide cost effectiveness analysis or research related to the proposed value for such a drug, the commission shall ensure that opportunities exist, at a time the commission determines appropriate, for consultations with stakeholders on the following topics:

(A) the disease treated by such drug;

(B) the severity of disease treated by such drug;

(C) the unmet medical need associated with the disease treated by such drug;

(D) the impact of particular coverage, cost-sharing, tiering, utilization management, prior authorization, medication therapy management, or other Medicaid policies on access to such drug;

(E) an assessment of the benefits and risks of such drug for patients;

(F) the impact of particular coverage, cost-sharing, tiering, utilization management, prior authorization, medication therapy management, or other policies on patients' adherence to the treatment regimen prescribed or otherwise recommended by their physicians;

(G) Whether beneficiaries who need treatment from or a consultation with a rare disease specialist or a specialist in the disease being treated by the first-in-class drug have adequate access and, if not, what factors are causing the limited access; and

(H) the demographics and the clinical description of patient populations.

(2) The commission shall develop and maintain a list of external experts who, because of their special expertise, are qualified to provide advice on rare disease issues and topics described

in subsection (h)(1) of this section. The commission may, when appropriate to address a specific question, consult such external experts when making a determination on a proposed supplemental rebate or proposed value of a drug approved for the treatment of a rare disease or that is designated first-in-class, when consultation is necessary because the commission lacks the specific scientific, medical, or technical expertise necessary for the performance of its responsibilities and the necessary expertise can be provided by the external experts.

(3) For purposes of this section, external experts are individuals who possess scientific or medical training that the commission lacks with respect to one or more rare diseases or the disease treated by the first-in-class therapy under review.

(i) Not later than 60 days after receiving information from the manufacturer, as required under subsection (b) or (e), the commission shall issue a determination on whether the manufacturer's pricing of a drug subject to the supplemental rebate negotiation that resulted in the provision of notice under section 12A of chapter 118E is unreasonable or excessive in relation to the commission's proposed value of the drug.

(j) If the manufacturer fails to timely comply with the commission's request for records under subsections (b) or otherwise knowingly obstructs the commission's ability to issue its determination under subsection (i), including, but not limited to, providing incomplete, false or misleading information, the commission may impose appropriate sanctions against the manufacturer, including reasonable monetary penalties not to exceed $500,000, in each instance. The commission shall seek to promote compliance with this section and shall only impose a civil penalty on the manufacturer as a last resort.

(k) The commission shall adopt any written policies, procedures or regulations the commission determines necessary to implement this section.

SECTION 14. Section 9 of said chapter 6D, as so appearing, is hereby amended by inserting after the word “organization”, in line 72, the following words:- , pharmacy benefit manager, pharmaceutical manufacturing company.

SECTION 15. Said chapter 6D is hereby further amended by adding the following section:-

Section 20. (a) In the course of its duties the commission may contract with a third-party entity, such as an accounting firm, to conduct an annual study of pharmaceutical or biopharmaceutical companies with pipeline drugs, generic drugs or biosimilar drugs that may have a significant impact on state health care expenditures.

(b) For purposes of this section, early notice as described in subsections (c) and (d) shall be provided in the timeframes set forth in subsection (e) for the following:

(1) Pipeline drugs, which are defined as those drugs that contain a new molecular entity (“NME”) for which the sponsor has submitted a new drug application or biologics license application (“BLA”);

(2) All abbreviated new drug applications for generic drugs; and

(3) All biosimilar biologics license applications,

(c) In connection with the annual study, if requested, the applicant for a pipeline brand, biosimilar or generic drug shall provide notice to the contracted third-party entity with a brief

description of the following for each drug, using data fields consistent with those employed by the United States National Institutes of Health in clinicaltrials.gov, if applicable:

(1) The primary disease, health condition or therapeutic area being studied and the indication;

(2) The routes of administration being studied;

(3) Clinical trial comparators, if applicable; and

(4) Estimated year of market entry or applicable FDA user fee action date, per the discretion of the manufacturer.

(d) As part of such submission, manufacturers shall also report the receipt of any of the following designations from the FDA for each pipeline drug:

(1) Orphan Drug;

(2) Fast Track;

(3) Breakthrough Therapy;

(4) Accelerated Approval; or

(5) Priority Review for New Molecular Entities (“NMEs”).

(e) The data submissions required by this section shall be submitted to the contracted third-party entity no later than 60 days after receipt of the FDA user fee action date

(1) Notwithstanding the foregoing, for drugs in development that receive any of the FDA designations listed in subsection (d) for NMEs, such submissions shall be provided as soon as practical upon receipt of the relevant designation.

(f) Notwithstanding any provision of law to the contrary, information provided to the contacted third-party entity or to the Secretary pursuant to this section, any analysis of such information, and any resulting study or studies shall be considered to be a trade secret and confidential commercial information, and shall not be a public record pursuant to clause Twenty-sixth of section 7 of chapter 4 or chapter 66, and shall not be subject to public inspection, and shall not be released in a manner that would allow for the identification of an individual drug, therapeutic class of drugs, or manufacturer, or in a manner that is likely to compromise the financial, competitive, or proprietary nature of the information. Information disclosed pursuant to this section and any analyses of such information shall be used only by the contracted third-party entity or by the Secretary, and shall be used only for development of the study described in (a).

SECTION 16. Section 11N of chapter 12 of the General Laws, as so appearing, is hereby amended by striking out subsection (a) and inserting in place thereof the following subsection:-

(a) The attorney general shall monitor trends in the health care market including, but not limited to, trends in provider organization size and composition, consolidation in the provider market, payer contracting trends, patient access and quality issues in the health care market and prescription drug cost and price trends. The attorney general may obtain the following information from a private health care payer, public health care payer, pharmacy benefit manager, provider or provider organization, as any of those terms may be defined in section 1 of

chapter 6D: (i) any information that is required to be submitted pursuant to sections 8, 9, 10 and 10B of chapter 12C; (ii) filings, applications and supporting documentation related to any cost and market impact review pursuant to section 13 of said chapter 6D; (iii) filings, applications and supporting documentation related to a determination of need application filed pursuant to section 25C of chapter 111; and (iv) filings, applications and supporting documentation submitted to the federal Centers for Medicare and Medicaid Services or the Office of the Inspector General for any demonstration project. Pursuant to section 8 of said chapter 6D and section 17 of said chapter 12C, and subject to the limitations in said sections, the attorney general may require that any provider, provider organization, pharmacy benefit manager, private health care payer or public health care payer produce documents, answer interrogatories and provide testimony under oath related to health care costs and cost trends, the factors that contribute to cost growth within the commonwealth's health care system and the relationship between provider costs and payer premium rates.

SECTION 17. Section 1 of chapter 12C of the General Laws, as so appearing, is hereby amended by inserting after the definition of “Patient-centered medical home” the following 3 definitions:-

“Pharmaceutical manufacturing company”, any entity engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drugs, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs; provided however, that “pharmaceutical manufacturing company” shall not include a wholesale

drug distributor licensed pursuant to section 36A of chapter 112 or a retail pharmacist registered pursuant to section 38 of said chapter 112.

"Pharmacy benefit manager", any person, business, or entity, however organized, that administers, either directly or through its subsidiaries, pharmacy benefit services for prescription drugs and devices on behalf of health benefit plan sponsors, including, but not limited to, self-insured employers, insurance companies and labor unions;

"Pharmacy benefit services" shall include, but not be limited to, formulary administration; drug benefit design; pharmacy network contracting; pharmacy claims processing; mail and specialty drug pharmacy services; and cost containment, clinical, safety, and adherence programs for pharmacy services. For the purposes of this section, a health benefit plan that does not contract with a pharmacy benefit manager shall be a pharmacy benefit manager, unless specifically exempted.

SECTION 18. Said section 1 of said chapter said 12C, as so appearing, is hereby further amended by adding the following definition:-

"Wholesale acquisition cost", the cost of a prescription drug as defined in 42 U.S.C. §1395w-3a(c)(6)(B).

SECTION 19. Section 3 of said chapter 12C, as so appearing, is hereby amended by inserting after the word "organizations", in lines 13 and 14, the following words:- , pharmaceutical manufacturing companies, pharmacy benefit managers.

SECTION 20. Said section 3 of said chapter 12C, as so appearing, is hereby further amended by striking out, in line 24, the words "and payer" and inserting in place thereof the

following words:- , payer, pharmaceutical manufacturing company and pharmacy benefit manager.

SECTION 21. Section 5 of said chapter 12C, as so appearing, is hereby amended by inserting after the word “organizations”, in line 11, the following words:- , pharmaceutical manufacturing companies, pharmacy benefit managers.

SECTION 22. Said section 5 of said chapter 12C, as so appearing, is hereby further amended by inserting after the word “providers”, in line 15, the following words:- , affected pharmaceutical manufacturing companies, affected pharmacy benefit managers.

SECTION 23. Section 7 of said chapter 12C, as so appearing, is hereby further amended by adding the following paragraph:-

To the extent that the analysis and reporting activities pursuant to sections 10A or 10B increases the expenses of the center, the estimated increase in the center’s expenses shall be fully assessed to pharmaceutical manufacturing companies and pharmacy benefit managers. Any fees assessed by the center under this section, when paid by every pharmaceutical manufacturing company and pharmacy benefit manager, shall not exceed the center’s actual and reasonably regulatory costs to implement and enforce sections 10A or 10B, and in no event shall exceed $2000 annually as assessed against each such pharmaceutical manufacturing company and pharmacy benefit manager.

SECTION 24. Said chapter 12C is hereby further amended by inserting after section 10 the following 2 sections:-

Section 10A. (a) On or before March 1, 2024, and annually thereafter, the center shall prepare a list of not more than ten outpatient prescription drugs that the center determines account for a significant share of state health care spending, considering the net cost of such drugs in the immediately preceding calendar year. The list shall include outpatient prescription drugs from different therapeutic classes and no more than three generic outpatient prescription drugs. The center shall not list any outpatient prescription drug pursuant to this subsection unless the wholesale acquisition cost of the prescription drug, less all rebates paid to the commonwealth for such drug during the immediately preceding calendar year, increased by not less than 25 per cent during the immediately preceding calendar year.

(b) The pharmaceutical manufacturing company that manufacturers a prescription drug included on a list prepared by the center pursuant to subsection (a) shall provide to the center the following:

(i) a written, narrative description, suitable for public release, of factors that caused the increase in the wholesale acquisition cost of the listed prescription drug; and

(ii) aggregate, company-level research and development costs and such other capital expenditures that the center deems relevant for the most recent year for which final audited data is available.

(c) The quality and types of information and data that a pharmaceutical manufacturing company submits to the center pursuant to this section shall be consistent with the quality and types of information and data that the pharmaceutical manufacturing company includes in: (i) such pharmaceutical manufacturing company’s annual consolidated report on Securities and Exchange Commission Form 10-K or (ii) any other public disclosure.

(d) The center shall consult with pharmaceutical manufacturing companies to establish a single, standardized form for reporting information and data pursuant to this section. The form shall minimize the administrative burden and cost imposed on the center and pharmaceutical manufacturing companies.

(e) The center shall compile an annual report based on the information that the center receives pursuant to subsection (b). The center shall post such report and the information described in this subsection on the center's website on or before October 1 of each year.

(f) Except as otherwise provided in this section, information and data submitted to the center pursuant to this section shall not be a public record and shall be exempt from disclosure pursuant to clause Twenty-sixth of section 7 of chapter 4 or section 10 of chapter 66. No such information and data shall be disclosed in a manner that may compromise the financial, competitive or proprietary nature of such information and data, or that would have enable a third party to identify an individual drug, therapeutic class of drugs or pharmaceutical manufacturing company the prices charged for any particular drug or therapeutic class of drugs, or the value of any rebate or discount provided for any particular drug or class of drugs.

Section 10B. The center shall promulgate regulations necessary to ensure the uniform analysis of information regarding pharmacy benefit managers that enables the center to analyze: (1) year-over-year wholesale acquisition cost changes; (2) year-over-year trends in formulary, maximum allowable costs list and cost-sharing design, including the establishment and management of specialty product lists; (3) aggregate information regarding discounts, utilizations limits, rebates, manufacturer administrative fees and other financial incentives or concessions related to pharmaceutical products or formulary programs; (4) information regarding

the aggregate amount of payments made to pharmacies owned or controlled by the pharmacy benefit managers and the aggregate amount of payments made to pharmacies that are not owned or controlled by the pharmacy benefit managers; and (5) additional information deemed reasonable and necessary by the center as set forth in the center's regulations.

SECTION 25. Section 11 of said chapter 12C, as so appearing, is hereby amended by striking out the first sentence and inserting in place thereof the following sentence:-

The center shall ensure the timely reporting of information required pursuant to sections 8, 9, 10, 10A, and 10B.

SECTION 26. Said section 11 of said chapter 12C, as so appearing, is hereby further amended by striking out, in line 11, the figure "$1,000" and inserting in place thereof the following figure:- $5,000.

SECTION 27. Said section 11 of said chapter 12C, as so appearing, is hereby further amended by striking out, in line 16, the figure "$50,000" and inserting in place thereof the following figure:- $200,000.

SECTION 28. Section 12 of said chapter 12C, as so appearing, is hereby amended by striking out, in line 2, the words "9, and 10" and inserting in place thereof the following words:- 9, 10, 10A and 10B.

SECTION 29. Subsection (a) of section 16 of said chapter 12C, as so appearing, is hereby amended by striking out the first sentence and inserting in place thereof the following sentence:- The center shall publish an annual report based on the information submitted pursuant to sections 8, 9, 10, 10A and 10B concerning health care provider, provider organization, pharmaceutical

manufacturing company, pharmacy benefit manager and private and public health care payer costs and cost and price trends, pursuant to section 13 of chapter 6D relative to market impact reviews and pursuant to section 15 relative to quality data.