

MICHIGAN SHOULD ADOPT THE POINT OF CARE MODEL FOR ITS HEALTH CARE DELIVERY SYSTEM TO SECURE IMPROVED HEALTH CARE OUTCOMES FOR MICHIGAN RESIDENTS AND REDUCE HEALTH CARE COSTS FOR MICHIGAN TAXPAYERS

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I. INTRODUCTION AND BACKGROUND

The unprecedented COVID-19¹ Pandemic has exposed many of the deficiencies in Michigan's healthcare delivery system. When the uprush of the COVID-19 tsunami was just beginning to touch Michigan, Governor Gretchen Whitmer responded through a series of Executive Orders designed to keep Michiganders as healthy and safe as possible. When two (2) presumptive positive cases of COVID-19 were identified in Michigan on March 10, 2020, Governor Whitmer issued Executive Order 2020-4, Declaration of State of Emergency COVID-19 to stem the tide of the COVID-19 Pandemic.²

The warriors on the frontline of the COVID-19 war are Michigan's healthcare professionals, physicians, nurses, nurse practitioners and pharmacists. Governor Whitmer understood this and that these warriors were in short supply due to restrictions in Michigan's Public Health Code ("PHC") related to the licensing of healthcare professionals³. Several more Executive Orders followed to ensure an adequate supply of healthcare professionals for the battle of the COVID-19 Pandemic, including the following:

Executive Order 2020-13, Temporary Enhancements to Operational Capacity and Efficiency of Health Care Facilities, which temporarily suspended licensing laws and the PHC requirements related to medical physicians, nurses, osteopathic physicians and pharmacists so that more residents could receive medical treatment.

Executive Order 2020-56, Temporary Enhancements to Operational Capacity, Flexibility, and Efficiency of Pharmacies, which allows pharmacists, among other things, to dispense 60-day re-fills of non-controlled, maintenance medications, to dispense and administer medications to treat the COVID-19 and, to substitute a therapeutically equivalent medications without the prescriber's authorization.⁴

Executive Order 2020-61, Temporary Relief from Certain Restrictions and Requirements Governing the Provision of Medical Services, which removed restrictions on scope of practice, supervision and delegation of duties allowing nurses and physician assistance to treat patients without the supervision of a physician. It also allowed pharmacists in healthcare facilities to provide care for routine health maintenance, chronic disease states, or similar conditions, as appropriate to the professional's education, training, and experience, without physician supervision.⁵ (collectively referred to as "COVID-19 Orders").

These COVID-19 Orders demonstrate that both prescriber designation for pharmacists and point of care treatment by pharmacists were critical components of Michigan's healthcare delivery system during the COVID-19 Pandemic.⁶ In fact, the State of Michigan negotiated an agreement with CVS Pharmacy whereby their pharmacists heroically and selflessly agreed to work numerous, statewide testing sites, testing Michigan residents to document those infected with the COVID-19 virus, those who have not been infected with the COVID-19 virus, and those who were infected, but have recovered and possess antibodies for the COVID-19 virus.

This paper illustrates how Michigan's current healthcare delivery system must be reformed to a Point of Care Model (term defined below). This paper will further demonstrate that the Point of Care Model of healthcare delivery ensures the health and safety of Michigan residents, by treating patients whose

¹ COVID-19 refers to the Coronavirus.

² Executive Order 2020-4 went into effect on March 11, 2020.

³ Public Health Code, 1978 PA 368, Section 333.1101 et. seq. as amended.

⁴ Originally Executive Order 2020-25, but extended after expiration.

⁵ Originally Executive Order 2020-30, but extended after expiration.

⁶ Prescriber status means a person that holds a license which allows that person to prescribe medications and medication therapies. Point of care testing and treatment is defined as a health and medical status investigation conducted through testing with rapid results of those tests so that the patient can be treated on the spot.

conditions are unstable, urgent or easily resolvable, through a virtual medical team; while providing cost savings for health insurance companies, and an adequate supply of healthcare professionals in Michigan. Finally, this paper will explain how the Point of Care Model of healthcare delivery can be implemented in Michigan by amending the PHC, related to the licensing of healthcare professionals,⁷ to allow pharmacists prescriber designation and to engage in point of care testing.

a. Defining Provider Status in the Healthcare Industry

“Provider Status” is a term used in the Social Security Act (“SSA”) to define which healthcare providers may bill for services performed and be reimbursed. Pharmacists and services provided by pharmacists are not included in the definition of “Provider Status” under the SSA which determines eligibility for Medicare Part B.⁸ Other health care professionals who are listed as providers in Part B of the SSA include physicians, physician’s assistants, certified nurse practitioners, qualified psychologists, clinical social workers, certified nurse midwives, and certified registered nurse anesthetists. State and private health plans often cite the omission of pharmacists and pharmacists’ services from “provider status” in Medicare Part B as a reason for refusing to cover pharmacy services or lack of compensation of pharmacists for providing comprehensive, patient-centered care.⁹

b. Defining Prescriber Pursuant to the PHC

Pursuant to the PHC, at MCL 333.17708(2), the health care professionals that are authorized to prescribe medications are defined as follows:

““Prescriber” means a licensed dentist, a licensed physician of medicine, a licensed physician of osteopathic medicine and surgery, a licensed physician of podiatric medicine and surgery, a licensed physician's assistant, a licensed optometrist certified under Part 174 to administer and prescribe therapeutic pharmaceutical agents, an advanced practice registered nurse as that term is defined in section 17201 who meets the requirements of section 17211a, a licensed veterinarian, or another licensed health professional acting under the delegation and using, recording, or otherwise indicating the name of the delegating licensed physician of medicine or licensed physician of osteopathic medicine and surgery.”¹⁰ MCL 333.17708(2).

There are two general categories of prescription medications: controlled substances medications (opioids, stimulants, certain pain medications etc. . . .) and non-controlled or legend medications. Physicians across the country, both medical physicians (“MD”) and osteopathic physicians (“DO”) are independent prescribers for controlled substances and non-controlled or legend medications. In Michigan, physician assistants (“PA”)¹¹ are prescribers for controlled substances and non-controlled substances through a collaborative practice agreement with a physician and advanced practice registered nurses (“APRN”) are prescribers for controlled substances under the license of their supervising physician¹². In addition, APRN are independent prescribers for non-controlled substance medications.

⁷ Public Health Code, 1978 PA 368, Section 333.1101 et. seq. as amended.

⁸ Social Security Administration, www.ssa.gov. Social Security Act of 1935, 42 USC Sections 301-1305

⁹ When APRNs became prescribers in Michigan, they earned Provider Status and can bill Medicare for their services. The same must occur for pharmacists. American Pharmacist Association, (September, 2013) retrieved at, https://www.pharmacist.com/sites/default/files/files/Provider%20Status%20FactSheet_Final.pdf

¹⁰ Notably, pharmacists are not included in the definition of “prescribers”.

¹¹ PAs under MCL 333.17076 (2), in their scope of practice, can prescribe both controlled substances and non-controlled substances as long as they have entered into a collaborative practice agreement with a physician.

¹² APRN can independently prescribe non-controlled medications, but can only prescribe controlled medications under the supervision of an MD or DO., MCL 333.17211a.

Prescribers or those with prescriber status are separate and distinct from individuals that are licensed to diagnose conditions or diseases. Both MDs and DOs diagnose, and prescribe ¹³while APRNs and PAs prescribe based on a diagnosis from an MD or DO.¹⁴

II. MICHIGAN'S CURRENT HEALTHCARE DELIVERY MODEL

If a diabetic patient feels ill or his diabetes is uncontrolled, that patient must call his physician's office, and if the physician can squeeze him in, the patient comes in on that day for an appointment. If the physician's schedule does not permit a same day appointment, the patient must make a doctor's appointment for a subsequent day. If the patient is managed by an endocrinologist, a physician specialized in diabetic patient management, the next available appointment may be weeks to months away. The patient then goes to the physician's office for an office visit. At the office visit, the patient checks in with the receptionist and the patient waits to be called in for his appointment. Once the patient is called in for the appointment, a nurse takes the patient's vital signs, including temperature, blood pressure, and weight; then ushers the patient into an examination room where the patient waits for the physician to see him. The physician will come into the examination room to examine the patient. The physician will review the patient's medical records, listen to the patient's current complaints and ask some questions and take some medical information related to the symptoms that the patient is experiencing. The physician will determine what laboratory tests are needed to fully diagnose or evaluate the patient's current health condition. The physician will then create a prescription to order these laboratory tests. The physician leaves the examination room and sends the nurse in to collect the specimen for the laboratory tests that he has prescribed.¹⁵

The nurse comes into the examination room to collect the specimen needed for the laboratory test (i.e. blood test, urine test swab of throat) that the physician has prescribed. The patient leaves the examination room and goes to the cashier to pay his co-pay for the physician's office visit. The patient is sent home at that time usually without a targeted treatment since there were no test results at the physician's office visit. The nurse then sends the specimen to a laboratory for analysis on a first come first served basis. The laboratory performs its investigation and then send the results of the test to the physician's office. The physician's office, usually a nurse, calls the patient to tell him his test results and issues a prescription for medication that is targeted to the condition of the patient days after the physician's office visit.¹⁶

Once the patient receives the prescription for medication, the patient goes to the pharmacy to fill the prescription. The pharmacist runs the prescription in order to fill it, which means that the pharmacist has contacted the patient's insurance company to verify that the medication is covered by his insurance company. If the medication is not covered, which is the case at least 30% of the time, the pharmacist must find an equivalent medication that is actually covered by the patient's insurance company.¹⁷ The pharmacist

¹³ Pursuant to MCL 333.17001 the "Practice of medicine means the diagnosis, treatment, prevention, cure, or relieving of a human disease, ailment, defect, complaint, or other physical or mental condition, by attendance, advice, device, diagnostic test, or other means."

¹⁴ APRN can independently prescribe non-controlled medications, but can only prescribe controlled medications under the supervision of an MD or DO., MCL 333.17211a. PAs can independently prescribe both controlled substances and non-controlled substances as long as they are engaged in a collocative practice agreement with an MD or DO. MCL 333.17076 (2).

¹⁵ In some cases, the physician does not have a nurse or phlebotomist on staff to take blood so the physician must send the patients to another location for laboratory testing further delaying and complicating healthcare delivery of services.

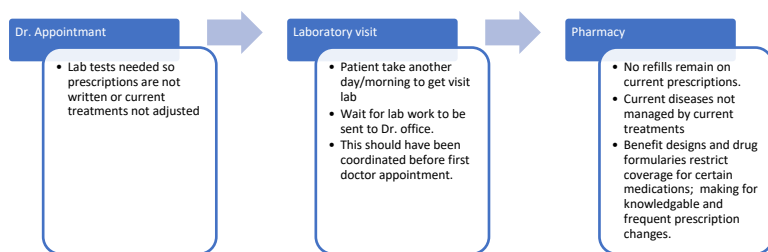
¹⁶ Medical conditions such as diabetes fluctuate constantly. A patient's blood glucose levels vary from day to day, and even from hour to hour depending on the severity of the condition, life-style of the patient and food consumed. This fluctuation could determine the type of treatment needed and the impact on the patient's health outcomes.

¹⁷ This is a crucial point that all 6 pharmacists interviewed for this paper point out. The pharmacist is now selecting the new medication to be prescribed for the patient's condition that the physician has diagnosed. This illustrates that the pharmacist could have selected the medication for the patient from the start and the only difference is that the pharmacist cannot physically write the prescription.

has to inform the patient that the physician has written a prescription that is not covered by the patient's insurance company and that he will call the physician's office to ask them to re-write a prescription for medication that is actually covered by his insurance company. The pharmacist must then call the physician's office to prescribe an equivalent medication that is covered by the patient's insurance company; a different medication *which the pharmacist selected*. The patient is forced to wait again for the physician to re-write his prescription. The pharmacist then dispenses the medication. Finally, the patient receives the medication that he has needed to deal with the illness or condition plaguing him after days have past.

About two (2) months after the physician's appointment, the patient will receive a billing statement from the physician's billing department notifying the patient what his portion of the bill for the doctor's appointment is and how he must pay the same. The patient pays the bill, usually just in time for another physician's office visit since conditions such as diabetes require life-long maintenance medications and these conditions are hard to control or stabilize. Sadly, the patient must engage in this time-consuming, costly healthcare process over and over again.

The system has a number of inefficiencies and redundancies that do not allow for best positive patient outcomes. At any step in this process patients can become overwhelmed, confused and feel that the system is against them. Patients may not follow up with a timely needed doctor visit, laboratory visit or pharmacy visit: and some may abandon pursuit of healthcare at any step or altogether because of a lack of coordination and support in this fractionalized, siloed and complex system. Michigan's current healthcare delivery model is summarized by the diagram below.



The most striking aspect of Michigan's current healthcare delivery system is that it is a reactive system. It waits until Michiganders contract diseases or experience healthcare concerns to act.

III. DEFINING THE POINT OF CARE MODEL

All facilities in the United States that perform laboratory testing on human specimens for health assessments or the diagnosis, prevention, or treatment of disease are highly regulated under the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”)¹⁸. However, CLIA contains an exception to this rigorous certification requirement if the test is simple and has a low risk for erroneous results. Manufacturers that produce tests qualifying under this exception can apply for a CLIA waiver. CLIA-waived tests can be performed in a non-traditional setting, including pharmacies.¹⁹

¹⁸ The Clinical Laboratory Improvement Amendments of 1988 statute is an amendment to the Public Health Services Act in which Congress revised the federal program for certification and oversight of clinical laboratory testing. Two subsequent amendments were made after 1988. The law continues to be cited as CLIA '88 as named in legislation. 42 USC Section 263a, The Division of Clinical Laboratory Improvement & Quality, within the Quality, Safety & Oversight Group, under the Center for Clinical Standards and Quality (CCSQ) has the responsibility for implementing the CLIA Program.

¹⁹ In 1988, the Clinical Laboratory Improvement Amendments (CLIA) were passed in an effort to ensure the accuracy, reliability and timeliness of laboratory test results regardless of where the test was performed. Under these regulations, laboratories had to undergo a rigorous certification process in order to be able to perform tests on clinical specimens. However, an exception was created if a laboratory test could be performed with a minimal level of complexity and had a low risk of erroneous results. If these

Currently, there are over 120 different CLIA-waived laboratory tests available in the United States, many of which can be conducted without dedicated equipment and provide results within 5-20 minutes. There are numerous examples of how pharmacists would be qualified to conduct, and have conducted, Point of Care testing and treatments for patients on the spot using these CLIA-waived tests.

“**Point of Care Testing and Treatment**” is defined as a health and medical status investigation conducted through testing on a patient at the time of consultation with instant or rapid results of those tests so that immediate informed decisions can be made regarding the patient’s current medical and health condition (“**Point of Care**”).²⁰ Point of Care tests are simple CLIA waived medical tests performed by a pharmacist, based on a physician’s diagnosis and the patients’ medical records, at the consultation so that the pharmacist can assess the test results and treat the patient in the fastest manner possible.²¹ It is essentially bringing the testing and treatment close to the patient in an effort to improve care, outcomes and reduce costs. The pharmacist will conduct the CLIA waived Point of Care test²² and once the pharmacist receives the results, within 5 to 20 minutes, the pharmacist can treat the condition on the spot with a prescription adjusting the patient’s medication.²³

In the Point of Care Model, patients could be referred to a pharmacist by their physician or make a same day appointment on their own. The Point of Care Model is designed to treat patients that are in immediate distress, in an unstable condition between physician’s appointments or have conditions that are easily resolvable. In the Point of Care Model, the pharmacist sits down with the patient and finds out about the patient’s lifestyle, then educates and counsels patients about the ways they could change their lifestyles to better regulate, or even eliminate, their conditions. Pharmacists also educate and counsel patients about their conditions and how they are likely to respond to medications and the methods of action of the medications. Pharmacists explain to patients’ why adhering to medication regimes will be important and what may happen if they fail to adhere to medication regimes. These are all core training requirements in pharmacy schooling. Finally, the pharmacist will tell the patients about any warning signs or symptoms to look for while taking the medication prescribed, and if they experience any of those, return to the pharmacy for a medication adjustment.²⁴

criteria were met, the manufactures of the test were allowed to apply for a CLIA-waiver. Approval of the CLIA-waiver application indicated that the test could be performed in a nontraditional laboratory setting if that site followed good laboratory practices and possessed a valid CLIA waiver. This includes pharmacies. Surprisingly, this one piece of legislation passed nearly 30 years ago to regulate clinical laboratories created one of the most significant opportunities for pharmacists to play a valuable role in advancing public health. Unfortunately, pharmacists have not yet taken full advantage of this legislation. Currently, there are more than 120 different CLIA-waived laboratory tests available in the U.S. Many of these tests can be performed without specialized equipment and provide results within 5-20 minutes. Imagine the impact a pharmacist could have in the care of a patient if they were able to quickly identify patients with treatable infections like influenza or streptococcal pharyngitis versus those whose symptoms were caused by a non-treatable etiology that required only symptomatic management. Michigan Pharmacists Association, <https://www.michiganpharmacists.org/resources/pointofcare>.

²⁰ Kamlesh Khunti (March 1, 2010), Near Patient Testing in Primary Care, retrieved at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2828826/>.

²¹ There are over 120 different CLIA-waived laboratory tests available in the United States, many of which can be conducted without dedicated equipment and provide results within 5-20 minutes. There are numerous examples of how pharmacists would be qualified to conduct, and have conducted, Point of Care testing and treatments for patients on the spot using these CLIA-waived tests. Michigan Pharmacists Association, <https://www.michiganpharmacists.org/resources/pointofcare>.

²² The Point of Care Model of testing and treatment by a pharmacist will be based on a diagnosis from the patients’ physician. The pharmacist is not licensed to, or educated, for diagnosis purposes.

²³ In an interview with a seasoned pharmacist who managed diabetes patients for years, she states, “It’s not just about adjusting dose. It is about getting patients to the minimum guidelines. In my experience, when I am managing diabetes medication - they are already lacking proper lab work like creatine clearance and proper glucose readings like A1c at least 1-2 times a year. Not to mention adding lifestyle changes needed to improve condition.”

²⁴ Physicians are limited in the time that they allocated for office visits, especially same day appointments. Imagine if the physician did all of this counseling and education, which is critical to successful outcomes, he could not meet his scheduled appointments. However, all of these tasks are necessary to increase health outcomes for Michiganders.

The Point of Care Model provides the patient with a virtual medical team combining their efforts for best practice results and better quality of life for patients. The availability of electronic medical record (“EMR”) today, enables all the laboratory testing results and Point of Care testing results performed on a given patient, even from multiple locations, to be compiled into one record. The Point of Care Model requires pharmacists to have access to the patient’s EMR.²⁵ The Point of Care test results that the pharmacist performs on the patient would be manually entered into the patient’s EMR. The pharmacist would also enter an office visit note into the patient’s EMR. This way the patient’s physician can see exactly what Point of Care tests the pharmacist performed, the results of those Point of Care tests and the treatment that the pharmacist provided. Imagine the impact a pharmacist could have in the care, health and wellbeing of a patient if they were able to quickly identify patients with treatable infections like influenza or streptococcal pharyngitis and treat them on the spot.²⁶ Pharmacists’ Point of Care testing could, by process of elimination, also rule out treatable infectious diseases so that the physician has those results, is not required to repeat them, and can further test for diagnosis purposes, such as determining a non-treatable condition that requires only symptomatic management.

Conversely, because the pharmacist is able to access the patient’s EMR, the pharmacist will review the patient’s medical history, the physician’s diagnosis and the results of any laboratory tests ordered by the physician. In the Point of Care model, the pharmacist is, therefore, basing his treatment of the patient on the physician’s diagnosis, the laboratory test results in the EMR, the Point of Care tests that the pharmacist conducted and his in-depth knowledge of pharmaceuticals. This ensures that the on the spot treatment is targeted to the immediate condition of the patient.

The ability to store all the laboratory test and Point of Care test results, along with physicians’ and pharmacists’ notes being generated from these different medical facilities and professionals in one repository has the benefit of avoiding replication of tests and related healthcare cost; as well as ensuring informed input from a virtual medical team of providers.²⁷ Test results obtained and inputted into the EMR can be downloaded into a central data bank for use across the entire spectrum of medical care providers, from pharmacist, to physician to specialists. This approach is supported by the Centers for Disease Control and Prevention (“CDC”).²⁸ This virtual medical team approach of care means more comprehensive and accurate patient test data, leading to more accurate and rapid diagnoses resulting in targeted treatments culminating in improved outcomes with reduced costs.

The Point of Care Model envisions that most patients would make same day appointments with pharmacists for simple on the spot testing, such as a pin-pick blood test to chart the patient’s cholesterol levels. The pharmacist would determine if the cholesterol levels have been elevated through this simple testing. Where there is no diagnosis and the patient’s cholesterol is elevated, the pharmacist could refer the

²⁵ In the CMS Connecticut Study, CMS indicates that pharmacists’ access to patients’ EMR is the best way to implement quality improvements and ensure accurate medications and adherence, Marie Smith, Margherita R. Giuliano, and Michael P. Starkowski (April, 2011) In Connecticut: Improving Patient Medication Management in Primary Care, retrieved at <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2011.0002>.

²⁶ Strep bacteria can be treated with common antibiotics like penicillin. Early treatment may reduce the risk of death from strep disease. For those with very severe illness, care in an intensive care unit may be needed. People that become infected with strep bacteria can require surgery to remove damaged tissue and stop it from spreading. Approximately 11,000 to 13,000 cases of invasive strep disease occur annually, and 1,100 to 1,600 die, Pennsylvania Department of Health, retrieved at <https://www.health.pa.gov/topics/Documents/Diseases%20and%20Conditions/Group%20A%20Strep.pdf>.

²⁷ Another incredibly beneficial consequence of allowing pharmacists to input test results and consultation information into the patients’ EMR is that it will virtually eliminate fraudulent prescriptions. The pharmacist is actually able to see when a patient visited the physician and all physician’s notes. It cannot be overstated how frequently fraudulent paper prescriptions and electronic prescriptions are submitted to the average pharmacy. While some are caught, a large percentage escape detection until a detailed audit, which happens sporadically and intermittently. Imagine the cost savings to Michigan’s healthcare system and the public purse. One simply cannot fake an EMR entry.

²⁸ Centers for Disease Control and Prevention, Collaborative Practice Agreements and Pharmacist’ Patient Care Services, retrieved at https://www.cdc.gov/dhbsp/pubs/doc/Translational_Tools_Pharmacists.pdf.

patient to his physician.²⁹ Alternatively, if a pharmacist conducted the Point of Care test on a patient with an existing diagnosis, the pharmacist would counsel the patient about lifestyle changes, and monitor the patient's levels. After the pharmacist receives the rapid results of those Point of Care tests, the pharmacist treats the patient by adjusting his medication, or dispensing the targeted treatment on the spot to the patient. The patient leaves with the medication they need on that same day to stabilize their condition until their next doctor's appointment. To distill it down to the basics, in terms of the time, cost and human suffering, the Point of Care Model eliminates sixteen (16) cumbersome, expensive and unnecessary steps that are typically involved in Michigan's current healthcare delivery model. The patient would see his physician at the next scheduled doctor's appointment. In the Point of Care Model, pharmacists are conducting the Point of Care tests based on a diagnosis from a physician and the patient's EMR. The pharmacist does not, and never will, engage in diagnosing the patient.³⁰

a. Types of Testing Possible with Pharmacist-Executed Point of Care Treatments and How Point of Care Treatment Can be Implemented

Some of the Point of Care testing is as simple as observing the patient, and requires no equipment at all; while other Point of Care testing must be accomplished through CLIA-waived tests. Most of the 120 different CLIA-waived laboratory tests available on the United States market can be completed without specialized equipment and produce results within 5-20 minutes. The following is a brief list of Point of Care testing and treatments that can be, and have been, performed by pharmacists in Michigan:

1) Pregnancy testing related to birth control medications. If the patient tests negative for pregnancy, the birth control medication could be dispensed on the spot.

2) Drugs of abuse screenings are simple blood or urine tests with rapid results. This is especially helpful in the fight against the Opioid Epidemic. The pharmacist could test the patient when he brings in a prescription for controlled substances. The pharmacist will also verify, through the EMRs that the physician did in fact prescribe the controlled substance. In addition, the pharmacist will have already performed a MAPS on the patient to see what, if any, controlled substances should be in his system.³¹ If the pharmacist finds that there are controlled substances that should not be in the patient's system, the controlled substance prescription will not be dispensed by the pharmacist.³²

3) Rapid coagulation tests measure the blood's ability to clot, and how long it takes to clot. This testing can be helpful for cardiac surgery patients who may experience excessive bleeding or develop clots

²⁹ Diagnosing is the primary focus of the physician's education, training, and experience. In fact, in relevant part, the scopes of practice of MD and DO are as follow:

"Practice of medicine" means the diagnosis, treatment, prevention, cure, or relieving of a human disease, ailment, defect, complaint, or other physical or mental condition, by attendance, advice, device, diagnostic test, or other means, or offering, undertaking, attempting to do, or holding oneself out as able to do, any of these acts.

"Practice of osteopathic medicine and surgery" means a separate, complete, and independent school of medicine and surgery utilizing full methods of diagnosis and treatment in physical and mental health and disease...placing special emphasis on the interrelationship of the musculoskeletal system to other body systems.

³⁰ Diagnosing is not within the scope of pharmacy practice and not part of their education or training, so the Point of Care Model requires that the pharmacist either relies on the most current diagnose of the physician, or if the pharmacist observes behavior, conditions or reviews test results that would require the diagnosis be re-visited, the pharmacist would refer the patient to his physician for further diagnosing. MCL 333.17707(7).

³¹ MAPS is the Michigan Automated Prescription System. MAPS is used by prescribers and dispensers to track controlled substance, schedule 2 through 5 drugs. Each time a controlled substance is prescribed or dispensed, the healthcare provider must use the MAPS tool to review the patient's records for controlled substances.

³² Requiring this Point of Care test, along with MAPS reviews and review of the physician's notes in the EMR, before controlled substances drugs could be dispensed could greatly reduce, if not eliminate controlled substance abuse and diversion. If Michigan is serious about eliminating the Opioid Crisis, this process must be implemented. The unplanned beneficial consequence is that it would be very difficult, if not impossible for controlled substances to continue to be abused or diverted.

(thrombosis) somewhere in their blood vessels after cardiac surgery.³³ The pharmacist can perform this test each time a cardiac surgery patient fills his prescription to ensure that the patient is within reasonable measurements for clotting, thereby lowering the chance of severe harm or death.

4) Cholesterol screening is a simple blood test that is based on the patient's cholesterol levels. It can determine the presence of heart disease, hardening or clogging of arteries, or stroke. The pharmacist inputs the patient's lipid levels and the patient's specific risk factors, such as age, medical history and family history, into an Atherosclerotic Cardiovascular Disease risk calculator, to determine the medication best suited for the patient based on the applicable hypertension guidelines.³⁴ Patients with these conditions are on maintenance medications, which are dispensed by the pharmacy on a monthly basis; so, the pharmacist is in the best position to understand how, when and why they should be adjusted.

5) C-Reactive Protein tests are blood tests that indicate high levels of inflammation, which can signify heart disease or stroke, especially in combination with high cholesterol. Patients with these conditions are on maintenance medications, which are dispensed by the pharmacy on a monthly basis; so, the pharmacist is in the best position to understand how, when and why they should be adjusted.³⁵

6) Blood Glucose testing determines the patient's blood glucose level on the day of the pharmacist's consultation. Additionally, Hemoglobin A1C blood test measures the average blood glucose over the past 3 months and is done to determine diabetes in patients. If the patients' A1C is still high even with diabetic medicates, the pharmacist can adjust this medication with notice to the physician on an emergency basis. This could be life-saving.³⁶

7) HIV Strip Test Rapid Blood or HIV Salivary Assay are rapid processing tests that determine the presence of HIV. These tests take about 15 to 20 minutes for the results. For patients that suspect they have HIV, or are exhibiting symptoms of HIV, but do not have a diagnosis, the pharmacist would perform one (1) of these Point of Care tests. If the patient tests positive for HIV, the pharmacist would refer the patient to his physician for further testing and diagnosis.³⁷ The pharmacist would also notify the physician if the patient has not been diagnosed through the EMR. Where the patient has a diagnosis of HIV, but the patient is unstable between physician appointments, the pharmacist would conduct a Point of Care test and depending on the results, prescribe or adjust the appropriate HIV medications.³⁸ Pharmacists are in the best position to evaluate the condition of patient, the adherence to the medication and the medication's efficacy because they see the patients at least once a month for medication re-fills.

8) Conjunctivitis (pink eye) is a highly contagious condition that can be observed without the need for testing. The pharmacist can dispense an antibiotic drop for the patient on the spot.

³³Science Direct (February, 2013) Continuing Education in Anesthesia Critical Care & Pain, retrieved at <https://doi.org/10.1093/bjaceaccp/mks049>.

³⁴ Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure ("JNC 7") or the American College of Cardiology/American Heart Association Guidelines ("ACC/AHA Guidelines") for arterial hypertension. Both of these recommendations are essentially different from all previous standards and guidelines, starting from cut-off values for blood pressure (BP) in various patient groups to treatment approach. The problem is that physicians are not using these guidelines and this a problem that pharmacists catch and adjust during MTM.

³⁵Axis-Shield PoC AS, Eldri Presteg (2006) The Future of C-Reactive Protein in Point of Care Testing, retrieved at <https://www.touchendocrinology.com/the-future-of-c-reactive-protein-in-point-of-care-testing/>.

³⁶Matthew J. O'Brien, MD, MSc1,2,3; David B. Sacks, MB, ChB4 (September 12, 2019) Point-of-Care Hemoglobin A_{1c}, retrieved at <https://jamanetwork.com/journals/jama/article-abstract/2751520>.

³⁷ Diagnosing HIV requires two (2) different, positive test results. The patient's physician will perform the second test and diagnose the patients with HIV.

³⁸ If the patient with HIV is adhering to his HIV medication regime and is given an HIV test, the HIV test will result in a false negative because the HIV medications would be regulating the patient's viral load. Daniel M. Keller, PhD (October 6, 2011) HIV Patients Treated Long-Term May Have False-Negative Tests, retrieved at <https://www.medscape.com/viewarticle/751067>.

9) Hepatitis B is a highly contagious, serious liver infection caused by the hepatitis B virus. The pharmacist can prescribe and administer a vaccination to prevent Hepatitis B infections, then place a note in the patients EMRs so that the physician is aware.

10) Hepatitis C is linked to HIV and is treatable. The Pharmacist would provide this Point of Care test and if there is a positive result, the pharmacist would refer the patient to an infectious disease physician for diagnosis and report the case to the local health authorities. In addition, patients with Hepatitis C, in many instances, are unstable; and, when they become unstable the pharmacist can adjust their medications between physician appointments.³⁹ Pharmacists are in the best position to evaluate the condition of the patient, the adherence to the medication and its efficacy of that medication since they see the patients at least once a month for medication re-fills.

11) The Flu is a viral infection that kills approximately 20,000 people each year in the United States. Pharmacists can, and do, administer a vaccination to prevent the Flu. Pharmacists can also conduct Point of Care testing for Influenzas A and B, especially since time is of the essence with these highly contagious infectious diseases. For Influenzas A and B, treatment is only effective within the first 72 hours of initial symptoms since the disease is shedding during that period. If the patient receives treatment within 72 hours of the initial symptoms, it will reduce the length and severity of these infectious diseases.⁴⁰ The community pharmacist is in the best position to treat patients in this time-sensitive situation.

12) Patients experiencing immediate, extreme allergic reactions can seek direct, timely and sometimes life-saving treatment on the spot from the community pharmacist by administration of an EpiPen or an epinephrine injection on the spot.⁴¹

13) Infectious Disease Testing for COVID-19, Influenza and other infectious diseases, can now be performed with a simple swab test that takes 15 minutes for results to develop.⁴² If there is no vaccine, cure or treatment, such as in the case of COVID-19, the pharmacist could direct the patient to immediately quarantine himself and report the case to the local health authorities. If there is a vaccine, cure or treatment, the pharmacist could dispense the vaccine, cure or treatment on the spot to the patient.⁴³ This will be a crucial service in future pandemics, epidemics or crises, which we now know are inevitable.

Clearly, the pharmacist's performance of these Point of Care tests can add tremendous value to the health and wellbeing of Michigan residents.⁴⁴ Even outside of a healthcare pandemics, epidemics or crisis, imagine the human suffering that could be spared with pharmacist- administered, on the spot, Point of Care testing just based on the small sample of Point of Care tests highlighted in this paper. Imagine the lives that could be improved or saved, through on the spot, Point of Care testing and treatments. Now consider the fact that there will be future healthcare pandemics, epidemics or crises where Michiganders will need to

³⁹National Institute of Health- Scientific Reports (October 17, 2018) Point-of-Care Screening for a Current Hepatitis C Virus Infection: Influence on Uptake of a Concomitant Offer of HIV Screening, retrieved at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6193009/>.

⁴⁰Center for Disease Control, Rapid Influenza Diagnostic Tests, retrieved at https://www.cdc.gov/flu/professionals/diagnosis/clinician_guidance_ridt.htm.

⁴¹ In Michigan's current healthcare delivery model, the patient would have to go to the emergency room and either move to the head of the line, if the condition was life-threatening, thereby extending other patients with serious conditions, time in the already over-taxed emergency room or having to wait themselves for hours in the emergency room. Also, the cost of treatment at a pharmacy would be a fraction of the costs of an emergency room.

⁴² This is exactly what Executive Order 2020-25 COVID-19 provides

⁴³ In fact, this is essentially how the COVID-19 Orders function, a recognition that the pharmacist does, and can, play a much larger and impactful role in Michigan's healthcare delivery system.

⁴⁴ This paper previews only a small sample of the 120 or so CLIA waived tests that pharmacists could perform. The only way this Point of Care Model could work is for the insurance companies to pay a fair, agreed upon rate across the board for each of these Point of Care tests and Point of Care treatments. That is precisely what has occurred in the PHC related to APRNs. MCL333.17211a(3) Otherwise, the pharmacists will be unable to provide these invaluable services.. Also, the health benefits to the patient and future healthcare cost savings make this model a "no-brainer".

marshal all the healthcare professionals available to fight the new scourge. The COVID-19 Orders demonstration that both prescriber status for pharmacists and Point of Care treatment by pharmacists were critical components of Michigan's healthcare delivery system in the urgent battle. Additionally, the pharmacist's performance of these Point of Care tests can add tremendous value for all taxpayers in the State of Michigan by drastically reducing the healthcare costs for testing and treatments, especially in times of healthcare pandemics, epidemics or crises. Why wait for the next crisis? Why not convert Michigan's healthcare delivery system into a proactive, ahead of the curve, Point of Care Model, rather than a slow reactive outdated healthcare delivery system?

b. Advantages of the Point of Care Model Over Michigan's Current Healthcare Delivery Model

1) In the current model, the patient must, in every instance, have some contact with a receptionist, appointment scheduler, a physician, at least 1 nurse, a laboratory, a medical biller and a pharmacist, before he receives any treatment, sometimes days after he experiences physical pain or menacing symptoms.⁴⁵ In the Point of Care Model, the patient interfaces with 1 person, the pharmacist to receive immediate Point of Care testing and treatment. Conditions such as Conjunctivitis/ pink eye do not require any further treatment or contact with the healthcare system. In other cases, such as cholesterol screening, a patient with a diagnosis from his physician, can simply have their medications adjusted. This reduces the need for an immediate or urgent physician's appointment and the patient can see their physician at the next scheduled appointment.

2) In the current model, the patient or his insurance company, in every instance, will be required to absorb the costs of a receptionist, appointment scheduler, a physician, at least one (1) nurse, a laboratory, a medical biller and a pharmacist. In the Point of Care Model, the patient, or his insurance company, in many instances, such as in the case of treating pink eye or adjusting the medications for blood pressure, there is no need for any additional appointments, and the only costs are for the Point of Care provider, the pharmacist.

3) In the current model, there are many uninsured patients and patients that are unable to afford their co-pays and deductibles; as a result, many people go untreated until they have a healthcare emergency. When a patient has reduced or limited access to medical care because of lack of insurance or financial resources, a Point of Care model reduces the number of touch points and reduces the highest cost elements in the process, the Physicians' fees and medical clinic or hospital fees. This allows Michiganders with no insurance or insufficient resources to access medical treatment so that medical emergencies can be avoided.

4) In the current model, the patient often times leaves the physician's office without an accurate diagnosis or targeted treatment because there are no test results on the day of the appointment, and it takes days to get an accurate diagnosis and targeted treatment. In the Point of Care Model, the patient receives the results of the Point of Care testing on the spot and leaves with a targeted treatment and/or their condition stabilized. The pharmacist has the patient's attention when they are in pain or in an unstable condition and can counsel the patient regarding lifestyle changes and medication adherence, then on the spot dispense the medication; unlike in the disjointed process of the current model.

5) With the Point of Care Model, in future healthcare crises, which we now understand are part of our future, there is a high possibility of contagion in the hub of the current healthcare delivery model, the hospital. The Point of Care Model pulls the patient away from the hospital and therefore away from the hub

⁴⁵ Telemedicine is not a substitute for an in-person physician's appointment, or a Point of Care consultation and treatment with a pharmacist. As illustrated by the conditions discussed above, a video conference will not suffice because the patient's blood glucose levels, blood pressure or controlled substances in his system must be tested. A real analysis, based on current levels from specimens is necessary when the goal is stabilizing a patient's condition (such as diabetes or high blood pressure); or, when a patient is experiencing a time sensitive emergency (allergic reactions, need for immediate insulin or drug overdose).

of contagion; which keeps patients safe and reduces the stress on hospital resources so that they can concentrate on the victims of the newest healthcare crisis.

6) In the current model, Michigan's healthcare delivery system is a reactive system. First, many people fail to undergo annual physicals after reaching adulthood so they are not being monitored appropriately. This means that early intervention is sacrificed and these people can end up with serious, life-long, chronic conditions such as diabetes, which hit the public purse hard. Conversely, people who do require and schedule specialty visits, require frequent follow up appointments for accurate monitoring and medication adjustment, but they are often unable to be seen by a physician in a timely fashion because of the lack of physician appointment availability. As a result, Michigan's healthcare delivery system waits until Michiganders contract diseases or experience healthcare concerns to act. This results in poor healthcare outcomes for patients and exorbitant healthcare costs for all Michigan residents.

In the Point of Care Model, the patient receives preventive care services so that life-changing conditions such as diabetes, high blood pressure and hypertension can be immediately mitigated, if not avoided all together through the pharmacist counseling aspect of Point of Care model. The Point of Care Model also increases the quality of life for individuals with diseases and chronic conditions through medication therapy management⁴⁶ and on the spot Point of Care testing with rapid results leading to timely and targeted treatment, such as adjustment of medications for chronic conditions.⁴⁷

7) The Point of Care Model provides the patient with a virtual medical team working together to ensure the best outcome for the patient. The availability of EMRs enables all the laboratory test and Point of Care test results performed by multiple providers, in multiple locations, on a patient to be compiled into one record. The Point of Care tests are entered into the patient EMR so that the patient's physician can review the Point of Care test results conducted which avoids duplicate testing and reduces healthcare costs; as well as allows for informed input from a virtual medical team of providers.⁴⁸ This virtual medical team approach means more complete and precise patient test data, leading to more accurate diagnoses, resulting in targeted treatments, concluding in better outcomes with reduced costs.

8) In the current model, when pharmacists are not involved in managing patients' medications, the result is massive unnecessary costs to the United States healthcare system. The financial impact of patients' incorrect medication use is staggering. Each year, there are over 1.5 million preventable medication-related adverse events in the United States.⁴⁹ Moreover, the health care system incurs nearly \$290 billion dollars annually in mostly avoidable costs to treat adverse events from inappropriate medication use.⁵⁰ Medication

⁴⁶ The term medication therapy management is defined as a systematic process of collecting patient-specific information, assessing medication therapies to identify medication-related problems, developing a prioritized list of medication-related problems, and creating a plan to resolve them, by varying the time, manner or dose of a medication, providing suggestions for alternative medications or making recommendations for discontinuing a medication or combination of medications. American Pharmacists Association (October 1, 2014) Policy 101: Collaborative practice empowers pharmacists to practice as providers, retrieved at <https://www.pharmacist.com/article/policy-101-collaborative-practice-empowers-pharmacists-practice-providers>.

⁴⁷ Example of this approach are Michigan Medicine's Ambulatory Care Model and Beaumont Health Care Systems' 'Ambulatory Care Model. Both models employ ambulatory care prescribing pharmacists that manage patients who are "unstable", between physician's visits.

⁴⁸ Another beneficial consequence of allowing pharmacists to input point of care test results and consultation information into the patients' EMR is that it will reduce fraudulent prescriptions. The pharmacist is able to see all physician's notes. It cannot be overstated how frequently fraudulent paper prescriptions and electronic prescriptions are submitted to the average pharmacy. While some are caught, a large percentage escape detection until a detailed audit. Imagine the cost savings to Michigan's healthcare system and the public purse. One simply cannot fake an EMR entry.

⁴⁹ Institute of Medicine (July 18, 2013) Report Brief: Preventing Medication Errors. retrieved at www.iom.edu/~media/Files/Report%20Files/2006/Preventing-Medication-Errors-Quality-Chasm-Series/medicationerrorsnew.pdf.

⁵⁰ Network for Excellence in Healthcare Innovation (July 16, 2016) Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease. Accessed at

non-adherence for chronic conditions (hypertension, diabetes, cholesterol etc....) alone results in \$100 billion each year in excess hospitalizations.⁵¹

When pharmacists are managing the patient's medication therapy and selecting the prescription drug for the physician-provided diagnosis, the risks to the patient are minimized, resulting in reduced costs to the healthcare industry and Michigan taxpayers. If a pharmacist learns nothing else in his four (4) to six (6) years of concentrated pharmacy schooling, he learns about drug interactions. The average pharmacy software system contains 180,000 prescription medications⁵² and they are familiar with them. It really takes an expert in medications, mechanisms of medications and drug interactions to effectively and safely prescribe, under these circumstances. There are numerous situations where a pharmacist receives prescriptions for two (2) or more medications and the combination would cause dangerous drug-to-drug interactions.⁵³

This problem was studied and documented in a 2010 Center for Medicare and Medicaid Services ("CMS") study which followed nine (9) pharmacists who worked closely with eighty-eight (88) Medicaid patients from July 2009 through May 2010 reviewing their medical records. The pharmacists discovered 917 medication therapy problems and 3248 medication discrepancies. The pharmacists were able to completely resolve over 80% of these issues ("CMS Connecticut Study").⁵⁴ Medication therapy problems and medication discrepancies are due to a number of factors, including time crunches that physicians are under to perform all of the functions required by their critical and complicated jobs. The pharmacist can, and should, be able to alleviate the stresses of physicians allowing them to concentrate on their forte, diagnosis. Pharmacists should not be in a position to call the physician to revise the prescription, they should be able to write prescriptions so that this risk is minimized, a virtual medical team, each playing to their strengths.⁵⁵

c. Examples of Pharmacists Performing Point of Care Treatments and Prescribing

The CDC counsels, "Pharmacists can improve patients' health and the health care delivery system if they are part of the patient's health care team. One way to meet this goal is with a collaborative practice agreement ("CPA") between pharmacists and other health care providers."⁵⁶ CPAs have been authorized between one or more physician(s) and pharmacist(s) whereby pharmacists working within the context of a defined protocol are permitted to assume professional responsibility for performing medication therapy management ("MTM") reviews and recommendations. The MTM review is a systematic process of collecting patient-specific information, assessing medication therapies to identify medication-related problems, developing a prioritized list of medication-related problems, and creating a plan to resolve them, by varying the time, manner or dose of a medication, providing suggestions for alternative medications or making recommendations for discontinuing a medication or combination of medications.

www.nehi.net/publications/44/thinking_outside_the_pillbox_a_systemwide_approach_to_improving_patient_medication_adherence_for_chronic_disease,

⁵¹ Osterberg L, Blaschke T. Adherence to medication. *N Engl J Med*. 2005;353:487-97; American Pharmacist Association (September 2013), retrieved at https://www.pharmacist.com/sites/default/files/files/Provider%20Status%20FactSheet_Final.pdf In Pursuit of Provider Status.

⁵² Interview with Wayne Seiler, Director of Business Operations for SRS Pharmacy Software System.

⁵³ This information was garnered through 6 interviews with community pharmacists recounting specific instances.

⁵⁴ Marie Smith, Margherita R. Giuliano, and Michael P. Starkowski (April, 2011) In Connecticut: Improving Patient Medication Management in Primary Care, retrieved at <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2011.0002>.

⁵⁵ The Point of Care Model does not attempt to strip any current prescribers of their prescribing authority, just to allow pharmacists to prescribe under the scenarios set out in this paper.

⁵⁶ A CPA is a formal agreement in which a licensed provider makes a diagnosis, supervises patient care, and refers patients to a pharmacist under a protocol that allows the pharmacist to perform specific patient care functions. Centers for Disease Control and Prevention, Collaborative Practice Agreements and Pharmacist' Patient Care Services, retrieved at https://www.cdc.gov/dhsp/pubs/docs/Translational_Tools_Pharmacists.pdf

Forty-eight (48) states have passed laws authorizing CPAs between physicians and pharmacists within the scope of their practice.⁵⁷ MTMs have demonstrated that patients have improved healthcare outcomes because pharmacists are intimately familiar with the side effects of medications, have an in-depth understanding of medications' methods of action and know how to mitigate risks associated with medications better than any other professional, including physicians, APRNs and PAs. In short, pharmacists' MTM analyses review a patient's medications and their protocol to resolve medication-related problems by adjusting the medications, or the manner of taking the medication.

Under North Carolina's public health code, for instance, Clinical Pharmacist Practitioners ("CPP") are prescribing pharmacists who enter into a CPA with a supervising physician to manage patients in specialized or therapeutic areas, including anticoagulation, hyperlipidemia, diabetes, respiratory diseases, hypertension, endocrinology, pain management, cardiology, geriatrics, and transplant. Some of the tasks that these prescribing pharmacists performed are managing medications, prescribing medications, crafting medication-related policies and procedures, contributing to continuous quality improvement initiatives, educating staff and providers, and counseling patients. The study concluded that, "By focusing on clinical tasks associated with medication management, CPPs allow physicians to spend more time performing the diagnostic and procedural responsibilities that are unique to medicine." Essentially, this study demonstrated that when each healthcare provider plays to his strengths, the patient benefits and healthcare costs are reduced.⁵⁸

In addition to North Carolina, currently there are ten (10) states that have designated pharmacists as prescribers in different ways and to different degrees, including Washington, Idaho and California.⁵⁹ Another state, Ohio, passed legislation giving pharmacists prescriber status to dispense life-saving maintenance medications when patients run out of refills and are unable to secure a prescription from their health care provider.⁶⁰ The Ohio law was triggered by the death of a patient that could not get his insulin from his pharmacy because he had no more re-fills on his prescription and the pharmacy could not get ahold of his physician.⁶¹ It is noteworthy that this Ohio law is the equivalent of combining Executive Order 2020-56 COVID-19 and Executive Order 2020-61 COVID-19, with respect to the expansion of pharmacists' prescribing and dispensing authority.

In 2000, Arizona law initially authorized CPAs between pharmacists and physicians only in healthcare facilities.⁶² In 2011, this law was amended to allow pharmacists in any venue, including community pharmacies, to enter into CPAs with physicians and nurse practitioners and fully prescribe for

⁵⁷ American Pharmacists Association (October 1, 2014) *Policy 101: Collaborative practice empowers pharmacists to practice as providers*, retrieved at <https://www.pharmacist.com/article/policy-101-collaborative-practice-empowers-pharmacists-practice-providers>.

⁵⁸ Jeffrey E. Heck and Courtenay Gilmore Wilson Mollie Ashe Scott, *North Carolina Medical Journal* (May 2017) *The Integral Role of the Clinical Pharmacist Practitioner in Primary Care*, retrieved at <https://doi.org/10.18043/nem.78.3.181>.

⁵⁹ Pharmacists are able to administer immunizations in most states; but must be engaged in a CPA with a physician. There are, however, a few states that allow pharmacists to administer immunizations in accordance with the CDC Guidelines without a specific prescription order.

⁶⁰ The Ohio law was instigated by the death of 36-year-old diabetic, whose pharmacist was unable to provide him with the insulin he needed on a holiday weekend in late 2013 because the man did not have a prescription. Following his death, his parents lobbied their local legislators to change the law to allow pharmacist to prescribe maintenance medications independently. The law allows pharmacists to order up to a 30-day supply of refills for patients whose lives will be endangered without their medication and whose physician cannot be reached to prescribe a refill. Maurine McKinney, *Pharmacy Times* (November 7, 2016) *Pharmacists' Services Expanded in Ohio*, retrieved at <https://www.pharmacytimes.com/news/pharmacists-services-expanded-in-ohio>. This case is not unique and a perfect example of how the laws related to pharmacy are in many instances illogical and frankly dangerous to the public safety.

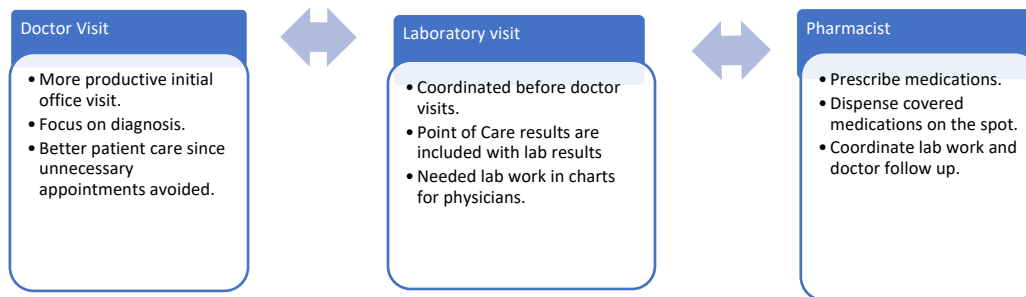
⁶¹ Sadly, this is not an unusual case as many pharmacists interviewed report. Unfortunately, Michigan does not record statistics on the number of deaths due to patients unable to access their medications in time to save their lives.

⁶² ARS §32-1970 [A-D]

emergency medications based on a diagnosis and also to perform immunizations.⁶³ A route that has proven successful in the CMS Connecticut Study, which promotes the integration of pharmacist into a patient’s medical delivery team.⁶⁴

Moreover, Oregon broadened its licensing laws regarding pharmacists’ scope of practice to allow prescribing to administer opioid overdose treatments, prescribing contraceptives and prescribing and dispensing emergency insulin prescriptions.⁶⁵ Oregon pharmacists are statutorily authorized to perform CLIA waived tests in order to perform these and other functions.⁶⁶

Finally, this is a tested, evidence-based model. High risk Medicaid patients that received services from a clinically integrated network of physicians and pharmacies that provide enhanced services such as MTMs and Point of Care treatments are 45% less likely to have an in-hospital admission, 35% less likely to have preventable hospital admission or a re-admission and 15% less likely to have an emergency department visit. Furthermore, Medicaid patients that worked with pharmacies in a clinically integrated network providing MTMs and Point of Care treatments were 25% more likely to engage their primary care physician and 20% more adherent to prescribed medications.⁶⁷ It only makes sense for Michigan to convert its costly, archaic model of healthcare delivery to a Point of Care model. The diagram below illustrates that with readily accessible prescribing pharmacists in the community, healthcare can be delivered along a fluid continuum allowing for healthcare to be timely, coordinated and supported. Patients’ healthcare is managed through a barrier-free delivery system focused on the patients and designed to provide improved and enhanced health outcomes.



IV. PATH TO PHARMACIST PRESCRIBER IN MICHIGAN IN ORDER TO IMPLEMENT THE POINT OF CARE MODEL

The PHC related to the delegation of duties by MDs and DOs, at MCL 333.16215(1) provides, in pertinent part, as follows:

⁶³ Senate Bill (SB) 1298 Ariz. Sess. Laws Ch 103 [2011]

⁶⁴ A 2010 CMS study followed nine (9) pharmacists who worked closely with eighty-eight (88) Medicaid patients from July 2009 through May 2010 reviewing their medical records. The pharmacists discovered 917 medication therapy problems and 3248 medication discrepancies. Marie Smith, Margherita R. Giuliano, and Michael P. Starkowski (April, 2011) In Connecticut: Improving Patient Medication Management in Primary Care, retrieved at <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2011.0002>.

⁶⁵ ORS 689.681 related to opioid prescribing and dispensing, ORS 689.689 related to contraceptives prescribing and dispensing and ORS 689.696 related to prescribing and dispensing of insulin.

⁶⁶ ORS 689.661.

⁶⁷ <https://www.cpesn.com/payors/services-available-from-cpesn-network-pharmacies/>

[A] licensee who holds a license ...may delegate to a licensed or unlicensed individual who is otherwise qualified by education, training, or experience the performance of selected acts, tasks, or functions where the acts, tasks, or functions fall within the scope of practice of the licensee's profession and will be performed under the licensee's supervision. MCL 333.16215(1)

Both the University of Michigan Healthcare System and Beaumont Hospital Healthcare System have used MCL Section 333.16215(1) to enter into CPAs between physicians and pharmacists within their network, whereby the physicians delegate prescribing authority for non-controlled medications to pharmacists. Michigan Medicine's Ambulatory Care Model is one in which Michigan Medicine employs ambulatory care pharmacists, who enter into CPAs with the physicians to manage "unstable" patients' cases between physician's visits, to ensure that the physicians are not overwhelmed, and that the patients' medications are managed and their conditions are appropriately monitored. Patients make appointments with the pharmacist who performs all of the testing required to managed the patient's medications. In fact, Michigan Medicine's Anticoagulation Clinic located at Domino Farms is where all complicated patient cases are referred and prescribing pharmacists are the ones initiating medications for these complicated cases. Pharmacists (and student pharmacists) are also regularly consulted by Michigan Medicine physicians and APRNs in regards to what medication they think is best for a given patient based on their diagnosis, laboratory values, and the patient's current medication list. Other Michigan Medicine healthcare providers acknowledge that pharmacists are the true "medication experts".⁶⁸

Beaumont Health Care System's Ambulatory Model is another model in which patients that have "unstable conditions" or conditions requiring additional care and monitoring are referred to Beaumont's ambulatory care pharmacists for periodic monitoring appointments. At the appointments, pharmacists conduct Point of Care testing, write prescriptions for laboratory tests and counsel patients, including providing patients with regimens such as logging blood pressure or glucose levels and weight. Based on the Point of Care test and laboratory test results and the consultation with the patient, the pharmacist will adjust the patient's medication as needed and initiate any therapy needed. The pharmacist has full access to the patient's EMR so that he can prescribe laboratory tests, review laboratory results and input office visit notes. The patient remains on the pharmacist's schedule as long as needed to stabilize the patient.⁶⁹

Both of these models have worked well, improved healthcare outcomes for patients' and conserved resource in Michigan's healthcare industry. They are a recognition that pharmacists are the healthcare professionals best educated, trained and suited to assess medication regimes and prescribe medications. It is time to expand this model to community pharmacies. It is appropriate and practical that the pharmacist's scope of practice, under the PHC, be expanded to designate them as independent prescribers based on their in-depth and highly relevant education, training, and experience and this is the key to the Point of Care Model. The roadmap for expansion of pharmacists' scope of practice to include prescribing is provided by the expanded scope of practice for APRNs and PAs in the State of Michigan.

a. APRNs' Qualifications to Prescribe and Medications APRN's are Authorized to Prescribe

The scope of practice of "Nursing" under the PHC is defined as follows:

'Practice of nursing' means the systematic application of substantial specialized knowledge and skill, derived from the biological, physical, and behavioral sciences, to the care, treatment, counsel, and health teaching of individuals who are experiencing changes in the

⁶⁸ The information regarding University of Michigan ambulatory care models was garnered through interviews and information from members of this program.

⁶⁹ The information regarding Beaumont Healthcare's ambulatory models was garnered through interviews.

normal health processes or who require assistance in the maintenance of health and the prevention or management of illness, injury, or disability.” MCL 333.17201(c).

Note that no mention is made of pharmaceuticals, pharmacology, pharmacokinetics, medications, prescribing of medications, or drug product selection in the scope of practice for nursing.

An APRN is a registered nurse in a specialty field as set forth in MCL 333.17201(a):

‘Advanced practice registered nurse’ or ‘a.p.r.n.’ means a registered professional nurse who has been granted a specialty certification under section 17210 in 1 of the following health profession specialty fields:

- (i) Nurse midwifery.
- (ii) Nurse practitioner.
- (iii) Clinical nurse specialist. MCL 333.17201(a)(i)-(iii).

Again, there is no mention made of pharmaceuticals, pharmacology, pharmacokinetics, medications, prescribing of medications, or drug product selection in the expanded scope of practice for APRN. Furthermore, the education and training for APRN’s mandates that they take the equivalent of one (1) course in Pharmacology, the branch of medicine concerned with the uses, effects, and modes of action of drugs, during their entire education.⁷⁰ Despite the lack of education, training or scope of practice authority, on April 9, 2017, the PHC, Part 172 for Nurses, at MCL 333.17211a, was amended to make APRNs independent or autonomous prescriber for non-controlled drugs and prescribers of controlled drugs under supervision of a physician as follows:

- “(1) An advanced practice registered nurse may prescribe any of the following:
 - (a) A nonscheduled prescription drugs.
 - (b) Subject to subsection (2), a controlled substance included in schedules 2 to 5 of part 72, as a delegated act of a physician.
- (2) If an advanced practice registered nurse prescribes a controlled substance under subsection (1)(b), both the advanced practice registered nurse's name and the physician's name shall be used, recorded, or otherwise indicated in connection with that prescription. If an advanced practice registered nurse prescribes a controlled substance under subsection (1)(b), both the advanced practice registered nurses and the physician's DEA registration numbers shall be used, recorded, or otherwise indicated in connection with that prescription.”
- (3) The amendatory act that added this section does not require new or additional third-party reimbursement or mandated worker's compensation benefits for services rendered by an advanced practice registered nurse who is authorized to prescribe nonscheduled prescription drugs and controlled substances included in schedules 2 to 5 of part 72 under this section. MCL 333.17211a(1)-(3).

⁷⁰ Michigan Administrative Rule R338.10307 (4) sets out the minimum course contents for APRNs educational requirements in Michigan as follows: (a) Understanding the nursing professions roles and responsibilities. (b) The principles of nursing and sciences for basic nursing practice care. (c) The provision of direct and indirect nursing care. (d) Effective human relations in nursing situations. (e) Understanding of physical, psychosocial, and spiritual needs of diverse patient populations. (f) The understanding of health underlying nursing care. (g) Developing skills and abilities in the administration of all aspects of nursing care using the nursing process, including all of the following: (i) Communications. (ii) Critical thinking, clinical reasoning, and problem solving. (iii) Understanding legal and professional responsibilities. (iv) Inter-professional relationships with other health care providers. (v) Evidence-based practice. (vi) Quality and safety. (h) Protecting the rights of patients.

Furthermore, MCL 333.17211a (3) clarifies that insurance companies and worker's compensation benefits services must pay for APRN's prescribing functions without the need for any further legislation.

b. PAs' Qualifications to Prescribe and Medications PAs are Authorized to Prescribe

PA programs are 24-month programs, which must include thirty-five (35) standards, one (1) of which is Pharmacology.⁷¹ The definition of "Physician Assistants" under the PHC, in pertinent part, is defined as follows:

Practice as a physician's assistant is a health profession subfield of the practice of medicine, osteopathic medicine and surgery, and podiatric medicine and surgery. MCL 333.17008

PAs scope of practice contained at MCL 333.17076(2) with respect to prescribing of controlled and non-controlled medications was amended and became effective on March 22, 2017, as follows:

A physician's assistant who is a party to a practice agreement may prescribe a drug in accordance with procedures and protocols for the prescription established by rule of the department in consultation with the appropriate board. A physician's assistant may prescribe a drug, including a controlled substance that is included in schedules 2 to 5 of part 72. If a physician's assistant prescribes a drug under this subsection, the physician's assistant's name shall be used, recorded, or otherwise indicated in connection with that prescription. If a physician's assistant prescribes a drug under this subsection that is included in schedules 2 to 5, the physician's assistant's DEA registration number shall be used, recorded, or otherwise indicated in connection with that prescription. MCL 333.17076(2)

This means as of March 22, 2017, PAs that are engaged in a CPA with a physician, may prescribe both controlled and non-controlled medications, limited only by any restrictions that the Board of Medicine may implement.

c. Pharmacists' Qualifications to Prescribe Medications, Offer Point of Care Testing, and Become Prescribers

There are numerous reasons why pharmacists are qualified to be designated as prescribers. This paper will address only the most significant and evident reasons.

1) Scope of Pharmacy Practice. The scope of practice of pharmacy under the PHC, is found at MCL 333.17707(7) and is defined as follows:

'Practice of pharmacy' means a health service, the clinical application of which includes the encouragement of safety and efficacy in the prescribing, dispensing, administering, and use of drugs and related articles for the prevention of illness, and the maintenance and management of health. Practice of pharmacy includes the direct or indirect provision of professional functions and services associated with the practice of pharmacy. Professional functions associated with the practice of pharmacy include: (a) The interpretation and evaluation of the prescription. (b) Drug product selection. (c) The compounding, dispensing,

⁷¹ Michigan Administrative Rule R 338.6201 sets out the educational requirements for PA programs in Michigan. R 338.6201 Educational program standards; adoption by reference. Rule 201. (1) The standards for accrediting educational programs for physician's assistants approved by the accreditation review commission on education for the physician assistant (ARC-PA) in the document entitled "Accreditation Standards for Physician Assistant Education, 4th Edition," effective September 1, 2010, updated March 8, 2018, are adopted by reference in these rules. (2) Only educational programs for physician's assistants that are accredited by the ARC-PA are approved physician's assistant educational programs.

safe storage, and distribution of drugs and devices. (d) The maintenance of legally required records. (e) Advising the prescriber and the patient as required as to contents, therapeutic action, utilization, and possible adverse reactions or interactions of drugs. MCL 333.17707(7)

Even a cursory review of the scope of pharmacy practice reveals that a pharmacist is uniquely qualified to be considered a prescriber under the PHC, when it directs that, “Drug product selection” is within the pharmacies’ scope of practice. MCL 333.17707(7)(b). Selecting medications for the patient is synonymous with prescribing medications for patients. Additionally, the scope of pharmacy practice includes. “Advising the prescriber and the patient as required as to contents, therapeutic action, utilization, and possible adverse reactions or interactions of drugs”. In order for the pharmacist to be able to advise on the “content, therapeutic action, utilization, and possible adverse reactions of medications”, he must have the education, training, knowledge and skill to know all of this, which makes the pharmacist the expert among the healthcare professional for prescribing purposes. Thus, the recognition of a pharmacist’s expertise in prescribing medications, which is contained in the pharmacist’s scope of practice, is one basis that qualifies him to be a prescriber under the PHC.

2) The Training and Education of the Pharmacist. Pharmacists’ education involves four (4) years of undergraduate study, with another with four (4) to six (6) years of graduate education focused on medications and their impact on the human body.⁷² Pharmacists learn the mechanisms of diseases and what medications impact those disease states. Part of the core training for pharmacists is learning about the appropriate guidelines for various levels in the human body, glucose, cholesterol, blood pressure, hypertension, and to ensure that they are always using the most current standards or guidelines to measure those levels. Pharmacists are educated to work with complex medication regimens, systematically review medications for effectiveness, safety, and appropriateness and consider the indications and contraindications. Pharmacists are trained to counsel patients on lifestyle changes and regarding medications that they have been prescribed, including how and when to take the medications, describe the side effects to look for, and what to avoid when taking the medications prescribed.⁷³

Pharmacists are scientists trained in the science of pharmaceuticals, which includes pharmacokinetics and pharmacology. A pharmacist licensed in Michigan is a Doctor of Pharmacy who studies, among other things, pharmacology, the branch of medicine concerned with the uses, effects, and modes of action of drugs and pharmacokinetics, the branch of pharmacology concerned with the movement of drugs within the body. In short, pharmacists are the medical experts in the healthcare profession to prescribe by education. As scientists, pharmacists are experts in drugs—the way drugs work; how, why, and when drugs should be used; how to reduce the risks associated with drugs; how to compound and mix drugs to make them more effectual; and considerably more.

Beyond the four (4) to six (6) years of education focused on medications, pharmacists are required to complete continuing education after graduation to, among other things, remain current on all new medications and treatments. There are over 180,000 medications in a pharmacy software system, including brands, generics and biosimilars; and, pharmacists know them all. The number and sophistication of newer

⁷² If a pharmacist is interested in a specialty field, such as transplant for instance, they will be required to complete two (2) additional one (1) year residencies in order to qualify. There are other specialty fields that only require one (1) additional year of residency.

⁷³ Center for Medicare & Medicaid Innovation (July 18, 2013) Medication Therapy Management in a Chronically Ill Population: Interim Report, retrieved at <http://innovation.cms.gov/Files/reports/MTM-Interim-Report-01-2013.pdf>. IMS Institute for Healthcare Informatics (July 16, 2013) The Responsible Use of Medicines: Applying Levers for Change, retrieved at www.responsibleuseofmedicines.org/research-findings, Health Resources and Services Administration (July 16, 2013) Patient Safety and Clinical Pharmacy Services Collaborative (PSPC). Frequently Asked Questions. retrieved at www.hrsa.gov/publichealth/clinical/patientsafety/faq.html

medications creates more challenges to keeping abreast of medications and biologicals entering the market. The scientific knowledge pharmacists possess will become even more valuable as medications evolve.

By contrast, the study of medicine is so vast and complex, so the minimum requirement is the equivalent of a single semester in pharmacology throughout medical school.⁷⁴ Imagine how complicated the human body is, with all of the inter-related systems and functions, from the digestive system to the endocrine system to the immune system, to the nervous system, and much more. Physicians need to understand how each one of these systems functions in a healthy body. Then imagine that they need to learn all of the things that could go wrong with each of these highly complicated systems, from birth defects, to disease states, to infections to trauma. Clearly, physicians have their hands and heads full just learning how to diagnose highly complicated conditions in the highly complicated human body, containing highly complicated systems.

Furthermore, physicians never come into contact with even a fraction of the 180,000 plus prescription medications on the market.⁷⁵ Physicians are also required to complete continuing education, but they are not required to take courses in pharmacology. Despite these facts, illogically, physicians are prescribers under the PHC and pharmacists are not⁷⁶. Even more baffling is the fact that APRNs and PAs have prescriber status, but pharmacists do not.

The implications of this distinction between physicians and pharmacists related to understanding medications and appropriate prescribing is illustrated by two (2) real world examples:

A) Because pharmacists are currently excluded from establishing the medical protocols and guidelines in hospitals, many people are not flagged as pre-diabetic in a timely and pursuant to the most current guidelines. For instance, Henry Ford Hospital uses the 2008 ADAG Study to guide their treatment of diabetes conditions. They do not flag a patient as pre-diabetic with blood glucose levels <117.⁷⁷ Pharmacists use the most current ADA Guidelines, updated in 2019, which flags patients as pre-diabetic at a blood glucose level of 100. The result is that some patients are not flagged until their blood glucose levels are in the diabetes range. People could become full-fledged diabetics before they receive treatment; when early detection and intervention could have prevented this life-altering disease. Pharmacists always know, and act on, the current applicable guidelines since it is part of their core education, training and continuing education. If pharmacists become prescribers and engaged in Point of Care treatment, they could: i). Craft the medical protocols and guidelines for the hospital ensuring that the most current guidelines are in place ii). Test for, and treat, pre-diabetes or diabetes, under the most current guidelines; and iii). Test for, and counsel pre-diabetics or diabetics, then refer them to their physicians. This would have a tremendous impact on Michigan's healthcare delivery outcomes and reduce costs significantly.

⁷⁴ The Board of Medicine rule R338.2421 adopted by reference, the Liaison Committee on Medical Education, "Functions and Structures of a Medical School", June 2013 edition, to establish requirements for medical school curriculum. Standard 7 deals with the curriculum and nowhere is pharmaceuticals, pharmacology or pharmaceutics mentioned. The Board of Osteopathic Medicine and Surgery rule R338.121 adopted by reference, the "Accreditation of Colleges of Osteopathic Medicine: COM Accreditation Standards and Procedures", effective July 1, 2014, to establish requirements for osteopathic medicine curriculum. Standard 6 deals with the curriculum and only requires core competencies for osteopathic medicine and clinical practice, but interestingly at Element 6.8 defines a core practice as "Interprofessional Education for Collaborative Practice requiring collaborate practice with other healthcare providers. In fact, University of Michigan medical students receive pharmacology education from pharmacy professors in the College of Pharmacy. Obviously, prescribing is an important function of the practice of medicine, it's just not defined as the core practice for physicians. The core practice is diagnosis and curing diseases, which dovetails with the scope of the practice of medicine.

⁷⁵ Interview with Wayne Seiler, Director of Business Development for SRS Pharmacy Software Systems interview.

⁷⁶ The Point of Care Model does not envision that any current prescribers would lose their prescriber status, only that pharmacists become prescribers under the confines set out in this paper.

⁷⁷ Henry Ford Hospital provides test results to patients and these are the standards that it is based on. These standards are not the current standards that students in the school of pharmacy are trained on.

B) The CMS Connecticut Study project in Connecticut was completed under a CMS Transformation Grant to the Connecticut Department of Social Services and followed nine (9) pharmacists who worked closely with eighty-eight (88) Medicaid patients from July 2009 through May 2010. The pharmacists discovered 917 medication therapy problems and 3248 medication discrepancies. The pharmacists were able to resolve nearly 80 percent of them after four (4) appointments. The result was an estimated annual saving of \$1,123 per patient on medication claims and \$472 per patient on medical, hospital, and emergency department expenses, a cost that dwarfed the cost of contracted pharmacist services.⁷⁸ This CMS Connecticut Study is scalable. Imagine the cost savings in Michigan if these values are applied to all Medicaid and Medicare patients alone, and then think about the more than 40 private insurance companies operating in Michigan. Pharmacists have the expertise to identify, resolve, monitor, and prevent these problems that would otherwise remain unresolved and a financial drain on the public purse.

3) The Aging Population in Michigan. With increased lifespans and an increasing number of patients dealing with chronic conditions in Michigan, the patient population is going to require continuous medication management across all practice settings and areas. The pharmacist is crucial in identifying and reducing the number of drug-related problems occurring; as well as, making recommendations to mitigate those drug-related problems. This is exactly what pharmacists are currently doing through performing MTMs. Moreover, the reduction in, or prevention of, medication-related problems will allow a patient to remain in an independent living setting longer. In fact, the experts report that there was a shortage of 4000 physicians in Michigan by 2015, which will balloon to an 8000-physician shortage by 2025 and the reason is the aging number of “baby-boomers” on top of the fact that Obamacare expanded insurance coverage for more Michiganders.⁷⁹ Pharmacists in Michigan are already performing MTMs with incredible results. It is a way for Michigan’s healthcare system to work smarter not harder in times of inadequate healthcare professionals. The problem is pharmacists are performing MTMs, but sporadically, informally and not in a standardized manner. If pharmacists were reimbursed for pharmacist-provided services, such as MTMs, this would incentivize pharmacists and pharmacist employers to implement, expand, and integrate patient care services into a collaborative Point of Care Model. Relying on pharmacists to address complex medication issues through MTMs is the best solution to the rising demand for patient care, medication management and quality of life issues for Michigan’s aging population, not to mention reducing the continually expanding healthcare costs.

4) Underserved Areas, Disadvantaged Communities and Rural Communities. In underserved areas, rural areas and disadvantaged communities, the pharmacy is the first level of contact for many residents seeking health care because of limited access to physicians/ healthcare facilities, lack of transportation to access healthcare, and exorbitant healthcare costs. In some of these areas and communities, there are too few, or even a complete lack of, physicians.⁸⁰ In fact, seven (7) rural counties, mostly in the northern part of the Michigan’s Lower Peninsula, fall below suggested ratios in primary care fields.⁸¹ The community pharmacist already plays a critical role in the healthcare of residents in these communities. It makes sense to expand the pharmacist’s scope of practice to adequately serve these communities. Bringing health care as close as possible to where people live in underserved, disadvantaged or rural communities is crucial and

⁷⁸ Marie Smith, Margherita R. Giuliano, and Michael P. Starkowski (April, 2011) In Connecticut: Improving Patient Medication Management in Primary Care, retrieved at <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2011.0002>.

⁷⁹ General Medicine, PC, The Real Reason Behind Michigan’s Physician Shortage, retrieved at <https://www.generalmedicine.com/real-reason-behind-michigan-physician-shortage/>.

⁸⁰ Michigan Department of Health and Human Services, Where are Michigan’s Designated Shortage Areas?, retrieved at https://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_47514-176079--,00.html.

⁸¹ Ted Roelofs/Bridge Magazine (Originally posted July 21, 2015, Updated April 3, 2019) In rural Michigan, a physician shortage promises to get worse, retrieved at https://www.mlive.com/health/2015/07/in_rural_michigan_a_physician_sho.html.

possible by granting pharmacists prescriber status and allowing them to engage in Point of Care testing and treatment.

In fact, there should be incentives for pharmacist and pharmacies that physically locate in areas that are underserved, rural or disadvantaged under the Michigan Essential Health Provider Recruitment Strategy Act, just as there are for physicians, dentists, and nurse practitioners.⁸² Part of these incentives under that Act are academic grants that make it possible for students from disadvantaged or minority communities to graduate as physicians, dentists and nurse practitioners and then serve in their communities. Why shouldn't minority students be given the opportunity to become pharmacist in their communities? Allowing this is even more compelling in such communities since pharmacies are also simply small businesses, which is an added benefit to members of these communities.

Additionally, Pharmacists that perform Point of Care testing and MTMs in these areas should be reimbursed one and half times what they would be in other areas of Michigan to incentivize the move to these underserved communities. They should also be included in the definition of "Designated Professionals" in the Michigan Essential Health Provider Recruitment Strategy Act, which provides an array of incentives and rewards for professionals serving in underserved areas.

5) Preventative Care Services Already Provided. Pharmacists already provide preventative care services, known in the industry as "Cognitive Pharmacy Services". Community pharmacies are already, albeit sporadically and independently, providing medication management services such as MTMs, education related to long term adherence on maintenance medications (i.e. blood pressure, diabetes, cholesterol) and detecting adverse medication effects and mitigating the same. In addition, community pharmacies are already, albeit intermittently and autonomously, providing healthcare preventative services such as diabetes prevention, weight management, Osteoporosis screening and prevention, and immunization. These valuable services benefit the health and wellbeing of Michigan residents by preventing diseases and conditions, which in turn reduces healthcare costs and protects the public purse. Michigan must standardize these valuable services and compensate pharmacists. This will reduce healthcare cost.⁸³

6) Pharmacists are De Facto Recognized as Legitimate Prescribers. The University of Michigan Health Care System and Beaumont Health Care Systems both have an ambulatory care model where pharmacists are prescribers. Both health care systems employ ambulatory care pharmacists, who enter into CPAs with physicians, to manage "unstable" patients' cases between physician's visits and ensuring that medications are taken and their conditions are appropriately monitored. The pharmacists see patients by appointment and conduct Point of Care testing, order laboratory tests, review results of laboratory tests, treat patients, and prescribe medications.

In addition, the CMS Connecticut Study, the Michigan Health Care System and Beaumont Health Care Systems models have proven that a Point of Care Model works well, improves healthcare outcomes for patients' and would conserve resource in Michigan's healthcare industry. They are a recognition that pharmacists' education, training and experience make them best suited to prescribe medications. It is appropriate and reasonable that the pharmacist's scope of practice, under the PHC, be expanded to designate them as independent prescribers based on their in-depth and highly relevant education, training, and experience.

⁸² MCL 333.2701 through 333.2725 provide a variety of incentives and rewards for practicing in underserved and disadvantaged areas and for minorities entering the profession and serving in these underserved and disadvantaged areas.

⁸³ The CMS Connecticut Study, illustrated that incorporating point of care testing by pharmacists, along with prescriber status, resulted in annual savings of \$1,123 per patient on medication claims and \$472 per patient on medical, hospital, and emergency department expenses. Marie Smith, Margherita R. Giuliano, and Michael P. Starkowski (April, 2011) In Connecticut: Improving Patient Medication Management in Primary Care, retrieved at <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2011.0002>.

7) Crisis Related Prescribing. Michigan has recognized the value of allowing pharmacists to dispense prescription level medications without a prescription in healthcare crises situations. The Opioid Crisis has hit Michigan especially hard. Not only were people abusing illicit drugs, they were abusing and diverting controlled substances. There was early recognition that pharmacists could assist in many ways to fight Michigan's Opioid Crisis, and helping to prevent overdoses was one way. Michigan implemented a standing order that allowed pharmacists to dispense opioid antagonists, such as Narcan, without a prescription each time an opioid prescription was dispensed.⁸⁴ In addition, currently, if the pharmacist finds that the patient could be experiencing a drug overdose, the pharmacist could immediately dispense an opioid antagonist, such as Narcan, to reverse an opioid overdose. Many pharmacists have performed this life-saving function.

Furthermore, as a result of the COVID-19 Pandemic, Governor Whitmer issued two (2) executive orders that temporarily suspended the licensing restrictions in the PHC related to pharmacists' prescribing. Executive Order 2020-56, allows pharmacists to dispense and administer medications to treat the COVID-19 and, to substitute a therapeutically equivalent medications without the prescriber's authorization. Executive Order 2020-61, allowed pharmacists in healthcare facilities to write prescriptions for routine health maintenance, chronic disease states, or similar conditions.

8) CLIA Waived Testing Leads to Prescribing. CLIA regulations are some of the most rigorous and difficult to navigate in the healthcare field. Even this strict regulatory scheme recognizes the value of pharmacies in public and patients' health and safety. Pharmacies fall into a category of non-traditional settings where CLIA-waived or Point of Care tests can be performed.⁸⁵ The pharmacist performs these CLIA-waived or Point of Care tests, receives the results within minutes and prescribes a treatment on the spot. This is one of the most meaningful ways for pharmacists to perform a valuable role in reforming Michigan's archaic healthcare model.

d. Statutory Pathway to Implementing the Point of Care Model in Michigan

Pharmacists already receive the general education and training necessary to qualify them to perform the vast majority of Point of Care testing so their curriculum does not have to be revised.⁸⁶ However, they would need to become CLIA-certified; and the Board of Pharmacy must promulgate rules determining which, if any CLIA waived Point of Care tests require may not be delegated.

Pharmacists have all of the education and training necessary to qualify for prescriber status. However, in order for pharmacists to achieve prescriber status several statutory section of the Michigan laws must be amended. First, the PHC must be amended. Section MCL 333.17708(2), defining a "prescriber" would have to be amended to add the words "licensed pharmacist" to the list of prescribers as follows:

'Prescriber' means a licensed dentist, a licensed physician of medicine, a licensed physician of osteopathic medicine and surgery, a licensed physician of podiatric medicine and surgery, a licensed physician's assistant, a licensed optometrist certified under Part 174 to administer and prescribe therapeutic pharmaceutical agents, an advanced practice registered nurse as that term is defined in section 17201 who meets the requirements of section 17211a, a licensed veterinarian, *a licensed pharmacist practicing as set forth in 333.17707(7)* or another licensed health professional acting under the delegation and using, recording, or otherwise indicating the name of the delegating licensed physician of

⁸⁴ Michigan Department of Health and Human Services, https://www.michigan.gov/mdhhs/0,5885,7-339-71550_2941_4871_79678---,00.html

⁸⁵ Michigan Pharmacists Association, retrieved at <https://www.michiganpharmacists.org/resources/pointofcare>.

⁸⁶ In fact, pharmacies are included in the CLIA exception allowing certain facilities to perform CLIA waived point of care tests. There are more than 120 CLIA waiver tests on the market that can be implemented by pharmacies.

medicine or licensed physician of osteopathic medicine and surgery. MCL 333.17708(2) (Suggested revisions italicized).

The definition of “pharmacy” under MCL 333.17707(6) would have to be amended to read as follows:

‘Pharmacy’ means a facility or part of a facility that is:

- (i) licensed under this part *to prescribe prescription drugs*, dispense prescription drugs or prepare prescription drugs for delivery or distribution.; and
- (ii) *where Point of Care testing is conducted, which shall be defined as a Clinical Laboratory Improvement Amendments (“CLIA”) waived test as defined in 42 USC Section 263a,*
- (iii) *a facility where medication therapy management is conducted.*

For the purpose of a duty placed on a pharmacy under this part, "pharmacy" means the person to which the pharmacy license is issued, unless otherwise specifically provided. Pharmacy does not include the office of a dispensing prescriber or an automated device.

- (iv) *The amendatory act that added this section does not require new or additional third-party reimbursement or mandated worker's compensation benefits for services rendered by a pharmacist who is authorized to prescribe non-scheduled prescription drugs and controlled substances prescription drugs, included in schedules 2 to 5 of part 72”* MCL 333.17707(6)(i)-(iv) (Suggested revisions italicized).

The “practice of pharmacy” under the PHC, MCL 333.17707(7) must be amended as follows:

‘Practice of pharmacy’ means a health service, the clinical application of which *includes the prescribing, dispensing, administering, and use of drugs and related articles for the prevention of illness, and the maintenance and management of health.* Practice of pharmacy includes the direct or indirect provision of professional functions and services associated with the practice of pharmacy. Professional functions associated with the practice of pharmacy include:

- (a) *Writing prescriptions for drugs, including, non-controlled substances and controlled substance included in schedules 2 to 5 of part 72, so long as:*
 - (i) *The prescription written by the pharmacist is based on a diagnosis made by a licensed physician of medicine, a licensed physician of osteopathic medicine and surgery or a licensed physician of podiatric medicine and surgery.*
 - (ii) *The pharmacist possesses a doctor of pharmacy degree or the knowledge, skill, experience and training necessary, which knowledge, skill, experience and training shall be determined by the Board, by promulgating well-defined rules setting forth the knowledge, skill, experience and training which equates to a doctor of pharmacy degree.*
 - (iii) *Notwithstanding anything contained in this section 17707(7)(a), if the prescription is for an immunization, antibiotic for a condition such as conjunctivitis or a condition that does not require diagnosis, a pharmacist may write such a prescription.*
- (b) *Drug product selection, which duty shall not be a delegated.*
- (c) *The compounding, dispensing, safe storage, and distribution of drugs and devices.*
- (d) *The maintenance of legally required records.*
- (e) *Advising other prescribers and the patient as to contents, therapeutic action, utilization, and possible adverse reactions or interactions of prescription drugs, which duty shall not be a delegated.*
- (f) *Conducting point of care testing in order to determine the appropriate prescription drug to prescribe and/or dispense. A pharmacy must obtain a waiver from the United States Department of Health and Human Services pursuant to 42 C.F.R. 493.35 and comply with*

the requirements of 42 C.F.R. 493.35, 493.37 and 493.39 in order to perform Point of Care testing.

(g) Conducting medication management therapy, which duty shall not be a delegated.

(h) Entering Point of Care test results and appointment notes into the electronic medical records of each patient.

(i) A pharmacist that provides full time pharmacy services in a pharmacy that is located within a health resource shortage area, as defined in MCL 333.2701(j) and MCL 333.2717, shall:

(A) be a “designated professional” as that term is defined in 333.2701(i)

(B) shall receive the incentives contained in 333.2701 through 333.2725.

(C) where the pharmacist provides full time services in, and is the owner of at least 75% of the pharmacy located in the health resource shortage area, the pharmacy shall be reimbursed one and half times the amount of reimbursement in other areas for performing Point of Care testing and medication therapy management.

(j) The amendatory act that added this section does not require new or additional third-party reimbursement or mandated worker's compensation benefits for services rendered by a pharmacist who is authorized to prescribe non-scheduled prescription drugs and controlled substances prescription drugs, included in schedules 2 to 5 of part 72, or any other function in sub-sections (a) through (g) herein. MCL 333.17707(7)(a)-(j) (Suggested revisions italicized).

Second, the Michigan Essential Health Provider Recruitment Strategy Act (“**Health Provider Act**”) provides enticements and rewards for health care professionals that practice in areas that are designated as “health resource shortage area”, underserved and disadvantaged areas. The Health Provider Act also provides enticements for students from minority and disadvantaged communities to enter into various healthcare fields. Just as it made sense to entice minority or disadvantaged students from disadvantaged communities to become physicians, dentists, or physician assistant and serve their communities; it makes even more sense to encourage students from these communities to become pharmacists and serve their communities. In these underserved areas, the pharmacy is the first level of contact for many residents seeking health care. With the expansion of the scope of pharmacy practice in the Point of Care Model, it would be unconscionable to exclude pharmacists that have been serving these communities, and will be more intensely, meaningfully and impactfully doing so, from the incentives provided in the Health Provider Act. The definition of “Designated professional” contained in the Health Provider Act at MCL 333.2701(i) would have to be amended to reads as follows:

‘Designated professional’ means a designated physician, designated nurse, dentist, physician's assistant or pharmacist. MCL 333.2701(i) (Suggested revisions italicized).

The Health Provider Act must also be amended to add section MCL 333.2705a, to provide as follows:

(1) a designated professional that is a pharmacist who provides full time pharmacy services in a pharmacy that is located within a health resource shortage area, as defined in MCL 333.2701(j) and MCL 333.2717, shall:

(a) receive the incentives contained in 333.2701 through 333.2725; and

(b) where the pharmacist provides full time services in, and is the owner of at least 75% of the pharmacy located in the health resource shortage area, the pharmacy shall be reimbursed one and half times the amount of reimbursement in other areas for performing services as set forth in 333.17707(7).

(2) The amendatory act that added this section does not require new or additional third-party reimbursement or mandated worker's compensation benefits for services rendered by

a pharmacist who is authorized to prescribe non-scheduled prescription drugs and controlled substances prescription drugs, included in schedules 2 to 5 of part 72. MCL 333.2705a(1)-(2) (Suggested revisions italicized).

Additionally, The Health Provider Act at MCL 333.2707 must be amended to add pharmacy schools as grant eligible programs to minority students for professional education as follows:

(1) The department shall administer a grant program for minority students enrolled in medical schools, dental schools, nursing programs, *pharmacy schools*, or physician's assistant programs. Only minority students who meet the financial resources eligibility standards for federal student loan programs under title IV of the higher education act of 1965, Public Law 89-329, are eligible to receive a grant under this section.

(2) The department may award a grant to a minority student enrolled in a medical school who is training to become a designated physician, to a minority student enrolled in a dental school who is training to become a dentist, or to a minority student enrolled in a *pharmacy school*, nursing program or physician's assistant program. As a condition for the award of the grant, the recipient of the grant shall enter into a written contract with the department that requires the recipient to provide, upon completion of training, full-time health care services in a health resource shortage area to which he or she is assigned by the department for a period equal to the number of years for which a grant is accepted. In awarding grants, the department shall give priority to students who are residents of this state and enrolled in a medical school, dental school, *pharmacy school*, nursing program, or physician's assistant program in this state. MCL 333.2707(1)-(2) (Suggested revisions italicized).

Third, pharmacists will need access to the patients' EMRs, so that they can prescribe based on the diagnosis and laboratory test results in the EMR, their Point of Care tests and their immense knowledge and education. Access can be accomplished in two (2) ways: 1) the physician provides the pharmacist with access rights to the physician's software system; or 2) Michigan statutorily mandates that pharmacy software systems and physician software systems, for EMR purposes, must include specified and identical fields so that all systems operating in Michigan are compatible and connectivity is possible across the board.

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Finally, the Board of Medicine would have to promulgate a rule similar to R338.2409 and the Board of Osteopathic Medicine would have to promulgate a rule similar to R338.117 (which specify the requirements for the delegation of duties to PAs) that would allow MDs and DOs to delegate any or all prescribing powers to pharmacists. The Board of Pharmacy would also have to promulgate a rule, mirroring the Board of Medicine and Board of Osteopathic Medicine rules defining how this delegated authority would be established and restricting the authority to instances where there is a diagnosis.

Just as with APRNs once Michigan amends the above referenced statutes and administrative rules, pharmacists will be able to claim provider status and bill for the invaluable services that they provide.

V. CONCLUSION

The Point of Care Model is the most cost-effective and expeditious way to deliver medical care to Michigan residents. It allows patients whose conditions are unstable, urgent or easily resolvable to receive

⁸⁷ There are twelve (12) different pharmacy software systems operating in Michigan and about ten (10) different physicians' software systems. This is exactly the case for insurance billing purposes. All pharmacy and physicians' systems use the NCPDP D.O mandated fields so that they can all bill insurance companies. The same requirements must be implemented for treatment and diagnosis purposes.

rapid relief, through a virtual medical team. The patient's physician diagnoses the patient, his forte and within his scope of practice. The pharmacist treats the patient based on the diagnosis or prescribes medication, his forte. This is not a radical idea, only a practical solution. Ask yourself who is better at deciding which medications works best for which conditions? Who has received in-depth knowledge, education, training and experience in pharmacology? Who has received in-depth knowledge, education, training and experience in the mechanism of medications and disease? Who has received in-depth knowledge, education, training and experience in the impact of medications on the human body? Who has received a doctorate degree in Pharmacy? Clearly, the pharmacist's education and training make him abundantly qualified to prescribe medications, which is the foundation of the Point of Care Model.

Michigan has recognized the value of pharmacists as prescribers and Point of Care providers in many official and unofficial ways, from Governor Whitmer's COVID-19 Orders related to the COVID-19 Pandemic, to the standing order related to the Opioid Crisis, to accepting their valuable contributions in the University of Michigan Health Care System and Beaumont Health Care System's ambulatory care models, and to accepting their courageous and self-sacrificing efforts to test Michigan residents for their safety and the public safety in clearing them to work. Michigan has called on its legion of pharmacists in times of dire need; and Michigan's pharmacists have answered the call to duty diligently, steadfastly, without any sort of recognition, and even to their financial and physical peril. The logical, prudent, and economical choice is to allow pharmacists to conduct Point of Care testing and treatment with prescriber status in the State of Michigan. In short, Michigan must replace its ineffective, costly and archaic healthcare delivery system with this Point of Care Model and set the standard for the nation.

VI. POINT OF CARE MODEL IS SCALABLE

This Point of Care Model is scalable, and can be implemented nationally. With the possibility of achieving 45% fewer in-hospital admission, 35% fewer preventable hospital re-admission and 15% fewer emergency department visits resulting in an average annual savings of \$472 dollars per person; along with the possibility of 20% more adherence to prescribed medications resulting in an average annual savings of \$1,123 dollars per person, the model sells itself. The most effective and efficient way to accomplish this is by amending the PHC as set forth above, which means that Medicaid, Medicare⁸⁸ and private insurance companies would comply with Michigan's law and work with Michigan's Department of Health and Human Services to streamline the process through reimbursement requirements since they will be paying for these services, further solidifying and improving the model. Thereafter, Michigan's statutory scheme would serve as model rules to be adopted in all other states, the incentive being cost savings and improved outcomes as the CMS, the CDC, the University of Michigan Healthcare System, and the Beaumont Hospital Healthcare System studies and programs have all demonstrated.

⁸⁸ Since Medicare and Medicaid are federally funded programs, they are not required to comply with the payments sections, but the pattern that we are seeing is that they are allowing a revenue sharing approach in other states because the results make it sensible to do so; and even in Michigan under CPAs there are billing codes that allow revenue sharing.