

MedChi

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TO: The Honorable Peter A. Hammen, Chair
Members, Health and Government Operations Committee
The Honorable Joan Carter Conway

FROM: Joseph A. Schwartz, III
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DATE: March 27, 2014

RE: **SUPPORT WITH AMENDMENT**– Senate Bill 1108 – *Sterile Compounding Permits – Definition of “Compounding”*

The Maryland State Medical Society (MedChi), which represents more than 8,000 Maryland physicians and their patients, supports Senate Bill 1108 but believes that a single amendment is necessary.

Senate Bill 1108 addresses one of several unintended consequences of the “Sterile Compounding” regulatory legislation passed in 2013. Because of the definitions contained in that earlier legislation, several perfectly acceptable in-office medical procedures are effectively banned because they come within the technical definition of “compounding.” For example, oncologists mix chemotherapy agents which are administered to a patient and rheumatologists reconstitute medications whether they are infusible or injectible biologics or injectible immunomodulators. These are common and time-honored practices and the doctor is not combining medicines or creating new ones.

Oncologists do not “compound” medicines in the normal understanding of that word. Chemotherapy is mixed in an office infusion center and then immediately administered to the patient. This mixing or preparation is presently performed in a special clean airflow pressure hood with HIPPA filters which provide safe chemotherapy medications for patients. The medicines are not prepared ahead of time, but only as the patient arrives in the office infusion center, and it has been established that their CBCs (Complete Blood Counts) and other lab

work are appropriate for the treatment. This permits adequate hydration, the administration of medications to prevent nausea and vomiting as well as the chemotherapy itself. The patient is not inconvenienced by having to travel long distances and can return home safely after drug administration. This is especially important given that a large majority of oncology care in Maryland is delivered in the local community close to the patient's home. This method has been proven to be both safe, and comforting to patients and families. Further it is the least costly and yet highly effective care to patients.

So too, rheumatologists, do not "compound" these agents but rather add sterile water or saline, using a sterile syringe-needle to a prepackaged vial of powder for mixing so it can be injected into a specific patient.

Last year's legislation (House Bill 986), when enforced, will upset the delicate balance of the community doctors with their patients by imposing many additional steps and costs with no way to recoup the money spent to implement the rules of this new law. The law will require implementation of USP 797 and essentially make it impossible for the community practice physician to provide such services. There will be additional costs in setting up a mixing center to meet USP797 rules with no indication that this would provide safer medications to our patients. The additional costs, if provided in a hospital infusion center could be recouped by the use of a facility fee. However, as the rules are now written, the community physician is not able to charge facility fees and will literally have to get out of the business of providing chemotherapy in an office setting. Sending patients to hospital settings for what service had been provided in the community setting will increase the stress and inconvenience of the cancer patient. The overall cost to the health care system through insurance and other payments will be triple what the current costs are in community based settings. This is in direct conflict with the aim of the new waiver.

It is counter intuitive to change what has been the best medical practice for patients. It is for these reasons MedChi requests a favorable report for Senate Bill 1108 with the following amendment to include rheumatologists: "on page 2, line 19 before the "OR" add ", RHEUMATOLOGIST".

For more information call:

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