

SB539 Reporting Timelines

Report Due Dates	MISC Due Dates	Section	Description	Responsible Entity	Frequency
February 01	Initial List posted November 1, 2017; subsequent years Feb. 1, 2019.	3.6	<p>List of Essential Drugs for Treating Diabetes and Asthma</p> <ul style="list-style-type: none"> -Department must assemble list and wholesale acquisition cost of drugs essential to treating diabetes and asthma. The list must include all insulins and biguanides. -Department must designate which of the above drugs has been subject to a price increase of a percentage equal to or greater than the CPI-M from the previous year or Twice the CPI-M in the preceding two years. 	DHHS	Annually
February 01		4.9	<p>Non-Profit Reporting</p> <ul style="list-style-type: none"> -A non-profit that advocates on behalf of patients or funds medical research and has received payment, donation, or subsidy or anything else of value from a manufacturer, third party, or PBM, or trade or advocacy group for manufacturers, third parties or PBM's must: <ul style="list-style-type: none"> -compile a report which includes the amount of each contribution, the entity that provided the payment, donation, or subsidy, and the percentage of the total gross income of the organization that was attributable to payments, donations, subsidies or other contributions from each manufacturer, third party, PBM, or group. -report must be posted on their website or if they don't have a website they must provide the report to DHHS to post on the DHHS website. 	Non-Profits	Annually
March 01		4.6(3)	<p>Pharmaceutical Sales Representatives Reporting</p> <p>Sales representatives included on the list shall report for the immediately preceding calendar year: a list of providers of health care to who they provided any type of compensation greater than \$10, total compensation with a value that exceeds \$100 in aggregate; the name and manufacturer of each drug for which they provided a free sample.</p>	Pharmaceutical Sales Representatives	Annually
June 01		4.6(5)	<p>Annual Report on Pharmaceutical Sales Representatives</p> <ul style="list-style-type: none"> - DHHS will analyze the data and prepare a report on the activities of pharmaceutical sales representatives in the state. - Any information must be reported in aggregate. -DHHS will post the report on their website and submit a copy to the Governor and the Director of LCB for transmittal to the Legislative Committee on Health Care and, in even numbered years, the next regular session of the legislature. 	DHHS	Annually
April 01	July 1 For 2018, and subsequent years April 1.	3.8	<p>Manufacturer Reporting</p> <p>For all drugs included on the DHHS list the manufacturer must report in a format prescribed by the Department the:</p> <ul style="list-style-type: none"> -costs of producing the drug; -the total administrative expenditures (including marketing and advertising costs); -the profit earned and percentage of total profit attributable to the drug; -total amount of financial assistance provided through patient assistance; -cost associated with coupons; -the wholesale acquisition cost; - history of any increase over the 5 years including percentage increase, date of increase, and explanation; -aggregate amount of all rebates provided to PBM's; -any additional information prescribed by regulation by DHHS. 	Manufacturers	Annually

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April 01	July 1, 2018; subsequent years due April 1.	4	Manufacturer Reporting on Price Increases For all drugs included on the DHHS list where there was a price increase, the manufacturer must report to the Department: -a list of each factor that contributed to the increase; -the percentage of total increase attributable to each factor; -an explanation of the role of each factor in the increase; -any other information prescribed by DHHS in regulation.	Manufacturers	Annually
April 01	July 1, 2018; subsequent years due April 1	4.2	PBM Reporting -the amount of rebates negotiated for the drugs included on the list; -the amount of the rebate retained by the PBM; -the total amount of all rebates that were negotiated for: recipients of Medicare, Medicaid, or third parties that are governmental entities, or third parties that are non- governmental. -This does not apply to ERISA plans.	PBMs	Annually
October 01		4.6	Pharmaceutical Sales Representatives -Manufacturers will submit a list of each pharmaceutical sales representative that markets prescription drugs on behalf of the manufacturer to providers of health care and update the list annually. -DHHS shall provide electronic access to the most recent list upon request. -Anyone not included on the list shall not market prescription drugs on behalf of a manufacturer.	Manufacturers	Annually
October 01		6	Internet Posting of Information DHHS must post the information received from non-profits, pharmacies, the list of essential drugs, the wholesale acquisition cost, and reports as required by the bill on their website.	DHHS	Annually
June 01	September 30, 2018; subsequent years due June 1	4.3	Annual Report on Drug Prices DHHS will analyze the information submitted and prepare a report on the price of the drugs that appear on the list, the reasons for any increases in those prices, and the effect of those prices on overall spending on prescription drugs.	DHHS	Annually
July 01	Biennially - each odd numbered year	7.5	DHHS Funding -DHHS shall determine if there is sufficient funding to carry out the provisions of this bill and may suspend any component for which there is not sufficient funding. -The Department may apply for and accept any available grants, bequests, devises, donations, or gifts from any public or private source.	DHHS	Biennially each odd numbered year
October 1		8	Financial Penalty -manufacturers, PBMs, or non-profits that fails to provide the information to the department may be fined up to \$5,000 per day. -a representative who fails to provide the required information may be fined up to \$500 per day. -funding may be used by DHHS to establish and carry out programs to provide diabetes education and to prevent diabetes.	TBD	Ongoing

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January 1, 2018		19	<p>PBM Fiduciary Responsibility</p> <p>A pharmacy benefit manager has a fiduciary duty to a third party with which the pharmacy benefit manager has entered into a contract to manage the pharmacy benefits plan of the third party and shall notify the third party in writing of any activity, policy or practice of the pharmacy benefit manager that presents a conflict of interest that interferes with the ability of the pharmacy benefit manager to discharge that fiduciary duty.</p>	TBD	Ongoing
January 01		20	<p>PBM Gag Rule</p> <p>A PBM shall not:</p> <ul style="list-style-type: none"> -prohibit a pharmacist or pharmacy from providing information to a covered person concerning the amount of any copayment or coinsurance or inform them of a less expensive drug; -penalize the pharmacist or pharmacy for providing information or selling a less expensive alternative; -prohibit a pharmacy from offering or providing delivery services directly to a covered person; -charge a copayment or coinsurance that is greater than the amount paid to a pharmacy in their network. 	TBD	Ongoing