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April 30, 2013

The Honorable Martin O'Malley
Governor of Maryland
State House
100 State Circle
Annapolis, Maryland 21401-1991

Re: House Bill 986

Dear Governor O'Malley:

We have reviewed and hereby approve for legal sufficiency House Bill 986, titled "State Board of Pharmacy – Sterile Compounding – Permits." We write specially, however, regarding a provision of the bill that, if improperly construed, could be found to be preempted by federal law.

House Bill 986 amends the Maryland Pharmacy Act, imposing regulatory requirements with respect to the sterile preparation of drugs and related activities. The bill differentiates between two practices: "sterile compounding" and "prepar[ing] and distribut[ing] sterile drug products." *Compare* proposed Health Occupations Article § 12-4A-02(a) *with id.* § 12-4A-02(f). Both activities involve the preparation of drugs "using aseptic techniques," *see id.* § 12-4A-01(d)&(f), but "sterile drug product" is defined to mean "a drug product that . . . is not required to be prepared in response to a patient specific prescription," *id.* § 12-4A-01(f).

Proposed § 12-4A-02 of the Health Occupations Article would require a person engaging in "sterile compounding" to hold a sterile compounding permit issued by the Board of Pharmacy. Under subsection (f) of that provision, however, a person "prepar[ing] and distribut[ing] sterile drug products" – that is, preparing and distributing drug products other than in response to a "patient specific prescription" – would *not* be required to hold a sterile compounding permit, and would instead be required to hold both "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 "a wholesale distributor's permit issued by the Board [of Pharmacy]." *Id.* § 12-4A-02(f). In subsection (g), the bill goes on to provide that "[t]he Board may waive any requirement of this subtitle, *including the requirements of subsection (f)* . . . , in accordance with regulations adopted by the Board." *Id.* § 12-4A-02(g) (emphasis added).

Thus, House Bill 986 incorporates into State law (in subsection (f) of proposed § 12-4A-02) a requirement that a person preparing and distributing "sterile drug products" must obtain a permit from the federal government, while at the same time authorizing the Board of Pharmacy (in subsection (g)) to waive that State law requirement. Significantly, any such waiver would be for State law purposes only. The bill states that the Board may waive "the requirements of subsection (f)," not any permit requirement imposed by federal law itself. If subsection (g) were construed to authorize the waiver of any federally-imposed permit requirement, it would be subject to preemption.

Current federal law does not clearly differentiate between sterile compounding, which has traditionally been understood to be within the scope of pharmacy practice and subject to regulation by the states, and drug manufacturing, which is subject to substantial federal oversight. The boundary may be particularly difficult to discern where drugs are prepared in anticipation of, rather than in response to, patient specific prescriptions. Guidance from the Food and Drug Administration ("FDA") identifies, as among the factors that it will consider in determining whether to take enforcement action, whether the activity at issue involves "[c]ompounding in anticipation of receipt of a prescription, except in very limited quantities." FDA Compliance Policy Guide 460.200 (issued May 2002).

We expect the federal law to evolve in this area. In the meantime, a waiver by the Board of Pharmacy of the *State-imposed* federal permit requirement, as set forth in subsection (f) of proposed § 12-4A-02, would not function as a waiver of any requirement imposed by federal law itself. Such a waiver, therefore, could not serve as a defense to any enforcement action undertaken by the federal government.

With this comment, we find House Bill 986 to be constitutional and legally sufficient.

Very truly yours,

Douglas F. Gansler
Attorney General

DFG/DF/kk

cc: The Honorable John P. McDonough
Stacy Mayer
Karl Aro