Out Of Order

NORTH CAROLINA GENERAL ASSEMBLY
AMENDMENT
House Bill 206

AMENDMENT NO. A1
(to be filled in by
Principal Clerk)

H206-ALR-8 [v.3]

Amends Title [NO]
First Edition

Date ,2017

Representative Collins

moves to amend the bill on page 2, lines 4-5, by inserting the following between the lines:

"(d) As used in this section, "manufacturer" has the same meaning as in 42 U.S.C. sec. 1396r-8(k)(5) and "wholesale acquisition cost" has the same meaning as in 42 U.S.C. 1395w-3a(c)(6)(B).

(e) A manufacturer of anti-cancer medication is subject to reporting for any anti-cancer medication in its product portfolio that experiences a five percent (5%) or more price increase from the previous calendar year. A price increase shall be determined by the difference in the wholesale acquisition cost of the anti-cancer medication as of December 31 in the current calendar year and the wholesale acquisition cost as of December 31 in the previous calendar year. A manufacturer of anti-cancer medication is also subject to reporting under this subsection (c) for any anti-cancer mediation in its product portfolio that experiences a five percent (5%) or more price increase from the previous calendar year or the difference in the average wholesale price of the anti-cancer medication as of December 31 in the current calendar year and the average wholesale price of December 31 in the previous calendar year.

(f) A manufacturer subject to reporting under subsection (d) of this shall report the following information about the anti-cancer medication to the department no later than March 1 of the following calendar year:

(1) The current wholesale acquisition cost of the anti-cancer medication, including a five-year history of wholesale acquisition cost price increases as a percentage and including the month each increase took effect;

(2) The current average wholesale price of the anti-cancer medication, including a five-year history of average wholesale price increases as a percentage and including the month each increase took effect;

(3) After-tax research and development costs of the drug, listing separately the total costs paid by any entity other than the manufacturer or predecessor for research and development, including any amount from federal, state, or other governmental programs or any form of subsidies, grants, or other support;

(4) The total costs of promotion of the anti-cancer medication, including marketing and advertising costs, apportioned by the costs of marketing activities that are directed to consumers and the costs of marketing activities that are directed to prescribers;

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(5) Names and addresses of North Carolina physicians who speak on behalf, compensated or not compensated, of a pharmaceutical company, or any of its drugs or products. Participation in a clinical trial is not subject to this reporting requirements.

(6) Gross sales of the anti-cancer medication for the most recent calendar year as represented in total dollars;

(7) Net income of the anti-cancer medication for the most recent calendar year as represented in total dollars; and

(8) The total amount of financial assistance the manufacturer has provided to North Carolina consumers through patient prescription assistance programs if such programs are available.

Upon receipt, the department shall post the reports submitted pursuant to subsection (c) on the department's website. The commissioner shall annually update any all committees relating to commerce, health or insurance committees of the Senate and the House as to the number of price increases submitted pursuant to this subsection (c), as well as the range of the percentage increases.

In its sole discretion, the department may remove any additional information provided by the manufacturer in the manufacturer's report that is not specifically subject to reporting requirements under section prior to publishing the report on the department's website. Additionally, the department may summarize the information more accessible to North Carolina consumers.

(g) Failure to comply with the reporting requirements of this section may subject a manufacturer to a monetary penalty of not more than one thousand ($1000) for each violation, but not to exceed an aggregate penalty of one hundred thousand dollars ($100,000), unless the insurer, person, or entity knowingly violates a statute, rule or order, in which case the penalty shall not be more than twenty-five thousand dollars ($25,000) for each violation, not to exceed an aggregate penalty of two hundred fifty thousand dollars ($250,000). This subsection does not apply where a statute or rule specifically provides for other civil penalties for the violation. For purposes of this subsection, each day of continued violation shall constitute a separate violation.'";

and further amends the bill by changing "**SECTION 2.**" to "**SECTION 3.**".

SIGNED _____
Amendment Sponsor

SIGNED _____
Committee Chair if Senate Committee Amendment

ADOPTED _____ FAILED _____ TABLED _____