HOUSE AMENDMENTS TO HOUSE BILL 4005

By COMMITTEE ON HEALTH CARE

February 13

On page 2 of the printed bill, line 41, delete "cumulative" and insert "net".

In line 42, delete "during" and insert "over the course of".

Delete line 45.

On page 3, delete line 1 and insert:

"(a) The name and price of the prescription drug and the net increase, expressed as a percentage, in the price of the drug over the course of the previous calendar year;".

In line 16, delete "cumulative" and insert "net".

In line 19, delete "and".

After line 19, insert:

"(k) Any other information that the manufacturer deems relevant to the price increase described in subsection (2)(b) of this section; and".

In line 20, delete "(k)" and insert "(L)".

Delete lines 36 through 45 and delete page 4 and insert:

"(6) No later than 30 days after a manufacturer introduces a new prescription drug for sale in the United States at a price that exceeds the threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program, the manufacturer shall notify the department, in the form and manner prescribed by the department, of all the following information:

"(a) A description of the marketing used in the introduction of the new prescription drug;

"(b) The methodology used to establish the price of the new prescription drug;

"(c) Whether the United States Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review;

"(d) If the new prescription drug was not developed by the manufacturer, the date of and the price paid for acquisition of the new prescription drug by the manufacturer;

"(e) The manufacturer's estimate of the average number of patients who will be prescribed the new prescription drug each month; and

"(f) The research and development costs associated with the new prescription drug that were paid using public funds.

"(7)(a) After receiving the report or information described in subsections (2), (3), (5) or (6) of this section, the department may make a written request to the manufacturer for supporting documentation or additional information concerning the report. The department shall prescribe by rule the periods:

"(A) Following the receipt of the report or information during which the department may request additional information; and

"(B) Following a request by the department for additional information during which a manufac-

turer may respond to the request.

"(b) The department may extend the period prescribed under paragraph (a)(B) of this subsection, as necessary, on a case-by-case basis.

"(8) A manufacturer may be subject to a civil penalty, as provided in section 3 of this 2018 Act, for:

"(a) Failing to submit timely reports or notices as required by this section;

"(b) Failing to provide information required under this section;

"(c) Failing to respond in a timely manner to a written request by the department for additional information under subsection (7) of this section; or

"(d) Providing inaccurate or incomplete information under this section.

"(9) Except as provided in subsection (10) of this section, the department shall post to its website all of the following information:

"(a) A list of the prescription drugs reported under subsection (2) of this section and the manufacturers of those prescription drugs;

"(b) Information reported to the department under subsections (3) and (5) to (7) of this section; and

"(c) Written requests by the department for additional information under subsection (7) of this section.

"(10)(a) The department may not post to its website any information described in subsection (9) of this section if:".

On page 5, delete line 1.

In line 11, delete "(12)" and insert "(11)".

In line 14, delete "(13)" and insert "(12)".

In line 18, delete "(14)" and insert "(13)".