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TO: The Honorable Peter A. Hammen, Chairman
Members, House Health & Government Operations Committee

FROM: Joseph A. Schwartz, III
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J. Steven Wise

DATE: February 28, 2013

RE: **SUPPORT WITH AMENDMENTS** – House Bill 986 – *State Board of Pharmacy – Sterile Compounding - Permits*

The Maryland State Medical Society (MedChi), which represents over 7,500 Maryland physicians and their patients, supports House Bill 986 with amendments.

House Bill 986 is a measure designed to tighten the permitting and regulatory process for sterile compounding facilities and it is undoubtedly in response to the adulterated compounding medicines from the well publicized manufacturing facility in Massachusetts. MedChi believes that the motives behind House Bill 986 are deserving of support but also believes that Maryland's rules on "compounded" medicines need to be adjusted in response to actual clinical conditions.

The present Maryland pharmacy law does not allow physicians to keep emergency supplies of compounded drugs in their offices. The reason for this is that the Maryland pharmacy law requires that any compounded medication (sterile or non-sterile) may only be ordered on a patient-specific basis. Hence a compounding pharmacy may not ship any compounded drugs to a doctor's office without a patient name, date of birth and allergies. Any compounding pharmacy which breaks these rules risks losing their license in Maryland.

The problem is there are emergency situations where the compounded drugs need to be in a doctor's office to be used immediately. For instance, in ophthalmology, conditions such as infectious endophthalmitis and neovascular glaucoma need to be treated immediately as patients cannot wait a minimum of 2-3 days to have compounded drugs shipped to their doctor's offices.

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MedChi believes that the proposed bill should be amended to allow physicians to keep a small supply of non-patient specific compounded medications that can be used if the delay in filling the compounded order would result in irreparable harm to the patient. Doctors could provide the compounding pharmacy with the patient's name, date of birth and allergies after the medication was used for emergency purposes. There needs to be recognition that there are a small (but very real) number of clinical situations where emergency use of compounded medications needs to be available. A copy of a proposed amendment to South Carolina's law is attached for the Committee's review. MedChi believes the following more narrowly drawn amendment should suffice.

Proposed Amendment No. 1: On page 2, in line 30 after (I) add: "SUBJECT TO SUBPARAGRAPH (3) OF THIS PARAGRAPH,"; on page 3 in the unnumbered line after line 3 add the following: "(III) THE COMPOUNDING PHARMACY MAY PROVIDE EMERGENCY SUPPLIES TO A PRACTITIONER WITHOUT A PRESCRIPTION DRUG ORDER PROVIDED THAT THE PRACTITIONER IDENTIFIES TO THE COMPOUNDING PHARMACY ANY PATIENT TO WHOM THE EMERGENCY SUPPLY WAS DISPENSED."

Proposed Amendment No. 2: The same amendment needs to be made to §12-101 (d) which is the similar definition section for the pharmacy code that applies to all prescriptions; in addition appropriate title amendments need to be made.

With these amendments, MedChi would support House Bill 986.

For more information call:

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