HB0584/146788/1

BY: Health and Government Operations Committee

AMENDMENTS TO HOUSE BILL 584
(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in the sponsor line, strike "and Vogt" and substitute "Vogt, Angel, Barron, Bromwell, Cullison, Hayes, Hill, Kelly, Kipke, Miele, Morales, Morgan, Pendergrass, Platt, Rosenberg, Saab, Sample-Hughes, Szeliga, and West"; strike beginning with "establishing" in line 8 down through "debts" in line 9 and substitute "requiring a manufacturer of an investigational drug, biological product, or device to notify a certain patient and a certain health care provider of certain side effects or risks; requiring the Office of the Attorney General to develop an informed consent form that meets certain requirements; providing for the construction of certain provisions of this Act; establishing that a certain manufacturer may enforce a certain claim against the estate of a certain patient, but not the patient's heirs or legatees, except"; and in line 15, after "provider" insert "or certain treatment provided by a health care provider".

AMENDMENT NO. 2

On page 2, after line 7, insert:

"**(B) "CARRIER" HAS THE MEANING STATED IN § 15-10A-01(C) OF THE INSURANCE ARTICLE.**";

and in lines 8, 27, and 30, strike "**(B)**", "**(C)**", and "**(D)**", respectively, and substitute "**(C)**", "**(D)**", and "**(E)**", respectively.

On page 3, after line 15, insert:

"**(IV) INFORMS THE PROVIDER AND ELIGIBLE PATIENT OF ANY KNOWN OR ANTICIPATED SIDE EFFECTS, RISKS, OR REPORTED PATIENT DISCOMFORT THAT IS LIKELY RELATED TO THE TREATMENT;**";

(Over)

in lines 16, 23, and 28, strike "**(IV)**", "**(V)**", and "**(VI)**", respectively, and substitute "**(V)**", "**(VI)**", and "**(VII)**", respectively; in line 23, strike "**HEALTH INSURANCE**"; in line 25, strike "**MAY BE**" and substitute "**ARE**"; and strike beginning with "**UNLESS**" in line 26 down through "**BY**" in line 27 and substitute "**EXCEPT AS REQUIRED BY FEDERAL OR STATE**".

On page 4, in line 1, strike "**(VII)**" and substitute "**(VIII)**"; in line 2, strike "**IS**" and substitute "**MAY BE**"; in line 4, after "**ESTATE**" insert "**, BUT NOT THE HEIRS OR LEGATEES OF THE PATIENT,**"; in lines 7 and 14, strike "**(E)**" and "**(F)**", respectively, and substitute "**(F)**" and "**(G)**", respectively; and in line 12, after "**INVESTIGATION**" insert "**OR**".

On page 5, after line 3, insert:

"**(C) AFTER THE DATE THAT AN ELIGIBLE PATIENT BEGINS TAKING OR USING THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE AND DURING THE TIME THE ELIGIBLE PATIENT IS TAKING OR USING THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, THE MANUFACTURER SHALL NOTIFY THE ELIGIBLE PATIENT AND THE ELIGIBLE PATIENT'S HEALTH CARE PROVIDER OF ANY SIDE EFFECTS OR RISKS ASSOCIATED WITH THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE THAT ARE REQUIRED TO BE DISCLOSED TO THE UNITED STATES FOOD AND DRUG ADMINISTRATION DURING THE DRUG APPROVAL PROCESS.**

(D) (1) THE OFFICE OF THE ATTORNEY GENERAL SHALL DEVELOP AN INFORMED CONSENT FORM THAT:

(I) COMPLIES WITH THE REQUIREMENTS OF § 21-2B-01(D)(3) OF THIS SUBTITLE;

(II) INCLUDES INSTRUCTIONS FOR THE PHYSICIAN OR PATIENT ON HOW TO COMPLETE THE FORM; AND

(III) PROVIDES SPACES FOR A PHYSICIAN TO INCLUDE THE INFORMATION RELATING TO A PARTICULAR PATIENT AND THE PHYSICIAN'S RECOMMENDATION FOR THE PATIENT.

(2) THIS SUBSECTION MAY NOT BE CONSTRUED TO PROHIBIT A TREATING PHYSICIAN OR A MANUFACTURER OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE FROM INCLUDING ADDITIONAL INFORMATION OR ADVISEMENTS WITH THE INFORMED CONSENT FORM DEVELOPED UNDER PARAGRAPH (1) OF THIS SUBSECTION.";

strike beginning with "**ELIGIBLE**" in line 6 down through "**LIABLE**" in line 7 and substitute "**MANUFACTURER OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE MAY ENFORCE A CLAIM AGAINST THE ESTATE OF THE ELIGIBLE PATIENT, BUT NOT THE ELIGIBLE PATIENT'S HEIRS OR LEGATEES,**"; in line 8, after the second "**TREATMENT**" insert "**UNLESS A CONTRACT BETWEEN THE ELIGIBLE PATIENT AND THE MANUFACTURER STATES OTHERWISE**"; strike beginning with the third comma in line 14 down through "**CARE**" in line 15; and in line 19, after "**DEVICE**" insert "**OR THE HEALTH CARE PROVIDER'S TREATMENT OF AN ELIGIBLE PATIENT WITH AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE**".