

**Oakland County Pharmacists Association Written Testimony on Senate Bill No. 373
October 8, 2013**

The Oakland County Pharmacists Association (OCPA) is the largest county affiliate of the Michigan Pharmacists Association with a membership of over 350 individuals. Our membership includes pharmacists and pharmacy technicians that practice in community pharmacies, health care systems, health plans, long-term care, ambulatory care, academia, and the pharmaceutical industry.

The Oakland County Pharmacists Association (OCPA) is in opposition to SB 373 as written. We do support innovation in pharmacy practice and the concept of pilot projects. We thank you for your consideration of this important matter.

OCPA suggests the law and future accompanying promulgated rules for pilot projects meet the principles outlined below.

- The law should be based on the National Association of Boards of Pharmacy (NABP) Model State Pharmacy Act for pharmacy practice initiatives. It is a national guideline for Pharmacy Practice Act language.
- The responsibility for the pilot projects should be given to the Board of Pharmacy.
- The primary goal of the pilot projects should be to meet a documented public health need in the petitioner's community.
- Pilot projects should be designed based on sound scientific methods and protect patient safety to the greatest degree possible.
- Pilot projects should be selected based on the scientific merits of the petition proposal and the potential significance of the project to public health.
- Neither the law nor rules should cap the number of project approvals so that innovation is encouraged on an on-going basis and unfair market competition that may arise from ending project approvals is avoided.

Background

Pharmacy innovation and practice-based research are flourishing in Michigan. Innovative pharmacy practices have been adopted by health care systems and community pharmacies across the state. These innovations address patient care needs such as improving transitions in care, establishing pharmacists in medical homes, and decreasing hospital readmissions through improved disease management. Michigan pharmacy practice is recognized nationally for its innovative practices and strong research base.

Our current regulatory environment supports the vast majority of innovations needed to improve access to cost-effective care in this state. There is no urgent need for the passage of legislation that approves pilot projects requiring an exception to the Public Health Code rules. We believe further discussion of the legislation's goals and parameters and potential alternative statutory language will serve the public good.

OCPA recognizes that meeting some public health needs may require changes in Michigan Public Health Code rules. Our healthcare delivery and financing systems are bringing forth new models of care and expanding demand for healthcare services. New technologies create opportunities to improve access to cost-effective care. Our state needs to ensure that we can adapt to these changes so that health outcomes are optimized and healthcare resources are used wisely.

While innovation is supported, OCPA strongly believes that pharmacy innovations must protect patient safety and promote safe medication practices. According to the CDC (Centers for Disease Control and Prevention), each year medication adverse events result in 700,000 emergency department (ED) visits, 120,000 hospitalizations and \$3.5 billion in additional health care costs. (<http://www.cdc.gov/medicationsafety/basics.html>) Pharmacist direct care has been shown to improve medication use and patient health outcomes. (Please see <http://www.communitypharmacyfoundation.org/resource> for an extensive list of references.)

The National Quality Forum (Preventing Medication Errors: A \$21 Billion Opportunity. 2010) estimates that medication errors related to medication use, administration and dispensing result in 3.8 million inpatient admissions, 3.3 million outpatient visits and 7,000 deaths per year. It notes that pharmacist involvement in patient care reduces preventable medication errors resulting in a dramatic decline in ED visits and hospitalizations. Pharmacy innovations should build on pharmacist care strategies that promote medication safety and optimal patient outcomes.

OCPA recommends that the Michigan legislature look to the National Association of Boards of Pharmacy (NABP) Model State Pharmacy Act as a foundation for new statutory language.

We believe that health laws should be broad in nature and permit sufficient flexibility so they can remain relevant as healthcare evolves. The NABP-recommended language provides a framework for meeting these objectives.

NABP is the national association whose membership includes all 50 state boards of pharmacy. The NABP Legislative and Regulatory Committee reviews and creates recommendations for statutory and regulatory language for approval by the NABP Executive Committee. Approved language is included within the NABP Model State Pharmacy Act (Act) available at www.NABP.net. Language for pharmacy practice initiatives exists within Section 213, which expands powers and responsibilities of the Board of Pharmacy as follows:

“the approval of Pharmacy practice initiatives that improve the quality of or access to Pharmacist Care, but which fall outside the scope of present regulations. This subsection shall not be construed to expand the definition of the Practice of Pharmacy as defined in this Act.”

Responsibility for the pilot projects should be given to the Board of Pharmacy.

The Act places pilot projects under the auspices of the Board of Pharmacy, which is the state regulatory body that possesses the greatest expertise in pharmacy practice. Placing all activities under this Board enhances transparency and provides opportunities for public input.

The NABP suggested language differs significantly from SB 373. OCPA believes that the NABP-recommended broad approach to statutory language should be adopted in its stead.

The law should state that the primary purpose of pilot projects is to meet a documented public health need.

Granting an exception to a rule creates a public health risk of which the magnitude of effect is unknown until tested. Therefore, to ensure that the benefits of pilot projects outweigh any ill effects, the projects should be designed to evaluate pharmacy services and/or products that address a documented public health need in the community in which the project will be conducted. Such a requirement balances the unknown effects of waiving safeguards with potential public health benefits.

Pilot project approval and oversight will require the use of public resources. Given the use of such resources, it is not unreasonable to require that projects benefit the good of the public.

Pilot projects should be scientifically sound and protect patient safety to the highest degree possible.

Pilot projects are a suitable framework for testing innovative pharmacy practices. Such studies are a means to test new ideas and determine the feasibility, time, cost, adverse events and effect sizes needed for broader adoption.

Pilot projects petitions should include a community needs assessment that documents a targeted public health need within the petitioner’s community, have clear goals and objectives, an appropriate target population for testing the hypothesis, a recruitment process that does not entice individuals to take unnecessary risks, an informed consent process if human subjects are involved, a scientifically sound research methodology with data collection and security methods clearly defined, an appropriate time frame in which to conduct patient recruitment and the project overall, and a data analysis process that is appropriate to answer project goals and objectives. Board of Pharmacy review of study processes and documentation should be required throughout the pilot project. A process for early termination of projects if data indicate that harm outweighs benefits should be

established. Study results must consider all data, provide an unbiased assessment of the findings, discuss study limitations, and make conclusions supported by the findings.

Neither the law nor the rules should place arbitrary limitations on innovation.

Innovation is an essential component of advancing pharmacy practice to best meet patient healthcare needs. Michigan is a state rich in research-intensive universities and colleges, forward-thinking healthcare systems, innovation centers and other entities that can create new ways of improving patient care. We should not place artificial boundaries on this creative potential.

Pilot project approvals may create unfair competition within the highly competitive pharmacy market. Pilot projects that may have a negative impact on the pharmacy market should not be approved. No project should be approved that meets a financial need of the petitioner unless the project also meets a documented public health need.

Pilot projects should be selected based on the scientific merits of the petition proposal and its potential significance to public health.

If the number of proposals approved within a given time period must be limited due to scarce state resources, proposal selection should be based on the scientific soundness of the petition proposal and its potential significance to public health; not based on scope or type of petition. The use of public funds for this initiative requires that the greatest good for the public be sought.

We recommend that the Health Policy Committee delay its vote on SB 373 and provide an opportunity for further discussion and work on this legislation so that it can meet these important principles designed to protect patient safety and promote public health and to allow the legislation to conform with national guidelines for pilot projects in pharmacy practice.

Thank you for giving the Oakland County Pharmacists Association an opportunity to share its concerns about Senate Bill 373. We stand ready to work with you to create a safe, scientifically sound and fair approach to pilot project innovation.