HB0986/386888/1

BY: Health and Government Operations Committee

AMENDMENTS TO HOUSE BILL 986
(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in line 12, after "permit;" insert "providing that a person that prepares and distributes sterile drug products into or within the State is not required to hold a sterile compounding permit but must hold certain other permits; authorizing the Board to waive certain requirements in accordance with regulations adopted by the Board; establishing the requirements that must be met for a waiver to be issued; requiring the Board to post certain waivers on its Web site; requiring the Board to include certain information for each waiver posted on its Web site; providing for the duration, renewal, and rescission of a waiver;"; in line 14, after "Board" insert ", by regulation,"; strike beginning with "in" in line 14 down through "category" in line 16 and substitute "based on risk"; and in line 31, after "prohibiting" insert ", with a certain exception,".

On page 2, in line 3, after "Board;" insert "prohibiting, with a certain exception, a person from distributing sterile drug products in the State unless the sterile drug products are produced in a facility that holds a certain permit;"; in line 5, after "holders;" insert "requiring a wholesale distributor applicant or permit holder that prepares sterile drug products to submit to the Board, at certain times, a report of a certain inspection;"; in line 7, after "violations;" insert "authorizing the Board to phase in the requirements of certain provisions of this Act, with full implementation on or before a certain date; requiring the Board to report to the Governor and the General Assembly on the implementation of certain provisions of this Act;"; and in line 13, after "Permits"" insert "; and 12-6C-03.2".

AMENDMENT NO. 2

On page 2, in line 26, strike "**SECTION**" and substitute "**SUBTITLE**"; in line 28, strike "**(1)**"; in line 29, strike "**OR DEVICE**" and substitute "**ONLY**"; in line 30, strike

(Over)

"**(I)**" and substitute "**(1)**"; in line 32, strike "**/PHARMACIST**"; and in line 33, strike "**OR**".

On page 3, in line 1, strike "**(II)**" and substitute "**(2)**"; in line 3, strike the period and substitute "**; OR**"; strike beginning with "**(2)**" in line 4 down through "**IN**" in line 5 and substitute "**(3) IN**"; in lines 9 and 10, strike "**APPLICANTS OR PERMIT HOLDERS LOCATED OUTSIDE THE STATE**" and substitute "**FACILITIES OR ENTITIES THAT PREPARE STERILE DRUG PRODUCTS**"; in line 13, strike "**STERILE WHEN ADMINISTERED TO PATIENTS**" and substitute "**PREPARED USING ASEPTIC TECHNIQUES**"; in line 16, strike "**PREPARATIONS ARE COMPOUNDED**" and substitute "**COMPOUNDING IS PERFORMED**"; after line 16, insert:

"**(F) "STERILE DRUG PRODUCT" MEANS A DRUG PRODUCT THAT:**

(1) MUST BE PREPARED USING ASEPTIC TECHNIQUES; AND

(2) IS NOT REQUIRED TO BE PREPARED IN RESPONSE TO A PATIENT SPECIFIC PRESCRIPTION.";

and in line 17, strike "**(F)**" and substitute "**(G)**".

AMENDMENT NO. 3

On page 4, after line 3, insert:

"**(F) A PERSON THAT PREPARES AND DISTRIBUTES STERILE DRUG PRODUCTS INTO OR WITHIN THE STATE:**

(1) IS NOT REQUIRED TO HOLD A STERILE COMPOUNDING PERMIT UNDER SUBSECTION (A) OR (C) OF THIS SECTION; AND

(2) SHALL HOLD:

(I) A MANUFACTURER'S PERMIT OR OTHER PERMIT DESIGNATED BY THE U.S. FOOD AND DRUG ADMINISTRATION TO ENSURE THE SAFETY OF STERILE DRUG PRODUCTS; AND

(II) A WHOLESALE DISTRIBUTOR'S PERMIT ISSUED BY THE BOARD UNDER SUBTITLE 6C OF THIS TITLE.

(G) (1) THE BOARD MAY WAIVE ANY REQUIREMENTS OF THIS SUBTITLE, INCLUDING THE REQUIREMENTS OF SUBSECTION (F) OF THIS SECTION, IN ACCORDANCE WITH REGULATIONS ADOPTED BY THE BOARD.

(2) A WAIVER MAY BE ISSUED TO A STERILE COMPOUNDING FACILITY OR A PERSON DESCRIBED IN SUBSECTION (F) OF THIS SECTION ONLY:

(I) FOR SPECIFIED STERILE COMPOUNDED PREPARATIONS OR STERILE DRUG PRODUCTS FOR WHICH THERE IS A CLINICAL NEED, AS DETERMINED BY THE BOARD WITH INPUT FROM HEALTH CARE PROVIDERS IN THE STATE;

(II) IN EXIGENT CIRCUMSTANCES THAT, AS DETERMINED BY THE BOARD, OTHERWISE PREVENT HEALTH CARE PROVIDERS FROM OBTAINING, IN THE SIZE AND STRENGTH NEEDED, THE SPECIFIED STERILE COMPOUNDED PREPARATIONS OR STERILE DRUG PRODUCTS UNDER ITEM (I) OF THIS PARAGRAPH; AND

(III) IF THE STERILE COMPOUNDING FACILITY OR PERSON DESCRIBED IN SUBSECTION (F) OF THIS SECTION MEETS REQUIREMENTS ESTABLISHED BY THE BOARD, INCLUDING:

1. PROVISION OF:

A. REPORTS OF INSPECTIONS CONDUCTED BY A DESIGNEE OR THE U.S. FOOD AND DRUG ADMINISTRATION;

B. A STATEMENT OF COMPLIANCE WITH USP 797; AND

C. A REVIEW OF ADVERSE REGULATORY ACTION; AND

2. ANY OTHER REQUIREMENT AS DETERMINED BY THE BOARD.

(3) (I) THE BOARD SHALL POST ON ITS WEB SITE ANY WAIVER ISSUED UNDER THIS SUBSECTION.

(II) FOR EACH WAIVER POSTED ON ITS WEB SITE, THE BOARD SHALL INCLUDE:

1. THE NAME OF THE STERILE COMPOUNDING FACILITY OR OTHER PERSON RECEIVING THE WAIVER;

2. THE STERILE COMPOUNDED PREPARATION OR STERILE DRUG PRODUCT FOR WHICH THE WAIVER IS ISSUED;

3. THE BASIS FOR ISSUING THE WAIVER;

4. THE DURATION OF THE WAIVER; AND

5. ANY OTHER INFORMATION RELATING TO THE WAIVER OR LIMITATIONS ON THE WAIVER DETERMINED APPROPRIATE BY THE BOARD.

(4) ANY WAIVER ISSUED BY THE BOARD:

(I) MAY NOT EXCEED 2 YEARS IN DURATION;

(II) MAY BE RENEWED BY THE BOARD; AND

(III) MAY BE RESCINDED BY THE BOARD IF THE BOARD FINDS THAT ANY REQUIREMENTS OF THIS SUBTITLE ARE NOT MET.

(5) (I) THE BOARD SHALL INCLUDE IN THE REGULATIONS ADOPTED UNDER PARAGRAPH (1) OF THIS SUBSECTION REQUIREMENTS FOR DOCUMENTING, IN A RECORD ACCEPTABLE TO THE BOARD, THE ADMINISTRATION TO A PATIENT OF A STERILE COMPOUNDED PREPARATION OR STERILE DRUG PRODUCT OBTAINED UNDER A WAIVER ISSUED UNDER THIS SUBSECTION.

(II) THE REQUIREMENTS SHALL INCLUDE:

1. DOCUMENTATION OF THE LOT NUMBER OR OTHER MECHANISM FOR IDENTIFYING THE STERILE COMPOUNDED

PREPARATION OR STERILE DRUG PRODUCT FOR THE PURPOSE OF TRACING THE STERILE COMPOUNDED PREPARATION OR STERILE DRUG PRODUCT BACK TO THE STERILE COMPOUNDING FACILITY OR OTHER PERSON THAT PREPARED IT; OR

2. IF DOCUMENTATION OF THE LOT NUMBER OR OTHER IDENTIFICATION MECHANISM IS NOT FEASIBLE, DOCUMENTATION OF THE SOURCE OF THE STERILE COMPOUNDED PREPARATION OR STERILE DRUG PRODUCT FOR THE PURPOSE OF TRACKING THE STERILE COMPOUNDED PREPARATION OR STERILE DRUG PRODUCT BACK TO THE STERILE COMPOUNDING FACILITY OR OTHER PERSON THAT PREPARED IT.".

AMENDMENT NO. 4

On page 4, strike beginning with the colon in line 8 down through "**FACILITY**" in line 17 and substitute "**ESTABLISH, BY REGULATION, REQUIREMENTS FOR APPLICANTS BASED ON RISK**".

On page 5, in lines 6 and 7, strike "**THE SECOND ANNIVERSARY**" and substitute "**MAY 31 OF THE NEXT EVEN-NUMBERED YEAR**"; in line 8, strike "**AN ADDITIONAL**" and substitute "**A**"; strike beginning with the colon in line 16 down through "**A**" in line 17 and substitute "**A**"; and strike beginning with the semicolon in line 18 down through "**PERMIT**" in line 20.

On page 6, in lines 4 and 5, strike "**, FOR EACH STERILE COMPOUNDING PERMIT CATEGORY**"; strike beginning with the colon in line 21 down through "**REQUIRED**" in line 24 and substitute "**WITH A FREQUENCY BASED ON RISK AS SET FORTH IN REGULATIONS ADOPTED**"; in line 26, after "**INCLUDE**" insert a comma; in the same line, strike "**PARAGRAPH**" and substitute "**ITEM**"; and in line 27, strike "**MICROBIAL**" and substitute "**A REVIEW IN ACCORDANCE WITH REGULATIONS ADOPTED BY THE BOARD, OF:**

(I) QUALITY ASSURANCE TESTING REPORTS; AND

(II) MICROBIAL".

AMENDMENT NO. 5

On page 8, in line 31, after "**SUBTITLE**" insert "**OR ANY REGULATION ADOPTED UNDER THIS SUBTITLE**".

On page 9, in line 21, strike "**A**" and substitute "**(A) EXCEPT AS PROVIDED IN SUBSECTION (C) OF THIS SECTION, A**"; and after line 25, insert:

"**(B) EXCEPT AS PROVIDED IN SUBSECTION (C) OF THIS SECTION, A PERSON MAY NOT DISTRIBUTE STERILE DRUG PRODUCTS IN THE STATE UNLESS THE STERILE DRUG PRODUCTS ARE PRODUCED IN A FACILITY THAT HOLDS A MANUFACTURER'S PERMIT OR OTHER PERMIT DESIGNATED BY THE U.S. FOOD AND DRUG ADMINISTRATION TO ENSURE THE SAFETY OF STERILE DRUG PRODUCTS.**

(C) A PERSON MAY DISPENSE OR DISTRIBUTE STERILE COMPOUNDED PREPARATIONS OR STERILE DRUG PRODUCTS IN THE STATE WITHOUT MEETING THE REQUIREMENTS OF SUBSECTION (A) OR (B) OF THIS SECTION ONLY IN ACCORDANCE WITH A WAIVER ISSUED BY THE BOARD UNDER § 12-4A-02 OF THIS SUBTITLE.".

AMENDMENT NO. 6

On page 10, after line 3, insert:

"**12-6C-03.2.**

(A) NOTWITHSTANDING ANY OTHER PROVISION OF THIS SUBTITLE, A WHOLESALE DISTRIBUTOR APPLICANT OR PERMIT HOLDER THAT PREPARES STERILE DRUG PRODUCTS SHALL SUBMIT TO THE BOARD A REPORT OF AN INSPECTION CONDUCTED BY THE U.S. FOOD AND DRUG ADMINISTRATION OR A BOARD DESIGNEE:

(1) AT THE TIME OF APPLICATION; AND

(2) ON RENEWAL.

(B) THE INSPECTION REPORT REQUIRED UNDER SUBSECTION (A) OF THIS SECTION SHALL BE:

(1) CONDUCTED WITHIN 1 YEAR BEFORE THE DATE OF APPLICATION OR RENEWAL; AND

(2) DEMONSTRATE COMPLIANCE WITH APPLICABLE FEDERAL GOOD MANUFACTURING PRACTICE STANDARDS OR USP 797, AS DEFINED IN § 12-4A-01 OF THIS TITLE.

(C) AN APPLICANT OR PERMIT HOLDER IS RESPONSIBLE FOR OBTAINING AN INSPECTION TO MEET THE REQUIREMENTS OF THIS SECTION.".

AMENDMENT NO. 7

On page 11, after line 11, insert:

"SECTION 2. AND BE IT FURTHER ENACTED, That the State Board of Pharmacy may phase in the requirements of Title 12, Subtitle 4A of the Health Occupations Article, as enacted by Section 1 of this Act, with full implementation to be completed on or before April 1, 2014.

SECTION 3. AND BE IT FURTHER ENACTED, That on or before January 1, 2014 the State Board of Pharmacy shall report to the Governor and, in accordance with § 2-1246 of the State Government Article, the General Assembly on the implementation of Title 12, Subtitle 4A of the Health Occupations Article, as enacted by Section 1 of this Act.";

in line 12, strike "2." and substitute "4."; and in line 13, strike "October" and substitute "July".