

**BOARD OF PHARMACY  
RULES COMMITTEE MEETING  
RULES WORKSHOP  
August 24, 2020  
1:00 P.M. ET  
Call In Number: (888) 585-9008  
Conference Code: 599-196-982(#)**

Participants in this public meeting should be aware that these proceedings are being recorded  
and that an audio file of the meeting will be posted to the board's website.

**I. CALL TO ORDER/ROLL CALL**

**MEMBERS PRESENT**

Jeffrey Mesaros, PharmD, JD, Chair  
Jeenu Philip, BPharm,  
Jonathan Hickman, PharmD  
Mark Mikhael, PharmD  
David Wright, BPharm

**COURT REPORTER**

For the Record  
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**STAFF PRESENT**

Jessica Sapp, Executive Director  
Traci Zeh, Program Administrator

**BOARD COUNSEL**

David Flynn, Esq.  
Senior Assistant Attorney General  
Christopher Dierlam, Esq.  
Assistant Attorney General

**II. RULES DEVELOPMENT WORKSHOP**

- a. 64B16-31.007, F.A.C., Collaborative Practice Certification: Chronic Health Conditions

**III. RULES DISCUSSION**

- a. HB 389 Practice of Pharmacy
  - i. Chapter 64B16-31, F.A.C., Collaborative Practice and Test and Treat Certifications
- b. HB 599 Consultant Pharmacists
  - i. 64B16-26.300, F.A.C., Consultant Pharmacist Licensure
  - ii. 64B16-26.301, F.A.C., Subject Matter for Consultant Pharmacist Training Program
- c. HB 59 Automated Pharmacy Systems
  - i. 64B16-28.141, F.A.C., Requirements for use if an Automated Pharmacy System by a Community Pharmacy

**IV. ADJOURNMENT**

**64B16-31.007 Collaborative Practice Certification: Chronic Health Conditions.**

Pursuant to Section 465.1865, F.S., the Board hereby adopts the following list of chronic health conditions for which a pharmacist certified pursuant to section 465.1865, F.S., can provide specified patient care services to patients of a collaborating physician pursuant to a pending Collaborative Pharmacy Practice Agreement:

- 1) Hyperlipidemia;
- 2) Hypertension;
- 3) Anti-coagulation management;
- 4) Smoking cessation;
- 5) Opioid use disorder;
- 6) Heart / Cardiovascular Disease (*Cont. Discussion*);
- 7) Behavioral Health (*Begin Discussion*); and
- 8) Those chronic health conditions enumerated in section 465.1865(1)(b), F.S.

Place holder for discussion with Board to determine appropriate list of chronic health conditions in consultation with BOM and BOOM.

**Subject:** FW: HB 389 Committee meeting info

Here is some information to assist with providing fact based discussion around pharmacists involvement in cardiac patients.

### Cardiovascular Disease

1. **JACC: Journal of the American College of Cardiology:** <https://www.onlinejacc.org/content/66/19/2129>; The Role of the Clinical Pharmacist in the Care of Patients With Cardiovascular Disease; Steven P. Dunn, Kim K. Birtcher, Craig J. Beavers, William L. Baker, Sara D. Brouse, Robert L. Page II, Vera Bittner and Mary Norine Walsh.
  - a. **Conclusions:** Clinical pharmacists, through their unique training and practice focused on medication use, are positioned to serve an important role for patients on the cardiovascular care team. Clinical pharmacists currently engaged with medical practices also make substantial contributions to practice through the optimization of drug use and avoidance of preventable adverse drug events. The ACC advocates team-based care, which includes clinical pharmacists, as a means to “transform care, improve heart health, and help meet the demands of the future.” However, the use of pharmacists is limited in current care delivery models because pharmacists are not currently recognized as providers and are not eligible for payment under Medicare Part B. With more inclusive legislation, pharmacists could continue expansion of their roles to meet the demands, reduce medication-related costs, and improve quality of care for cardiac patients in an ever-changing health care system. Multidisciplinary organizations, including the ACC, should support efforts to overcome legislative and compensation barriers so that pharmacists may be included in health care delivery models that allow full use of their education and training to provide high-quality patient care.
2. **British Cardiovascular Society, Openheart:** <https://openheart.bmj.com/content/5/1/e000687.full> Effectiveness of pharmacist’s intervention in the management of cardiovascular diseases;
  - a. **Conclusion:** Some sensitivity of pharmacist’s intervention on outcomes of patients with cardiovascular disease has been shown in case of hypertension, dyslipidaemia, diabetes or smoking cessation and in heart failure. A common finding of the systematic reviews on these studies is that a greater involvement of pharmacists in activities directed to the patients and collaboration with other healthcare professionals in a team may provide an enhanced effect on various outcomes and may ultimately positively affect public health. However, the clinical importance of pharmacist’s interventions remains not fully demonstrated, and further well-designed and well-conducted studies are required in this research field. In our opinion, such studies should particularly focus on the demonstration of a possible sensitivity to community pharmacist’s intervention. Since pharmacy services are easily accessible and widely distributed in the community setting, a maximum benefit should be expected from these interventions.

### Cardiac Heart Failure

1. Schulz M, Griese-Mammen N, Anker SD, et al. Pharmacy-based interdisciplinary intervention for patients with chronic heart failure: results of the PHARM-CHF randomized controlled trial. *Eur J Heart Fail.* 2019;21(8):1012-1021. doi:10.1002/ejhf.1503 (Pharmacy care compared with usual care resulted in an absolute increase in mean adherence to three heart failure medications for 365 days [adjusted difference 5.7%, 95% confidence interval (CI) 1.6-9.8, P = 0.007]. The proportion of patients classified as adherent increased (odds ratio 2.9, 95% CI 1.4-5.9, P = 0.005). Pharmacy care improved quality of life after 2 years (adjusted difference in Minnesota Living with Heart Failure Questionnaire scores -7.8 points (-14.5 to -1.1; P = 0.02), compared to usual care.)
  - **Conclusion:** Pharmacy care safely improved adherence to heart failure medications and quality of life. A pharmacy-based interdisciplinary intervention improved mean adherence to three HF medication classes and the proportion of adherent patients, and led to clinically important improvements in QoL.

For these important aims, pharmacy care represents a valuable addition to the comprehensive care for HF patients. Morbidity and mortality effects need to be scrutinized in an adequately powered RCT.

2. Noschese, Bergman, Brar, Kansal. The Pharmacist's Role in Medication Optimization for Patients With Chronic Heart Failure Fed Pract. 2017 November;34(suppl 10):S10-S15 (there is a role for a pharmacist who has prescribing authority and interacts face-to-face with patients in the clinic. Significantly more patients in the PMTC group achieved target BB doses by the end of the study. )
3. Pharmacist-Led Clinics Reduce Readmissions: <https://www.pharmacypracticenews.com/Operations-and-Management/Article/05-19/Pharmacist-Led-Clinics-Reduce-Readmissions/54803?sub=AF723D667A984402DA262CD22BA2EF583AA351421EDE73EB4FD7DE24FC3ED> (Medication adherence for patients referred to the HF clinic increased from 51% to 88%)
4. Stough WG, Patterson JH. Role and Value of Clinical Pharmacy in Heart Failure Management. *Clin Pharmacol Ther.* 2017;102(2):209-212. doi:10.1002/cpt.687 (This practice paper highlights the pharmacist's role in the management of patients with heart failure, the evidence supporting their functions, and steps to ensure the pharmacist resource is available to the broad population of patients with heart failure.)
5. Milfred-Laforest SK, Chow SL, Didomenico RJ, et al. Clinical pharmacy services in heart failure: an opinion paper from the Heart Failure Society of America and American College of Clinical Pharmacy Cardiology Practice and Research Network. *J Card Fail.* 2013;19(5):354-369. (Positive outcomes associated with clinical pharmacist activities support the value of making this resource available to HF teams.)
6. Kitts NK, Reeve AR, Tsu L. Care transitions in elderly heart failure patients: current practices and the pharmacist's role. *Consult Pharm.* 2014;29(3):179-190. doi:10.4140/TCP.n.2014.179. (Pharmacists are an integral part of the multidisciplinary team in optimizing care for elderly HF patients to prevent readmissions.)
7. Won KJ, Bethishou L, Tsu LV. Management of Heart Failure in the Older Adult: Treatment and Opportunities. *Sr Care Pharm* 2019 Mar 1;34(3):169-186. (Pharmacists can improve patient care outcomes in patients with HF by providing updated recommendations on pharmacotherapy and being involved in the TOC process)
8. Milfred-LaForest SK, Gee JA, Pugacz AM, et al. Heart Failure Transitions of Care: A Pharmacist-Led Post-Discharge Pilot Experience. *Prog Cardiovasc Dis.* 2017;60(2):249-258. doi:10.1016/j.pcad.2017.08.005 (Medications were optimized in 70%, most frequently beta blockers, ace inhibitors, and diuretics.)
9. Cheng JW. Current perspectives on the role of the pharmacist in heart failure management. *Integr Pharm Res Pract.* 2018;7:1-11. Published 2018 Mar 9. doi:10.2147/IPRP.S137882 (Pharmacists play an important role within a multidisciplinary health care team in the care of patients with heart failure (HF).)
10. Koshman SL, Charrois TL, Simpson SH, McAlister FA, Tsuyuki RT. Pharmacist Care of Patients With Heart Failure: A Systematic Review of Randomized Trials. *Arch Intern Med.* 2008;168(7):687-694. doi:10.1001/archinte.168.7.687 (Pharmacist collaborative care led to greater reductions in the rate of HF hospitalizations (OR, 0.42; 95%CI, 0.24-0.74) than pharmacist-directed care (OR, 0.89; 95% CI, 0.68-1.17).)

**CHF with thyroid monitoring:** Ziman ME, Bui HT, Smith CS, et al. The pharmacists' role in improving guideline compliance for thyroid function testing in patients with heart failure. *J Pharm Pract.* 2012;25(2):195-200. doi:10.1177/0897190011416008

Thank you!

Regards,  
Jeenu

Jeenu Philip

**Director, Pharmacy Affairs**

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# JACC

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY

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### COUNCIL PERSPECTIVES

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## The Role of the Clinical Pharmacist in the Care of Patients With Cardiovascular Disease

Steven P. Dunn, Kim K. Birtcher, Craig J. Beavers, William L. Baker, Sara D. Brouse, Robert L. Page II, Vera Bittner and Mary Norine Walsh

### Author + information

### Abstract

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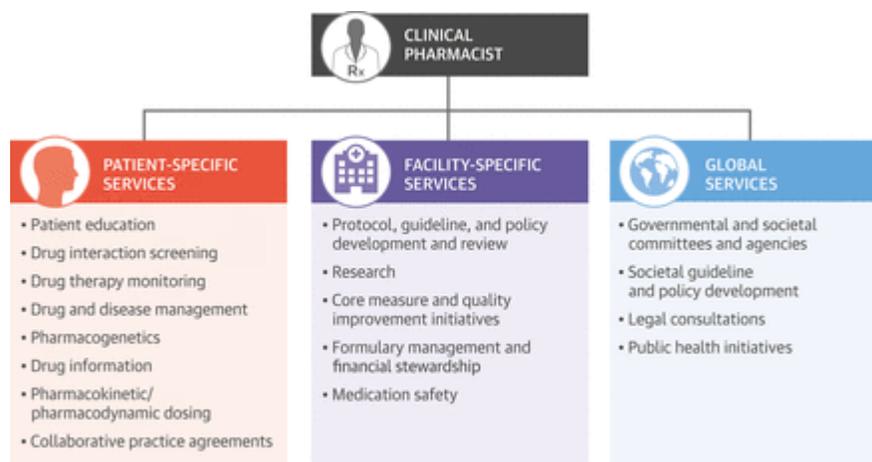
Team-based cardiovascular care, including the use of clinical pharmacists, can efficiently deliver high-quality care. This Joint Council Perspectives paper from the Cardiovascular Team and Prevention Councils of the American College of Cardiology provides background information on the clinical pharmacist's role, training, certification, and potential utilization in a variety of practice models. Selected systematic reviews and meta-analyses, highlighting the benefit of clinical pharmacy services, are summarized. Clinical pharmacists have a substantial effect in a wide variety of roles in inpatient and ambulatory settings, largely through optimization of drug use, avoidance of adverse drug events, and transitional care activities focusing on medication reconciliation and patient education. Expansion of clinical pharmacy services is often impeded by policy, legislation, and compensation barriers. Multidisciplinary organizations, including the American College of Cardiology, should support efforts to overcome these barriers, allowing pharmacists to deliver high-quality patient care to the full extent of their education and training.

### Key Words

**collaborative practice    medication adherence    medication therapy management    team-based care**

The American College of Cardiology (ACC) Board of Trustees and Strategic Plan endorse team-based care as a means to address the growing cardiovascular disease (CVD) epidemic (1,2). With a critical shortage of cardiologists, it is important that collaboration is developed with nonphysician providers, including clinical pharmacists, as an efficient and cost-effective means to improve patient outcomes. As with other qualified nonphysician practitioners, clinical pharmacists are underutilized; a 2009 ACC survey demonstrated that many cardiologists are unfamiliar with how best to apply a nonphysician team approach to patient care (3). Importantly, the major application of a clinical pharmacist to direct patient care is team-centric and not independent of physicians or other licensed providers.

Patients with CVD are at significant risk for adverse drug events and medication errors due to polypharmacy (4,5); they also have proportionally greater utilization of high-risk medications, such as anticoagulant agents. By focusing on preventing medication-related adverse events and error, financial waste related to these events can be decreased and patient outcomes improved (6,7). In addition, patients with CVD are often underprescribed critical, evidence-based therapies for a variety of reasons (8,9). Clinical pharmacists are pharmacists who, through advanced training, experiences, and/or certification requirements for licensure as a general pharmacist, have the skills and knowledge to provide clinical pharmacy services (CPS) to the health care team and patients. CPS includes, but is not limited to, complex medication management, transitional care related to medications, and patient or clinician medication education (10). A summary of CPS is included in the **Central Illustration**, demonstrating that the clinical pharmacist may operate on a patient-specific, facility, or global level to achieve optimal medication outcomes. The American College of Clinical Pharmacy (ACCP) defines CPS as, "a health sciences discipline in which pharmacists provide patient care that optimizes medication therapy and promotes health, wellness, and disease prevention" (11). Clinical pharmacists also play a pivotal role in ensuring medication safety, either through specific medication interventions or in designing macroprocesses to reduce the medication-related risk of error. In the MEDAP (Medication Error Detection, Amelioration, and Prevention) study, an observational analysis of clinical pharmacists engaged in patient safety initiatives, cardiovascular drugs comprised the third most-commonly prescribed class of medications resulting in errors that required pharmacist intervention (12). Clinical pharmacists are uniquely positioned to address medication safety, due to their intimate understanding of the medication-use process and clinical pharmacology.



Dunn, S.P. et al. J Am Coll Cardiol. 2015; 66(19):2129-39.

**Central Illustration**  
**Clinical Pharmacists: Their Role in Cardiovascular Disease**

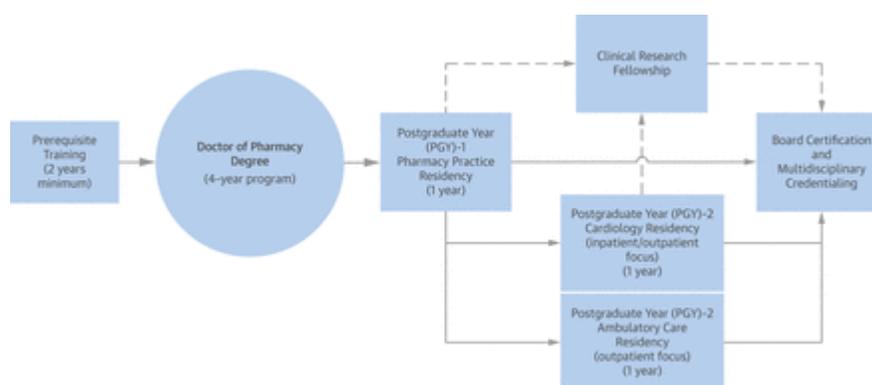
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The various roles clinical pharmacists perform in both inpatient and outpatient settings are depicted. A clinical pharmacist or team of clinical pharmacists may perform a variety of patient-specific functions related to medications. Clinical pharmacists often lead facility-level initiatives and even global initiatives toward improving and optimizing systems of medication use.

To maximize the role of the clinical pharmacist, the care team will benefit from understanding the training, development, utilization, and potential value of the clinical pharmacist in the cardiovascular care team. This paper will provide background information on clinical pharmacists' education, training, credentialing, and practice models in a variety of settings; it will also discuss collaborative practice opportunities for integrating clinical pharmacists into a team-based care model.

## Training and Certification

**Figure 1** depicts the typical training pathway of a clinical pharmacist working in cardiovascular practice. There are currently 134 schools and colleges of pharmacy in the United States, a number that continues to grow (**13**). Pharmacy school training is preceded by a minimum of 2 years of undergraduate coursework, although many students have completed a bachelor's degree. Most pharmacy school curricula consist of 3 years of didactic coursework, followed by a fourth year of experiential education. The Doctor of Pharmacy (PharmD) degree is awarded upon graduation. Curricula must meet the core standards overseen by the American College of Pharmaceutical Education (ACPE), which have been recently updated (**14**). Integration of interprofessional education into curricula is recommended by the ACPE to better prepare students to provide patient-centered care. This involves pharmacy students interacting with medical, nursing, and other health professional students at various levels of training in coordinated educational or patient care activities (**14**). Introductory pharmacy practice experiences are completed in community pharmacy and hospital settings during the first 3 years, whereas advanced pharmacy practice experiences occur in the final year of school. The ACPE requires that these advanced experiences involve direct patient care, interactions with prescribers, and the provision of CPS alongside and supervised by clinical pharmacists (**14,15**).



**Figure 1** Education and Training of a Clinical Pharmacist in a Cardiology Practice

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The most traditional routes to practice as a clinical pharmacist in cardiology are depicted. Participants complete a Doctor of Pharmacy program and then 1 or 2 years of post-graduate residency training (post-graduate year [PGY]-1 and -2). Ambulatory care-trained pharmacists are focused on outpatient care and would mostly focus on modifying chronic cardiovascular risk with pharmacotherapy with a broad understanding of pharmacotherapeutic management of chronic disease. Cardiology-trained clinical pharmacists are adaptable to a wide variety of cardiology practice settings, including inpatient and outpatient practices, which would provide a greater understanding of patient care in the cardiovascular continuum. Pharmacists may also complete a clinical research fellowship, designed to train the participant to be an independent research investigator.

Post-graduate education and training for a cardiovascular clinical pharmacist may differ from that of pharmacists working in other settings. Following graduation from an ACPE-accredited school of pharmacy, approximately 25% of pharmacists choose to continue their education in the form of either residency and/or fellowship training. These programs continue to grow in response to increased demand (**16**). A post-graduate year (PGY)-1 pharmacy residency program is intended to produce pharmacy practitioners competent in patient-centered care and pharmacy operational services that can be applied to any practice setting (**17**). Individuals desiring more specialized clinical training in a cardiovascular area can complete a PGY2 residency. The aim of a PGY2 pharmacy residency in

cardiology is to train pharmacy practitioners in the care of patients with CVD, both from a prevention and treatment perspective (18). Cardiology pharmacy residency programs also train in the conduct of clinical research projects, the interpretation of cardiovascular biomedical published data, quality improvement initiatives, leadership and practice management, teaching and educational activities, and advocacy for CVD prevention. The American Society of Health-System Pharmacists currently lists 29 PGY2 training programs in cardiology pharmacy; these programs have collectively graduated at least 123 graduates since 2007 (19).

A clinical research fellowship is a highly individualized post-graduate program designed to train pharmacists to become independent investigators (Figure 1). Its aim is for graduates to develop competency in all aspects of the scientific research process, from hypothesis generation to paper preparation and publication. Fellowships are offered through a variety of settings, including schools and colleges of pharmacy, the pharmaceutical industry, and academic health centers. Like PGY2 residency programs, fellowships are often focused on a specific area of pharmacy practice. The ACCP offers peer-review designation for qualified programs, and lists 6 fellowship programs with a primary or secondary specialty of cardiology.

Beyond formal didactic education and clinical training, pharmacy has mechanisms to ensure that entry-level practitioners have met the minimum qualifications through certification (20). For most health care professionals, this initial step in ensuring qualification to practice is through licensure. Beyond licensure, certification for the pharmacist is different from that of physicians and nonphysician practitioners. For pharmacists, certification is voluntary, consisting of pharmacist-only and multidisciplinary certifications (21). One of the major organizations with a long history of awarding specialty certification credentials to pharmacists is the Board of Pharmacy Specialties (BPS) (11). The mission of the BPS is to recognize pharmacy specialty practice and certify pharmacists' knowledge and skill to practice in the areas of nuclear, nutrition support, oncology, pharmacotherapy, ambulatory care, pediatrics, critical care, and psychiatric pharmacy; cardiology specialty certification is also being considered. Eligibility for certification through BPS requires pharmacy licensure, and documentation of 3 years of experience within a practice area or completion of a PGY1 and/or PGY2 residency, plus successful passing of a standardized, written examination. Through the BPS, pharmacists can also obtain certification in certain areas of subspecialization, including added qualifications in cardiology (22), which involves participation in specialty-related practice, teaching, research, and scholarship. As of 2013, more than 19,000 pharmacists have been credentialed by the BPS, with over 100 practitioners receiving added qualifications in cardiology (23).

Pharmacists may also obtain more broad-based, multidisciplinary certifications covering various areas of CVD. These types of certifications assess health care-related competency for an array of different professions (e.g., nurses, nurse practitioners, and physician assistants) (24). Eligibility requirements for each of these vary, but are typically dependent upon documentation of practice and completion of an examination. Table 1 provides examples of multidisciplinary credentials for pharmacists in terms of the credentialing organization and intended scope of professional practice (24,25).

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### Table 1

#### Examples of Multidisciplinary Certifications for Pharmacists

## Pharmacist Practice Models and Clinical Activities

The benefits of CPS in federal, nonfederal, hospital, clinic, managed care, and other community settings have been extensively documented (26). However, there is no unified national model of CPS; practices may vary across institutions. CPS have been associated with decreased costs of care, hospital mortality, drug costs, length of stay, and medication error rates (27–29). The Institute of Medicine recognizes that the pharmacist-physician-patient collaboration improves medication safety (30). Interacting with the health care team on inpatient rounds, interviewing patients and family, selecting and reconciling medications, performing dose titration, assisting with insurance coverage, and providing patient discharge counseling and follow-up are among the many efforts by clinical pharmacists that have resulted in improved outcomes in the inpatient setting (31–33). Interacting with a pharmacist in the inpatient setting has also helped improve post-discharge medication adherence (31,34), reduce adverse drug reactions and medication errors (31), and shorten hospital length of stay (31).

Several reviews and meta-analyses have demonstrated the effect of CPS in cardiovascular patients (**Table 2**). Clinical pharmacists have helped to improve CVD risk factor management (**35–39**). The results are consistent with other studies that showed improvements in CVD risk factor management by pharmacists in primary care offices (**40,41**), cardiology practices (**42,43**), a managed care organization (**44**), and a chain pharmacy setting (**45**). In general, the addition of inpatient and outpatient CPS resulted in improved care, with no evidence of harm.

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## Table 2

### Selected Systematic Reviews and Meta-Analyses of the Effect of Pharmacist Services on Cardiovascular Patient Care

Clinical pharmacists have shown a particular effect in patients with heart failure. For inpatient services, Gattis et al. (**46**), in a single-center, randomized clinical trial of 180 patients with heart failure, measured the effect of pharmacist participation in heart failure rounds. The composite of all-cause mortality and heart failure events was significantly lower after 6 months in the team with pharmacist participation (4 events vs. 16 events [all-cause mortality or heart failure];  $p = 0.005$ ). Pharmacists' care of inpatients and outpatients with heart failure has resulted in decreased hospitalizations (**47,48**) and readmissions (**48**). The Heart Failure Society of America recently coauthored a joint opinion paper with the ACCP Cardiology Practice and Research Network that outlined and supported roles for pharmacists in multidisciplinary heart failure teams (**10**).

Whereas many patient care services by clinical pharmacists can be performed concurrently with or complementary to physician practice (e.g., medication reviews, patient education and counseling, disease screening, referral, among others), clinical pharmacists may also perform independent direct medication management through a collaborative practice agreement (CPA) that expands the depth and breadth of services the pharmacist can provide. CPAs that include a pharmacist can help alleviate some of the demand for physician-provided care. CPAs create a formal relationship between physicians and pharmacists and define patient care functions (e.g., patient assessments, counseling, and referrals; ordering laboratory tests; administering drugs; and selecting, initiating, monitoring, continuing, and adjusting drug regimens) that a pharmacist can autonomously provide within the context of a protocol. CPAs are not new; federal pharmacists have collaboratively managed disease through medication use, cognitive services, and CPS for over 40 years (**49**). When a CPA is in place, a licensed health care professional makes a diagnosis and maintains ongoing supervision of patient care. Currently, 46 states and the District of Columbia allow for some form of CPAs. CPA provisions vary greatly from state to state with respect to the extent of the pharmacists' authorized services, limitations on practice sites and health conditions, authority to order laboratory tests, and requirements for pharmacist participation (e.g., certification, training, or enhanced licensure requirements or designations).

Kaiser Permanente of Colorado's collaborative practice model uses nurses and clinical pharmacists in direct patient care roles, guided by a physician. This model reduced all-cause mortality (adjusted hazard ratio: 0.24; 95% confidence interval: 0.20 to 0.29;  $p < 0.001$ ) or coronary heart disease–related mortality (adjusted hazard ratio: 0.27; 95% confidence interval: 0.22 to 0.34;  $p < 0.001$ ) in patients with coronary artery disease who were followed in the program for more than 3 years. Patients enrolled <90 days (“early exposure”) after their coronary event had lower all-cause mortality over a 10-year follow-up period compared with other groups of patients not enrolled within 90 days post-event (4.7% early vs. 8.6% delayed, 16.4% intermittent, and 46.9% none;  $p < 0.001$ ) (**50**). Patients usually enrolled in the nurse-managed cardiac rehabilitation program within 3 to 6 months after discharge for a coronary event, followed by enrollment in the pharmacist-managed program. The goals were to increase use of evidence-based therapies, help monitor and control diseases that increase CVD risk (e.g., hypertension, hyperlipidemia, diabetes, and abuse), and provide information to patients and other team members (**51**). Ripley et al. (**52**) describe in detail a similar practice model that uses cardiologist–clinical pharmacist collaboration in the long-term management of patients with CVD in both an academic faculty-based practice and a private sector specialty clinic. The practice model is structured around a defined scope-of-practice agreement between the cardiologists and pharmacists (**52**). Pharmacist involvement has also been demonstrated to improve medication adherence. A recent study by Ho et al. (**53**) evaluated a multifaceted intervention to improve medication adherence involving pharmacist-led medication reconciliation, education, and collaborative care between the pharmacists and physicians in the Veterans Affairs

health system. Patients randomized to the intervention had greater adherence to cardiovascular medications (clopidogrel, beta-blockers, statins, and angiotensin inhibitors) than the usual care group (89.3% vs. 73.9%;  $p = 0.003$ ) (53).

## Scope of Practice

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In 2012, a consortium of stakeholders identified effective policies, practices, and barriers to expanding the role of pharmacists in delivering patient care services and entering into CPAs. The group acknowledged that broad access to patient care services delivered by pharmacists is limited by scope of practice acts, state boards of pharmacy, medicine regulations, and compensation barriers. Recognizing that physician-pharmacist CPAs may help alleviate some of the gaps in health care, the consortium proposed strategies for expanding pharmacists' patient care services through team-based care and CPAs (54,55). The Centers for Disease Control and Prevention and the American Pharmacists Association Foundation developed a toolkit for creating physician-pharmacist CPAs (56).

CPAs may also exist in hospitals. In 2012, The Centers for Medicare & Medicaid Services expanded the concept of medical staff to allow hospitals the flexibility to include pharmacists as eligible candidates with privileges to practice in the hospital in accordance with state law. The rule gives practitioners in states that allow pharmacists to enter into CPAs more involvement in patient care. As a result, pharmacists will undergo the credentialing or privileging process established by the workplace (57). These CPAs may exist to provide specific services in patients with CVD, such as anticoagulation adjustment and monitoring, insulin management, and smoking cessation, among other potential applications that may benefit a cardiology practice.

## Advocacy and Public Health

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The public health role of the clinical pharmacist has been evolving as clinical practice opportunities have expanded. Starting with the Department of Health and Human Services "Healthy People" initiatives, and continuing with the current "Million Hearts" Initiative to prevent 1 million heart attacks and strokes by 2017, pharmacists have been sought out for their potential contributions to these national campaigns. Pharmacists have a unique role in community-based public health initiatives due to the sheer number of neighborhood pharmacies, which provide easy access to care for patients. Although evidence-based drug therapies and government educational campaigns have been successful in reducing cardiovascular deaths in the past several decades, much work remains to be done. The Million Hearts campaign estimated that baseline aspirin use for high-risk patients is still only 47%, blood pressure is controlled in only 46%, cholesterol is only controlled in 33%, and smoking cessation is only 23% at baseline, all of which are far from their clinical targets of 70% (58). Pharmacist participation in the campaign through chain pharmacy corporations has largely targeted enhanced cardiovascular risk screening, as well as educational efforts (59). Although the specific effect of pharmacists on the Million Hearts campaign is not known, the provision of CPS appears to be a commonality amongst several high-performing organizations contributing to the campaign (60). These roles may include direct patient management of blood pressure to treatment goal, monitoring and encouraging medication adherence, disease/medication education for patients, and support for physician staff. Pharmacists also participate significantly with registry or payor-directed efforts to systematically improve quality through improved medication use and optimization, such as the Joint Commission Core Measures. For example, hospitals employing clinical pharmacists credentialed in cardiology performed better in cardiovascular medication-related core measures (61).

Pharmacists, both clinical and general practitioners, play a valuable role in public disease prevention and health promotion through education, preventive health screenings, and quality assurance. Education of patients about cardiac risk factors, methods of risk factor modification, and diet and exercise contributes to reductions of cardiovascular events and promotes healthy lifestyles (62), including the promotion of medication adherence (63,64). Several demonstration projects and innovative practice settings with pharmacist involvement have yielded beneficial outcomes. The most notable of these was the Asheville Project, where pharmacist-provided education and monitoring positively affected long-term health outcomes, such as hemoglobin A<sub>1c</sub> and serum lipid concentrations, while also reducing health care costs (65). Ramalho de Oliveira et al. (64) evaluated 10 years of pharmacy medication therapy management interventions in a large health system. Along with cost savings and improved patient outcomes, patient satisfaction scores were also high.

Targeting of higher cardiac-risk patients by pharmacists through implementation of quality assurance programs, disease-state management drug therapy protocols, and health outcomes research influences outcomes and decreases the likelihood of medication errors. Once a diagnosis is made, pharmacists can assist in chronic disease-state management, particularly with medication education and optimizing medication therapies for a given disease state.

## Implications for Medical Practices

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The potential for clinical pharmacy services in an ambulatory or hospital-based practice is vast, as optimization of medication use requires thorough evaluation of each aspect of the medication-use spectrum. At a minimum, having a clinical pharmacist available to a practice as a consultant to evaluate medication protocols and guidelines, offer suggestions for individual patient care through prospective or retrospective review on the basis of pharmacological principles, and provide medication education for patients and health care practitioners at all levels would provide significant benefit to a medical practice. Going further, as medication-related transitional care becomes a prominent goal of accountable care organizations and other health care quality organizations, clinical pharmacists could potentially have a larger role in ensuring that medication-related transitions are performed safely, either as direct participants or by directing or reviewing medication transitional care processes. In addition, much of complex medication management (e.g., pharmacological treatment of hypertension, diabetes, dyslipidemia, and anticoagulation, among others) could be directly delegated through the use of CPAs to a clinical pharmacist under the supervision of an individual practitioner or the medical practice, enabling greater efficiency for physicians and other providers in seeing patients. The information provided by Ripley et al. (52) and the ACCP is a valuable "how-to" for others wanting to implement CPAs in a physician office (52,66). Pharmacists can also play an important role in improving medication adherence in at-risk patients, either through direct consultation or other medication education-related activities.

Although the benefits of utilizing clinical pharmacists are bountiful, widespread adoption of this care model is impeded by the lack of a consistent direct reimbursement source for these activities. Pharmacists are not currently recognized as providers by the Social Security Act or Centers for Medicare & Medicaid Services and are, therefore, compensated at the lowest-level reimbursement code (i.e., level 1 or 99211) in most clinic settings or provided no compensation for activities. The Social Security Act is the reference point for current and emerging delivery systems and payment models, so it is important for pharmacists to be listed in the Social Security Act, along with other providers. Alternatively, pharmacists may utilize incident-to-billing for higher levels of reimbursement, provided that the medical practice has the infrastructure to support this model. However, the comprehensive scope and patient complexity requires that the pharmacists have adequate and variable time per visit, which precludes patient volume as a means to generating a sustainable income in the current reimbursement model.

To provide a sustainable platform for the incorporation of clinical pharmacists in a team-based care model, more support from the medical community and changes in legislation are required. The 2011 U.S. Surgeon General Report: Improving Patient and Health System Outcomes through Advanced Pharmacy Practice publicly supported health care reform that includes pharmacists providing expanded patient care services (26). On the basis of the documented benefits of pharmacist-delivered care in many health care settings, the report recommends that health care leadership and policy makers optimize pharmacists' roles to deliver patient-centered care and disease prevention services in collaboration with physicians or as part of a health care team. The report further recognizes that the expansion of pharmacist services is often impeded due to policy, legislation, and compensation barriers; it recommends recognizing pharmacists as providers and allowing appropriate compensation for services provided.

Several legislative efforts have since been brought forth, including bills proposed within the last 2 Congresses that are designed to give Medicare beneficiaries in medically underserved communities access to pharmacist-provided ambulatory services under Medicare Part B (67). A proposed Medicare program to provide a separate payment for chronic care management, for which the physician may also bill for supervision of clinical staff, may be another pathway for the utilization of clinical pharmacists (68). Regardless, as "population health" reimbursement models with bundled payments and accountable care organizations become more prominent, direct fee-for-service reimbursement may be less important, as the financial incentives to provide optimal care, while also reducing preventable harm, are more closely aligned. Alignment on the basis of quality incentives can also be encouraged

through multidisciplinary organizational involvement. Some examples of this are the ACC Surviving MI program (69), a key tenet of which is the involvement of pharmacists in care of patients with myocardial infarction, and in the Hospital to Home (H2H) Mind Your Meds program, which features accurate medication reconciliation as a key metric of success (70).

## Conclusions

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Clinical pharmacists, through their unique training and practice focused on medication use, are positioned to serve an important role for patients on the cardiovascular care team. Clinical pharmacists currently engaged with medical practices also make substantial contributions to practice through the optimization of drug use and avoidance of preventable adverse drug events. The ACC advocates team-based care, which includes clinical pharmacists, as a means to “transform care, improve heart health, and help meet the demands of the future.” However, the use of pharmacists is limited in current care delivery models because pharmacists are not currently recognized as providers and are not eligible for payment under Medicare Part B. With more inclusive legislation, pharmacists could continue expansion of their roles to meet the demands, reduce medication-related costs, and improve quality of care for cardiac patients in an ever-changing health care system. Multidisciplinary organizations, including the ACC, should support efforts to overcome legislative and compensation barriers so that pharmacists may be included in health care delivery models that allow full use of their education and training to provide high-quality patient care.

## Footnotes

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**The views expressed in this paper by the ACC’s Cardiovascular Team and Prevention Councils do not necessarily reflect the views of the JACC or of the ACC.**

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## Abbreviations and Acronyms

ACC	American College of Cardiology
ACCP	American College of Clinical Pharmacy
ACPE	American College of Pharmaceutical Education
BPS	Board of Pharmacy Specialties
CPA	collaborative practice agreement
CPS	clinical pharmacy services
CVD	cardiovascular disease

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## Effectiveness of pharmacist's intervention in the management of cardiovascular diseases

 Stefano Omboni and Marina Caserini

Author affiliations 

### Abstract

The pharmacist may play a relevant role in primary and secondary prevention of cardiovascular diseases, mainly through patient education and counselling, drug safety management, medication review, monitoring and reconciliation, detection and control of specific cardiovascular risk factors (eg, blood pressure, blood glucose, serum lipids) and clinical outcomes. Systematic reviews of randomised controlled and observational studies have documented an improved control of hypertension, dyslipidaemia or diabetes, smoking cessation and reduced hospitalisation in patients with heart failure, following a pharmacist's intervention. Limited proof for effectiveness is available for humanistic (patient satisfaction, adherence and knowledge) and economic outcomes. A multidisciplinary approach, including medical input plus a pharmacist, specialist nurse or both, and a greater involvement of community rather than hospital pharmacists, seems to represent the most efficient and modern healthcare delivery model. However, further well-designed research is demanded in order to quantitatively and qualitatively evaluate the impact of pharmacist's interventions on cardiovascular disease and to identify specific areas of impact of collaborative practice. Such research should particularly focus on the demonstration of a sensitivity to community pharmacist's intervention. Since pharmacy services are easily accessible and widely distributed in the community setting, a maximum benefit should be expected from interventions provided in this context.

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## Introduction

The relationship between decreasing cardiovascular disease risk factors and the improvement in cardiovascular disease outcomes is well established, and current guidelines recommend an aggressive reduction in these risks in order to prevent major cardiovascular accidents.<sup>1</sup> The pharmacist may play a relevant role in primary and secondary prevention of cardiovascular diseases. In addition to medication dispensing, the pharmacist can provide more direct interventions (eg, medication education and disease management), as a support to the physician's action, in order to improve medication adherence, to achieve the goals of desired therapeutic outcomes and to improve safe medication use and humanistic control.<sup>2</sup> The direct pharmacist's intervention in patients' care, in alternative to conventional approach, has proved to favourably affect therapeutic and safety outcomes in different diseases or conditions including diabetes, dyslipidaemia, arterial hypertension, obesity, asthma or chronic obstructive pulmonary disease, infective diseases (including influenza immunisation), psychiatric conditions and osteoporosis prevention.<sup>3–5</sup> A recent overview of systematic reviews has documented a positive impact on patients' outcomes (blood pressure and haemoglobin A1c reduction) of clinical pharmacy services targeting specific cardiovascular conditions, such as hypertension or diabetes mellitus.<sup>6</sup> Effects on humanistic outcomes such as patient adherence, patient satisfaction, patient knowledge and quality of life were variable and inconclusive across the various studies.

Given these premises, in the present review, we aim to update the reader on the current services that the pharmacist may provide in order to help manage the patients with cardiovascular disease or individuals at risk of cardiovascular disease. We will also discuss the actual benefits of such interventions at the light of the current evidence from randomised or observational studies and the perspectives and potentials for the development of appropriate healthcare delivery models. The primary focus of this review will be the discussion of current evidence on the benefit provided by models based on a multidisciplinary approach, which is the most popular and best accepted by the medical community worldwide.

Given the large amount of available studies, with different levels of quality, and the heterogeneity of settings (hospital, outpatient clinic and community) and outcomes, we opted for showing results from large and well-conducted meta-analyses published in the literature in recent years.

## Pharmacy services for patients with cardiovascular disease

Pharmacy services provided to patients with cardiovascular disease may be roughly classified into three groups: activities directed at patients, activities directed at healthcare professionals and those provided within the frame of a multidisciplinary teamwork.<sup>7,8</sup> A simplified list of most common services is provided in box 1.

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### Box 1 Pharmacy services for cardiovascular prevention and management

- Educational activities directed at patients
  - Patient education and counselling
  - Drug safety management
- Informative activities directed at healthcare professionals
  - Documenting adverse drug reactions occurring to the patients
  - Monitoring patient's adherence to physician's prescription
- Direct intervention in a multidisciplinary team
  - Collaborative medication management (including drug administration)
  - Medication review and dose adjustment or titration
  - Medication monitoring and reconciliation
  - Definition and application of disease management pathways and protocols
  - Detection, prevention or control of specific cardiovascular risk factors
  - Monitoring patients' outcomes
  - Posthospital discharge follow-up and home visits for critical patients

Patient education and counselling about medication, diseases and non-pharmacological treatment (including indication on appropriate lifestyle) are traditional pharmacist's activities. These services are aimed at improving patient knowledge and at promoting the correct use of medicines, favouring the adherence to treatment and preserving a healthy status. The pharmacist also needs to assess possible issues related to drug safety in treated patients, providing specific advises and documenting such occurrences to the physician in charge of the patient. However, the most interesting and potentially successful and useful activities which a pharmacist may accomplish are those involving a direct intervention in a multidisciplinary team: the potentiality of such an approach will be addressed and discussed in detail in the present paper. Team-based multidisciplinary services include medication review and drug therapy adjustments, in which the pharmacist has the autonomy to manage medicines according to predefined clinical protocols or collaborative agreements with the physician, and elaboration or refinement of a complete and reliable medication history and therapeutic reconciliation following hospital discharge and follow-up. Of particular interest is the development of structured programmes for detection, prevention or control of specific risk factors, including measurement of blood pressure, blood glucose and lipids, and provision of diagnostic tests with medical reporting, such as 12-lead resting ECG, 24 hour ambulatory blood pressure monitoring or 24 hour ECG Holter monitoring, through telemedicine tools, in connection with providers of medical reporting services.

In the current practice more complex interventions, such as for instance those focused on the application of clinical guidelines and dosage adjustment and titration are typically provided by hospital pharmacists, whereas community pharmacists are usually more concerned with improving patient knowledge and compliance, eventually by monitoring some patient's outcomes. The pharmacist working within a community pharmacy is also sometimes in charge of home visits of critical or frail patients under the supervision of a primary care outpatient clinic.

### Effectiveness of the pharmacist's intervention in diverse cardiovascular conditions

In the last decade, several systematic reviews were conducted to measure the effect of indirect or direct pharmacist care of patients with cardiovascular diseases. We searched the literature for such publications, which included both randomised controlled and observational studies, performed in specific settings or pooling together interventions from different settings (community, outpatient clinic or hospital). The results of these meta-analyses are summarised in table 1 and will be discussed in detail in the next sections.

**Table 1**

Summary of principal systematic reviews or meta-analyses assessing the impact of the pharmacist's intervention on cardiovascular risk factors and diseases

**Patients with multiple risk factors for coronary disease**

One of the first published work evaluating the effectiveness of the pharmacist's intervention to reduce risk behaviours and risk factors for coronary heart disease was limited to community pharmacy-based activities. The systematic review included 9 studies and 4091 individuals at high risk for coronary heart disease and showed a clear positive contribution of pharmacist to smoking cessation and an important role in managing lipid levels.<sup>9</sup> However, these benefits were evident only in the few randomised controlled studies and the authors concluded that further investigations were warranted in this area. Santschi *et al*<sup>10</sup> conducted a systematic review of 30 randomised controlled studies and documented a significant reduction in blood pressure (8.1 (10.1 to 5.9) mm Hg for systolic and 3.8 (5.3 to 2.3) mm Hg for diastolic;  $P < 0.001$  for both), total cholesterol (17.4 (25.5 to 9.2) mg/L;  $P < 0.001$ ) and low density lipoprotein (LDL) cholesterol (13.4 (23.0 to 3.8) mg/L;  $P = 0.006$ ) and a reduction in the risk of smoking (relative risk: 0.77 (0.67 to 0.89);  $P = 0.001$ ), following pharmacist's intervention, which in some cases included a direct care in collaboration with the physician. Tan *et al*<sup>5</sup> reviewed 17 studies based on clinical pharmacy services delivered in primary care general practice clinics. The pharmacist's intervention, mainly involving medication review with or without other activities delivered collaboratively with the family physician, resulted in significant ( $P < 0.05$ ) reductions in blood pressure (5.7 (7.1 to 4.3) mm Hg for systolic and 3.5 (4.4 to 2.6) mm Hg for diastolic), haemoglobin A1c (0.9 (1.2, 0.6) %), LDL-cholesterol (18.7 (34.1 to 3.4) mg/dL), total cholesterol (32.0 (54.9 to 9.1) mg/dL) and 10-year Framingham risk score (1.8 (3.7 to 0.0) %). More recently, Brown *et al*<sup>11</sup> identified 24 relevant studies of pharmacy-delivered interventions, with most of the evidence focused on smoking cessation interventions (behavioural support and/or nicotine replacement therapy). These interventions were effective and cost-effective in helping adults to stop smoking, particularly compared with usual care (the OR was 1.85 (1.125 to 2.75), an indicator of positive effect of the intervention on 9714 participants smoking cessation). Pharmacy-based weight loss interventions appeared to be as effective as similar interventions in other primary care settings, but not as effective or cost-effective as commercially provided weight management services in community settings. In the five studies evaluating multicomponent interventions (pharmacotherapy and lifestyle changes) compared with usual care in participants with comorbidities (diabetes mellitus, dyslipidaemia and hypertension), a significant improvement in the relevant primary outcomes of glycaemic control, lipids and blood pressure could be observed. However, a quantitative meta-analysis could not be performed because of the paucity of available studies.

In summary, in all the aforementioned meta-analyses a benefit of pharmacy services on major cardiovascular risk factors and an improvement in inappropriate lifestyles predisposing to cardiovascular disease could be demonstrated. However, a common finding of these reviews was the substantial heterogeneity among the various studies.

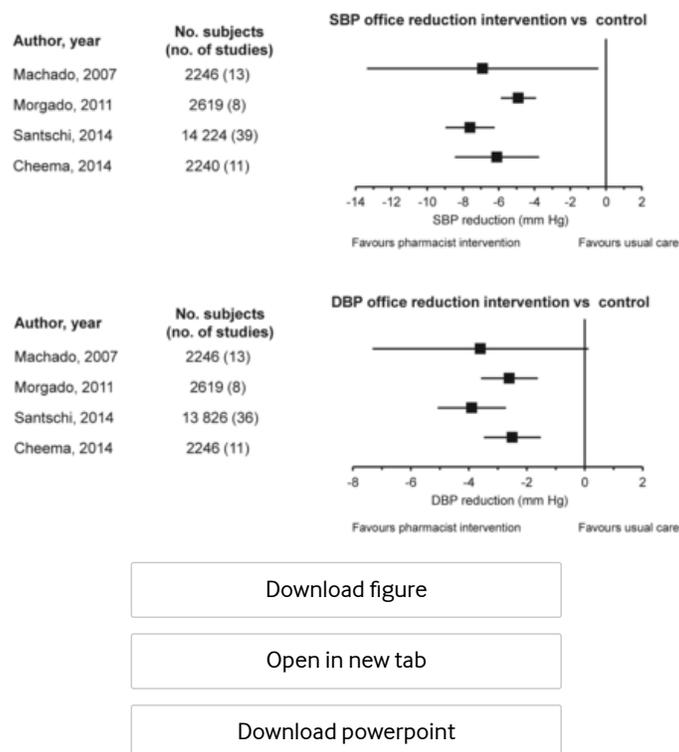
**Hypertension**

As shown in a recent systematic review of the literature which examined 520 articles published in the last 40 years, reporting 439 randomised controlled trials assessing clinical pharmacy services, the most successful results were observed when specific medical conditions such as hypertension or diabetes were considered.<sup>12</sup>

In case of hypertension, systematic reviews and meta-analyses concluded that pharmacist's intervention, including education and blood pressure measurement, enhances blood pressure control and improves adherence to antihypertensive therapy (figure 1).

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## Figure 1

Difference in changes in SBP and DBP in patients with hypertension after the pharmacist's intervention versus control. Data are shown as mean difference and 95% CI (redrawn from <sup>13–16</sup> with permission). DBP, diastolic blood pressure; SBP, systolic blood pressure.

In the meta-analysis of Machado *et al*,<sup>13</sup> including 2246 patients from 13 studies, systolic blood pressure was significantly ( $P=0.002$ ) reduced by  $10.7 \pm 11.6$  mm Hg following the pharmacist's intervention, while it remained unchanged in the standard care group ( $3.2 \pm 12.1$  mm Hg,  $P=0.361$ ), with a further reduction in systolic blood pressure over controls following pharmacist's intervention of  $6.9 \pm 12.1$  mm Hg ( $P=0.047$ ). Medication management (82%) and hypertension education (68%) were the most used interventions. In this meta-analysis, pharmacist's intervention did not have a significant influence on diastolic blood pressure, adherence to the therapy (five of three studies with significant effect) and quality of life (one of eight significant). Another meta-analysis by Morgado *et al*,<sup>14</sup> including 2619 patients recruited in 8 studies, found that the pharmacist's intervention reduced both systolic blood pressure ( $19.4 \pm 3.5$  mm Hg) and diastolic blood pressure ( $8.8 \pm 2.9$  mm Hg) significantly ( $P < 0.001$ ) more than in the control group ( $11.3 \pm 4.2$  and  $4.9 \pm 3.0$  mm Hg). Also, the rate of blood pressure control was larger in the intervention group (62.8% vs 32.6% control group). Interestingly, medication adherence increased only when the intervention significantly reduced blood pressure. A more recent meta-analysis of 39 randomised controlled trials and 14 224 patients showed that the pharmacist's intervention was associated with greater blood pressure reductions compared with usual care and that the effect tended to be larger if the intervention was led by the pharmacist (systolic and diastolic blood pressure reductions 8.5 and 4.6 mm Hg vs 6.3 and 2.8 mm Hg under collaborative care) and was done at least monthly ( $9.1/4.5$  mm Hg vs  $6.7/1.9$  mm Hg less than once a month).<sup>15</sup>

Cheema *et al*<sup>16</sup> examined 16 randomised controlled trials studying 3032 patients with or without associated cardiovascular comorbidities and found that community pharmacist-led interventions were associated with significant ( $P < 0.001$ ) reductions in systolic blood pressure ( $6.1$  (3.8 to 8.4) mm Hg) and diastolic blood pressure ( $2.5$  (1.5 to 3.4) mm Hg) compared with usual care, thus contributing to improve clinical management of hypertension. A non-significant trend was observed for a smaller blood pressure reduction from community pharmacist's interventions in patients with cardiovascular comorbidities in comparison to those without comorbidities (systolic blood pressure difference:  $1.9$  (–3.1 to –6.9) mm Hg and diastolic blood pressure difference:  $1.5$  (–0.4 to –3.4) mm Hg;  $P=0.460$  and  $0.127$ , respectively). Adherence was increased more often in the intervention group (OR 12.1 (4.2 to 34.6),  $P < 0.001$ ).

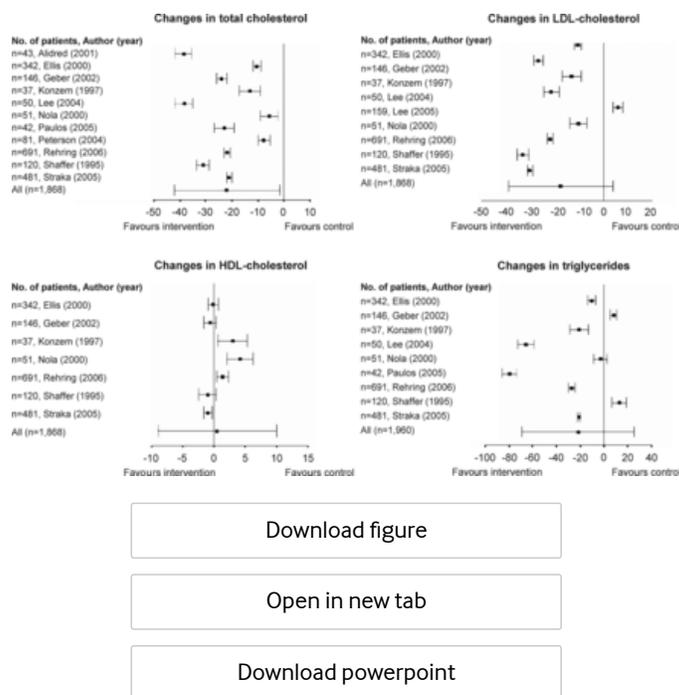
Community pharmacies may represent the ideal site for implementing community-based self-screening to detect hypertension in the population. Fleming *et al*<sup>17</sup> systematically analysed 73 studies which described screening in 9 settings, with pharmacies representing the most common setting (22% of studies) followed by public areas or retail (15%). Although authors found a high heterogeneity across studies, they were able to show an average proportion of 39% of patients with hypertension detected in community pharmacies. The rate of

screened participants with raised blood pressure was larger in the pharmacy setting than in other sites and in any case the review allowed to demonstrate the usefulness of community screening of blood pressure by non-physician for detecting raised blood pressure, though they concluded that the evidence base for its effectiveness is still very poor.

## Dyslipidaemia

In patients with hyperlipidaemia two meta-analyses documented significant improvements as a result of the pharmacist's intervention on specific, but not all, patient's health outcomes. The most notable effect was observed on total cholesterol and LDL cholesterol, although both systematic reviews reported a moderate heterogeneity. In the selected studies, most common interventions included education, followed by drug therapy recommendations and adherence assessment.

In the systematic review of Machado<sup>18</sup> including 23 studies and 2343 patients, the pharmacist's intervention was associated with a statistically significant ( $P<0.001$ ) reduction in total cholesterol of  $34.2\pm 10.3$  mg/dL, corresponding to a further significant ( $P=0.034$ ) reduction of  $22.0\pm 10.4$  mg/dL as compared with the control group (figure 2).



**Figure 2**

Differences in changes in total cholesterol, LDL-cholesterol, HDL-cholesterol and triglycerides (expressed as mg/dL) between patients with hyperlipidaemia receiving a pharmacist's intervention and patients in control groups in a meta-analysis of different studies. Data are shown as mean difference and 95% CI (redrawn from 18 with permission). HDL, high density lipoprotein; LDL, low density lipoprotein.

LDL cholesterol and triglycerides levels were also reduced due to pharmacist's intervention but the additional reduction, although clinically relevant, was not statistically significant compared with that observed in the control group ( $17.5\pm 10.9$  mg/dL  $P=0.109$  for LDL cholesterol and  $21.8\pm 24.2$  mg/dL  $P=0.368$  for triglycerides) (figure 2). The pharmacist's intervention did not impact on high density lipoprotein (HDL) cholesterol ( $0.5\pm 4.8$  mg/dL,  $P=0.910$ ) (figure 2), patient-reported outcomes, adherence and quality of life.

Charrois and coworkers<sup>19</sup> evaluated 21 randomised controlled trials, with 5416 patients receiving enhanced pharmacist care or standard care. In this meta-analysis at the end of the follow-up the mean LDL cholesterol level (primary outcome measure) was significantly ( $P<0.01$ ) lower by  $10.7$  ( $16.9, 4.6$ ) mg/dL in the intervention group in the 9 studies reporting this measure. Also, total cholesterol and triglycerides levels were significantly ( $P<0.01$ ) lower in the enhanced pharmacist care group by  $15.2$  ( $24.0$  to  $6.4$ ) mg/dL and  $23.0$  ( $37.2$  to  $8.9$ ) mg/dL, respectively (10 studies). However, for all these assessments the results were highly heterogeneous. No significant effect of intervention was observed on HDL cholesterol ( $+0.4$  ( $1.9$  to  $+2.3$ ) mg/dL). Interestingly in this meta-analysis, the primary outcome was compared between subgroups of independent practice (pharmacist directed) versus collaborative care. The latter had a  $10.7$  mg/dL larger effect on LDL cholesterol than independent care, though the difference did not achieve statistical significance. Finally, patients who received enhanced

pharmacist care were more likely than those receiving standard care to attain target lipid levels (OR and 95% CI 2.46 (1.43 to 4.25), eight studies) to have a lipid panel ordered or recommended by a pharmacist during the study (2.02 (1.30 to 3.24), four studies) or to change their lipid-lowering therapy (1.82 (1.09 to 3.06), five studies).

## Diabetes

Studies targeting adult diabetic patients documented an overall improvement in glycaemic control (haemoglobin A1c) with various pharmacist's interventions, across diverse groups of settings and study designs. Strategies that used direct medical management by pharmacists reported the greatest benefit compared with those that used the addition of pharmacists who provided drug reviews and disease education alone.

Wubben and Vivian<sup>20</sup> performed a qualitative meta-analysis of 21 studies (9 randomised controlled studies, 1 controlled clinical trial and 11 cohort studies) including 3981 diabetics. All interventions involved additional visits by pharmacists with expanded roles to care for adult patients with diabetes. An overall improvement in haemoglobin A1c was observed in different settings and across multiple study designs: the differences in change for haemoglobin A1c ranged from an increase of 0.2% to a decrease of 2.1%. The same authors also demonstrated that glycaemic control in patients with diabetes is much more improved in case of prescribing pharmacist. As a matter of fact, the improvement in haemoglobin A1c respect to the control group was 1.0% when the pharmacist had the authority to prescribe antidiabetic drugs under the supervision of the physician, whereas was only 0.5% without such authority ( $P=0.007$ ). Two studies also conducted economic analyses which helped showing a trend to a saving in long-term costs of the disease by improving glycaemic control.

A significant ( $P<0.001$ ) reduction in haemoglobin A1c ( $1.0\%\pm 0.3\%$ ) was observed after pharmacists' intervention in diabetics but not in control ( $0.3\%\pm 0.3\%$ ) also in another meta-analysis of 30 studies, including 2247 patients.<sup>21</sup>

Diabetes education (69% of cases, consisting in verbal instructions on diet, exercise, drug therapy and disease itself) and medication dosage adjustment (61%) were the most frequently used interventions. In the same meta-analysis, no sensitive outcomes were reported for treatment adherence, changes in lipid levels, knowledge and quality of life, whereas a possible clinical benefit was documented for fasting plasma glucose and systolic blood pressure.

A more recent meta-analysis of 40 studies, of which 11 randomised controlled, failed to document any benefits to major health outcomes following community pharmacist's intervention.<sup>22</sup> The studies involved patient-directed interventions, such as education and follow-up, and physician-directed interventions, the most common of which was the identification of drug-related problems and provision of therapeutic recommendations. Unfortunately, studies were generally of poor quality and evaluated interventions that typically appeared to be time intensive. The interesting aspect of this review is that, at variance from previous meta-analyses, it focused on interventions specific to community pharmacists and included diabetics with additional cardiovascular risk factors or diseases.

## Coronary heart disease

The contribution from pharmacists in the management of ischaemic heart disease patients has been evaluated in several studies with mixed results, allegedly because of the limited number of participants in each study and of the small number of studies available so far. While results always highlight and confirm the important role of the pharmacist for the improvement of medication adherence of these patients, the impact of pharmacist care with respect to secondary prevention of morbidity and mortality is still unclear.

Cai *et al*<sup>23</sup> provided a qualitative analysis of five randomised controlled studies including 2568 patients with coronary heart disease. The outcomes were mortality, cardiovascular events, and hospitalisations in one study (421 patients), medication adherence in five studies, blood pressure in two studies (1914 patients), and lipid management in three studies (932 patients). The interventions of pharmacists included patient education, medication management, feedback to healthcare professionals and disease management. The authors were unable to show any survival benefits or reduction in cardiac events and hospitalisations from pharmacist care. However, significant positive effects of pharmacist's intervention could be shown on medication adherence in three studies, on blood pressure control in one study and on lipid management in one study.

Altowarijri *et al*<sup>24</sup> performed a systematic review of 59 studies conducted on patients with coronary heart disease, heart failure or with cardiovascular risk factors. The involvement of a pharmacist demonstrated an ability to improve different outcomes through provision of educational intervention, medicine management intervention or a combination of both. In particular, five of the seven randomised controlled studies assessing improvement in cardiovascular morbidity or mortality as their outcomes were able to show that clinical pharmacists have a significant effect, whereas two showed no effect. The same authors also analysed eight economic studies, demonstrating that the clinical pharmacist may have an impact in decreasing healthcare costs through improvement of cardiovascular disease risk factor control and patient outcomes.

## Heart failure

Heart failure is a common and serious public health problem, whose prevalence is increasing because of ageing of the population and improved treatment of acute cardiovascular events.<sup>25</sup> Heart failure accounts for substantial morbidity and mortality worldwide and it is the ideal target for multidisciplinary approach for achieving optimal management. Numerous studies have documented the role of the pharmacist in the care of patients with heart failure. These studies analysed services performed with varied scopes, in different settings, but mainly in the hospital, and with various outcome measures. At variance from other cardiovascular diseases and conditions, a substantive body of evidence exists on the effectiveness of the pharmacist's intervention in terms of decrease length of stay and reduced number of hospital readmissions. Furthermore, improvement in patient wellness and overall self-perception of well-being has been observed in patients with heart failure following educational efforts implemented by the pharmacist.

A first systematic review was published by Ponniah *et al*<sup>26</sup> and evaluated the prognostic impact of pharmacy services on postdischarge patients with heart failure: in six of the seven included studies positive outcomes, such as decreases in unplanned hospital readmissions, death rates and greater compliance and medication knowledge were demonstrated. Koshman *et al*<sup>27</sup> identified 12 randomised controlled studies, showing a significant ( $P=0.020$ ) association between pharmacist care and reductions in the rate of all-cause hospitalisations (OR and 95% CI 0.71 (0.54 to 0.94)) and heart failure hospitalisations (0.69 (0.51 to 0.94)) and a non-significant ( $P=0.270$ ) association with the reduction in mortality (0.84 (0.61 to 1.15)). In addition, pharmacist collaborative care led to greater ( $P=0.020$ ) reductions in the rate of heart failure hospitalisation (0.42 (0.24 to 0.74)) than pharmacist-directed care (0.89 (0.68 to 1.17)).

Davis *et al*<sup>28</sup> specifically assessed the impact and value of pharmacist's interventions on adherence in patients with heart failure, demonstrating an improvement which lacked durability once the intervention ceased. The study also assessed and listed specific predictors associated with adherence to heart failure medications and concluded that pharmacist's interventions should be part of a multidisciplinary system of care initiated at discharge and that involves personal contact and must be continued indefinitely in order to sustain the achieved benefits.

Thomas *et al*<sup>29</sup> demonstrated that interventions delivered by a hospital pharmacist who followed older patients with heart failure after discharge significantly ( $P<0.01$ ) reduced the risk of unplanned hospital readmission (relative risk and 95% CI 0.75 (0.59 to 0.95)). A review of 13 major studies in the literature confirmed that pharmacist's interventions based on medication reconciliation, patient education and collaborative medication management, may effect significant positive change in therapeutics outcomes, decrease hospitalisations and readmissions, and improve overall patient perception of self.<sup>30</sup> Very recently, Kang *et al*<sup>31</sup> confirmed in a meta-analysis of 14 randomised controlled studies that pharmacy services in patient with heart failure and coronary heart disease significantly ( $P<0.05$ ) decrease all-cause hospitalisation (OR and 95% CI 0.74 (0.58 to 0.94)), but neither all-cause mortality (1.04 (0.89 to 1.21)) nor cardiac-related hospitalisation (0.90 (0.78 to 1.03)). They also observed a significantly ( $P<0.05$ ) higher prescription rate of ACE inhibitor (1.43 (1.07 to 1.91)) and beta-blocker (1.92 (1.24 to 2.96)) in the intervention group. The strength of evidence for other measures of the intervention was either insufficient or low, due to the diversity of pharmaceutical care, the heterogeneity of patient populations or clinical settings.

## Limitation of current evidence

Current evidence from the systematic reviews and meta-analyses shows that there are still several methodological limitations in pharmacy practice research (box 2).

## Box 2 Main reasons of the current limited evidence from systematic reviews and meta-analyses on the effectiveness of pharmacist's intervention in cardiovascular disease management

- Non-homogeneous interventions (most interventions based on education, medication or disease management)
- Heterogeneity of study designs (few randomised controlled trials)
- Benefit of direct care not fully explored
- Lack of standardisation of the intervention and of the outcome assessment
- Selection bias
- Mixed effects of hospital and community pharmacists
- Cost effectiveness poorly explored

Heterogeneity is high across studies conducted in this area, and pharmacists' interventions are often poorly and inconsistently described across primary studies, which limits the performance of meta-analyses. As a matter of fact, after applying sensitivity analyses, in order to remove studies of lower methodological quality, particularly the oldest studies, the strength of the evidence was blunted in most systematic reviews: only few outcomes were sensitive to pharmacists' interventions from both clinical and statistical perspectives.

Variability in the study designs, specifically with respect to the type and complexity of pharmacist's intervention, inclusion criteria, duration of observation and follow-up, end-points considered, adequacy of sample size, are major drawbacks of studies in this setting. No standardisation in types of education, drug management protocols and use of self-monitored data (blood pressure, blood glucose, serum lipids) to adjust drug therapy was made across the studies. Most studies were affected by an important selection bias: patients receiving the intervention had often been referred to the pharmacist, while controls were not. Thus, patients in the intervention group were likely more motivated, were interested in their care and were more willing and/or able to comply with study procedures. In most studies addressing patients with hypertension, lipid disorders or diabetes, these conditions were often simultaneously present in the same subjects, thus making it difficult to extrapolate the effectiveness of the pharmacist's intervention on a given condition or risk factor. In most cases, the magnitude of the effect on blood pressure, blood glucose or serum lipids was modest and thus a relatively small decrease in cardiovascular effect could be expected.

Several studies lacked to focus on variables that are part of the core outcome set in clinical practice guidelines: as a matter of fact interventions using objective parameters such as blood pressure or serum glucose, to assess patients' health status rather than end-point outcomes such as hospitalisation or mortality, were the most successful in demonstrating the positive impact of the pharmacist's intervention. Interestingly, a higher chance of success was observed when comorbidities were present or when patients were at higher risk of cardiovascular accidents. In these cases, the strength of the pharmacist's intervention was sufficient to achieve a clear benefit. In other conditions at lower risk, the effectiveness of the intervention varied widely across studies and was difficult to be properly estimated. Unfortunately, very few studies assessed the healthcare costs associated with pharmacist case managers. The cost-effectiveness of adding a pharmacist case manager, compared with a nurse case manager or a certified educator, thus remains unclear.

Other important limitations of many studies in this field are the lack of randomisation and control, and the high heterogeneity in study settings. Some studies were randomised and controlled, others were non-randomised and non-comparative, very few were prospective, whereas most were observational and retrospective. Some studies took place in a hospital or medical centre, others in community pharmacies. Only few studies focused on prescribing pharmacist, whereas most of them were based on interventions part of a multidisciplinary approach, sometimes involving other healthcare professionals, under the supervision of a physician. Likely, this occurred because the model based on the pharmacist's independent prescription is rather uncommon, not always well accepted by doctors and thus available only in few countries. Some studies addressed hospitalised or hospital-discharged patients others healthy subjects or relatively low-risk patients dwelled in the community. However, though studies were performed in several types of settings, medical clinics and community pharmacies were the most common settings where pharmacy services were delivered, and a team-based collaborative approach including a physician was the most common healthcare model.

### Possible benefits of pharmacist's intervention in patients with cardiovascular disease

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Because of their accessibility, pharmacists are in a distinct position to provide appropriate interaction and/or collaboration with patients and physicians to ensure successful treatment. Pharmacist involvement from screening patients right up to initiation of therapy and follow-up had proved to be essential in achieving positive outcomes in most but not all patients with cardiovascular risk factors or diseases.

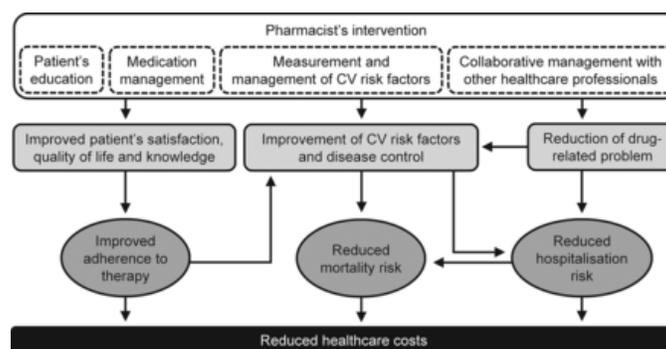
Randomised controlled and observational studies have demonstrated that interventions provided by pharmacists are in general beneficial in the management of major cardiovascular risk factors such as hypertension, dyslipidaemia, diabetes or smoking cessation, and in heart failure, with a positive effect on clinical outcomes. However, pharmacist's intervention to improve humanistic outcomes such as patient satisfaction, adherence and knowledge were found effective in some but not in all studies. A good deal of randomised controlled studies documented a positive impact of pharmacist-directed care, including measurement of cardiovascular risk factors or medication adjustments, particularly in collaboration with the managing physician, but the evidence is not conclusive. A summary of possible benefits of pharmacist's intervention in patients at high risk of cardiovascular diseases or with established cardiovascular disease is summarised in table 2.

**Table 2**

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Level of benefit of pharmacist's intervention on clinical, humanistic and economic outcomes in cardiovascular disease

As shown in figure 3, the benefits of pharmacist's intervention on the patient with cardiovascular disease may be complex and interrelated.



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**Figure 3**

Effects of pharmacist's intervention on humanistic, clinical and economic outcomes in patients with cardiovascular disease. CV, cardiovascular.

Patient's education, medicine management, direct measurements and management of cardiovascular risk factors (eg, blood pressure, blood glucose or serum cholesterol) and interprofessional collaborative practice may impact on humanistic (patient's satisfaction, quality of life and knowledge), clinical (cardiovascular risk factors and diseases, hospitalisation, adherence to treatment, adverse drug reactions and medication errors) and economic outcomes. The net effect of the pharmacist's intervention is the use of fewer healthcare resources and cost saving, although this evidence still needs to be confirmed in large intervention trials.

### Collaborative practice: the future of pharmacy practice?

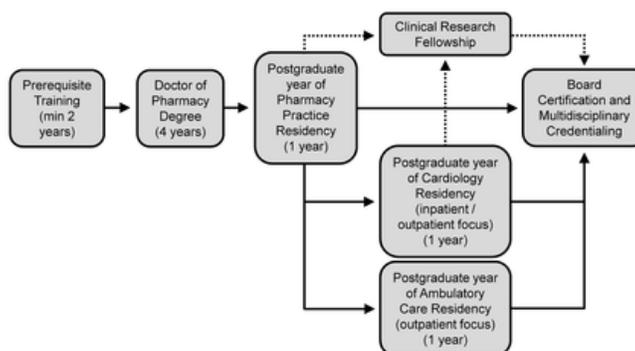
In studies evaluating the effectiveness of pharmacy services, the interventions were provided independently of other healthcare professionals' supervision or in the context of a collaborative practice with other healthcare professionals. Indeed, the multidisciplinary approach should be regarded as ideal in order to enhance patient's outcomes, rather than unilateral interventions: this approach has been the objective of several recent studies.<sup>12</sup> In addition to a multidisciplinary approach, more research has been recently oriented toward the primary care setting and home care, and toward a progressive involvement of community rather than hospital pharmacies.

The importance of a collaborative practice has been highlighted in a recent review:<sup>12</sup> after the year 2000, many more studies were based on a multidisciplinary approach for early identification and follow-up of specific chronic conditions, in particular for diabetes and arterial hypertension. In recent years, the pharmacist increased the interaction with both the patients and their caregivers, mainly the referring physician, and this has turned out in a greater effectiveness of the pharmacist's intervention. Overall, evidence demonstrates that the collaborative and patient-centred model of care is beneficial through improving control of chronic diseases, appropriate use of pharmacotherapy or promotion of health and wellness.<sup>3</sup>

In heart failure, multidisciplinary interventions which included medical input plus a pharmacist, specialist nurse, a health educator, a dietician or a social worker, reduced the risk of all cause admission by 13% (OR and 95% CI 0.87 (0.79 to 0.95); P=0.002), mortality by 21% (0.79 (0.69 to 0.92); P=0.002) and heart failure admission by 30% (0.70 (0.61 to 0.81); P<0.001), in a meta-analysis of 30 trials including 3238 patients.<sup>32</sup> Team-based care interventions involving pharmacists were associated with improved blood pressure control compared with usual care in a meta-analysis of 37 studies.<sup>33</sup> Interestingly, the effect was larger for studies involving community pharmacies (OR and 95% CI 2.89 (1.83 to 4.55)) than for those involving pharmacists within primary care clinics (2.17 (1.75 to 2.68)). No significant differences were observed in the effect between the studies involving pharmacists rather than nurses. This finding was strengthened in a more recent review based on 52 studies.<sup>34</sup> A team-based care approach predominantly including pharmacists, nurses or both, collaborating with hypertensive patients and primary care providers was effective in improving blood pressure outcomes during a median follow-up of 12 months. Patients receiving team-based care were more likely to have blood pressure at target compared with usual care (+12%) and display larger systolic and diastolic blood pressure reductions during follow-up (5.4 and 1.8 mm Hg, respectively). Two interesting findings of this meta-analysis were that the extent of the improvement in blood pressure control was larger when pharmacists rather than nurses were added to the team and that no difference in the effect was observed between interventions provided in the healthcare or in the community settings. Outcomes for diabetes and lipids, other cardiovascular risk factors often comorbid with hypertension, were also analysed by Proia and coworkers. Team-based care resulted in improvement in total cholesterol (-6.3 mg/dL, +13.0% of patients at goal), LDL cholesterol (-4.3 mg/dL, +3.2%), HDL cholesterol (+1.3 mg/dL, +6% at goal), haemoglobin A1c (-0.3%, +10.0%) and blood glucose (-7.0 mg/dL).

As a matter of fact, with the increasing complexity of disease management and drug regimens for patients with cardiovascular disease, pharmacists have become a necessary part of the management team for these patients. Providing care for patients with heart failure or coronary heart disease or for those at high risk of a cardiovascular disease (eg. patients with hypertension or diabetes), with a complementary role to that of the referring physician and nurse practitioner, is a role that continues to emerge for pharmacists. They have the potential to build a strong relationship with patients and become a reliable source of information. Thanks to their enduring relationship with other healthcare providers, pharmacists can serve as a link between these healthcare providers and the patients, thus ensuring continuity of care. In addition, pharmacists may provide recommendations to the patients and their providers in order to optimise therapeutic outcomes.

In the future pharmacists and other healthcare professionals, including nurses, may play a relevant role in a patient-centred medical home model for managing cardiovascular diseases, particularly in case of coronary heart disease and heart failure. In such a model, patients have a direct relationship with a provider who coordinates a cooperative team of healthcare professionals, including pharmacists, providing a comprehensive medication management.<sup>35</sup> Such an approach will require an individualised care plan that achieves the intended goals of therapy with appropriate follow-up to determine actual patient outcome and will need a cooperation of several healthcare professionals, including the pharmacist. The success of the collaborative practice agreement is strongly dependent on the pharmacist's ability, time and willingness to change his/her professional attitude. The pharmacist needs to update his/her competencies and skills on specific disease management through training and certification processes under the supervision of the physician. To this regard, the American College of Cardiology has recently published a guide to a training pathway and certification process to be followed by clinical pharmacists in the USA in order to deliver high-quality patient care within the context of a cardiology practice (figure 4).<sup>36</sup>



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## Figure 4

Education and training route of a clinical pharmacist in a cardiology practice (redrawn from<sup>36</sup> with permission).

According to this model, following graduation, the pharmacist has to complete a 1-year postgraduate pharmacy residency programme which is intended to produce pharmacy practitioners competent in patient-centred care and pharmacy operational services that can be applied to any practice setting (including the community pharmacy). Individuals desiring more specialised clinical training in a cardiovascular area can complete a further 1 year of residency which serves to train pharmacy practitioners in the care of patients with cardiovascular diseases. Pharmacists may obtain multidisciplinary certification covering various areas of cardiovascular disease prevention and management, such as that of certified anticoagulation care provider, certified diabetes educator or clinical lipid specialist. The residency programme may also train in the conduct of clinical research projects, the interpretation of cardiovascular biomedical published data, quality improvement initiatives, leadership and practice management, teaching and educational activities and advocacy for cardiovascular disease prevention.

Other medical Societies have published similar recommendations to guide pharmacist's practice in collaboration with the physician. The Heart Failure Society of America and the American College of Clinical Pharmacy Cardiology Practice and Research Network have outlined guidelines for training and certification process of clinical pharmacists in a multidisciplinary heart failure team.<sup>37</sup> The Canadian Hypertension Education Programme has published a set of guidelines on hypertension management, for pharmacists.<sup>38</sup> The American Association of Colleges of Pharmacy published a document with recommendations on potential delivery care models with integration of pharmacists in primary care practice in the community, in the context of partnership with patients and healthcare service providers.<sup>35</sup>

## Future challenges

Although in the pharmacy setting patient education and medication management are currently the most frequently used interventions, a growing request of additional services is required. These services should be focused on simple rather than complex interventions which could be affected by a number of unknown confounders and make the outcome unpredictable and only partly beneficial to the patient. Such interventions should focus on what the patient is expecting to receive from pharmacist in actual practice.

Future research should quantitatively and qualitatively evaluate the impact of pharmacists' interventions on main chronic diseases and try to identify specific areas of impact of collaborative practice. Intervention studies should be large enough, both in sample size and length of follow-up, controlled and randomised and should evaluate different types of outcomes in the studied population and be directed toward high-risk or complex patients, because the current evidence suggest that pharmacist's interventions are more efficacious in these patients. Community pharmacists should be preferentially involved in these studies, given the accessibility and distribution of community pharmacies and the continuous relationship of such professional figures with patients and other healthcare managers.

Finally, the progressive introduction of health information technologies and in particular of telemedicine in pharmacies and primary practices may provide new ways for patients and their healthcare team to communicate and to electronically share information on medications, life style behaviours and patient's health status. Use of telemedicine will facilitate the screening of subjects at risk for cardiovascular diseases and provide a quick and accurate feedback and adjustments of care plans in treated patients, by promoting a more close and optimised relationship between pharmacists and doctors in a collaborative agreement practice.<sup>39</sup>

## Conclusion

Some sensitivity of pharmacist's intervention on outcomes of patients with cardiovascular disease has been shown in case of hypertension, dyslipidaemia, diabetes or smoking cessation and in heart failure. A common finding of the systematic reviews on these studies is that a greater involvement of pharmacists in activities directed to the patients and collaboration with other healthcare professionals in a team may provide an enhanced effect on various outcomes and may ultimately positively affect public health. However, the clinical importance of pharmacist's interventions remains not fully demonstrated, and further well-designed and well-conducted studies are required in this

research field. In our opinion, such studies should particularly focus on the demonstration of a possible sensitivity to community pharmacist's intervention. Since pharmacy services are easily accessible and widely distributed in the community setting, a maximum benefit should be expected from these interventions.

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## Operations & Management (/Section/Operations-and-Management/53)

MAY 23, 2019

# Pharmacist-Led Clinics Reduce Readmissions

## Heart failure alone yielded \$1.57 million benefit

By Lynne Peoples

Anaheim, Calif.—A suite of pharmacist-led chronic disease management clinics have helped one health system in Ohio reduce hospital readmission rates fivefold and reap nearly \$4 million in cost savings.

“It’s one thing to optimize care in the hospital; it’s another thing to try to keep people healthy over the long run,” said Britt Cummins, MS, RPh, the recently retired director of pharmacy for Memorial Health in Marysville, Ohio, and a co-author of a series of posters presented at the ASHP 2018 Midyear Clinical Meeting (7-001, 7-002 and 7-003). The researchers found that fewer readmissions resulted in significant cost savings and better patient outcomes.

About nine years ago, Mr. Cummins and his colleagues realized that nearly one-fourth of patients with common chronic diseases are readmitted to their hospital within 30 days, due to treatment failures or exacerbations of their disease. Many patients—approximately 70%—also did not take their chronic disease medications properly.

“We wondered what we could do to keep these patients healthy over the long term,” Mr. Cummins recalled.

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Toward that end, they began developing clinics to manage patients with chronic diseases, starting with patients taking anticoagulants and then those with heart failure. The program's success largely stems from the pharmacist's ability to coordinate better care with the patient's long-term (TOC) clinic to



The pharmacist-led multidisciplinary efforts have so far proven beneficial. Between April 2015 and September 2017, the hospital saw a dramatic reduction in 30-day readmission rates, from 21% to 4%. Also, ER visits for COPD dropped 27% during the first two years of the COPD clinic. Medication adherence for patients referred to the HF clinic increased from 51% to 88%.

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In that same period, pharmacists initiated 2,224 medication-related interventions to correct issues with drug therapy: 2.77 per patient and 2.31 per visit.

The interventions also achieved impressive bottom-line results. The HF clinic, for example, yielded a net financial benefit of more than \$1.5 million during its first three years—largely a result of cost savings associated with reduced hospital admissions, Mr. Cummins and his colleagues reported. The COPD clinic also impressed, racking up a net financial benefit of \$905,785 during the January 2016 to December 2017 study period. And the TOC program's net financial benefit was approximately \$1.5 million over 30 months, as tracked in a 97-bed community hospital.

### **Risk Stratification**

The ongoing effort starts in the hospital, Mr. Cummins noted. There, pharmacists identify inpatients who are at high risk for readmission based on their medical history. They then start working with the patients, discussing any financial concerns and medication management while underscoring the importance of follow-up appointments and tests. They also schedule clinic appointments within two weeks after discharge. Those appointments, which include both a pharmacist and nurse practitioner, can last 45 minutes to an hour—as opposed to physician visits, which may be only 15 minutes.

“Lots of times when a patient fails, they haven't seen a primary care or specialist in a timely manner or returned for tests,” Mr. Cummins said. “Things fall through the cracks in those first 30 days.”

Craig Baker, PharmD, the new director of pharmacy for Memorial Health and a co-author on the posters, noted that he has witnessed a lot of "aha moments" where patients finally understand the importance of medication adherence and see a big increase in adherence.

To optimize the effects of the program, the Memorial Health team has begun putting pharmacists in primary care offices. "We want to get to those patients 10 or 15 years earlier—when they are first diagnosed," Mr. Cummins said. "Then we can get them on the right path managing their medications, avoiding complications and readmissions."

Toni Fera, PharmD, an independent health care consultant in Pittsburgh, who was not involved in the posters, agreed with that approach. "For chronic diseases, the cost curve increases rapidly over time," Dr. Fera said. "Most efforts focus on the highest cost patients, who are more toward the end of that curve. For health plans and provider organizations making a long-term commitment to these patients, it makes sense to shift the resources earlier in their disease, from the point of diagnosis, which will truly shift the cost curve and hopefully delay, or even prevent, longer term complications from the conditions."

As far as the overall approach taken by Dr. Cummins and his colleagues, the results speak for themselves, Dr. Fera said, adding that the positive outcomes were "quite promising and consistent across all three programs."

She also stressed the unique skills that pharmacists bring to ambulatory care. "Comprehensive management of medications, including addressing medication access and adherence, optimizing medications prescribed, and prevention or management of medication therapy problems is critical to achieve good outcomes for patients with chronic diseases," Dr. Fera said, "and pharmacists are perfectly positioned to make an impact."

**Scope of Services for COPD and HF Clinics<sup>a</sup>**

- Medication therapy management
- Clinical/physical assessment
- Comprehensive medication review/medication reconciliation
- Medication adherence monitoring, coaching and improvement
- Custom medication plan individualized to each patient's lifestyle, personal/work schedules, social habits, sleep patterns, learning styles and technology capabilities; healthy lifestyles coaching/education longitudinally
- Financial screening/assistance for meds (medication therapy navigator)
- Lab tests—point of care in-clinic testing using Piccolo Xpress (Abbott) analyzer for rapid results; used for most common tests (facilitates timely medical decision making and patient education)
- Immunizations
- Integration with pulmonary and cardiac rehab programs

<sup>a</sup> Also includes spirometry testing and education on inhaler technique for COPD patients.

**COPD**, chronic obstructive pulmonary disease; **HF**, heart failure

The sources reported no relevant financial relationships.

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**WJacob** wrote on: 11/21/2019 3:38:15 PM (EST) 263 days ago.

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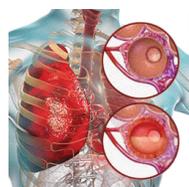
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## AMA Journal of Ethics

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CASE AND COMMENTARY  
AUG 2020

# What Does Good Pharmacist-Physician Pain Management Collaboration Look Like?

Kyle Bryan, PharmD and Thomas E. Menighan, MBA

## Abstract

Physicians and pharmacists have critical roles in addressing the current opioid epidemic and ensuring appropriate care for patients with pain. Both physicians and pharmacists have responsibilities to ensure that opioids are prescribed and dispensed for legitimate medical purposes and to meet legal requirements. Health care systems have implemented policies to curb opioid prescribing and dispensing, but many of these policies place additional pressures on clinicians and can cause friction between physicians and pharmacists. Cases discussed in this article highlight 5 optimal physician and pharmacist behaviors that can help foster better collaboration between these clinicians, improve management strategies, and improve care of patients with pain.

## Multiple Opioid Prescribers

**Case.** KT is a 33-year-old man who enters a pharmacy with a history of chronic back pain. He hands the pharmacy technician 2 prescriptions: one for oxycodone extended release (ER) 40 mg, 1 tablet every 12 hours; and one for oxycodone 5 mg, 1 tablet every 4 to 6 hours as needed for pain. As the pharmacist is reviewing the prescriptions, she sees the patient has recently been taking hydrocodone/acetaminophen 10 mg/325 mg, 1 tablet every 4 to 6 hours as needed for pain, and that these new prescriptions are from a different physician who practices in a nearby state. Concerned about the significant increase in opioid dosage and the potential presence of multiple prescribers, the pharmacist calls the office of the physician who wrote the new prescriptions and asks to speak with the physician. After a brief hold, the physician answers the phone and asks the pharmacist in a noticeably defensive tone, "Why are you questioning me? What do you know about this patient?" The pharmacist begins to explain her concerns about the patient's dosage, but the physician interjects and states that she should fill the prescriptions as they were written. The pharmacist then tries to discuss the potential concurrent opioid prescriptions from 2 different prescribers and verify the increase in dosage. The physician reiterates that the pharmacist should fill the prescriptions as written. At this point, the pharmacist states that she won't be able to fill the prescription without verification that the physician is aware of the other prescriber and the past use of a lower dosage prescription opioid. The physician quickly provides the needed information, confirming that the patient has been instructed to take the long-acting ER dosage consistently, discontinue hydrocodone/acetaminophen, and hold off on the short-acting opioid for a week to adjust to the higher ER dose and take that medication only as needed. The physician ends the call by telling the pharmacist, "You don't have the knowledge, so you shouldn't attempt to practice medicine."

**Commentary.** A patient has obtained opioid prescriptions from 2 different physicians, with a significant increase in dose and associated risk. Pharmacists, like physicians and other health care professionals, are committed to optimizing patient outcomes and ensuring patient safety. Pharmacists have a professional responsibility to comprehensively review a patient's medication profile and to review all possible safety concerns in a patient's medication regimen while also considering current [evidence-based pain management](https://journalofethics.ama-assn.org/article/addressing-obstacles-evidence-informed-pain-care/2020-08) (<https://journalofethics.ama-assn.org/article/addressing-obstacles-evidence-informed-pain-care/2020-08>) and geriatrics guidelines. In addition to their professional practice responsibilities, pharmacists must also meet legal obligations, including Drug Enforcement Administration (DEA) requirements for controlled

must also meet legal obligations, including Drug Enforcement Administration (DEA) [requirements for controlled substances](https://journalofethics.ama-assn.org/article/fighting-prescription-drug-abuse-federal-and-state-law/2013-05) (<https://journalofethics.ama-assn.org/article/fighting-prescription-drug-abuse-federal-and-state-law/2013-05>). DEA rules mandate that both physicians and pharmacists have responsibilities to ensure that controlled substance prescriptions are written for a legitimate medical purpose.<sup>1</sup> Certain factors, such as prescriptions from different states and multiple prescribers, can be red flags for potential opioid use disorder.

Community pharmacists often have the benefit of access to information about patients' medications prescribed by multiple physicians and can comprehensively evaluate medication regimens for safety and other potential therapeutic

problems. What they often lack is access to important information such as diagnoses and prescribers' goals of therapy. Significant concerns about a patient's medication(s) might require the pharmacist to contact the prescriber to discuss the concerns, verify information, and provide recommendations. In addition, a patient's health plan might also require that pharmacists verify information with the physician's office in order to adjudicate the prescription claim. Increasingly, pharmacists are required to include a diagnosis code with the prescription claim or verify that the prescriber was contacted to discuss high opioid dosages. Physicians and pharmacists are under tremendous time pressure, and calls are not made lightly. Some questions can be addressed by office staff, but others are most effectively resolved by a direct conversation between the prescribing physician and the pharmacist.

Effective, comprehensive chronic pain management often necessitates [multidisciplinary coordination](https://journalofethics.ama-assn.org/article/teamwork-health-care-maximizing-collective-intelligence-inclusive-collaboration-and-open/2016-09) (<https://journalofethics.ama-assn.org/article/teamwork-health-care-maximizing-collective-intelligence-inclusive-collaboration-and-open/2016-09>) and a multimodal approach to care.<sup>2</sup> More generally, interprofessional collaboration is key to high-quality, patient-centered care.<sup>3</sup> The Table details selected behaviors that can facilitate improved physician-pharmacist collaboration and the resultant management of patients with pain.<sup>3</sup> In all cases, the patient is best served when pharmacists and physicians communicate in an effective, efficient, and professional manner, without bias, and with a patient-centered focus that facilitates collaboration and active engagement in finding solutions and resolving conflict. Clinicians also have a professional responsibility to understand and appreciate the roles and responsibilities of others in promoting the best care.

**Table.** Desired Behaviors of Clinicians for Optimal Collaboration in Pain Management

- Communicate respectfully, openly, and without bias, with a patient-centered focus.
- Establish rapport and build trusting relationships.
- Embrace and appreciate the roles and responsibilities of other health care professionals.
- Show empathetic behaviors for the patient and other health care professionals that include avoidance of stigma.
- Actively engage in finding solutions and resolving conflict.

Source: Interprofessional Education Collaborative<sup>3</sup> and Owen JA, Skelton, JB, Miller WA, Moon JY, and Romanelli F (unpublished data, 2020).

Additional information from the prescriber will often assist the pharmacist in (1) discussing with the patient how to take the medication(s); (2) providing education on topics such as side effects, drug interactions, risks and benefits, and storage and disposal; (3) monitoring patient experience with medication(s) and medication adherence; (4) identifying and mitigating risks, ensuring that prescriptions are legitimate, and ensuring that unintended duplication of therapy from multiple prescribers is addressed; and (5) improving coordination of medications among clinicians. Without this information, the pharmacist in this case could be faced with the ethical and legal dilemma of deciding whether to fill prescriptions that could be unsafe for KT, while recognizing KT's need for effective pain management.

## Transition of Care

**Case.** CR is a 70-year-old woman who enters the pharmacy with all of her medication bottles and a set of discharge orders from her most recent visit to the hospital after undergoing orthopedic surgery. CR asks the pharmacist for help in sorting everything out and states she is worried about taking too many medications. Looking at the orders, the pharmacist notes that several medications from CR's home regimen have been discontinued and helps CR go through her medications to clarify which ones she should stop taking. After reviewing CR's remaining medications, the pharmacist notes that the discharging clinician has retained her home medications of tramadol 50 mg, 1 to 2 tablets every 8 hours as needed for pain; and cyclobenzaprine 10 mg, 1 tablet every 8 hours as needed for muscle spasms. Additionally, the hospitalist added to CR's regimen oxycodone 10 mg, 1 tablet every 4 to 6 hours as needed for pain; and zolpidem 10 mg, 1 tablet at bedtime for sleep. The pharmacist contacts the hospitalist to explore possible changes in therapy, recognizing the patient's interests in decreasing the number of medications she takes and noting safety concerns for a patient of CR's age taking concurrent opioids and hypnotics, due to the increased risk of overt central nervous system (CNS) depression and falls.<sup>4</sup>

### **Effective, comprehensive chronic pain management often necessitates multidisciplinary coordination and a multimodal approach to care.**

The physician who comes on the line is familiar with the pharmacist and greets her warmly. She states that a nurse colleague took the medication history and verified that the patient had been taking all these medications regularly. The pharmacist explains that the cyclobenzaprine and zolpidem prescribed are on the American Geriatrics Society BEERS Criteria<sup>®</sup>, a list of medications that are potentially inappropriate to use in the elderly and therefore should be avoided in most instances.<sup>4</sup> The physician agrees with the pharmacist that the zolpidem warrants caution and gives a verbal order to change the zolpidem to 5 mg 1 tablet by mouth at bedtime for sleep, with a plan to discontinue in 10 days. While CR's pain is too severe to go without opioid analgesics, the physician agrees with the pharmacist that she does not need both tramadol and oxycodone. Together, they decide to advise CR to use the oxycodone for a short period of time for severe pain and to discontinue tramadol while taking the oxycodone. The pharmacist asks the physician about the cyclobenzaprine, stating concern about the patient continuing it with the opioid and zolpidem because of the risks associated with CR's regimen containing 3 CNS depressants. The physician informs the pharmacist that the patient expressed a strong desire to stay on the cyclobenzaprine. The pharmacist contacts the patient's primary care clinician to discuss the changes in therapy, including a plan to wean her off the cyclobenzaprine and reduce her fall risk.

*Commentary.* This case presents a very common scenario in community pharmacy in which problems arise for patients in transitions of care from hospital discharge to home. Patients often have questions regarding discharge orders, and community pharmacists often have limited information available except what is written on the discharge prescription orders. Adding to the complexity of the situation is the fact that open lines of communication between pharmacists and physicians can be lacking, with messages often having to be relayed through several intermediaries. There are often multiple clinicians whose input is needed in order to effectively coordinate care, involving many practice settings across the health care system.

The 5 behaviors detailed in the Table were optimally exhibited in this case. Good rapport and trust were exemplified by the physician and pharmacist, and both clinicians placed the patient at the center of care. The physician and pharmacist both expressed empathy for the patient and understood the complexities of navigating the health system. They actively collaborated to promote optimal outcomes for the patient. Once again, recognizing time constraints, the pharmacist succinctly and effectively detailed the problems and provided recommendations for moving forward. Care was improved by both clinicians sharing information about the patient, and a readmission might have been prevented.

In care transitions and common practice situations, collaboration between physicians and pharmacists is paramount to ensuring the best possible care. [Transitions of care](https://journalofethics.ama-assn.org/article/transitions-care-putting-pieces-together/2019-08) (<https://journalofethics.ama-assn.org/article/transitions-care-putting-pieces-together/2019-08>) are among the most vulnerable points for patients during the completion of their health care transition.

[together/2013-02](#)) are among the most vulnerable points for patients, given the complexities of their having multiple clinicians and needing to navigate new, existing, and discontinued medications. There is also need for better mechanisms to collect medication histories<sup>5</sup> and better methods to coordinate care. Pharmacists often find that patients begin taking discharge medications while simultaneously taking medications they had at home prior to discharge.<sup>6, 7</sup> Emphasizing behaviors that reinforce empathy for the patient, together with appropriate communication, collaboration, and respect for the roles of all parties involved, is critical for addressing and resolving potential safety problems and optimizing patients' medication regimens.

## Conclusion

Effective management of chronic pain often requires a multidisciplinary, multimodal approach. These cases highlight 5 behaviors that can improve care, avoid untoward events, and facilitate collaboration among physicians, pharmacists, and other clinicians: (1) communicating respectfully, openly, without bias, and in a patient-centered manner; (2) establishing rapport and building trusting relationships; (3) embracing and appreciating the roles and responsibilities of other health care professionals; (4) showing empathy for the patient and other health care professionals and avoiding stigma; and (5) actively engaging in finding solutions and resolving conflict. Incorporating these behaviors into daily practice can foster a coordinated, patient-centered approach to care and optimize patient outcomes.

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The author(s) had no conflicts of interest to disclose.

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**Advancing Team-Based Care Through  
Collaborative Practice Agreements  
A Resource and Implementation Guide  
for Adding Pharmacists to the Care Team**

Dear Pharmacists and Collaborating Prescribers:

Nearly one in every three deaths in the United States is caused by cardiovascular disease (CVD).<sup>1</sup> Sixty percent of preventable heart disease and stroke deaths happen to people under age 65.<sup>2</sup> With the burden of chronic disease in the US increasing, we need new ways to empower patients and improve care. Pharmacists have long been identified as an underutilized public health resource.<sup>3</sup> Pharmacists are well positioned to help fill the chronic disease management gap and can make a difference when they are actively engaged as part of a team-based care approach.

Collaborative practice agreements increase the efficiencies of team-based care and formalize practice relationships between pharmacists and collaborating prescribers. For this reason, the **National Alliance of State Pharmacy Associations (NASPA), American Pharmacists Association (APhA), American Medical Association (AMA), the American Association of Nurse Practitioners (AANP), the Network for Public Health Law – Eastern Region, and University of Maryland Francis King Carey School of Law** have collaborated with the **Centers for Disease Control and Prevention, Division for Heart Disease and Stroke Prevention**, to develop this guide, **Advancing Team-Based Care through Collaborative Practice Agreements**.

The guide is a resource for pharmacists to use in developing and executing collaborative practice agreements in the spirit of advancing team-based care. It provides a customizable template that can be used as a starting point to developing a collaborative practice agreement.

The collaborating organizations recognize the value of pharmacists as a necessary member of the patient care team and endorse use of this guide to form collaborative practice agreements. Together, we can work to improve the quality of patient care, better prevent and treat chronic disease and improve population health.

National Alliance of State Pharmacy Associations (NASPA)

American Pharmacists Association (APhA)

American Medical Association (AMA)

American Association of Nurse Practitioners (AANP)

Network for Public Health Law – Eastern Region

University of Maryland Francis King Carey School of Law

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1 Centers for Disease Control and Prevention. National Statistics Report: Deaths: Final Data for 2014. 2016(June);65(4). Chamblee, GA: CDC, U.S. Department of Health and Human Services; 2016. Accessed December 19, 2016.

2 Centers for Disease Control and Prevention. [Vital Signs: Preventable Deaths from Heart Disease & Stroke](#). Accessed December 19, 2016.

3 American Public Health Association. APHA policy 8024: The Role of the Pharmacist in Public Health. 1981; 71:213–6. American Journal of Public Health.



## Executive Summary

### Rationale

Chronic diseases are the leading causes of death and disability in the United States, accounting for seven of every ten deaths in this country. In 2014, one in every three deaths was due to cardiovascular disease (CVD). One in three U.S. adults has high blood pressure, and almost half of these individuals do not have this condition under control. Team-based care results in personalized, timely, and empowered patient care—and it facilitates communication and coordination among team members. The evidence is strong that when pharmacists are members of the health care team, outcomes related to preventing or managing chronic disease (e.g., blood pressure, blood glucose, cholesterol, obesity, smoking cessation) and medication adherence improve. The purpose of this guide is to empower community pharmacists and collaborating prescribers to initiate collaborative practice agreements (CPAs) focused on caring for patients with chronic diseases, including CVD.

### Collaborative Practice Agreements

CPAs create a formal practice relationship between a pharmacist and a prescriber, who is most often a physician, although a growing number of states are allowing for CPAs between pharmacists and other health professionals, such as nurse practitioners. The agreement specifies what functions (in addition to the pharmacist's typical scope of practice) can be delegated to the pharmacist by the collaborating prescriber. The terms used and the functions provided under a CPA vary from state to state based on the pharmacist's and prescriber's scope of practice and the state's collaborative practice laws. Most often, the functions delegated to pharmacists by prescribers include initiating, modifying, or discontinuing medication therapy. Ordering and

interpreting laboratory tests may also be included if those services are not already authorized in the pharmacist's regular scope of practice.

### CPAs Support Team-Based Care

CPAs are built upon a foundation of trust between pharmacists and prescribers and serve as a useful mechanism for increasing efficiencies of team-based care. When designed correctly, CPAs are beneficial to the collaborative delivery of care through delegation by the physician or other prescriber of specific patient care services to pharmacists. This delegation can expand available services to patients and increase coordination of care. For example, the use of CPAs can decrease the number of requests to authorize refills, modify prescriptions, initiate therapeutic interchanges (in which the pharmacist can substitute another drug for the medication prescribed), and order and interpret laboratory tests, while keeping the prescriber apprised of the pharmacist's actions through established communication mechanisms. This allows each member of the health care team to complement the skills and knowledge of the other members and more effectively facilitate patient care, resulting in improved patient outcomes.

### Scope of Service and Requirements

Many pharmacists' services do not require a CPA. For example, assessing medication therapy for drug-related problems, performing hypertension and cholesterol screenings, and educating patients are already within pharmacists' regular scope of practice. A CPA is not required for pharmacists or practitioners to collaborate in providing care. The only requirement is cooperation toward achieving a common goal—providing optimal patient care. While it is important to have shared goals,

clear roles, effective communication, and measurable processes and outcomes, the degree of trust within the relationship is often the deciding factor for turning collaborative relationships into contractual CPAs.

Building trust is often a progressive process. For example, a collaborative relationship may begin with a pharmacist dispensing a prescriber's prescription, followed by an exchange of medication information. This advances to a prescriber accepting a pharmacist's recommendations for medication therapy, and then to a prescriber delegating disease management responsibilities and granting authority for medication therapy management to a pharmacist under a formal CPA. Trustworthiness, role specification, and professional interactions are three critical factors to establishing trust within a collaborative relationship.

### Components of a CPA and Applicable Laws

Pharmacists interested in pursuing CPAs with prescribers should seek to understand the laws on CPAs within their state, identify prescribers with whom a relationship already exists or build a relationship with prescribers with mutual interests, and consider offering basic services (e.g., refill authorizations, therapeutic interchange) as an initial step. Seeking to identify and understand the prescriber's unmet needs and demonstrating competency as it relates to

the prescriber's patient population and the services provided will help to facilitate the uptake of a CPA. Finally, pharmacists can anticipate prescribers' concerns related to delegating authority for care and be prepared to respond to those concerns in an effective manner.

### Steps to Implementation

A CPA template and sample language for each component are included in this resource guide. The implementation of a CPA involves a series of steps that depend on state laws and pharmacist-prescriber preferences. The implementation steps may include registering the CPA with the board of pharmacy or some other governing body, developing data sharing and business associate agreements, obtaining a pharmacist National Provider Identifier number, and identifying a business model that sustains the agreed-upon scope of services.

CPAs offer a unique opportunity for pharmacists to collaborate with prescribers in the treatment and management of chronic conditions, including CVD and hypertension. This guide offers resources to develop and implement a CPA between pharmacists and prescribers for the purpose of advancing public health and improving patient outcomes, quality and process measures, efficacy, and patient and provider satisfaction.

A formal CPA can have many components including the following:

#### Scope of Agreement

- Parties to the agreement
- Patient inclusion criteria
- Patient care functions authorized

#### Legal Components

- Authority and purpose
- Liability insurance
- Informed consent of the patient
- Review of the agreement and maximum period of validity
- Rescindment or alteration of agreement
- Signatures of the parties to the agreement

#### Administrative Components

- Training and education
- Documentation
- Communication
- Quality assurance (or quality measurement)
- Retention of records

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# Overview

## Impact of Chronic Disease

Chronic diseases are the leading causes of death and disability in the United States, accounting for seven of every ten deaths.<sup>1</sup> In 2012, 117 million Americans (about half of the adult population) had at least one chronic illness.<sup>2</sup> An estimated 25% of U.S. adults with chronic conditions have one or more limitations in daily activities.<sup>2</sup> In 2014, one in every three deaths was due to cardiovascular disease (CVD).<sup>3,4</sup>

Hypertension, hyperlipidemia, and smoking are key risk factors for CVD, and 47% of Americans have at least one of these three risk factors.<sup>5</sup> One in three U.S. adults has high blood pressure, and almost half of these individuals do not have this condition under control.<sup>5</sup> Another 11.5 million of these adults are neither aware of their hypertension nor taking antihypertensive medications.<sup>3,5</sup> In addition, only one third of people with high cholesterol have adequate control of their hyperlipidemia, and 17% of U.S. adults smoke cigarettes.<sup>6,7,8</sup> Improved control of the risk factors for CVD requires an expanded effort from health care systems and health care professionals in the health system, including pharmacists.<sup>6</sup>

## Value of Pharmacists' Patient Care Services

Interventions to manage and control hypertension and other risk factors for CVD can focus on removing health care professional- and patient-related barriers.<sup>9,10,11</sup>

A team-based model organizes care around patient needs and commonly involves systems that support clinical decision making through collaborations between health care professionals or between these professionals and their patients. There is strong evidence that when pharmacists are part of the health care team, outcomes related to preventing or managing chronic diseases (e.g., blood pressure, blood glucose, cholesterol, obesity, smoking cessation) and adherence to medication improve.<sup>12,13</sup> Team-based care results in

personalized, timely, and empowered patient care and facilitates communication and coordination among team members.

In 1981, the American Public Health Association declared that pharmacists were an underutilized resource in promoting public health. Since then, several public health needs—such as public access to immunizations—have been addressed by community pharmacists. One of the reasons that pharmacists can address emerging public health needs is that they are among the most accessible health care professionals in the United States. Notably, an estimated 86% of the U.S. population lives within 5 miles of a community pharmacy.<sup>14</sup> While examples of pharmacists practicing in team-based environments exist, there remains an opportunity to increase and accelerate the inclusion of pharmacists as part of the patient care team.

In 2011, the chief pharmacist officer of the U.S. Public Health Service authored a report, titled *Improving Patient and Health System Outcomes Through Advanced Pharmacy Practice*, to the U.S. surgeon general.<sup>15</sup> This report highlighted the efficacy of pharmacists in advanced practice roles and advocated for intensified utilization of pharmacists in alleviating our nation's imminent primary care provider crisis. The findings of the report were promptly endorsed and supported by the 18th surgeon general, Vice Admiral Dr. Regina Benjamin, who recommended that health leadership and policy makers optimize the pharmacist's role.<sup>16</sup> Vice Admiral Benjamin recommended that this be done through implementation of collaborative practice models; recognition of pharmacists as providers, clinicians, and essential members of the health care team; and exploration of additional compensation models to support pharmacists in these expanded roles.



### Advancing Pharmacists in Team-Based Care

The Centers for Disease Control and Prevention (CDC) recognizes the role of pharmacists in team-based care for chronic disease management. The CDC Division for Heart Disease and Stroke Prevention has created resources to encourage pharmacists and prescribers (physicians and others who prescribe drugs) to work collaboratively and formalize those relationships through collaborative practice agreements (CPAs), when possible. These resources include:

- [A Program Guide for Public Health: Partnering with Pharmacists in the Prevention and Control of Chronic Diseases](#). This resource provides examples of how pharmacists can work within the four public health domains (i.e., environmental approaches, health systems, community-clinical linkages, and epidemiology and surveillance) to have a positive effect on patient health outcomes.<sup>17</sup>
- [How Pharmacists Can Improve Our Nation's Health](#). This resource (a CDC Public Health Grand Rounds presentation) provides examples of the roles that pharmacists can play in team-based care.<sup>18</sup>
- [Collaborative Practice Agreements and Pharmacists' Patient Care Services](#). This resource provides an overview of CPAs.<sup>19</sup>

- [Collaborative Drug Therapy Management: Case Studies of Three Community-Based Models of Care](#).<sup>20</sup> This resource illustrates how CPAs have been successfully implemented in three pharmacy practice settings.

### Purpose and Development Process

The purpose of this resource guide is to empower community pharmacists and collaborating prescribers to initiate CPAs that are focused on caring for patients with chronic diseases. CVD and its risk factors are used as an example throughout the resource guide. The primary audience is pharmacists practicing in states where existing regulations permit them to engage in CPAs for the monitoring and management of chronic disease.

The information contained in this resource guide was collected in these four ways: (1) reviewing existing literature and resources; (2) analyzing laws and regulations on collaborative practice; (3) reviewing examples of CPAs currently in use; and (4) holding roundtable meetings with pharmacists, physicians, public health professionals, academicians, and payer representatives in five states (i.e., Kentucky, Minnesota, Tennessee, Washington, and Wisconsin).



### CPA-related Terminology

Other terms for a CPA include:

- Collaborative pharmacy practice agreement.
- Collaborative care agreement.
- Consult agreement.
- Physician-pharmacist agreement.
- Standing order or protocol.
- Delegation of authority by physician.

Terms used to describe the services provided under a CPA include:

- Collaborative drug therapy management.
- Drug therapy management.
- Pharmaceutical care.
- Medication therapy services.
- Collaborative pharmacy practice.<sup>22</sup>

## About Collaborative Practice Agreements

### Definition of a CPA

CPAs create a formal practice relationship between a pharmacist and a prescriber. The agreement specifies what functions—in addition to the pharmacist’s typical scope of practice—are delegated to the pharmacist by the collaborating prescriber. The collaborating prescriber is most often a physician, but a growing number of states are allowing for CPAs between pharmacists and nurse practitioners or other nonphysicians. This resource guide uses the term “prescriber” to reference the collaborating provider who is delegating patient care services to the pharmacist under the CPA.

The functions provided under the agreement vary from state to state based on the pharmacist’s scope of practice and the state’s collaborative practice laws.<sup>21</sup>

Most often, CPAs are used in the context of authorizing pharmacists to initiate, modify, or discontinue medication therapy. Functions performed under a CPA may also include ordering and interpreting laboratory tests if those services are not already authorized in the pharmacist’s scope of practice.

### Using CPAs to Facilitate Team-Based Patient Care<sup>22</sup>

When trust has been established, CPAs are a useful way to increase the efficiency of team-based care. When designed correctly, CPAs benefit the collaborative delivery of care by delegating specific patient care services to pharmacists. This delegation can expand available services to patients and increase the efficiency and coordination of care. For example, CPAs can decrease the number of phone calls required to authorize refills or modify prescriptions, thus allowing each member of the health care team to complement the skills and knowledge of the other member(s) and more effectively facilitate patient care, resulting in improved patient outcomes.

### Terminology

This resource guide uses the term “collaborative practice agreement,” “collaborative agreement,” or “CPA” to describe a practice relationship in which a prescriber delegates selected patient care services to a pharmacist. The terminology used to describe this authority varies among states as do the terms used to describe the services provided under a CPA.

## States Permitting CPAs

As of May 2016, 48 states permit some type of pharmacist-prescriber collaborative practice authority. However, some of these states' laws and regulations may not support the implementation of a CPA. For example, in Alabama and Delaware, prescribers cannot delegate authority to pharmacists via a CPA, and in Florida and Oklahoma, pharmacists are restricted to providing only limited services under a CPA.

State laws for CPAs vary widely; the key variables in these laws are below. Thus, the terms of the written CPA will need to be customized to the laws and regulations of a given state.

## Finding the Applicable State Laws and Regulations

Before entering into a CPA, pharmacists and prescribers may benefit by reviewing their state's current laws and regulations pertaining to CPAs. Appendix A contains CPA laws for each state (as of December 31, 2015). State boards of pharmacy and medicine and state pharmacy and medical associations can serve as points of contact for the most up-to-date information on CPA authority. To obtain access to a specific state's current pharmacy laws and regulations, visit the [National Association of Boards of Pharmacy](#) website.

## Pharmacy Services Under CPAs

A variety of pharmacist-provided services can be performed under a CPA. CVD-related services are used as examples below to illustrate how pharmacists may define pharmacy services within a CPA. Because of variations in state laws, some of the services may be permitted under a pharmacist's regular scope of practice in some states but represent an expansion of practice in others.

**Authorization of refills.** In this service, the prescriber authorizes the pharmacist to extend refills based on the pharmacist's assessment (e.g., using the [pharmacists' patient care process](#)) of the patient. For example, under the terms of a CPA, a pharmacist may be permitted to extend refills of a patient's medications for treating chronic hypertension and hypercholesterolemia, thereby removing delays in therapy and administrative barriers and potentially increasing medication adherence. Without a CPA, in most states, pharmacists would need to contact the prescriber to obtain authorization for a refill.



### Variables in State CPA Laws and Regulations

#### CPA Participants

- Number of pharmacists.
- Number of prescribers.
- Number of patients.
- Types of prescribers.
- Relationship between patient and prescriber.
- Pharmacist-to-prescriber ratio.

#### Authorized Functions

- Modify medication therapy.
- Initiate medication therapy.
- Discontinue medication therapy.
- Conduct physical assessment.
- Order laboratory studies.
- Interpret laboratory studies.
- Perform laboratory tests.

#### Requirements and Restrictions

- Continuing education.
- Qualifications of pharmacist.
- Liability insurance.
- Disease state of patient.
- Practice setting.
- Medications to be managed.
- Involvement of patient.
- Agreements approved or reported, and to which entity.
- Length of time that agreement is valid.
- Documentation.
- Communications.
- Review by physician.

**Therapeutic interchange.** Here the prescriber authorizes the pharmacist, under a CPA, to substitute another drug in the same drug class (e.g., angiotensin-converting enzyme inhibitors to treat hypertension) for the medication originally prescribed. This usually happens because of the variability in a particular health plan's formulary of accepted drugs. The pharmacist's clinical knowledge of medications informs his or her choice of medication within a particular class of drugs.

**Hypertension management.** In this service, the prescriber authorizes the pharmacist to initiate, modify, or discontinue medications. For example, under the terms of a CPA, a pharmacist may be permitted to add therapies if the patient's hypertension is uncontrolled, adjust doses of medication, or discontinue medications that are not working or cause side effects. The medications or medication classes that pharmacists are permitted to initiate, modify, or discontinue may be indicated in the agreement. Without the CPA, the pharmacist would have to assess the patient and make a

recommendation to the prescriber. The prescriber would then have to act on the recommendation in order for the pharmacist to make a change in therapy. The CPA leverages the pharmacist's medication and health-related expertise to extend the care of the prescriber's patients while coordinating care with the prescriber.

#### **Ordering laboratory tests.**

Here the CPA may authorize the pharmacist to order and interpret laboratory tests that are essential for effectively monitoring medications or the status of chronic conditions. For example, as part of a hypertension CPA, the pharmacist could order urine and blood analyses to test for electrolyte levels, fluid balance, and kidney function.

Note that some pharmacists' CVD-related services, such as assessing medication therapy for medication-related problems, performing hypertension and cholesterol screenings, and educating the patient, are within pharmacists' regular scope of practice.

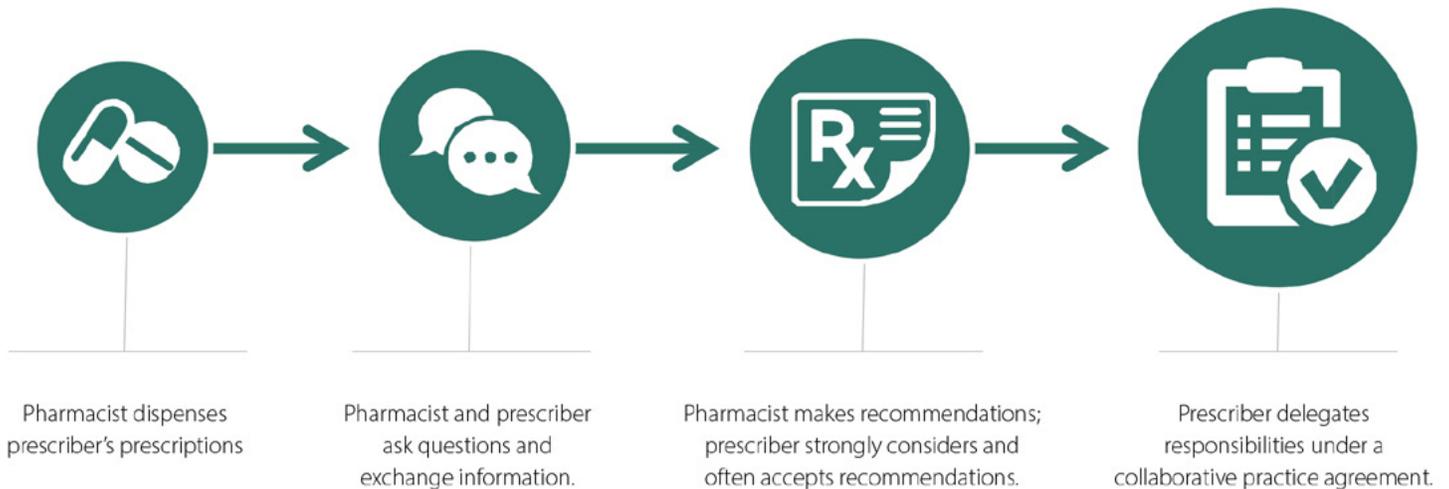


### **State Scope of Practice & CPAs**

The patient care functions that pharmacists are authorized to perform with and without a CPA are highly variable from state to state. A function that a pharmacist can perform only if authorized under a CPA in one state may be a function that a pharmacist can perform autonomously in another state. This resource guide's primary focus is on developing a CPA to facilitate those patient care functions required by state law to be delegated to the pharmacist through a written CPA. However, it is important to note that pharmacists

and other health care professionals may still choose to formalize their collaboration with an agreement—to outline communications, documentation, and other pertinent subjects—even if the activities the parties agree to collaborate on can be performed autonomously by the pharmacist pursuant to the state pharmacy practice act. Pharmacists should consult with the state board of pharmacy or a licensed attorney when there is a question regarding whether an agreement must comply with a given state's CPA laws.

**Figure 1: Level of Professional Interaction Reflects Degree of Trust Between the Pharmacist and the Prescriber**



## Collaborative Care as a Basis for CPAs

The World Health Organization has stated that “Collaborative care in health care occurs when multiple health providers from different professional backgrounds provide comprehensive services by working with patients, their families, care providers, and communities to deliver the highest quality of care across settings.”<sup>23</sup> Thus, a CPA is not required for practitioners to collaborate in providing care. The only requirement is cooperation toward achieving a common goal—providing optimal patient care. As part of collaboration, it is important to have shared goals, clear roles, effective communication, and measurable processes and outcomes. The degree of trust within the relationship is often the deciding factor for collaborative relationships becoming contractual CPAs.<sup>24</sup> Figure 1 illustrates the relationship between greater trust within a collaborative relationship and a higher degree of professional interactions.

### Developing the Relationship and Building Trust

Once an initial relationship is established, the collaborating providers can work together to develop mutual trust. Three factors that may be important to the development of a working clinical relationship are trustworthiness, role specification, and professional interactions.<sup>24,25,26,27,28,29</sup>

**Trustworthiness.** The development of trust requires time and the demonstration of competence.<sup>29</sup> Physicians may be more trusting when they know the amount of training, experience, and credentials that the pharmacist has.<sup>24,25,26,27,28,29</sup> Pharmacists may recognize this tendency and be open to sharing this information about themselves.

Patients also benefit from developing trust with the members of their care team. One way to accomplish

this is for the prescriber and pharmacist to meet with the patient together. If a joint appointment is not possible, the prescriber can advise the patient of the benefits from seeing the pharmacist. Regardless, the expectation is that trust will be built gradually among pharmacists, providers, and patients.

**Role specification.** Defining which activities will be performed by pharmacists and which by the prescriber enables both parties to have shared expectations about how they will collaborate. When first establishing a collaborative relationship, health care professionals may choose to begin with focusing on basic services until trust can be established. As both health care professionals work together to understand each other's skills and competence, trust will grow, and more complex services can be introduced.<sup>30</sup> Many pharmacists have reported that as prescribers experience pharmacists' skills firsthand, the prescribers begin to offer ideas for more collaboration.

**Professional interactions.** Direct interactions between pharmacists, prescribers, and their patients are essential to growing trust and collaboration. Effective communication is key to building professional interactions and demonstrating trustworthiness. When pharmacists and physicians start their collaborative relationship, frequent in-person communication may be ideal.<sup>25</sup> For example, pharmacists may consider practicing in the prescriber's office for a specific time frame (e.g., a half day each week for 2 months) to learn the prescriber's approach to patient care and style of communication. When building the relationship, pharmacists can consider providing an example of the type of communication the prescriber can expect to receive after patient visits. This may serve as a conversation starter when developing the CPA.<sup>25</sup> Communication between providers can be initiated by either party; communication could include, for example, sharing relevant patient information, discussing drug-related problems, or requesting a pharmacist

consultation. Increasing professional interactions leads to increased collaboration.<sup>28</sup>

## Formalizing Collaborative Relationships Through CPAs

Once pharmacists and prescribers have established collaborative relationships built upon trust, they may choose to enter into a formalized CPA to facilitate the pharmacist's ability to care for the prescriber's patients in accordance with mutually established role specifications. In the beginning of the collaborative relationship, the pharmacist will likely initiate the conversation about the CPA; he or she should be prepared to make the case for the value of formalizing the relationship. Pharmacists should be aware that the collaborating prescriber would be increasing his or her own liability by entering into a CPA, and so it will be important to let the prescriber ask questions, voice concerns, and help to shape the scope of the CPA. When first establishing a formal collaborative arrangement, pharmacists and prescribers may choose to begin with focusing on basic services such as authorization for refills or therapeutic interchange.



## Identifying Partners

Finding and approaching a potential collaborator without having a prior relationship with that person can seem daunting. One approach is for pharmacists to work with prescribers they already know. This familiarity might come from collaborating on initiatives, such as the delivery of immunizations, or through mutual involvement in community organizations or local coalitions.<sup>25</sup> In addition, pharmacists can approach prescribers in their community with whom they do not have a prior relationship but where common goals exist.



Pharmacists' ability to improve metrics of quality—both clinical and financial—can also create opportunities for collaboration. Hospitals are increasingly under pressure to reduce readmissions, and the services of pharmacists can help here. Pharmacists can meet with the medical director and pharmacy director from local hospitals to explore collaboration on transitions of care from the hospital to an outpatient/office or clinic setting. Clinics and physicians' offices, as well as hospitals, are held to quality measurements that pharmacists' services can often improve. Other potential collaborators include state and local public health agencies, accountable care organizations, and patient-centered medical homes. It can be helpful for pharmacists to understand the metrics for which potential collaborators are responsible and then think of ways to help them improve those scores.

When identifying providers for new collaborative relationships, pharmacists may consider those provisions in state CPA laws that limit which prescribers can enter into CPAs with pharmacists. In all states, pharmacists may partner with physicians in their community to deliver collaborative care. Additionally, in states where nurse practitioners and physician assistants can enter into CPAs with pharmacists, these prescribers may be familiar candidates for collaboration because they were previously required to have CPAs with physicians in order to prescribe. Table 1 in Appendix A describes state laws and regulations, including those governing which prescribers can authorize a CPA.

### Initiating the Relationship

Pharmacists seeking to start a collaborative model of care delivery may benefit from taking the first step in initiating the relationship.<sup>25,26</sup>

To initiate discussions, a face-to-face meeting should be held with the prospective collaborating prescriber.

The meeting can be scheduled in advance by the pharmacist, and might take place over lunch or dinner and include other staff members whose buy-in may be important.<sup>25</sup>



During the initial meeting with a prospective collaborator, the pharmacist should be prepared to articulate specific goals and benefits of collaboration and discuss how the collaboration can lead to enhanced patient care. He or she should consider focusing on unmet patient needs in the prescriber's practice and in the community. Where are there gaps that the pharmacist could fill? If the pharmacist has worked with other prescribers in the past, using examples of how that collaboration worked can spark conversation. For example, a pharmacist can use the first collaborating prescriber as a reference for future potential collaborations. If this is a new endeavor, one place to start is for the pharmacist to assist with improving medication adherence for patients in the prescriber's practice. Improving medication adherence is a service that pharmacists can provide without a CPA. In brief, it is a way to engage in offering a basic service with the intent to demonstrate success, build trust, and work collaboratively before a CPA is started. In a study reported in 2011, physicians' belief that collaboration with pharmacists could result in increased patient adherence to medication regimens was a predictor of a positive attitude toward collaboration.<sup>27</sup> Regardless, pharmacists should expect that prescribers, especially those who have not previously worked in collaborative relationships, might have many questions. It is important to consider each of the questions set forth on the next page titled "Anticipating the Concerns of Prescribers" before meeting with a prescriber and to have a well-formulated response to each one.

Garnering the support of prescribers for entering into a CPA might require various approaches and timelines. Once the partners agree to formalize their collaboration, creating the legal agreement may require consideration of the components included in state CPA laws (Appendix A). Figure 2 presents a sample CPA and sample language that may be customized by pharmacists and prescribers using their specific state laws to create a CPA.

## Anticipating the Concerns of Prescribers

### 1. What is the pharmacist's training, and what credentials does the pharmacist have?

Pharmacists can educate the prescriber on the pharmacist's training and focus on the skills and credentials of the particular pharmacist(s) who would be working in the practice.

### 2. What has been the pharmacist's experience in delivering various patient care services?

Pharmacists can explain how their experience aligns with the needs of the patient population cared for by the prescriber and elaborate on how that experience can benefit the patient and improve outcomes.

### 3. What is the pharmacist's scope of practice in the state?

Pharmacists can educate the prescriber about which patient care functions pharmacists can perform pursuant to the state's pharmacy practice act as well as the functions that can be authorized in a CPA. Providing specific examples can be very helpful.

### 4. How will the pharmacist communicate with the prescriber?

Pharmacists can discuss the prescriber's preferred method of communication and review opportunities for using health information technology to facilitate the exchange of information. In addition, they should provide examples of how pharmacists communicate (using health information technology and other means) with prescribers in collaborative care models.

### 5. Will the prescriber incur additional liability?

In a collaborative care relationship that is not governed by a CPA, the prescriber is not likely to incur additional liability for any actions of the pharmacist. This is because the prescriber must approve any recommendations made by the pharmacist before medication therapy is initiated or modified. In this scenario, the risk may be lower because care is likely to be better coordinated in a collaborative care relationship. When using a CPA, pharmacists should discuss terms of liability—which can be clearly described in the CPA—to mitigate risk and any concerns of either party to the agreement.

### 6. What costs will be incurred by the prescriber in collaborating with the pharmacist?

The prescriber is likely to bring up issues of cost and reimbursement. Costs may vary depending on where the pharmacist will practice (e.g., within the physician's office or remotely). Pharmacists should be prepared to discuss needs for resources and payment. During this discussion, it may be important to include the value that pharmacists can bring to the practice. Appendix B provides general information about payment for pharmacy services.<sup>28</sup>





**1 in 3 adults**

has high blood pressure



**1 in every 3 deaths**

was from cardiovascular disease

## **Adapting a Template CPA for a Hypertension and Cardiovascular Disease Service\***

This section provides examples of language that can be used to draft a CPA. Figure 2, the sample CPA, demonstrates how the language options presented in the following call-out boxes can be applied to create a customized CPA. (Note that Figure 2 uses Virginia's provisions as an example and thus would not meet the requirements in all states.)

The language in the call-out boxes was adapted from CPAs that are currently in use and from feedback received at the roundtable meetings. This language is provided solely for educational purposes and is only for use as an example. Pharmacists may benefit from consulting legal counsel when drafting a CPA based on the laws

and regulations in the jurisdiction where the CPA will be implemented. To get a better understanding of state laws and regulations—as of December 2015—those drafting a CPA should refer to the tables in Appendix A and be sure to check the current laws and regulations.

Not every state addresses every component that appears in these tables. The word “silent” indicates that the state has not addressed that particular issue in its laws and regulations. In these cases, pharmacists and prescribers should work within their scope of practice, use their judgment while developing a CPA, and keep the best interests of the patient in mind.

\*Disclaimer: The information contained in this document does not constitute legal advice. Use of any provision herein should be contemplated only in conjunction with advice from legal counsel. The CPA language in the text boxes below was provided by attorneys at the University of Maryland Francis King Carey School of Law as example CPA language for educational purposes only and is adapted from CPA language from multiple states. Provisions may need to be modified, supplemented, or replaced to ensure appropriate citation of or compliance with relevant laws, to accurately reflect the intent of the parties to a particular agreement, or to otherwise address the needs or requirements of a specific jurisdiction.

Figure 2: Sample Collaborative Practice Agreement for Hypertension/Cardiovascular Disease (Continued on next page)

## COLLABORATIVE PRACTICE AGREEMENT

*for authorization of therapy continuation and therapeutic interchange*

### A. AUTHORITY AND PURPOSE

**I, Dr. Susan Patel and Jessica Johnson authorize the pharmacist(s) named herein,** who hold an active license to practice from the Commonwealth of Virginia, to manage and/or treat patients pursuant to the parameters outlined in this agreement. This authority follows the laws and regulations of the Commonwealth of Virginia. The purpose of this agreement is to facilitate consistent access to medications for the collaborating providers' mutual patients.

### B. PARTIES TO THE AGREEMENT

The following providers agree to the parameters outlined in this agreement:

Pharmacists:	Prescribers:
James Lee, PharmD	Susan Patel, MD
Alexa Garcia, PharmD	Jessica Johnson, ANP

### C. PATIENTS

Patients whose therapy may be managed pursuant to this agreement include those who are currently receiving hypertension or dyslipidemia therapy prescribed by a prescriber listed in Section B of this agreement.

### D. PATIENT CARE FUNCTIONS AUTHORIZED

Pharmacist(s) included in Section B of this agreement will have the authority to manage and/or treat patients in accordance with this section.

In managing and/or treating patients, the pharmacist(s) may authorize continuation of drug therapy and modification of drug therapy to a therapeutic alternative medication (defined as a medication in the same class with an equivalent dose), if appropriate, based on current literature and clinical judgment.

#### D.1. Dyslipidemia<sup>1</sup>

The pharmacist(s) will evaluate dyslipidemia as outlined by 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults and other nationally recognized standards of care as supported by current literature. Pharmacist(s) will have authority to authorize continuation of therapy or therapeutic interchange for the treatment of lipids which may include, but are not limited to the following classes: HMG-CoA reductase inhibitors (statins), bile-acid sequestrants, cholesterol absorption inhibitors, fibrates, omega-3 fatty acids, niacin.

#### D.2. Hypertension<sup>2</sup>

The pharmacist(s) will evaluate hypertension therapy as outlined in 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults Report from the Panel Members Appointed to the Eighth Joint National Committee (JNC 8) and other nationally recognized standards of care as supported by current literature. Pharmacist(s) will have authority to authorize continuation of therapy or therapeutic interchange for the treatment of hypertension which may include, but are not limited to the following classes: beta-blockers, calcium channel blockers, ACE inhibitors, angiotensin II receptor blockers, direct renin inhibitors, diuretics, alpha-blockers,  $\alpha_1$ -centrally active agents.

### E. TRAINING/EDUCATION

All parties to this agreement are expected to maintain up-to-date competencies and knowledge of current guidelines for disease states covered under this agreement.

### F. LIABILITY INSURANCE

All parties to this agreement shall maintain at least \$1,000,000 (per occurrence) of professional liability insurance during the term of the agreement which specifically covers drug therapy.

### G. PATIENT INFORMED CONSENT

The pharmacist shall obtain written informed consent from the patient upon first meeting with the patient. A record of provision of care by a pharmacist shall be maintained in the patient's pharmacy record, which is available to the pharmacist.

**Figure 2: Sample Collaborative Practice Agreement for Hypertension/Cardiovascular Disease** (Continued from previous page)

**H. DOCUMENTATION**

The pharmacist(s) shall document each continuation or modification of therapy authorization in the patient’s pharmacy record.

**I. COMMUNICATION**

The pharmacists shall provide the patient’s original prescriber with notification in the form of fax or secure email when their patient’s therapy is continued or therapeutically interchanged pursuant to this agreement. In this notification, the pharmacists will include any relevant information that was collected from the patient such as current blood pressure, adherence issues, or any socioeconomic challenges identified.

The pharmacist shall report any new patient complaints and/or deterioration in the patient’s condition to the patient’s primary care provider and/or other provider immediately after learning of the new condition or as soon as possible thereafter.

**J. QUALITY ASSURANCE**

Care provided as a result of this collaborative practice agreement will be routinely evaluated to assure delivery of high quality patient care. Annual evaluation of pharmacist(s) may include clinical outcomes, number of patients treated, and satisfaction surveys of patients and providers as appropriate.

**K. AGREEMENT REVIEW AND DURATION**

This agreement shall be valid for a period not to exceed two years from the effective date. However, it may be reviewed and revised at any time at the request of any signatories.

**L. RECORD RETENTION**

Each signatory to this agreement shall keep a signed copy, written or electronic, of this agreement on file at their primary place of practice. Record of each therapeutic interchange made for a specific patient shall be maintained in the patient’s pharmacy record.

**M. RESCINDMENT OR ALTERATION OF AGREEMENT**

A signatory may rescind from this agreement or a patient may withdraw from treatment under this agreement at any time. The prescriber(s) may override this agreement whenever he or she deems such action necessary or appropriate for a specific patient without affecting the agreement relative to other patients.

**N. REFERENCES**

1. Stone NJ, Robinson J, Lichtenstein AH, et al. "2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults." *Circulation* (2013) [Epub ahead of print: <http://www.ncbi.nlm.nih.gov/pubmed/24222016?dopt=Abstract>.
2. James PA, Oparil S, Carter BL, et al. 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults Report From the Panel Members Appointed to the Eighth Joint National Committee (JNC 8). *JAMA*. doi:10.1001/jama.2013.284427. Published online December 18, 2013

**O. AGREEMENT SIGNATURES**

This agreement includes patients under the care of the practitioner(s) and extends for a period of two (2) years from this date unless rescinded earlier in writing.

Signatures:

_____	_____	_____	_____
<b>[Prescriber name and credentials]</b>	<b>[Prescriber Signature]</b>	<b>License #</b>	<b>Date</b>
_____	_____	_____	_____
<b>[Prescriber name and credentials]</b>	<b>[Prescriber Signature]</b>	<b>License #</b>	<b>Date</b>
_____	_____	_____	_____
<b>[Pharmacist name and credentials]</b>	<b>[Pharmacist Signature]</b>	<b>License #</b>	<b>Date</b>
_____	_____	_____	_____
<b>[Pharmacist name and credentials]</b>	<b>[Pharmacist Signature]</b>	<b>License #</b>	<b>Date</b>

## A. Authority and Purpose

This section is not required by law to be included in a CPA but may help the collaborating providers establish their vision for the purpose of the agreement.



### AUTHORITY AND PURPOSE:

I, [INSERT PRESCRIBER NAMES], authorize the pharmacist(s) named herein, who hold an active license to practice issued by [STATE NAME], to manage and/or treat patients pursuant to the parameters outlined in this agreement. This authority follows the laws and regulations of [STATE NAME]. The purpose of this agreement is to facilitate consistent access to medications for the collaborating providers' mutual patients.

-OR-

### PURPOSE:

In order to enhance collaborative patient care and optimize medication-related outcomes, patient care services will be provided by the pharmacists listed in Section B of this agreement in collaboration with the prescribers listed in Section B of this agreement. Services will include those listed in Section D of this agreement. The pharmacists will deliver these services in a manner consistent with the parameters outlined in this collaborative practice agreement and in compliance with the protocols included in the appendices to this agreement.

## B. Parties to the Agreement

Both the pharmacists and the prescribers who are participating in the CPA are identified in this section. In some states, a medical director may be authorized to sign onto an agreement on behalf of the providers within a given practice. In this case, each practitioner may or may not have to individually sign the agreement, depending on state laws and regulations. Which prescribers may authorize a CPA and how many pharmacists and prescribers may be on an agreement varies from state to state.

See Table 1 in Appendix A for more information on the authority and restrictions in a particular state.



### PARTIES TO THE AGREEMENT:

The following parties agree to the parameters outlined in this agreement:

Pharmacists:	Prescribers:

## C. Patients

In this section, either the specific patient(s) or the defined population of patients that will receive care can be specified. Some state laws restrict eligibility to only those patients who are actively being treated by the collaborating provider. Others specify that each patient who will receive care under the parameters of the agreement be listed in the agreement. Still others may even require that the agreement be specific to a single patient and disease state. Drafters of a CPA should see Table 1 in Appendix A for more information on their state.



### PATIENTS [PRESCRIBER'S PATIENT PANEL]:

Patients whose therapy may be managed pursuant to this agreement include those who are currently receiving hypertension or dyslipidemia therapy prescribed by one of the prescribers listed in Section B of this agreement.

-OR-

PATIENTS [SPECIFIC LIST OF PATIENTS]:

The pharmacists listed in Section B of this agreement are authorized to provide care to the following patients, pursuant to this agreement:

-OR-

PATIENTS [SPECIFIC TO A SINGLE PATIENT]:

Pursuant to this agreement, the pharmacist(s) listed in Section B of this agreement are authorized to provide care, in the manner outlined in this agreement, to [INSERT PATIENT], a patient of [AUTHORIZING PRESCRIBER].



## D. Patient Care Functions Authorized

Role specification allows for mutual understanding of each provider's role in care delivery. As trust develops and the collaborative relationship grows, providers can become interdependent, and their roles can evolve over time.<sup>27,29</sup> Setting expectations for each provider's role can help all parties to feel more comfortable with moving forward. Note that it may be helpful to set expectations for when the initial role specification will be assessed and adjusted. Setting such expectations allows for open communication and continual process improvement.

All CPAs define the scope of the patient care functions that pharmacists are authorized to provide pursuant to the agreement. In the sample agreement, pharmacists are authorized to continue prescription therapy for a medication that does not have refills remaining and make a therapeutic substitution for medications in the same drug class as that prescribed.

Not all states require that a treatment protocol be used as part of a CPA. For example, in Michigan and Wisconsin, physicians can delegate any patient care service to a pharmacist, and the pharmacist's authority does not require the use of a treatment protocol. Even in states where such a protocol is required, providing general guidance, such as referring to evidence-based guidelines, may be appropriate.

Additionally, some states require that the CPA specify which drugs the pharmacist may initiate and/or modify. If this is required, the list of drugs could be included in the "Patient Care Functions Authorized" or in an appendix to the agreement.

It may also be useful to include language covering the instances when the pharmacist refers the patient back to the prescriber. This language would discuss issues outside the scope of the agreement.

Those interested in drafting a CPA should look at Table 2 in Appendix A for more information on what patient care functions can be authorized under such an agreement.

## PATIENT CARE FUNCTIONS AUTHORIZED:

Pharmacist(s) included in Section B of this agreement will have the authority to manage and/or treat patients in accordance with this section. In managing and/or treating patients, the pharmacist(s) may [INSERT PATIENT CARE FUNCTIONS AUTHORIZED, SUCH AS INITIATE, MODIFY, OR DISCONTINUE DRUG THERAPY], if appropriate, based on current literature and clinical judgment. The pharmacist(s) will refer the patient back to her/his prescriber for issues that are outside the scope of this agreement. [DEPENDING ON STATE LAW, IT MAY BE NECESSARY TO LIST THE DRUGS, DRUG CLASSES, AND/OR TREATMENT PROTOCOLS AS WELL. THESE ELEMENTS COULD BE INCLUDED IN AN APPENDIX TO THE AGREEMENT.]

## E. Training/Education

Some states require that specific education and/or training be completed before a pharmacist is allowed to enter into a CPA. In other states, the education and training that is appropriate for each situation should be determined by the collaborating prescribers. In the example CPA in Figure 2, Virginia does not require any specific education or training. Thus, the collaborating prescribers wrote the agreement so that the responsibility rested with each provider to ensure that he or she actively maintained his or her clinical competencies. Those interested in developing a CPA should see Table 3 in Appendix A for the requirements in their state.

## TRAINING/EDUCATION:

All parties to this agreement are expected to maintain up-to-date competencies and knowledge of current guidelines for disease states covered under this agreement.



## F. Liability Insurance

State laws/regulations in some states require that providers maintain professional liability insurance in order to participate in a CPA. Regardless of whether it is required by law, health care professionals may want to maintain

liability insurance and may consider including that as a requirement in the CPA. Those interested in developing a CPA should see Table 3 in Appendix A for the requirements in their state.

#### **LIABILITY INSURANCE:**

All parties to this agreement shall maintain at least \$1,000,000 (per occurrence) of professional liability insurance during the term of the agreement, which specifically covers drug therapy.



#### **G. Informed Consent of the Patient**

Although obtaining a written informed consent from the patient is not required in all states, it is beneficial for patients to have an understanding of how their care is delivered. Even in states where a specific form of patient consent is not mandated, health care professionals can discuss whether it needs to be obtained at the first meeting with the patient and the procedure that will be used. Those interested in creating a CPA should see Table 3 in Appendix A for the requirements in their state.

#### **INFORMED CONSENT OF THE PATIENT [WRITTEN CONSENT REQUIRED]:**

The pharmacist shall obtain written informed consent from the patient upon first meeting with that patient. A record of provision of care by a pharmacist shall be maintained in the patient's pharmacy record, which is available to the pharmacist.

-OR-

#### **INFORMED CONSENT OF THE PATIENT [WRITTEN CONSENT NOT REQUIRED]:**

At the start of care provided by the pharmacist, each new patient will be provided with an explanation of the collaborative relationship between the pharmacist and the collaborating prescriber. Patients will be informed of their right to opt out of care.



#### **H. Documentation**

Several states have specific laws and regulations pertaining to the documentation of care delivered under a CPA (see Table 3 in Appendix A for more information). Regardless of whether it is required by law, thorough documentation of clinical activities is considered standard practice. Clinical documentation is a relatively new concept for the community pharmacy setting, however, especially beyond formal medication therapy management services. Documentation can be performed using electronic software systems or in a paper chart, although some states require that services provided pursuant to a CPA be documented in an electronic health record. It is sometimes required that the collaborating prescriber and pharmacist both have access to the patients' medical records. Documentation can be done in the traditional subjective, objective, assessment, plan (SOAP note) method or using forms that are more tailored to the specific service(s) the pharmacist is providing.<sup>31</sup>

It can be beneficial to include specifications on documentation and the maintenance of records in the CPA. Some states may require it and even have a minimum duration for retaining records.<sup>32</sup> Table 3 in Appendix A lists state requirements for documentation and the maintenance of records associated with CPAs. Because provisions related to documentation are often complex, those interested in a CPA should refer to the actual legal language in their state to be sure that they are in compliance with the requirements.



### **DOCUMENTATION [SIMPLE]:**

The pharmacist(s) shall document each continuation or modification of an authorization for therapy in the patient's pharmacy record.

-OR-

### **DOCUMENTATION [NO SHARED ACCESS TO AN ELECTRONIC RECORD]:**

The pharmacist will complete a progress note for each patient encounter. For each visit, the pharmacist will record subjective/objective information, the assessment, and the plan. Following each visit, the pharmacist will communicate (e.g., fax) the visit note to the referring provider.

-OR-

### **DOCUMENTATION [SHARED ACCESS TO AN ELECTRONIC RECORD]:**

The pharmacist shall document each scheduled visit with the patient in the patient's medical record. The documentation contained in the medical record shall include medical and medication history, assessment, recommendations, monitoring, educational interventions, and documentation of decisions made, including medications initiated, modified, or discontinued.

-OR-

### **DOCUMENTATION [SHARED ACCESS TO AN ELECTRONIC RECORD; PRESCRIBER REVIEW REQUIRED]:**

The pharmacist shall document each scheduled visit with the patient in the patient's medical record. The documentation contained in the medical record shall include medical and medication history, assessment, recommendations, monitoring, educational interventions, and documentation of decisions made, including medications initiated, modified, or discontinued. The collaborating prescriber will review and cosign all notes in the patient chart and provide feedback to the pharmacist on a regular basis.

## **I. Communication**

As discussed earlier, communication among providers can be helpful for building trust, and it is essential for providing high-quality care. Without efficient and consistent communications, care can become fragmented, duplicative, ineffective, or even harmful.<sup>24</sup> Communication can occur through a variety of media, such as mutually accessed patient records, telephonic and live conversations, email, and text messages or instant messaging.<sup>24</sup> Expectations for the methods used, their frequency, and the timing of communications can be discussed among providers and, when appropriate, outlined in the CPA. When initiating work under a CPA, there may need to be more collaboration on individual clinical decisions and, therefore, more regular communications. Once both parties are comfortable with the care plan and each other's communication needs, the communication procedures outlined in the CPA could be reexamined.

Some states do have specific requirements for communications between providers (see Table 3 in Appendix A and relevant state laws and regulations, as these provisions can be complex).



### **COMMUNICATION:**

The pharmacist shall provide the patient's original prescriber with notification in the form of a fax or secure email when her/his patient's therapy is continued or there is a therapeutic interchange pursuant to this agreement. In this notification, the pharmacist will include any relevant information that was collected from the patient, such as current blood pressure, adherence issues, or any socioeconomic challenges identified.

The pharmacist shall report any new patient complaints and/or deterioration in the patient's condition to the patient's primary care provider and/or other provider/prescriber immediately after learning of the new condition or as soon as possible thereafter.

### J. Quality Assurance [and/or Quality Measurement]

Although a specific plan for quality assurance is not required in most states, it may be best to implement a program for continuous quality improvement.

A few states specifically require that a section on quality assurance be included in the CPA (see Table 3 in Appendix A).

Additionally, practitioners may consider collecting and analyzing data related to outcomes. This information can be used to assess the effectiveness of interactions, to market services in the future, and to demonstrate value to payers, patients, and potential collaborating prescribers. It may be helpful to consider a variety of outcome measures, including those that are economic (e.g., reduction in overall health costs), clinical (e.g., adherence measures, reduction in blood pressure), and personal (e.g., patient satisfaction, quality of life). More information about quality measurements related to pharmacy and to health care in general can be found on the [Pharmacy Quality Alliance website](#) and the [Agency for Healthcare Research and Quality website](#).



#### QUALITY ASSURANCE [MORE GENERAL LANGUAGE]:

Care provided as a result of this collaborative practice agreement will be routinely evaluated to assure delivery of high-quality patient care. Annual evaluation of pharmacist(s) may include clinical outcomes, number of patients treated, and surveys of patient and provider satisfaction, as appropriate.

-OR-

#### QUALITY ASSURANCE [MORE SPECIFIC LANGUAGE]:

Care provided as a result of this collaborative practice agreement will be routinely evaluated to assure delivery of high-quality patient care. For each visit with the patient, parties to this agreement will collect and share information, including the patient's blood pressure, recent hospital admissions, and days missed from work or school. Outcomes will be analyzed and discussed among the parties to the agreement at least once per year.

### K. Review of the Agreement and Maximum Period of Validity

About half of the states have set a maximum length of time that agreements are valid — typically 1 to 2 years. Even in those states where it is not required, the parties to the agreement may find it beneficial to discuss and agree upon a period for review and renewal of the agreement.

Those interested in creating a CPA should review Table 3 in Appendix A for their state's requirements.



#### REVIEW OF THE AGREEMENT AND MAXIMUM PERIOD OF VALIDITY:

This agreement shall be valid for a period not to exceed 2 years from the effective date. However, it may be reviewed and revised at any time at the request of any signatories.

## L. Retention of Records

Some states have provisions regarding how long and in what manner patient records should be maintained (see Table 3 in Appendix A). In addition to any state requirements, pharmacists should know that if any insurer contracts are in place, these contracts may include separate requirements for maintenance of records. Record retention methods should be compliant with federal laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA), state laws and regulations, and any payer contracts in place.

### RETENTION OF RECORDS:

Each signatory to this agreement shall keep a signed copy, written or electronic, of this agreement on file at his/her primary place of practice. A record of each therapeutic interchange made for a specific patient shall be maintained in the patient's pharmacy record.



## M. Rescindment or Amendment of Agreement

It may be beneficial to have a method for providers to withdraw their participation in the agreement and a procedure for altering the terms of that agreement.

### RESCINDMENT OR AMENDMENT OF AGREEMENT:

A signatory may rescind this agreement or a patient may withdraw from treatment under this agreement at any time. Prescribers may override this agreement whenever they deem such action necessary or appropriate for a specific patient without affecting the agreement relative to other patients.



## N. References

If any clinical guidelines are referred to within the text of the agreement, it may be advisable to include the sources so that providers can quickly reference them and ensure that the most up-to-date resources are being used.

## O. Signatures of the Parties to the Agreement

The providers or designees of organizations (e.g., medical directors) who are listed as parties to the agreement must sign the agreement in this section. Note that there are some states that also require the patient(s) to sign the agreement. Because this requirement can make implementation of the agreement challenging in the community setting, providers may want to work together to create a procedure that allows for compliance with this requirement.

The parties should see Table 3 in Appendix A for their state's requirements regarding patient signatures on the CPA.



## Facilitating the Use of CPAs: Other Considerations

While writing the agreement is the key step for entering into a CPA, other logistical steps may be considered. The list below outlines several of these steps, although there may be others, depending on the circumstances.

### Registering With State Agencies

Some states require registration with the board of pharmacy or a similar body for the pharmacist to qualify for participation in a CPA. Others require that the CPA be submitted to or approved by such a body. Those interested in developing a CPA should see Table 3 in Appendix A for their state's requirements.

### Data Sharing and Business Associate's Agreements

Per HIPAA, protected health information can be shared with a health care provider for treatment of an individual patient. Covered entities include health plans, health care clearinghouses, and certain health care providers.<sup>33</sup>

According to the U.S. Department of Health & Human Services, "The Privacy Rule does not require you to obtain a signed consent form before sharing information for treatment purposes. Health care providers can freely share information for treatment purposes without a signed patient authorization."<sup>34</sup> However, if patient health information is used by or is accessible to an organization that is not a covered entity, such as legal counsel or a firm of certified public accountants, a business associate agreement may already be in place. Sample business associate agreements are available from the U.S. Department of Health & Human Services.<sup>35</sup>

### Sustainability of Pharmacists' Patient Care Services

The focus of this resource guide is to help pharmacists establish CPAs to facilitate the treatment and management of chronic conditions. For any services to be incorporated into a pharmacist's practice, it also can be beneficial to have a viable business model in place, regardless of whether there is a CPA. Appendix B of this resource guide provides an introduction to the topic as well as recommendations for other resources that are available.

### Pharmacist's National Provider Identifier Number

If the pharmacist is the provider listed on a prescription, his or her National Provider Identifier (NPI) number may need to be updated to reflect the appropriate taxonomy code. Pharmacists should consult Appendix C for information on why and how to update their NPI number.

## Conclusion

CPAs offer a unique opportunity for pharmacists and prescribers to collaborate in a formal way. Such collaboration increases the efficiency of team-based care in the treatment and management of chronic conditions, including CVD and hypertension. This resource guide provides pharmacists with information and resources to empower them to initiate CPAs with collaborating prescribers. Although the target audience is community pharmacists, CPAs can be used in all pharmacy practice settings, such as long-term care facilities, primary care offices or clinics, specialty clinics, and general and specialty hospitals. Each of these practice settings has its own nuances, challenges, and opportunities.

CVD and hypertension were used in this resource guide as examples of disease states that can be managed using a CPA, but the concepts presented here can be applied to many other chronic conditions, treatments for acute illness, and preventive health measures as well.

No two collaborative relationships look exactly the same, and the development process will vary.<sup>28</sup>

The information in this resource guide is intended to provide ideas and spur innovation, but it is not intended to be rigid steps in a process. Pharmacists attempting to initiate collaborative relationships should have patience and be flexible. Both the collaborative relationship and the CPA are likely to change over time. By keeping patients and a continuous improvement in their outcomes the central goal of therapy, it is clear that collaborative care delivery, facilitated by CPAs, can result in improved health, efficiency, and patient and provider satisfaction.<sup>28</sup>



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# Appendix A: Collaborative Practice Agreement Authority Tables

**Table 1: Participants**

State	Site restrictions	Pharmacist qualifications	Multiple or single pharmacist(s)	Which prescribers (MD, NP, PA?)	Multiple or single prescriber(s)?	Multiple or single patient(s)?	Prescriber–Patient Relationship defined?
<b>AK</b>	Silent	Yes - H	Multiple	All prescribers	Multiple	Multiple - T	Silent
<b>AL</b>	CPAs not allowed under state law.						
<b>AZ</b>	Silent	Silent	Single	Physician + NP	Single	Single	Yes - LL
<b>AR</b>	Silent	Silent	Single	All prescribers - U	Single	Single - HH	Silent
<b>CA</b>	Silent	Yes - I	Single	All prescribers - V	Single	Single	Yes - MM
<b>CO</b>	Yes - A	Yes - I	Multiple	Physician + NP	Multiple	Multiple	Yes - NN
<b>CT</b>	Silent	Yes - J	Multiple	Physician	Multiple	Single - II	Yes - OO
<b>DC</b>	Silent – E3	Silent – E3	Single – E3	Physician, others – E3, F3	Single	Silent – E3	Silent – E3
<b>DE</b>	CPAs not allowed under state law.						
<b>FL</b>	Silent	Silent	Multiple	Physician	Single	Single	Yes - PP
<b>GA</b>	Silent	Yes - K	Single	Physician	Single	Multiple - T, JJ	Yes - QQ
<b>HI</b>	Silent	Silent	Multiple	Physician	Single	Single	Yes - RR
<b>ID</b>	Silent	Silent	Multiple	All prescribers	Multiple	Multiple	Silent
<b>IL</b>	Silent	Silent	Multiple	Physician	Single	Multiple	Silent
<b>IN</b>	Yes - A	Yes - L	Multiple	Physician, others - W	Multiple	Multiple	Yes - RR
<b>IA</b>	Yes - A	Yes - M	Multiple - S	Physician	Multiple	Single	Yes - MM
<b>KS</b>	Silent	Silent	Multiple	Physician	Multiple	Single	Yes - SS
<b>KY</b>	Silent	Silent	Multiple - T	All prescribers - X	Multiple	Multiple - T	Yes - TT
<b>LA</b>	Yes - B	Yes - N	Single	Physician	Single	Single	Yes - UU
<b>ME</b>	No - C	Yes - I	Multiple	All prescribers - Y	Single	Multiple - T	Yes - QQ
<b>MD</b>	Silent	Yes - I	Multiple - GG	Physician, others - Z	Multiple - GG	Single	Yes - VV
<b>MA</b>	Yes - A	Yes - J, O	Single	Physician - C3	Single	Single	Yes - WW
<b>MI</b>	Silent	Silent	Multiple	Physician	Single	Silent	Silent
<b>MN</b>	Silent	Silent	Multiple	Physician, others - AA	Multiple	Silent	Silent
<b>MS</b>	Silent	Yes - I	Multiple	All prescribers - BB	Multiple	Single - KK	Silent
<b>MO</b>	Yes - A, B	Yes - I	Multiple	Physician	Multiple	Single	Yes - QQ
<b>MT</b>	Yes - B	Silent	Multiple	Medical practitioner - CC	Multiple	Silent	Silent
<b>NE</b>	Silent	Silent	Single	Medical practitioner	Single	Silent	Silent
<b>NV</b>	No - D	Silent	Single	All prescribers	Single	Single	Silent
<b>NH</b>	Yes - E	Yes - J, O, P	Single	All prescribers	Single	Single	Yes - OO
<b>NJ</b>	Silent	Yes - I	Multiple - T	Physician	Multiple - T	Single	Yes - MM
<b>NM</b>	Silent	Yes - I	Multiple	Physician	Multiple	Multiple	Silent
<b>NY</b>	Yes - F	Yes - I	Single	Physician	Single	Single	Yes - MM
<b>NC</b>	Silent	Yes - I	Single - A3	Physician - DD, A3	Single	Single	Yes - XX
<b>ND</b>	Silent	Yes - M	Multiple - S, B3	Physician + NP - A3	Multiple - S	Silent	Silent
<b>OH</b>	Silent	Yes - D3	Multiple	Physician	Multiple	Multiple	Yes - SS
<b>OK</b>	Silent	Silent	Silent	Physicians	Silent	Silent	Silent
<b>OR</b>	Silent	Yes - Q	Multiple - S	Physician - EE	Multiple - S	Single	Silent
<b>PA</b>	Silent	Silent	Single	Physician	Single	Multiple	Yes - TT
<b>RI</b>	No - C	Yes - I	Single	All prescribers	Multiple	Single	Silent
<b>SC</b>	Silent	Silent	Silent	All prescribers	Multiple	Silent	Silent
<b>SD</b>	Silent	Silent	Silent	All prescribers	Single	Silent	Silent
<b>TN</b>	Silent	Silent	Multiple	All prescribers - C3	Multiple	Multiple	Silent
<b>TX</b>	Yes - E	Yes - R	Single	Physician	Single	Single	Yes - YY
<b>UT</b>	Silent	Silent	Multiple	All prescribers	Multiple	Multiple	Silent

State	Site restrictions	Pharmacist qualifications	Multiple or single pharmacist(s)	Which prescribers (MD, NP, PA?)	Multiple or single prescriber(s)?	Multiple or single patient(s)?	Prescriber–Patient Relationship defined?
<b>VT</b>	Silent	Silent	Single	All prescribers	Multiple	Multiple	Silent
<b>VA</b>	Yes - G	Silent	Multiple - S	All prescribers - FF	Multiple	Multiple - ZZ	Yes - TT, ZZ
<b>WA</b>	Silent	Silent	Multiple	All prescribers	Single	Multiple	Silent
<b>WV</b>	Yes - A	Yes - I	Multiple	Physician	Multiple	Single	Silent
<b>WI</b>	Silent	Silent	Multiple	Physician	Multiple	Silent	Silent
<b>WY</b>	Silent	Silent	Multiple	All prescribers	Multiple	Single	Yes - TT, XX

### Key for Table 1: Participants

A	Allowed in most or all settings but with different rules for some
B	Physician must be nearby the collaborating pharmacist - see law/regulations for more details
C	Site must be specifically identified in the agreement
D	Nearly all locations allowed
E	Not allowed in community pharmacy settings
F	Limited to teaching hospitals
G	If multiple pharmacists are included in an agreement, all must be at a single physical location where patients receive services
H	Unless the board is satisfied that the pharmacist has been adequately trained in the procedures outlined in the written protocol, the board will specify and require completion of additional training that covers those procedures before issuing approval of the protocol
I	Complicated requirements - see state law/regulations for details
J	Nearly all pharmacists would qualify - see state law/regulations for details
K	Application to board of pharmacy, additional continuing education, and a fee required - see state law/regulations for details
L	Physician responsible for ensuring pharmacist is properly trained to administer the protocol
M	Nearly all pharmacists would qualify, extra requirements for non-PharmD
N	Must register with the board and renew annually
O	Additional logistical requirements - see law/regulations for details
P	Must register with the board
Q	As specified in the agreement
R	Additional continuing education required
S	All must work within the same practice
T	All must be listed on the agreement
U	Practitioner authorized to prescribe drugs and responsible for the delegation of disease state management
V	Patient's treating prescriber
W	Physician, nurse practitioner, physician assistant
X	Medical/osteopathic physicians, dentists, chiropractors, veterinarians, optometrists when administering or prescribing pharmaceutical agents, advanced practice registered nurses, physician assistants when administering or prescribing pharmaceutical agents, and other health care professionals who are residents of and actively practicing in a state other than Kentucky and who are licensed and have prescriptive authority under the professional licensing laws of another state
Y	Any individual who is licensed, registered, or otherwise authorized in the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice
Z	Licensed physician, licensed podiatrist, or certified advanced practice nurse with prescriptive authority
AA	Dentist, optometrists, physicians, podiatrists, veterinarians, nurse practitioners, physician assistants
BB	Physician, dentist, veterinarian, or other health care provider authorized by law to diagnose and prescribe drugs
CC	Any person licensed by the state of Montana to engage in the practice of medicine, dentistry, osteopathy, podiatry, optometry, or a nursing specialty
DD	Must be approved by the board - see law/regulations for details
EE	Physician or group of physicians

FF	Any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in §32.1-276.3 (Virginia Law), provided such collaborative agreement is signed by each physician participating in the collaborative practice agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working as part of a patient care team as defined in § 54.1-2900 (Virginia Law), involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners
GG	One plus a designated alternate
HH	A standard protocol may be used, or the attending practitioner may develop a disease state management protocol for the individual patient
II	Multiple patients under one agreement; protocol is patient specific
JJ	Multiple but each patient's diagnoses and current medication list must be listed in agreement
KK	Single in community setting, multiple in institutional setting
LL	Collaborating prescriber must be acting as a primary care provider
MM	Individual patient's treating prescriber
NN	All physicians who are actively involved in the management of the relevant conditions shall be parties to the agreement
OO	Physician-patient relationship narrowly defined - see law/regulations for details
PP	Individualized assessment
QQ	Patient specific information must be included in the protocol/agreement - see laws/regulations for details
RR	Agreement must be related to the condition(s) for which the patient has been seen by the collaborating prescriber/physician
SS	Established "physician-patient relationship"
TT	Referral from collaborating prescriber required
UU	Patient/ drug/disease or condition specific order set prepared by the physician must be based on a face-to-face visit with the patient
VV	Directly involved in patient care
WW	Referral required, must include a diagnosis from the supervising physician
XX	Diagnosis and initial drug therapy must be prescribed
YY	The delegation must follow a diagnosis, initial patient assessment, and drug therapy order by the physician. The physician must have an established a physician-patient relationship with each patient who is provided drug therapy management by a delegated pharmacist. Physician-patient relationship must be maintained.
ZZ	Pharmacist may only implement drug therapy post diagnosis by the prescriber
A3	Limited to one physician to three pharmacists
B3	A pharmacist may have an agreement with one or more physicians, the number of which may be limited by the board based on individual circumstances
C3	Pharmacies can't hire physicians to maintain CPAs
D3	Training and experience related to the particular diagnosis for which drug therapy is prescribed
E3	For immunization or vaccination written protocols: multiple pharmacists may participate, pharmacists must be board certified and meet continuing education requirements; a written immunization or vaccination protocol may apply to individual or groups of patients; some setting limitations apply; patient informed consent required. Board of pharmacy and board of medicine are required to issue regulations jointly governing the implementation and use of CPAs between a pharmacist and physician; however, as of 11/2016, no new rules have been promulgated.
F3	Additional licensed health practitioners with independent prescriptive authority may participate in CPAs if authorized by rule (none authorized as of 11/2016)

**Table 2: Functions Authorized**

State	Modify Existing Therapy	Initiate New Therapy	Perform a Physical Assessment	Order Laboratory Tests	Interpret Laboratory Tests	Perform Laboratory Tests
<b>AK</b>	Yes - W, AA	Yes - W, AA	Silent	Silent	Silent	Silent
<b>AL</b>	CPAs not allowed under state law.					
<b>AZ</b>	Yes - W, AA	Yes - A, W, AA	Silent	Yes	Silent	Silent
<b>AR</b>	Yes - V, AA	Yes - A, V, AA	Silent	Silent	Silent	Silent
<b>CA</b>	Yes - Z	Yes - A, Z	Yes	Yes	Yes	Silent
<b>CO</b>	Yes - A, V, AA	Yes - A, M, V, AA	Yes - G	Yes - I, M	Yes - I, M	Silent
<b>CT</b>	Yes - B, W, AA	Yes - W, AA	Silent	Yes	Silent	Silent
<b>DC</b>	Yes - DD	Yes - DD	Silent	Silent	Silent	Silent
<b>DE</b>	CPAs not allowed under state law.					
<b>FL</b>	No	No - GG	Silent	Yes	Yes	Silent
<b>GA</b>	Yes - W, AA	Yes - W, AA	Silent	Silent	Silent	Silent
<b>HI</b>	Yes	Yes	Yes - H	Yes	Silent	Silent
<b>ID</b>	Yes - AA	Yes - AA	Yes - I	Silent	Silent	Yes
<b>IL</b>	Yes - A	Yes - A	Silent	Yes - I	Yes - I	Silent
<b>IN</b>	Yes	Yes	Silent	Silent	Silent	Silent
<b>IA</b>	Yes - BB	Yes - BB	Yes	Yes	Yes	Yes
<b>KS</b>	Silent	Silent	Silent	Silent	Silent	Silent
<b>KY</b>	Yes - AA	Yes - AA	Silent	Yes	Silent	Silent
<b>LA</b>	Yes - C, W, CC	No	Yes	Yes	Yes - P	Silent
<b>ME</b>	Yes - D, V, AA	Yes - D, V, AA	Yes	Yes	Yes - P, Q	Silent
<b>MD</b>	Yes - A, V, AA	Silent	Yes - J	Yes - I	Yes, I	Silent
<b>MA</b>	Yes - X, FF	Yes - X, FF	Yes - G	Yes - N	Yes - P	Silent
<b>MI</b>	Yes	Yes	Silent	Silent	Silent	Silent
<b>MN</b>	Yes	Yes	Silent	Silent	Silent	Yes
<b>MS</b>	Yes - AA	Yes - AA	Silent	Yes	Silent	Silent
<b>MO</b>	Yes - E, W, CC	Yes - E, W, CC	Yes	Yes	Yes	Yes
<b>MT</b>	Yes - W, AA	Yes - W, AA	Silent	Silent	Silent	Silent
<b>NE</b>	Yes - W	Yes - W	Silent	Silent	Silent	Silent
<b>NV</b>	Yes - AA	Yes - AA	Yes - K	Yes	Yes	Silent
<b>NH</b>	Yes - W, AA	Yes - W, AA	Silent	Yes	Silent	Silent
<b>NJ</b>	Yes - W, AA	No	Silent	Yes	Yes - Q	Yes
<b>NM</b>	Yes - W, AA	Yes - W, AA	Silent	Yes - I	Yes	Silent
<b>NY</b>	Yes - F, W, AA	No - F	Yes - I	Yes	Yes - R	Silent
<b>NC</b>	Yes - U, AA	Yes - U, AA	Silent	Yes - I	Silent	Silent
<b>ND</b>	Yes - BB	Yes - BB	Silent	Silent	Silent	Silent
<b>OH</b>	Yes - W	Yes - W	Silent	Yes	Yes - P	Silent
<b>OK</b>	No	No - EE	Silent	Silent	Silent	Silent
<b>OR</b>	Yes - W, AA	Yes - W, AA	Silent	Yes - I	Yes - I	Silent
<b>PA</b>	Yes - AA	No	Yes	Yes	Silent	Yes
<b>RI</b>	Yes - W, AA	No	Yes - G	Yes	Yes - R	Yes
<b>SC</b>	Yes - DD	Yes - DD	Silent	Silent	Silent	Silent
<b>SD</b>	Yes	Yes	Silent	Silent	Silent	Silent
<b>TN</b>	Yes	Yes	Yes	No	Silent	Silent
<b>TX</b>	Yes - W, AA	Yes - A, W, AA	Yes - H	Yes	Silent	Silent
<b>UT</b>	Yes	Yes	Yes - G	Yes	Yes - S	Silent

State	Modify Existing Therapy	Initiate New Therapy	Perform a Physical Assessment	Order Laboratory Tests	Interpret Laboratory Tests	Perform Laboratory Tests
<b>VT</b>	Yes - W, AA	Yes - W, AA	Yes	Yes - I	Yes - I	Silent
<b>VA</b>	Yes - Y, AA	Yes - Y, AA	Silent	Yes	Silent	Silent
<b>WA</b>	Yes - W, AA	Yes - A, W, AA	Yes - G	Yes	Yes - R	Silent
<b>WV</b>	Yes - CC	No	Yes - L	Yes - O	Yes - T	Yes
<b>WI</b>	Yes	Yes	Silent	Silent	Silent	Silent
<b>WY</b>	Yes - W, AA	Yes - A, W, AA	Yes	Yes	Silent	Yes

**Key for Table 2: Functions Authorized**

A	Drugs limited to those in the protocol
B	Notify physician within 24 hours if therapy is discontinued
C	Therapeutic substitution not allowed without the physician's explicit consent
D	First 3 months limited to monitoring
E	State specific rules regarding initiation and modification of a prescription - refer to state laws/regulations for details
F	Therapeutic substitution allowed but not initiation of new therapy
G	Obtaining and checking vital signs
H	Ordering or performing routine drug therapy-related patient assessment procedures
I	As specified in the agreement/protocol
J	Other patient care management measures related to monitoring or improving the outcomes of drug or device therapy
K	Examinations
L	The protocol may authorize the pharmacist to check only these findings: vital signs, oximetry, or peak flows that enable the pharmacist to assess and adjust the drug therapy, detect adverse drug reactions, or determine if the patient should be referred to the patient's physician for follow-up. Pharmacists shall not conduct any physical examination of the patient other than taking vital signs.
M	Protocol requirements outlined in the regulations are very prescriptive - see Colorado regulations before initiating a CPA
N	Under the supervision of, or in direct consultation with, a physician, ordering and evaluating the results of laboratory tests directly related to drug therapy when performed in accordance with approved protocols applicable to the practice setting and when the evaluation shall not include a diagnostic component
O	Ordering screening laboratory tests that are dose related and specific to the patient's medication or are protocol driven and are also specifically set out in the collaborative pharmacy practice agreement between the pharmacist and physician
P	Evaluate but not to be used for diagnosis

Q	In direct consultation with the physician
R	Evaluate
S	Ordering and evaluating the results of laboratory tests directly applicable to the drug therapy, when performed in accordance with approved protocols applicable to the practice setting
T	Laboratories utilized by the pharmacist may be in a pharmacy or pharmacy center. All laboratory results obtained are to be sent to the physician within 48 hours, except that any severely abnormal or critical values shall be sent by the pharmacist to the physician immediately.
U	Agreement is disease specific
V	Disease states limited to those defined in agreement for each individual patient
W	Disease states limited to those specified in protocol or agreement
X	Disease states limited to those specified in the protocol or agreement; restrictions for community pharmacists only
Y	Disease states limited to those with a defined standard of care required or the protocol must be approved by the board of pharmacy
Z	Restricted to conditions for which the patient has first been seen by a physician
AA	Medications limited to those specified in agreement or protocol
BB	Does not include CIs
CC	Does not include any controlled substances
DD	Medications limited to those specified in the therapeutic plan
EE	Limited to administering immunizations and therapeutic injections
FF	Restrictions for community pharmacists only
GG	Therapy initiation is limited to a defined list of drugs but does not require a collaborative agreement

**Table 3: Requirements**

State	Additional continuing education requirements	Requirement for liability insurance?	Documentation and/or notification requirements	Patient involvement in agreement – signature or opt out?	Must agreements be sent to or approved by a state agency?	Length of time agreement is valid defined?
<b>AK</b>	Silent	Silent	Yes - I, O, AA	Silent	Yes - WW	Yes - ZZ
<b>AL</b>	CPAs not allowed under state law.					
<b>AZ</b>	Silent	Silent	Yes - Z	Silent	Silent	Silent
<b>AR</b>	Silent	Silent	Yes - O, P, Q, Z	Silent	Yes - UU	Yes - YY
<b>CA</b>	Silent	Silent	Yes - R, S	Silent	Silent	Silent
<b>CO</b>	Silent	Yes - L	Yes - T, U, Y	Yes - QQ	Yes - UU	Yes - YY
<b>CT</b>	No - A	Silent	Yes - V, W, X	Silent	Yes - UU	Silent
<b>DC</b>	Silent - E3	Silent	Yes - E3	Silent - E3	Silent - E3	Silent - E3
<b>DE</b>	CPAs not allowed under state law.					
<b>FL</b>	Silent	Silent	Yes - BB, Z	Silent	Silent	Silent
<b>GA</b>	Yes - B	Silent	Yes - H, Z, CC	Yes - RR	Silent	Yes - ZZ
<b>HI</b>	Silent	Silent	Yes - R	Silent	Silent	Silent
<b>ID</b>	Silent	Silent	Yes - S, Z	Silent	Yes - UU	Yes - YY
<b>IL</b>	Silent	Silent	Silent	Silent	Silent	Silent
<b>IN</b>	Silent	Silent	Yes - S, DD	Silent	Silent	Yes - YY
<b>IA</b>	Silent	Silent	Yes - I	Yes - SS	Yes - UU	Yes - ZZ
<b>KS</b>	Silent	Silent	Silent	Silent	Silent	Silent
<b>KY</b>	Silent	Silent	Yes - H, EE	Yes - SS	Yes - UU	Silent
<b>LA</b>	Silent	Silent	Yes - H	Yes - SS	Yes - UU	Yes - YY
<b>ME</b>	Yes - C	Yes - M	Yes	Silent	Yes - VV	Yes - I
<b>MD</b>	Silent - D3	Silent - D3	Yes - H, D3	Yes - SS, D3	Yes - VV, D3	Yes - YY, D3
<b>MA</b>	Yes - D	Yes - L	Yes - H	Yes - TT	Yes - UU	Yes - ZZ
<b>MI</b>	Silent	Silent	Silent	Silent	Silent	Silent
<b>MN</b>	Silent	Silent	Yes - FF	Silent	Silent	Silent
<b>MS</b>	Yes - E	Silent	Yes - I	Yes - RR	Yes - WW	Yes - YY
<b>MO</b>	Yes - F	Silent	Yes - H	Silent	Yes - VV	Yes - YY
<b>MT</b>	Silent	Silent	Yes - I, Y	Yes - SS	Yes - VV	Yes - YY
<b>NE</b>	Silent	Silent	Silent	Silent	Yes - VV	Yes - YY
<b>NV</b>	Silent	Silent	Yes - Z, GG	Silent	Yes - WW	Silent
<b>NH</b>	Yes - G	Yes - L	Yes - I, HH	Yes - SS	Yes - UU	Yes - ZZ
<b>NJ</b>	Yes - H	Silent	Yes - I, Y	Yes - TT	Yes - UU	Yes - YY
<b>NM</b>	Yes - H	Silent	Yes - I	Silent	Yes - VV	Yes - ZZ
<b>NY</b>	Silent	Silent	Yes - I, II	Yes - SS	Silent	Silent
<b>NC</b>	Yes - H	Silent	Yes - NN	Yes - RR	Yes - UU	Silent
<b>ND</b>	Silent	Silent	Yes - JJ, E3	Silent	Yes - WW	Yes - A3
<b>OH</b>	Silent	Silent	Yes - B3, F3	Yes - SS	Yes - UU	Yes - ZZ
<b>OK</b>	Silent	Silent	Silent	Silent	Yes - UU	Silent
<b>OR</b>	Yes - I	Silent	Yes - I	Silent	Yes - UU	Yes - ZZ
<b>PA</b>	Silent	Yes - L	Yes - I, KK, C3	Yes - RR	Yes - VV	Yes - ZZ
<b>RI</b>	Yes - J	Yes - M	Yes - I	Yes - TT	Yes - VV	Yes - ZZ
<b>SC</b>	Silent	Silent	Silent	Silent	Silent	Silent
<b>SD</b>	Silent	Silent	Silent	Silent	Yes - WW	Silent
<b>TN</b>	Silent	Silent	Yes - S, KK	Silent	Check	Yes - ZZ
<b>TX</b>	Yes - K	Silent	Yes - I, X, LL	Silent	Yes - VV	Yes - YY
<b>UT</b>	Silent	Silent	Silent	Silent	Silent	Silent
<b>VT</b>	Silent	Silent	Yes - OO	Silent	Silent	Yes - YY

State	Additional continuing education requirements	Requirement for liability insurance?	Documentation and/or notification requirements	Patient involvement in agreement – signature or opt out?	Must agreements be sent to or approved by a state agency?	Length of time agreement is valid defined?
<b>VA</b>	Silent	Silent	Yes - I	Yes - TT	Yes - XX	Silent
<b>WA</b>	Silent	Silent	Yes - I	Silent	Yes - VV	Yes - ZZ
<b>WV</b>	Silent	Yes - N	Yes - I, V, W, MM, PP	Yes - TT	Yes - WW	Yes - ZZ
<b>WI</b>	Silent	Silent	Silent	Silent	Silent	Silent
<b>WY</b>	Silent	Silent	Yes - I, O	Yes - SS	Yes - WW	Yes - YY

### Key for Table 3: Requirements

A	Continuing education is mentioned in CPA language but the requirements are the same as for licensure
B	Annual completion of 0.3 CEUs regarding modification of drug therapy
C	Fifteen hours per year: 2 hours in drug administration, 5 hours in the areas of practice covered by agreement
D	Five additional contact hours of continuing education that addresses areas of practice generally related to collaborative practice agreements
E	Biennial basis: obtain recertification in each disease state by completing a continuing education program consisting of not less than 6 hours focusing on nationally recognized updates
F	Biennial recertification required (6 hours of continuing education in medication therapy management)
G	Complete at least 5 contact hours or 0.5 CEUs of board-approved continuing education each year; such continuing education shall address the area or areas of practice generally related to the collaborative pharmacy practice agreement or agreements
H	Complicated requirements - see law/regulations for details
I	As specified in the agreement
J	Five hours of continuing education each year that must be in the practice area covered by the agreement; documentation must be maintained and available for inspection at the practice site
K	Six hours of continuing education related to drug therapy
L	At least \$1,000,000 of professional liability insurance
M	Agreement must include proof that liability insurance is maintained by all parties to the agreement
N	Personally have or have employer coverage of at least \$1,000,000 of professional liability insurance coverage
O	Documentation/patient records maintained for 2 years
P	Documentation recorded within a reasonable time of each intervention
Q	Documentation may be on the patient medication record, patient medical chart, or in a separate logbook
R	Written notification to patient's treating prescriber or entry into electronic patient record shared by the prescriber of any drug initiation within 24 hours
S	Medical records of the patient must be available to both the patient's treating prescriber and the pharmacist
T	Notification to the physician within 24 hours of modification of therapy
U	Physician must review and document acceptance or rejection of the drug therapy modification within 72 hours
V	All activities performed by the pharmacist in conjunction with the protocol shall be documented in the patient's medical record
W	The pharmacist shall report at least every 30 days to the physician regarding the patient's drug therapy management
X	Protocol must include a plan for periodic review, feedback, and quality assurance
Y	Records maintained for 7 years
Z	Physician notification/review as specified in agreement
AA	Physician review of pharmacist's decisions at least every 3 months
BB	Transferrable patient record for orders and progress notes
CC	Patient records maintained for 10 years after protocol is terminated
DD	Document in patient record immediately after making a change to drug therapy
EE	Records maintained for 5 years

FF	Document change of therapy in medical record or report to patient's provider
GG	Specific requirements for protocols developed for use in care transitions - see laws/regulations for details
HH	All agreements must include provisions for documentation of any initiation, modification, or discontinuation of a patient's medications in the patient's permanent medical record; community pharmacists must maintain a written record of the individual patient referral and the patients' written informed consent
II	Must immediately enter into the patient record any change or changes made to the patient's drug therapy and notify the physician (and the patient's other physicians)
JJ	The practitioner and the pharmacist must have access to the patient's appropriate medical records; the care provided to the patient by the pharmacist must be recorded in the patient's medical records and communicated to the practitioner
KK	Document as soon as possible, no longer than 72 hours after a change is made, as specified in the agreement
LL	The delegating physician must receive, as appropriate, a periodic status report on each patient, including any problem or complication encountered as defined in the protocol. Documentation shall be recorded within a reasonable time of each intervention and may be performed on the patient medication record, patient medical chart, or in a separate log book.
MM	Notify the treating physician of any discontinuation of drug therapy
NN	Agreement must include a plan and schedule for weekly quality control, review and countersignature of all orders written by the CPP in a face-to-face conference between the physician and CPP
OO	Annual quality assurance review by the collaborating practitioner
PP	All evaluation notes shall be in the physician's patient's chart within 1 week of the evaluation and drug management change
QQ	Patients must be informed of their right to refuse care under the agreement; patient's signature on the institution's general consent may be used
RR	Patient notification required
SS	Written consent required
TT	Informed consent required
UU	Maintained and available upon request
VV	Copy of agreement must be submitted to the relevant board(s)
WW	Agreement must be reported to and approved by the relevant board(s)
XX	Protocol only needs to be approved for conditions for which there is no accepted standard of care
YY	Agreement can only be valid for up to 1 year
ZZ	Agreement can only be valid for up to 2 years
A3	Agreement can only be valid for up to 4 years
B3	Records maintained for 3 years
C3	Records maintained in an electronic medical record
D3	Extensive requirements regarding components of the agreement - see regulations for details
E3	Pharmacist must notify the prescriber within 24 hours of initiating or modifying therapy; CPA may clarify some situations where notice within 72 hours is acceptable
F3	Communication must occur between providers on a regular basis - see laws/regulations for details

## Appendix B: Sustainability of Pharmacists' Services Delivered Under Collaborative Practice Agreements

Sustainable business models are needed to support pharmacists' patient care services, including those services delivered under collaborative practice agreements (CPAs). While CPAs can be very helpful in providing expanded authority for pharmacists to provide care to patients, a viable business model is critical for supporting the time commitment of the pharmacist and the expertise that he or she brings as part of a health care team. CPAs can improve access to care as well as facilitate efficiencies in the delivery of coordinated team-based care and sufficient payment to sustain pharmacists' services over the long term.

If revenue sources are already available for the services that pharmacists will be delivering under a CPA, then development of the CPA may focus on the operational aspects of the agreement. If revenue sources are not available, the negotiation phase of the CPA can also include discussions about the business model for compensating the pharmacist. Focus areas to consider include potential sources of direct payment and the value-added benefits that the pharmacist can provide. This appendix covers three key areas: potential payment sources for pharmacists' services, development of a value proposition, and monitoring the return on investment.

### Potential Payment Sources

The health care system is undergoing significant changes in payment models for health care. The long-standing fee-for-service (FFS) model is shifting toward value-based models that pay for services provided by health care providers based on the value of those services in meeting quality measures, improving outcomes, and containing costs. In addition, bundled payments to organizations to cover the medical management of a patient population are becoming more common. Many payment models are currently a mix of FFS and value-based incentives.

### Traditional FFS Payment Opportunities for Pharmacists

- FFS is currently the predominant compensation mechanism for health care providers in the United States. Under this model, health care providers are reimbursed for the number and array of clinical services they provide, typically through the use of specific billing codes that correspond to the level and type of services provided.<sup>1</sup> Commercial, public, and private insurers, along with pharmacy benefits managers and managed care organizations, all have potential to be payers for pharmacists' services. FFS payment opportunities for pharmacists' patient care services have been sporadic to date, however. As of 2016, many payers view pharmacists as being eligible for compensation only for dispensing medications, not for the provision of collaborative patient care services.<sup>2</sup>

Among the list of services below that pharmacists can currently provide, direct payment opportunities are available only for medication therapy management (MTM) and, in some cases, training in diabetes self-management. The other listed services are Medicare Part B services, where physicians or other qualified providers bill for the pharmacist's service under specific billing requirements:

- MTM.
- Training in diabetes self-management.
- A service incident to physician services in a physician-based practice or hospital outpatient clinic.
- Transitional care management as part of a team-based bundled payment.
- Chronic care management.
- Annual wellness visit.<sup>1</sup>

Potential payers for pharmacists' patient care services include those described below:

- **Centers for Medicare & Medicaid Services (CMS)**

**Part B**—Pharmacists' services are not currently recognized for payment through Medicare Part B (where outpatient health care professionals' services are covered). Under specific circumstances, physicians and qualified nonphysician practitioners (NPPs) can utilize their National Provider Identifier number to bill for pharmacists' services performed under the direct or general supervision of the physician or NPP (depending on the service). This process is often referred to as "incident to" billing, and the setting is either a physician-based practice or a hospital outpatient clinic.

- Because specific requirements for this type of billing must be met, and the requirements vary by the service, it is extremely important to consult applicable resources. Pharmacists must be in an employed, contracted, or leased arrangement in order for the physician to bill for the pharmacist's services.<sup>1</sup>
- For services requiring direct supervision, the physician or NPP must be present in the office suite or in the building and immediately available to the pharmacist. In contrast, under general supervision, the physician

provides overall direction and control, but the physician's presence is not required. Community pharmacists under the general supervision of the physician or NPP could perform Medicare services with a general supervision requirement (e.g., chronic care management, transitional care management) in the pharmacy.

- **CMS Medicare Part D**—CMS contracts with Part D Prescription Drug Plans (PDPs) to provide MTM services for eligible beneficiaries. PDPs can then contract with pharmacies or pharmacists to provide MTM services. MTM service opportunities are variable but, where present, could be a revenue source to support the pharmacist working under a CPA with a prescriber. Pharmacists would bill directly for any MTM services provided to the patient.
- **State Medicaid programs**—Some state Medicaid programs provide payment to pharmacists for various services, which can include medication management, chronic condition management, and wellness services. There also may be opportunities in some state Medicaid programs for physicians to bill for pharmacists' services under an "incident to" arrangement. Pharmacists should check with state boards of pharmacy or state pharmacy associations to learn about available opportunities in a given state.



- **Commercial health plans and self-insured employers**—Commercial health plans may cover pharmacists’ services delivered in an “incident to” arrangement with a prescriber. It will be helpful for pharmacists to become familiar with the requirements for specific plans because commercial health plans often follow CMS’s guidelines but may have their own requirements. In addition, some commercial health plans are involved in pilot programs to pay pharmacists directly for certain services, such as diabetes management. Many state pharmacy associations are working to address payment barriers for pharmacists’ services. For example, the state of Washington recently implemented a law that requires commercial health plans in that state to cover pharmacists’ services if the service is within the pharmacist’s scope of practice and that same service is covered for other health care practitioners. Self-insured employers are another potential source of payment for services such as the management of chronic conditions and wellness services. Pharmacists interested in these opportunities may benefit from networking to learn about available programs.

## Funding Opportunities in New Models for Delivering Care

In new care delivery models, such as accountable care organizations and patient-centered medical homes, various health care practitioners are compensated for delivering quality, affordable, and coordinated care to patients under new payment models. In these models, the focus is on “pay for value” instead of the “pay for volume” approach in FFS. Pharmacists may be able to contract directly with an organization for specific services or integrate directly into the organization as salaried employees. This will depend on the nature of the care provided and the interest of the collaborating providers or insurers.<sup>2</sup>

New care delivery models may include a mix of FFS payment, incentive payments for meeting quality metrics and cost targets, and payments for managing and coordinating the care of populations of patients. The incentive payments may be provided through payments for nontraditional services, higher rates for contracted services, lump sum payments, additional per-member per-month payments, shared savings when expected expenditures are below actual costs, or other pay-for-performance incentives.<sup>2</sup>

Payment models are not mutually exclusive. For example, a pharmacist may be contracted by a medical group to provide patient care services 3 days per week. Each time the pharmacist conducts services that are currently paid under the fee-for-service model, the medical group bills the insurer to recover reimbursement for the provided service. If the pharmacist improves the outcomes of patients who are part of an integrated care model, the medical group will earn an incentive payment. The reimbursement received by the medical group may be used to offset the cost of the pharmacist or may be shared with the pharmacist as a bonus payment, depending on the terms of the contract.

Pharmacists who plan to seek payment within integrated care models will benefit from being prepared to document, monitor, and improve specific quality measures that drive incentive payments. Because many care delivery organizations receive capitated payments to cover a patient population, there is a greater focus on keeping the population healthy and achieving better health outcomes. Pharmacists may want to focus on understanding the organization's relevant quality measures and how pharmacists' services can improve specific metrics and increase savings.

### Assessing Payer Mix

If the source of payment for pharmacists' services will come from the physician's practice, it will be helpful to understand the types of payers (the payer mix) in the practice in order to build a business model. For example, in a practice that has a payer mix of 60% Medicare, 30% commercial health plans, and 10% Medicaid, a pharmacist working in the practice might want to collaborate with the physician to deliver annual wellness visits (incident to physician services) and chronic care management services to the practice's Medicare beneficiaries. A pharmacist might collaborate to deliver chronic care management services and transitional care management while assisting the practice with meeting selected quality metrics. Payment opportunities available through Medicaid or commercial health plans could be considered as well. The pharmacist's contributions to meeting quality metrics could be covered through incentive payments.

### Formulating the Value Proposition<sup>3,4,5</sup>

With an understanding of potential payment sources, pharmacists can begin building the business case for collaborating with physicians to deliver services under a CPA. The value proposition is composed of the most persuasive reasons why a physician should consider entering into a business agreement with the pharmacist to deliver services under a CPA. Value propositions can also be developed for approaching payers directly for coverage of pharmacists' services. Potential elements of the value proposition include the following:

- Specific patient care services that the pharmacist can provide.
- Unique benefits that the pharmacist can bring to the practice, such as assistance with meeting quality metrics, providing drug information, and assistance with meeting evidence-based guidelines.
- Revenue opportunities and potential ROI as well as other factors that help to justify the business case for making the decision.

The value proposition is often summarized in an executive summary of one or two pages that creates a compelling case to be used during negotiations. A pro forma that projects anticipated revenues for specific services over a specified timeline is a helpful addition to the executive summary.

## Monitoring the Return on Investment (ROI)

A physician practice that is contemplating paying for the services of a pharmacist may be interested in the ROI, which is the ratio of the gains (revenue and other benefits) to the total costs of the collaborative services. An ROI greater than 1 indicates that the investment is beneficial, and the higher the ROI above 1, the better the investment.

$ROI = \text{Gains (revenues and other benefits)} / \text{Costs}$

Costs may include payment to the pharmacist, the physical space used by the pharmacist, health

information technology, and staff to support the pharmacist. Gains, which can be more difficult to quantify, can include direct revenues from pharmacists' services, cost savings to the practice, and indirect benefits such as physician efficiencies, patient and physician satisfaction, and meeting quality metrics. Published studies, previously collected data, and case studies can be used to help estimate these components to provide the overall "gains" in the ROI calculation. Pharmacists can anticipate that it may take time to reach a positive ROI, and tracking mechanisms should be in place to track the ROI over time.



## Appendix B: References

1. U.S. Department of Health & Human Services. Health information privacy: business associate contracts website. <https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html>. Accessed September 1, 2016.
2. Carrier E, Dowling MK, Pham HH. Care coordination agreements: barriers, facilitators, and lessons learned. *Am J Manag Care*. 2012;18(11):e398-e404.
3. Schumock GT, Butler MG, Meek PD, et al. Evidence of the economic benefit of clinical pharmacy services: 1996-2000. *Pharmacotherapy*. 2003;23(1):113-132.
4. Academy of Managed Care Pharmacy. Practice Advisory on Collaborative Drug Therapy Management. Alexandria, VA: Academy of Managed Care Pharmacy; 2012. <http://www.amcp.org/workarea/downloadasset.aspx?id=14710>. Accessed November 21, 2016.
5. Adams AJ, Klepser M, Klepser D. Physician-pharmacist collaborative practice agreements: a strategy to improve adherence to evidence-based guidelines. *Evidence-Based Med Public Health*. 2015;1:e923.

## Appendix C: Updating a National Provider Identifier Number

If the pharmacist will be the signatory on prescriptions that are initiated or modified under a collaborative practice agreement, it may be beneficial for him or her to obtain an updated National Provider Identifier (NPI). The updated NPI number will indicate to pharmacy benefit managers that the pharmacist has an expanded scope of practice that may include authority to write prescriptions. Although updating the NPI number will not ensure coverage of prescriptions written with that NPI number, it may increase the likelihood that the pharmacy benefit manager identifies the pharmacist as a valid prescriber. Having an NPI is also important for billing.

The instructions below outline how to update an existing NPI number. If the pharmacist is applying for an NPI for the first time, he or she should follow the instructions found on the NPI website (<https://nppes.cms.hhs.gov/NPPES/>), taking note of the instructions below to select the correct provider taxonomy.

**Step 1:** Pharmacists should log into their NPI account at <https://nppes.cms.hhs.gov/NPPES/>. Note: Because passwords expire every 60 days, the pharmacist may need to go through the “lost password” process available on this page.

**Step 2:** Select view/modify NPI data.

**Step 3:** *Most important step.* Update taxonomy. The pharmacist can add multiple taxonomies and should choose the taxonomy code for the primary taxonomy that most appropriately fits his or her position. Pharmacists in the community setting who are participating in medication initiation and/or modification should consider the pharmacist clinician (PhC)/clinical pharmacy specialist as their primary taxonomy. Note: More information about the provider taxonomies is available at <http://www.wpc-edi.com/reference/>.

**Step 4:** Update other information (e.g., password, profile, mailing address, practice location).

**Step 5:** Complete the certification statement.

**Step 6:** Submit and log off.





# MHID

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METZ, HUSBAND & DAUGHTON, PA

DOUGLAS S. BELL  
JAMES R. DAUGHTON, JR.  
PATRICIA B. GREENE\*  
WARREN H. HUSBAND  
ALLISON LIBY-SCHOONOVER\*  
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STEPHEN W. METZ\*\*  
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---

*\*Governmental Consultant-  
Not a Member of the Florida Bar  
\*\*Of Counsel*

REPLY TO:

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August 3, 2020

## VIA ELECTRONIC MAIL

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Executive Director  
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[Jessica.Sapp@flhealth.gov](mailto:Jessica.Sapp@flhealth.gov)

Re: Formal Workshop Request

Dear Mr. Flynn and Ms. Sapp:

On behalf of the Florida Psychiatric Society (FPS), we appreciate the opportunity to participate in the Board of Pharmacy Rules Committee's upcoming meeting on August 24, 2020 regarding the implementation of HB 389.

It is our understanding that the Rules Committee intends to present revised wording to the proposed rules relating to HB 389 including but not limited to # **64316-31007 Collaborative Practice Certification: Chronic Health Conditions** for the purpose of adding "mental illness" to the proposed implementing rules.

FPS respectfully requests a Formal Workshop be held on this issue pursuant to 120.54 (2)(c), F.S.

Thank you for your consideration of our request.

Sincerely,  
Metz, Husband & Daughton

A handwritten signature in blue ink that reads "James R. Daughton, Jr." in a cursive style.

James R. Daughton, Jr.

# Buchanan Ingersoll & Rooney PC

KNOW GREATER PARTNERSHIP

Mallory L. Harrell  
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July 31, 2020

## VIA ELECTRONIC MAIL

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[Jessica.Sapp@flhealth.gov](mailto:Jessica.Sapp@flhealth.gov)

Re: Formal Workshop Request for HB 389 Rules

Dear David and Jessica:

On behalf of the Florida Chapter, American College of Cardiology, we appreciate the opportunity to participate in the Board of Pharmacy Rules Committee's upcoming meeting on August 24, 2020 regarding the implementation of HB 389.

It is our understanding from our recent phone discussion with Jessica Sapp that the Rules Committee intends to present revised wording to the proposed rules relating to HB 389 including but not limited to # 64316-31007 Collaborative Practice Certification: Chronic Health Conditions for the purpose of adding "heart disease" or certain cardiac conditions to the proposed implementing rules.

As an interested and substantially affected party pursuant to Florida Statutes Section 120.54 (2)(c), the Florida Chapter, American College of Cardiology, respectfully requests a Formal Workshop be held on this issue to thoroughly discuss the specifics of adding heart disease or other cardiac terminology to the list of conditions in the proposed rule. Based on our understanding of what is being proposed, we believe that the term is vague, overly broad on its face and enlarges, modifies or contravenes the intent of the Legislature when it adopted language

David Flynn and Jessica Sapp  
Florida Board of Pharmacy  
July 31, 2020  
Page 2

specifically deleting “heart disease” from HB 389. As such, the proposed addition of heart disease and other cardiac conditions would be an invalid exercise of delegated authority. We also would request that the Workshop address the extent of the consultations undertaken by the Board or its Rules Committee with the Board of Medicine and the Board of Osteopathic Medicine with respect to the addition of heart disease or other cardiac conditions.

We welcome the opportunity to discuss this issue with the Rules Committee to present information, answer questions and address all unintended consequences of such a proposal given that cardiology is such a specific and complex area of critical patient care.

Thank you for your consideration of our request.

Sincerely,  
BUCHANAN INGERSOLL & ROONEY PC



Mallory L. Harrell

## Zeh, Traci

---

**From:** Sapp, Jessica  
**Sent:** Tuesday, August 4, 2020 8:54 AM  
**To:** 'Jim Daughton'  
**Cc:** 'David Flynn'; Aimee Diaz Lyon; Kendra Adams; Zeh, Traci  
**Subject:** RE: Workshop Request

Good morning Mr. Daughton,

This is to let you know that the rules workshop on proposed rule 64B16-31.007, F.A.C., is scheduled for Monday, August 24, 2020 at 1:00 p.m. by teleconference:

Conference number: 1-888-585-9008

Conference Code: 599-196-982

Please let me know if you have any questions.

Regards,

**Jessica Sapp**

**Executive Director**

Department of Health | Division of Medical Quality Assurance

Bureau of Health Care Practitioner Regulation

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[www.FloridasPharmacy.gov](http://www.FloridasPharmacy.gov)



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---

**From:** Jim Daughton <Jim.Daughton@MHDFirm.com>  
**Sent:** Monday, August 3, 2020 4:44 PM  
**To:** david.flynn@myfloridalegal.com; Sapp, Jessica <Jessica.Sapp@flhealth.gov>

**Cc:** Aimee Diaz Lyon <ADL@mhdfirm.com>; Kendra Adams <kendra@floridapsych.org>

**Subject:** Workshop Request

Good afternoon—on behalf of the Florida Psychiatric Society, attached is a request for a workshop regarding implementation of HB 389. Please feel free to contact me if you have any questions.

Sincerely,

Jim Daughton



**James R. Daughton, Jr.**  
119 S. Monroe Street | Suite 200  
Tallahassee, FL 32301  
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## Zeh, Traci

---

**From:** Sapp, Jessica  
**Sent:** Tuesday, August 4, 2020 8:52 AM  
**To:** 'Harrell, Mallory L.'  
**Cc:** 'David Flynn'; 'marnie.george@bipc.com'; Zeh, Traci  
**Subject:** RE: Board of Pharmacy HB 389 Proposed Rules - Workshop Request

Good morning Ms. Harrell,

This is to let you know that the rules workshop on proposed rule 64B16-31.007, F.A.C., is scheduled for Monday, August 24, 2020 at 1:00 p.m. by teleconference:

Conference number: 1-888-585-9008

Conference Code: 599-196-982

Please let me know if you have any questions.

Regards,

**Jessica Sapp**

**Executive Director**

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---

**From:** Harrell, Mallory L. <mallory.harrell@bipc.com>  
**Sent:** Friday, July 31, 2020 5:00 PM  
**To:** david.flynn@myfloridalegal.com; Sapp, Jessica <Jessica.Sapp@flhealth.gov>  
**Cc:** George, Marnie <marnie.george@bipc.com>  
**Subject:** Board of Pharmacy HB 389 Proposed Rules - Workshop Request

Good Afternoon,

On behalf of the Florida Chapter, American College of Cardiology, I appreciate the opportunity to submit the attached letter requesting a Formal Workshop related to the proposed rules of HB 389.

If you need this request in another format other than electronic mail, please let us know and we will be happy to provide.

I appreciate your assistance with this request and look forward to working with you both. I can be reached on my cell (850)321-7492.

Thank you,  
Mallory Harrell

**Mallory Harrell**  
**Senior Attorney**

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**Buchanan Ingersoll & Rooney PC**

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*Unifying and strengthening the voice of pharmacy  
while advancing pharmacy practice through  
education, advocacy collaboration, and relationships*

July 26, 2020

Florida Board of Pharmacy  
Attention: Jessica Sapp, Executive Director  
4052 Bald Cypress Way, Bin C-04  
Tallahassee, Florida 32399

**Re: Draft Rules Implementing HB389 and FPA Provided Comments**

Dear Ms. Sapp:

This correspondence is provided on behalf of the Florida Pharmacy Association, Inc. (FPA), a not-for-profit corporation which seeks to preserve and advance the practice of pharmacy and serves the professional needs of all pharmacists, pharmacy students, and pharmacy technicians in Florida. The FPA is committed to improving public health and patient care, enhancing professional development, and advocating for the interests of the profession. The purpose of this letter to provide the Board of Pharmacy with comments relating to the Board's most recent draft rules implementing HB 389.

The Board's most recent draft rules implementing HB 389 include several revisions to the prior version. We will focus our comments on two of the revisions. First, the Board has removed the chronic health condition "catch-all" from proposed rule 64B16-31.007 Collaborative Practice Certification: Chronic Health Conditions. This may have been done, in part, in response to concerns raised by the Florida Medical Association, the Florida Osteopathic Medical Association, and the Florida Society of Rheumatology. Each of these associations suggests that the Board may not have sufficient rulemaking authority to include a catch-all in the chronic health conditions rule.

We disagree. HB 389 specifically provides that the Board has the authority to include any other chronic condition adopted in rule. HB 389 does not limit the number or type of chronic conditions that the Board may include in the rule. Thus, the Board has the authority to include any and all chronic conditions, if it so chooses. Additionally, the Board's catch-all language nearly mirrors CDC's definition of chronic disease. Any suggestion that the language is arbitrary or capricious is without merit.

Pharmacists and supervising physicians should have the discretion and flexibility to determine which chronic conditions are best suited for collaborative pharmacy practice agreements based on the unique circumstances of their practice and expertise. The removal of the catch-all limits this discretion and significantly restricts the use of collaborative pharmacy practice agreements in Florida. We feel that this is contrary to the legislative intent behind HB 389 of increasing access to healthcare. With that said, we recognize the importance of expediting the adoption of rules relating to collaborative pharmacy practice agreements so that pharmacists and supervising physician can begin utilizing the agreements as soon as possible. However, as noted above, we believe the Board has the necessary authority for the catch-all and ask that the Board consider adding the language back to the rule.

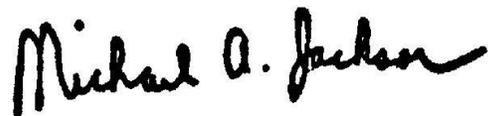
Second, the Board has included a requirement in proposed rule 64B16-31.003 Collaborative Practice Certification: Initial Certification Course and proposed rule 64B16-31.035 Test and Treat Certification: Initial Certification Course that each course must be developed in conjunction with a licensed pharmacist and a licensed physician. We are concerned that this requirement will unnecessarily delay the process of developing a certification course. It has been our experience that requiring a pharmacy course to be developed in conjunction with another profession will inevitably lead to a long, drawn out development process. For example, section 465.1893's 8-hour continuing education course to administer long-acting antipsychotic medications by injection is required to be developed by a statewide association of physicians and a statewide association of pharmacists. It took years for the course to be developed, thus delaying the implementation of the law. We are concerned that the requirement in the certification course rules could have a similar effect. In light of the current strain on the healthcare system, it is imperative that pharmacists and physicians have the ability to enter into collaborative pharmacy practice agreements and written protocols as soon as possible and any unnecessary requirements that could delay this should be avoided.

Additionally, it is not necessary for the certification course rules to require that the courses be developed in conjunction with other licensed practitioners. The rules already require that only certain accredited providers of continuing education may provide the certification courses. This

ensures the courses will only be offered by providers that have been approved by national accrediting organizations as meeting strict continuing education standards. With this requirement in place, there should be no concern that the course providers will not offer high quality content. It should also be noted that nothing in HB 389 requires that the certification courses must be developed in conjunction with licensed physicians. For these reasons, we ask that the Board remove the requirement that the certification courses must be developed in conjunction with licensed pharmacists and licensed physicians.

Thank you for the opportunity to submit these comments and we look forward to continuing to work with the Board on the development of these important rules.

With kindest regards,

A handwritten signature in black ink that reads "Michael A. Jackson". The signature is written in a cursive, flowing style.

Michael A. Jackson, BPharm, CPh  
Executive Vice President and CEO



AMERICAN ACADEMY of  
DERMATOLOGY | ASSOCIATION



July 27, 2020

Jeffrey J. Mesaros, PharmD, J.D.  
Florida Board of Pharmacy, Rules Committee  
3052 Bald Cypress Way  
Tallahassee, FL 32311

**Re: Implementation of HB 389**

Dear Members of the Rules Committee,

On behalf of the undersigned organizations representing approximately 14,000 U.S.-based members of the American Academy of Dermatology Association (“Academy”) and American Society for Dermatologic Surgery Association, we urge the Florida Board of Pharmacy (“Board”) to prohibit pharmacists from managing chronic skin conditions pursuant to a collaborative pharmacy practice agreement (CPPA). Skin disease is a leading cause of global disease burden, affecting millions of people worldwide.<sup>1</sup> Skin disease is a significant and serious public health consideration for the U.S. population. According to the 2016 Burden of Skin Disease report, skin disease resulted in direct health care costs of \$75 billion, and indirect lost opportunity costs of \$11 billion in a single year.<sup>2</sup> In addition to the economic consequences, misdiagnosing a skin condition can result in serious complications. As such, the accurate and efficient diagnosis and treatment of skin diseases require the medical education and training of a board-certified dermatologist.

We urge the Board to carefully consider the ramifications of HB 389, which authorizes a pharmacist to enter into a collaborative pharmacy practice agreement (CPPA) with a physician to manage chronic health conditions. There are enormous differences between pharmacy and medical education, as outlined below. Pharmacists will inevitably misdiagnose chronic skin diseases, resulting in significant patient safety threats and increased costs to the health care system. While there are numerous examples, we have highlighted four chronic skin conditions requiring a board-certified dermatologist to accurately differentiate numerous skin diseases.

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<sup>1</sup> Hay R.J Johns N.E. Williams H.C. et al. The global burden of skin disease in 2010: an analysis of the prevalence and impact of skin conditions. *J Invest Dermatol.* 2014; **134**: 1527-1534

<sup>2</sup> Lim Henry W, et al. The burden of skin disease in the United States. *J American Academy of Dermatol.* 2017; Vol 76; Issue 5: 958-972

## **Pharmacists lack the clinical training and experience to diagnose and treat chronic skin conditions.**

Board-certified dermatologists diagnose and treat over 3,000 different diseases and conditions. Our members see patients of all ages, from newborns to the elderly. Board-certified dermatologists undertake a minimum of 8 years of exhaustive medical education and training (4 years of medical school, 1 year of internship, 3 years (minimum) of dermatology residency), during which they complete 12,000 to 16,000 hours of direct patient care, before they can practice independently.

In stark contrast, pharmacists attend four years of pharmacy school, which includes 1,700 hours of practice experience. Pharmacists are trained to function as the medication expert within a collaborative health care team. Pharmacy school does not prepare pharmacists to develop the clinical judgment to diagnose or develop a treatment plan. A physician's medical education includes a comprehensive understanding of multiple organ systems, which allows them to order and interpret tests within the context of a patient's overall health condition.

By any measure, the differences in training are significant. Given the wide array of challenges and complexity that confronts health care practitioners, particularly during a public health emergency, board-certified dermatologists' additional training and expertise allows them to accurately and efficiently diagnose and treat chronic skin conditions.

## **Chronic skin conditions should be treated by a board-certified dermatologist due to its complexity and likelihood of misdiagnosis.**

### **1. Common skin cancers are hard to diagnose and may resemble harmless skin conditions**

Certain skin cancers may masquerade as warts. Warts are common benign skin growths that appear when the human papillomavirus infects the top layer of the skin. Pharmacists and other individuals who lack extensive knowledge and expertise in cutaneous medicine, surgery, and pathology, may easily mistakenly diagnose various forms of skin cancer as warts. Squamous cell carcinoma (SCC) is a common type of potentially serious skin cancer. SCC of the skin can appear on the skin very similar to a harmless wart. The majority of SCCs can be successfully treated when diagnosed early; however, if SCCs grow into deeper layers of the skin and spread to other areas of the body, it can be life-threatening.

Dry patches of irritated skin or eczema can resemble basal cell carcinoma (BCC), the most common type of skin cancer. An untreated BCC can grow deep into the skin and destroy areas of the body such as the nose and the ear. The cancer cells can develop into large tumors and possibly reach the bone. This can require extensive surgery which, for some people, it may be disfiguring.

Malignant melanoma of the foot can be misdiagnosed as a wart. Melanoma is the deadliest form of skin cancer. While it is highly treatable when detected early, advanced melanoma can spread to the lymph nodes and internal organs, and can be fatal. The average five-year survival rate for individuals whose melanoma is detected and treated before it spreads to the lymph nodes is 98 percent. The five-year survival rates after regional (lymph nodes) and distant (other organs/lymph nodes) spread are 64 percent and 23 percent, respectively.<sup>3 4 5</sup>

## **2. Hidradentitis Suppurative (HS)**

Hidradentitis Suppurativa (HS), a chronic systemic inflammatory disease, usually develops around hair follicles. An overactive immune system contributes to inflammation below the skin. HS may be mistaken for a bacteria infection, ingrown hairs or pimples. Painful bumps or large abscesses in the armpit, groin and genital areas may develop. Because HS may worsen over time, it is critical that the patient and board-certified dermatologist closely monitor any changing symptoms. Additionally, HS may have multiple comorbidities, including diabetes, anxiety and depression, inflammatory bowel diseases, inflammatory arthritis, acne conglobate, and polycystic ovarian syndrome. HS has no cure, and its treatment can involve many treatments and surgeries, and a myriad of medications. The skin manifestations do not provide the full picture, and pharmacy education and training do not provide the knowledge required to diagnose and treat HS. The potential risks of a misdiagnosis can be life-threatening and should not be ignored.

## **3. Mycosis Fungoides**

Mycosis Fungoides (MF) is a cutaneous lymphoma, and if not treated appropriately during the early stages, this malignancy has the potential to progress and result in death. MF can be easily misdiagnosed as dry irritated skin patches known as eczema. At a minimum, a medical education is necessary to obtain the appropriate clinical history to differentiate MF from eczema and recognize the features that distinguish it from eczema. Prompt recognition, the ability to perform a biopsy of the skin and access to a board certified dermatopathologist is essential.

Once diagnosed, a board-certified dermatologist stages the disease and develops a comprehensive treatment plan, which requires interpreting clinical, lab and imaging data. A board-certified dermatologist must also understand potential side effects of the various choices of therapy, including topical creams, and oral and radiation therapy.

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<sup>3</sup> American Cancer Society. Cancer Facts & Figures 2019. Atlanta: American Cancer Society; 2019.

<sup>4</sup> Siegel RL, Miller KD, Jemal A. Cancer statistics, 2019. CA Cancer J Clin. 2019; doi: 10.3322/caac.21551.

<sup>5</sup> Noone AM, Howlader N, Krapcho M, Miller D, Brest A, Yu M, Ruhl J, Tatalovich Z, Mariotto A, Lewis DR, Chen HS, Feuer EJ, Cronin KA (eds). SEER Cancer Statistics Review, 1975-2015, National Cancer Institute. Bethesda, MD, [https://seer.cancer.gov/csr/1975\\_2015/](https://seer.cancer.gov/csr/1975_2015/), based on November 2017 SEER data submission, posted to the SEER web site, April 2018.

Understanding and managing potential side effects of these drugs will lead to safer and improved patient outcome.

#### **4. Psoriasis**

Psoriasis is a chronic, inflammatory, multisystem disease that affects approximately 7.5 million people in the United States.<sup>6</sup> It is a condition that causes the body to make new skin cells in days rather than weeks. A person's immune system and genes play a role in causing psoriasis. Psoriasis cannot be cured and is often a life-long disease. There are different types of psoriasis, and a patient may have more than one type concurrently.

Because the immune system is overactive and can cause inflammation elsewhere in the body, psoriasis is associated with multiple comorbidities. Some inflammation is visible (skin and joints), but it may also impact other organs and tissues in the body. The comorbidities that can accompany psoriasis include psoriatic arthritis, cardiovascular problems, obesity, high blood pressure, and diabetes. Psoriatic arthritis is the most common comorbidity, which affects approximately 1 in 3 psoriasis patients.<sup>7</sup>

Like other chronic skin condition, psoriasis can be difficult to diagnose because it looks like other skin diseases. A study conducted in Australia found that most children who had psoriasis were initially diagnosed by their primary care doctor as having another disease, often eczema.<sup>8</sup> An accurate diagnosis has likely considered multiple factors, including the skin's appearance, location on skin, itchiness, and a skin biopsy. Psoriasis may look different on skin of color, so it is important to know the signs of psoriasis to prevent misdiagnosis.<sup>9</sup>

Once diagnosed, a board-certified dermatologist develops a treatment plan that enables patients to manage psoriasis and avoid triggers. Due to recent advances in psoriasis treatment, there are a number of options (topicals, traditional systemics/oral, phototherapy, biologics, biosimilars). A board-certified dermatologist knows which treatments can be safely combined and when a treatment is unacceptable for a patient. Some cases of psoriasis are so severe that patients do not respond to an FDA-approved psoriasis medicine. For those patients, board-certified dermatologists may prescribe off-label medicines.<sup>10</sup> The physician must know the patient's complete medical history to effectively evaluate the risks and benefits of the medicine.

Our organizations appreciate the opportunity to provide written comments on this important public health issue. It is a common goal of both physicians and pharmacists to

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<sup>6</sup> Menter A, Gottlieb A, Feldman SR, Van Voorhees AS et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol* 2008 May;58(5):826-50.

<sup>7</sup> [https://www.psoriasis.org/sites/default/files/comorbidities\\_fact\\_sheet\\_3.pdf](https://www.psoriasis.org/sites/default/files/comorbidities_fact_sheet_3.pdf)

<sup>8</sup> <https://www.aad.org/public/diseases/eczema/childhood/child-have/difference-psoriasis>

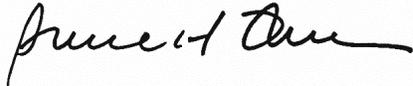
<sup>9</sup> [https://www.psoriasis.org/sites/default/files/diagnosing\\_psoriasis\\_fact\\_sheet\\_1.pdf](https://www.psoriasis.org/sites/default/files/diagnosing_psoriasis_fact_sheet_1.pdf)

<sup>10</sup> <https://www.aad.org/public/diseases/psoriasis/treatment/medications/off-label>

ensure that patients receive the highest quality care. Pharmacists play an instrumental role in the delivery of health care, but their education does not prepare pharmacists to treat chronic skin conditions. As discussed above, dermatologists receive many years of advanced training in correctly identifying conditions that affect the hair, skin, and nails. Correctly identifying the condition is crucial to determining the proper treatment.

Lastly, the physician-patient relationship differs from the relationship patients have with pharmacists. A pharmacist does not have access to the patient history or to provide a thorough evaluation of the patient, followed by the necessary patient monitoring. For the reasons stated above, we urge members of the Board to prohibit pharmacists from managing chronic skin conditions pursuant to a collaborative pharmacy practice agreement. For further information, please contact Lisa Albany, director of state policy, at [lalbany@aad.org](mailto:lalbany@aad.org) or 202.712.2605.

Sincerely,

A handwritten signature in black ink, appearing to read "Bruce H. Thiers".

Bruce H. Thiers MD, FAAD  
President  
American Academy of Dermatology Association

A handwritten signature in black ink, appearing to read "Marc D. Brown".

Marc D. Brown, MD  
President  
American Society for Dermatologic Surgery Association

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2020 Legislature

1  
2 An act relating to the practice of pharmacy; amending  
3 s. 381.0031, F.S.; requiring specified licensed  
4 pharmacists to report certain information relating to  
5 public health to the Department of Health; amending s.  
6 465.003, F.S.; revising the definition of the term  
7 "practice of the profession of pharmacy"; creating s.  
8 465.1865, F.S.; providing definitions; providing  
9 requirements for pharmacists to provide services under  
10 a collaborative pharmacy practice agreement; requiring  
11 the terms and conditions of such agreement to be  
12 appropriate to the training of the pharmacist and the  
13 scope of practice of the physician; requiring  
14 notification to the board upon practicing under a  
15 collaborative pharmacy practice agreement; requiring  
16 pharmacists to submit a copy of the signed  
17 collaborative pharmacy practice agreement to the Board  
18 of Pharmacy; providing for the maintenance of patient  
19 records for a certain period of time; providing for  
20 renewal of such agreement; requiring a pharmacist and  
21 the collaborating physician to maintain on file and  
22 make available the collaborative pharmacy practice  
23 agreement; prohibiting certain actions relating to  
24 such agreement; requiring specified continuing  
25 education for a pharmacist who practices under a

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26 | collaborative pharmacy practice agreement; requiring  
27 | the Board of Pharmacy to adopt rules in consultation  
28 | with the Board of Medicine and the Board of  
29 | Osteopathic Medicine; creating s. 465.1895, F.S.;  
30 | requiring the Board of Pharmacy to identify minor,  
31 | nonchronic health conditions that a pharmacist may  
32 | test or screen for and treat; providing requirements  
33 | for a pharmacist to test or screen for and treat  
34 | minor, nonchronic health conditions; requiring the  
35 | board to develop a formulary of medicinal drugs that a  
36 | pharmacist may prescribe; providing requirements for  
37 | the written protocol between a pharmacist and a  
38 | supervising physician; prohibiting a pharmacist from  
39 | providing certain services under certain  
40 | circumstances; requiring a pharmacist to complete a  
41 | specified amount of continuing education; providing  
42 | additional requirements for pharmacists and pharmacies  
43 | providing testing and screening services; providing  
44 | for applicability; providing an effective date.

45 |  
46 | Be It Enacted by the Legislature of the State of Florida:

47 |  
48 | Section 1. Subsection (2) of section 381.0031, Florida  
49 | Statutes, is amended to read:

50 | 381.0031 Epidemiological research; report of diseases of

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51 | public health significance to department.—

52 |       (2) Any practitioner licensed in this state to practice  
53 | medicine, osteopathic medicine, chiropractic medicine,  
54 | naturopathy, or veterinary medicine; any licensed pharmacist  
55 | authorized under a protocol with a supervising physician under  
56 | s. 465.1895, or a collaborative pharmacy practice agreement, as  
57 | defined in s. 465.1865, to perform or order and evaluate  
58 | laboratory and clinical tests; any hospital licensed under part  
59 | I of chapter 395; or any laboratory appropriately certified by  
60 | the Centers for Medicare and Medicaid Services under the federal  
61 | Clinical Laboratory Improvement Amendments and the federal rules  
62 | adopted thereunder which diagnoses or suspects the existence of  
63 | a disease of public health significance shall immediately report  
64 | the fact to the Department of Health.

65 |       Section 2. Subsection (13) of section 465.003, Florida  
66 | Statutes, is amended to read:

67 |       465.003 Definitions.—As used in this chapter, the term:

68 |       (13) "Practice of the profession of pharmacy" includes  
69 | compounding, dispensing, and consulting concerning contents,  
70 | therapeutic values, and uses of any medicinal drug; consulting  
71 | concerning therapeutic values and interactions of patent or  
72 | proprietary preparations, whether pursuant to prescriptions or  
73 | in the absence and entirely independent of such prescriptions or  
74 | orders; and conducting other pharmaceutical services. For  
75 | purposes of this subsection, "other pharmaceutical services"

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76 | means the monitoring of the patient's drug therapy and assisting  
77 | the patient in the management of his or her drug therapy, and  
78 | includes review of the patient's drug therapy and communication  
79 | with the patient's prescribing health care provider as licensed  
80 | under chapter 458, chapter 459, chapter 461, or chapter 466, or  
81 | similar statutory provision in another jurisdiction, or such  
82 | provider's agent or such other persons as specifically  
83 | authorized by the patient, regarding the drug therapy; and  
84 | initiating, modifying, or discontinuing drug therapy for a  
85 | chronic health condition under a collaborative pharmacy practice  
86 | agreement. ~~However,~~ Nothing in this subsection may be  
87 | interpreted to permit an alteration of a prescriber's  
88 | directions, the diagnosis or treatment of any disease, the  
89 | initiation of any drug therapy, the practice of medicine, or the  
90 | practice of osteopathic medicine, unless otherwise permitted by  
91 | law or specifically authorized by s. 465.1865 or s. 465.1895.  
92 | "Practice of the profession of pharmacy" also includes any other  
93 | act, service, operation, research, or transaction incidental to,  
94 | or forming a part of, any of the foregoing acts, requiring,  
95 | involving, or employing the science or art of any branch of the  
96 | pharmaceutical profession, study, or training, and shall  
97 | expressly permit a pharmacist to transmit information from  
98 | persons authorized to prescribe medicinal drugs to their  
99 | patients. The practice of the profession of pharmacy also  
100 | includes the administration of vaccines to adults pursuant to s.

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101 465.189, the testing or screening for and treatment of minor,  
 102 nonchronic health conditions pursuant to s. 465.1895, and the  
 103 preparation of prepackaged drug products in facilities holding  
 104 Class III institutional pharmacy permits.

105 Section 3. Section 465.1865, Florida Statutes, is created  
 106 to read:

107 465.1865 Collaborative pharmacy practice for chronic  
 108 health conditions.-

109 (1) For purposes of this section, the term:

110 (a) "Collaborative pharmacy practice agreement" means a  
 111 written agreement between a pharmacist who meets the  
 112 qualifications of this section and a physician licensed under  
 113 chapter 458 or chapter 459 in which a collaborating physician  
 114 authorizes a pharmacist to provide specified patient care  
 115 services to the collaborating physician's patients.

116 (b) "Chronic health condition" means:

117 1. Arthritis;

118 2. Asthma;

119 3. Chronic obstructive pulmonary diseases;

120 4. Type 2 diabetes;

121 5. Human immunodeficiency virus or acquired immune  
 122 deficiency syndrome;

123 6. Obesity; or

124 7. Any other chronic condition adopted in rule by the  
 125 board, in consultation with the Board of Medicine and Board of

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126 Osteopathic Medicine.

127 (2) To provide services under a collaborative pharmacy  
 128 practice agreement, a pharmacist must be certified by the board,  
 129 according to the rules adopted by the board in consultation with  
 130 the Board of Medicine and the Board of Osteopathic Medicine. To  
 131 be certified, a pharmacist must, at a minimum:

132 (a) Hold an active and unencumbered license to practice  
 133 pharmacy in this state.

134 (b) Have earned a degree of doctor of pharmacy or have  
 135 completed 5 years of experience as a licensed pharmacist.

136 (c) Have completed an initial 20-hour course approved by  
 137 the board, in consultation with the Board of Medicine and Board  
 138 of Osteopathic Medicine, that includes, at a minimum,  
 139 instruction on the following:

140 1. Performance of patient assessments.

141 2. Ordering, performing, and interpreting clinical and  
 142 laboratory tests related to collaborative pharmacy practice.

143 3. Evaluating and managing diseases and health conditions  
 144 in collaboration with other health care practitioners.

145 4. Any other area required by board.

146 (d) Maintain at least \$250,000 of professional liability  
 147 insurance coverage. However, a pharmacist who maintains  
 148 professional liability insurance coverage pursuant to s.  
 149 465.1895 satisfies this requirement.

150 (e) Have established a system to maintain records of all

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151 patients receiving services under a collaborative pharmacy  
152 practice agreement for a period of 5 years from each patient's  
153 most recent provision of service.

154 (3) The terms and conditions of the collaborative pharmacy  
155 practice agreement must be appropriate to the pharmacist's  
156 training and the services delegated to the pharmacist must be  
157 within the collaborating physician's scope of practice. A copy  
158 of the certification issued under subsection (2) must be  
159 included as an attachment to the collaborative pharmacy practice  
160 agreement.

161 (a) A collaborative pharmacy practice agreement must  
162 include the following:

163 1. Name of the collaborating physician's patient or  
164 patients for whom a pharmacist may provide services.

165 2. Each chronic health condition to be collaboratively  
166 managed.

167 3. Specific medicinal drug or drugs to be managed by the  
168 pharmacist for each patient.

169 4. Circumstances under which the pharmacist may order or  
170 perform and evaluate laboratory or clinical tests.

171 5. Conditions and events upon which the pharmacist must  
172 notify the collaborating physician and the manner and timeframe  
173 in which such notification must occur.

174 6. Beginning and ending dates for the collaborative  
175 pharmacy practice agreement and termination procedures,

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176 | including procedures for patient notification and medical  
177 | records transfers.

178 | 7. A statement that the collaborative pharmacy practice  
179 | agreement may be terminated, in writing, by either party at any  
180 | time.

181 | (b) A collaborative pharmacy practice agreement shall  
182 | automatically terminate 2 years after execution if not renewed.

183 | (c) The pharmacist, along with the collaborating  
184 | physician, must maintain on file the collaborative pharmacy  
185 | practice agreement at his or her practice location, and must  
186 | make such agreements available to the department or board upon  
187 | request or inspection.

188 | (d) A pharmacist who enters into a collaborative pharmacy  
189 | practice agreement must submit a copy of the signed agreement to  
190 | the board before the agreement may be implemented.

191 | (4) A pharmacist may not:

192 | (a) Modify or discontinue medicinal drugs prescribed by a  
193 | health care practitioner with whom he or she does not have a  
194 | collaborative pharmacy practice agreement.

195 | (b) Enter into a collaborative pharmacy practice agreement  
196 | while acting as an employee without the written approval of the  
197 | owner of the pharmacy.

198 | (5) A physician may not delegate the authority to initiate  
199 | or prescribe a controlled substance as described in s. 893.03 or  
200 | 21 U.S.C. s. 812 to a pharmacist.

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201           (6) A pharmacist who practices under a collaborative  
 202 pharmacy practice agreement must complete an 8-hour continuing  
 203 education course approved by the board that addresses issues  
 204 related to collaborative pharmacy practice each biennial  
 205 licensure renewal in addition to the continuing education  
 206 requirements under s. 465.009. A pharmacist must submit  
 207 confirmation of having completed such course when applying for  
 208 licensure renewal. A pharmacist who fails to comply with this  
 209 subsection shall be prohibited from practicing under a  
 210 collaborative pharmacy practice agreement under this section.

211           (7) The board, in consultation with the Board of Medicine  
 212 and the Board of Osteopathic Medicine, shall adopt rules  
 213 pursuant to ss. 120.536(1) and 120.54 to implement this section.

214           Section 4. Section 465.1895, Florida Statutes, is created  
 215 to read:

216           465.1895 Testing or screening for and treatment of minor,  
 217 nonchronic health conditions.—

218           (1) A pharmacist may test or screen for and treat minor,  
 219 nonchronic health conditions within the framework of an  
 220 established written protocol with a supervising physician  
 221 licensed under chapter 458 or chapter 459. For purposes of this  
 222 section, a minor, nonchronic health condition is typically a  
 223 short-term condition that is generally managed with minimal  
 224 treatment or self-care, and includes:

225           (a) Influenza.

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226        (b) Streptococcus.  
 227        (c) Lice.  
 228        (d) Skin conditions, such as ringworm and athlete's foot.  
 229        (e) Minor, uncomplicated infections.  
 230        (2) A pharmacist who tests or screens for and treats  
 231 minor, nonchronic health conditions under this section must:  
 232        (a) Hold an active and unencumbered license to practice  
 233 pharmacy in the state.  
 234        (b) Hold a certification issued by the board to test and  
 235 screen for and treat minor, nonchronic health conditions, in  
 236 accordance with requirements established by the board in rule in  
 237 consultation with the Board of Medicine and Board of Osteopathic  
 238 Medicine. The certification must require a pharmacist to  
 239 complete, on a one-time basis, a 20-hour education course  
 240 approved by the board in consultation with the Board of Medicine  
 241 and the Board of Osteopathic Medicine. The course, at a minimum,  
 242 must address patient assessments; point-of-care testing  
 243 procedures; safe and effective treatment of minor, nonchronic  
 244 health conditions; and identification of contraindications.  
 245        (c) Maintain at least \$250,000 of liability coverage. A  
 246 pharmacist who maintains liability coverage pursuant to s.  
 247 465.1865 satisfies this requirement.  
 248        (d) Report a diagnosis or suspected existence of a disease  
 249 of public health significance to the department pursuant to s.  
 250 381.0031.

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251 (e) Upon request of a patient, furnish patient records to  
 252 a health care practitioner designated by the patient.

253 (f) Maintain records of all patients receiving services  
 254 under this section for a period of 5 years from each patient's  
 255 most recent provision of service.

256 (3) The board shall adopt, by rule, a formulary of  
 257 medicinal drugs that a pharmacist may prescribe for the minor,  
 258 nonchronic health conditions approved under subsection (1). The  
 259 formulary must include medicinal drugs approved by the United  
 260 States Food and Drug Administration which are indicated for  
 261 treatment of the minor, nonchronic health condition. The  
 262 formulary may not include any controlled substance as described  
 263 in s. 893.03 or 21 U.S.C. s. 812.

264 (4) A pharmacist who tests or screens for and treats  
 265 minor, nonchronic health conditions under this section may use  
 266 any tests that may guide diagnosis or clinical decisionmaking  
 267 which the Centers for Medicare and Medicaid Services has  
 268 determined qualifies for a waiver under the federal Clinical  
 269 Laboratory Improvement Amendments of 1988, or the federal rules  
 270 adopted thereunder, or any established screening procedures that  
 271 can safely be performed by a pharmacist.

272 (5) The written protocol between a pharmacist and  
 273 supervising physician under this subsection must include  
 274 particular terms and conditions imposed by the supervising  
 275 physician relating to the testing and screening for and

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276 treatment of minor, nonchronic health conditions under this  
277 section. The terms and conditions must be appropriate to the  
278 pharmacist's training. A pharmacist who enters into such a  
279 protocol with a supervising physician must submit the protocol  
280 to the board.

281 (a) At a minimum, the protocol shall include:

282 1. Specific categories of patients who the pharmacist is  
283 authorized to test or screen for and treat minor, nonchronic  
284 health conditions.

285 2. The physician's instructions for obtaining relevant  
286 patient medical history for the purpose of identifying  
287 disqualifying health conditions, adverse reactions, and  
288 contraindications to the approved course of treatment.

289 3. The physician's instructions for the treatment of  
290 minor, nonchronic health conditions based on the patient's age,  
291 symptoms, and test results, including negative results.

292 4. A process and schedule for the physician to review the  
293 pharmacist's actions under the protocol.

294 5. A process and schedule for the pharmacist to notify the  
295 physician of the patient's condition, tests administered, test  
296 results, and course of treatment.

297 6. Any other requirements as established by the board in  
298 consultation with the Board of Medicine and the Board of  
299 Osteopathic Medicine.

300 (b) A pharmacist authorized to test and screen for and

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301 treat minor, nonchronic conditions under a protocol shall  
 302 provide evidence of current certification by the board to the  
 303 supervising physician. A supervising physician shall review the  
 304 pharmacist's actions in accordance with the protocol.

305 (6) A pharmacist providing services under this section may  
 306 not perform such services while acting as an employee without  
 307 the written approval of the owner of the pharmacy.

308 (7) A pharmacist providing services under this section  
 309 must complete a 3-hour continuing education course approved by  
 310 the board addressing issues related to minor, nonchronic health  
 311 conditions each biennial licensure renewal in addition to the  
 312 continuing education requirements under s. 465.009. Each  
 313 pharmacist must submit confirmation of having completed the  
 314 course when applying for licensure renewal. A pharmacist who  
 315 fails to comply with this subsection may not provide testing,  
 316 screening, or treatment services.

317 (8) A pharmacist providing services under this section  
 318 must provide a patient with written information to advise the  
 319 patient to seek followup care from his or her primary care  
 320 physician. The board, by rule, shall adopt guidelines for the  
 321 circumstances under which the information required under this  
 322 subsection shall be provided.

323 (9) The pharmacy in which a pharmacist tests and screens  
 324 for and treats minor, nonchronic health conditions must  
 325 prominently display signage indicating that any patient

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2020 Legislature

326 | receiving testing, screening, or treatment services under this  
 327 | section is advised to seek followup care from his or her primary  
 328 | care physician.

329 |       (10) A pharmacist providing services under this section  
 330 | must comply with applicable state and federal laws and  
 331 | regulations.

332 |       (11) The requirements of the section do not apply with  
 333 | respect to minor, nonchronic health conditions when treated with  
 334 | over-the-counter products.

335 |       Section 5. This act shall take effect July 1, 2020.  
 336 |

Board of Pharmacy  
Implementation Working Draft for Ch. 2020-7, Laws of Fla.<sup>1</sup> (CS HB  
No. 389<sup>2</sup>) (Eff. July 1, 2020).

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**CHAPTER 64B16-31**  
**COLLABORATIVE PRACTICE AND TEST AND TREAT CERTIFICATIONS**

64B16-31.001	Collaborative Practice Certification (CPC)
64B16-31.003	Collaborative Practice Certification: Initial Certification Course
64B16-31.005	Collaborative Practice Certification: Collaborative Pharmacy Practice Agreement Submission
64B16-31.007	Collaborative Practice Certification: Chronic Health Condition
64B16-31.009	Collaborative Practice Certification: Mandatory Continuing Education
64B16-31.033	Test and Treat Certification (TTC)
64B16-31.035	Test and Treat Certification: Initial Certification Course
64B16-31.037	Test and Treat Certification: Written Protocol and Written Protocol Submission
64B16-31.039	Test and Treat Certification: Formulary of Medicinal Drugs
64B16-31.041	Test and Treat Certification: Patient Records
64B16-31.043	Test and Treat Certification: Follow-Up Care
64B16-31.045	Test and Treat Certification: Mandatory Continuing Education
64B16-31.050	Mandatory Review of Rule Chapter 64B16-31, F.A.C.

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<sup>1</sup> Please See Appendix A for a Copy of [Chapter 2020-7, Laws of Florida](#).

<sup>2</sup> Please See Appendix B for a Copy of [Committee Substitute for House Bill No. 389](#).

**64B16-31.001 Collaborative Practice Certification (CPC).**

Applicants for CPC shall submit an application using Form DH-MQA XXXX (eff. 0X/20), “Application for Pharmacist Collaborative Practice Certification<sup>3</sup>” that is hereby incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX> or <http://floridapharmacy.gov>. Applicants for certification shall meet and comply with all requirements in Section 465.1865, F.S.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

**64B16-31.003 Collaborative Practice Certification: Initial Certification Course.**

(1) Applicants for Initial Certification Course approval shall submit an application using Form DH-MQA XXX (eff. XX/20) “Application for Initial Collaborative Practice Certification Course<sup>4</sup>” that is hereby incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX> or <http://floridapharmacy.gov>.

(2) Initial collaborative practice certification courses shall be a minimum of 20 hours in duration, and shall meet all the following mandatory requirements:

(a) The course may only be offered by a program provider who is accredited by the Accreditation Council for Pharmacy Education (ACPE), a program provider who is accredited to provide educational activities designated for the American Medical Association Physician’s Recognition Award Category 1 credit, or a program provider approved by the American Osteopathic Association to offer continuing medical education credits.

(b) The course content and objectives offered by an approved provider shall be developed in conjunction with an individual licensed to practice pharmacy and an individual who is a licensed allopathic or osteopathic physician.

(c) The course content shall include all those areas enumerated in section 465.1865 (2)(c), F.S., and shall also cover the following areas:

1. Laws and rules applicable to the collaborative practice for the treatment of chronic health care conditions; and

<sup>3</sup> Please See Appendix C for a Copy of the [Application](#).

<sup>4</sup> Please See Appendix D for a Copy of the [Application](#).

2. Writing and entering into a collaborative practice agreement.

(d) No less than 8 1/2 hours of the course shall be offered through a live seminar or a live video teleconference.

(3) A pharmacist who successfully completes a board approved collaborative practice certification course shall be awarded 20 hours of general continuing education credits.

Place holder for consultation with BOM and BOOM.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

### **64B16-31.005 Collaborative Practice Certification: Collaborative Pharmacy Practice Agreement Submission.**

(1) Prior to providing or implementing patient care services under a Collaborative Pharmacy Practice Agreement or immediately after the renewal of such an Agreement, the Pharmacist shall submit the executed Agreement to the Board Office through the pharmacist’s online licensure account at <http://www.flhealthsource.gov> or via U.S. Mail to 4052 Bald Cypress Way, Bin C-04, Tallahassee, FL 32399.

(2) In the event of an addendum to the material terms of an existing collaborative pharmacy practice agreement, the pharmacist shall maintain a copy of the addendum and the initial agreement pursuant to Section 465.1865(3)(c), F.S. Material terms shall be defined as those terms enumerated in Section 465.1865(3)(a), F.S.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

### **64B16-31.007 Collaborative Practice Certification: Chronic Health Conditions.**

Pursuant to Section 465.1865, F.S., the Board hereby adopts the following list of chronic health conditions for which a pharmacist certified pursuant to section 465.1865, F.S., can provide specified patient care services to patients of a collaborating physician pursuant to a pending Collaborative Pharmacy Practice Agreement:

- 1) Hyperlipidemia;
- 2) Hypertension;
- 3) Anti-coagulation management;
- 4) Smoking cessation;
- 5) Opioid use disorder;
- 6) Heart / Cardiovascular Disease (Cont. Discussion);

7) Behavioral Health (*Begin Discussion*); and

8) Those chronic health conditions enumerated in section 465.1865(1)(b), F.S.

Place holder for discussion with Board to determine appropriate list of chronic health conditions in consultation with BOM and BOOM.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

### **64B16-31.009 Collaborative Practice Certification: Mandatory Continuing Education.**

A licensee shall not be required to complete the 8-hour continuing education related to collaborative pharmacy practice if the initial certificate was issued less than 12 months prior to the expiration date of the license.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

### **64B16-31.033 Test and Treat Certification (TTC)**

Applicants for TTC shall submit an application using Form DH-MQA XXXX (eff. 0X/20), “Application for Pharmacist Test and Treat Certification<sup>5</sup>” that is hereby incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX> or <http://floridapharmacy.gov>. Applicants for certification shall meet and comply with all requirements in Section 465.1895, F.S.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

### **64B16-31.035 Test and Treat Certification: Initial Certification Course**

(1) Applicants for Initial Certification Course approval shall submit an application using Form DH-MQA XXX (eff. XX/20) “Application for Initial Test and Treat Certification Course<sup>6</sup>” that is hereby incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX> or <http://floridapharmacy.gov>.

<sup>5</sup> Please See Appendix E for a Copy of the [Application](#).

<sup>6</sup> Please See Appendix F for a Copy of the [Application](#).

(2) Initial test and treat certification courses shall be a minimum of 20 hours in duration, and shall meet all the following mandatory requirements:

(a) The course may only be offered by a program provider who is accredited by the Accreditation Council for Pharmacy Education (ACPE), a program provider who is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit, or a program provider approved by the American Osteopathic Association to offer continuing medical education credits.

(b) The course content and objectives offered by an approved provider shall be developed in conjunction with an individual licensed to practice pharmacy and an individual who is a licensed allopathic or osteopathic physician.

(c) The course content shall include all those areas enumerated in section 465.1895 (2)(b), F.S., and shall also cover the following areas:

1. Laws and rules applicable to test and treat certifications; and

2. Writing and entering into a written protocol.

(d) No less than 8 hours of the course shall be offered through a live seminar or a live video teleconference.

(3) A pharmacist who successfully completes a board approved test and treat certification course shall be awarded 20 hours of general continuing education credits.

Place holder for consultation with BOM and BOOM.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

### **64B16-31.037 Test and Treat Certification: Written Protocol and Written Protocol Submission**

(1) Within 5 business days of entering into a written protocol with a supervising physician pursuant to section 465.1895, F.S., the pharmacist shall submit a copy of the written agreement to the Board Office through the pharmacist's online licensure account at <http://www.flhealthsource.gov> or via U.S. Mail to 4052 Bald Cypress Way, Bin C-04, Tallahassee, FL 32399.

(2) In the event of an addendum to the material terms of an existing written protocol, the pharmacist shall maintain a copy of the addendum and the initial agreement. Material terms shall be defined as those terms enumerated in Section 465.1895(5)(a), F.S.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

### **64B16-31.039 Test and Treat Certification: Formulary of Medical Drugs**

(1) Pursuant to section 465.1895, F.S., the Board hereby incorporates all medicinal drugs approved by the United States Food and Drug Administration (“FDA”) as the formulary of medicinal drugs that a pharmacist may prescribe pursuant to a written test and treat protocol.

(b) All compounded medicinal drugs that utilize only active pharmaceutical ingredients approved by the FDA.

(2) A pharmacist may not prescribe controlled substances as described in s. 893.03 or 21 U.S.C. s. 812.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

### **64B16-31.041 Test and Treat Certification: Patient Records**

Upon receipt of a patient request, a pharmacist shall furnish patient records to a health care practitioner designated by the patient within a reasonable time frame, not to exceed 5 business days.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

### **64B16-31.043 Test and Treat Certification: Follow-up Care**

A pharmacist must provide written information to the patient advising the patient when to seek follow-up care from his or her primary care physician. A pharmacist shall provide follow-up care written information:

(1) Immediately prior to performing testing, screening, or treatment services on a patient for the first time; or

(2) As outlined in the written protocol; and

(3) When the pharmacist determines in his or her judgment that the patient should follow-up with his or her primary care provider.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

**64B16-31.045 Test and Treat Certification: Mandatory Continuing Education.**

A licensee shall not be required to complete the 3-hour continuing education related to minor, nonchronic health conditions if the initial certificate was issued less than 12 months prior to the expiration date of the license.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

**64B16-31.050 Mandatory Review of Rule Chapter 64B16-31, F.A.C.**

(1) No later than 90 days prior to December 31, 2025, the Board shall review each rule in this Chapter and amend, modify or repeal any rule that creates barriers to entry for private business competition, is duplicative, outdated, obsolete, overly burdensome, or imposes excessive costs.

(2) In the event the Board fails to complete this review, the board, for any rule that has not been reviewed in accordance with subsection (1), shall begin the rule repeal process in accordance with the Administrative Procedures Act.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*



Application  
*for*  
Pharmacist Collaborative Practice Certification

**Board of Pharmacy**  
P.O. Box 6330  
Tallahassee, FL 32314-6330  
Website: <https://floridaspharmacy.gov/>  
Email: [info@floridaspharmacy.gov](mailto:info@floridaspharmacy.gov)  
Phone: (850) 245-4474  
Fax: (850) 921-5389



# Application for Pharmacist Collaborative Practice Certification

Board of Pharmacy  
P.O. Box 6330  
Tallahassee, FL 32314-6330  
Fax: (850) 921-5389  
Email: info@floridaspharmacy.gov

All applicants must hold a current Florida Pharmacist license that is active and in good standing.

## Pharmacist Collaborative Practice Certification

Prior to providing services under a collaborative pharmacy practice agreement, a pharmacist must be certified by the board. Additionally, a pharmacist must enter into a written agreement with a physician licensed under Chapter 458 or Chapter 459, Florida Statutes, in which a collaborating physician authorizes a pharmacist to provide specified patient care services for chronic health conditions. Please refer to section 465.1865, Florida Statutes, prior to submitting your application.

### 1. PERSONAL INFORMATION

Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_  
Last/Surname First Middle MM/DD/YYYY

Mailing Address: (This address is where mail and your certification will be sent)

Street/P.O. Box Apt. No. City

State ZIP Country Home/Cell Telephone (Input without dashes)

Physical Location: (Required if mailing address is a P.O. Box – this address will be posted on the Department of Health’s website)

Street Apt. No. City

State ZIP Country Business Telephone (Input without dashes)

Email Notification: To be notified of the status of your application by email, check the “Yes” box and fill in your email address on the line provided. If you choose to be notified via email you will be responsible for checking your email regularly and updating your email address with the board office.

Yes  No Email Address: \_\_\_\_\_

Under Florida law, email addresses are public records. If you do not want your email address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.

Name: \_\_\_\_\_

## 2. LICENSURE HISTORY

A. What is your Florida Pharmacist (PS) license number? \_\_\_\_\_

## 3. CERTIFICATION TRAINING

To qualify for certification, an applicant must have completed an initial 20-hour certification course that meets the statutory and rule requirements of section 465.1865, Florida Statutes, and Rule 64B16-31.003, F.A.C.

B. Have you successfully completed an initial 20-hour course approved by the Florida Board of Pharmacy?  Yes  No

If **yes**, provide a copy of the certificate of completion and the following information.

Provider Name	Provider Number	Date of Completion	Certificate Number

## 4. APPLICANT BACKGROUND

To qualify for certification, an applicant must have earned a degree of doctor of pharmacy or have completed 5 years of experience as a licensed pharmacist.

A. Have you earned a degree of doctor of pharmacy?  Yes  No

If **yes**, please list the name of university, college, or school of pharmacy you attended.

School Name	City/State or Country	Graduation Date	Degree Awarded

B. Have you completed 5 years of experience as a licensed pharmacist?  Yes  No

If **yes**, please list your experience below.

Employer	Location Address	Dates (From-To) MM/DD/YYYY

Name: \_\_\_\_\_

## 5. PROFESSIONAL LIABILITY INSURANCE

To provide services under a collaborative pharmacy practice agreement, a pharmacist must maintain at least \$250,000 of professional liability insurance coverage. A pharmacist who maintains professional liability insurance coverage as a requirement of the Test and Treat Certification, pursuant to section 465.1895, Florida Statutes, satisfies this requirement.

A. Do you maintain at least \$250,000 of professional liability insurance?  Yes  No

If "Yes," provide the following information:

Insurance Provider Name	Policy Number	Policy Expiration Date

## 6. SYSTEM TO MAINTAIN RECORDS

To provide services under a collaborative pharmacy practice agreement, a pharmacist must have established a system to maintain records of all patients receiving services under a collaborative pharmacy practice agreement for a period of 5 years from each patient's most recent provision of services, pursuant to section 465.1865, Florida Statutes.

A. Have you established a system to maintain records of all patients receiving services under a collaborative pharmacy practice agreement?  Yes  No

## 7. COLLABORATING PHYSICIAN

If available, provide the following information for the physician licensed under chapter 458 or 459, Florida Statutes, with whom you have entered into an agreement.

Physician Name: \_\_\_\_\_

Physician License #: \_\_\_\_\_

## COLLABORATIVE PHARMACY PRACTICE AGREEMENT INFORMATION

Section 465.1865(3), Florida Statutes, requires each collaborative pharmacy practice agreement include terms and conditions that are appropriate to the pharmacist's training and the services delegated to the pharmacist must be within the collaborating physician's scope of practice.

The collaborative practice agreement must include the following information:

1. Name of the collaborating physician's patient or patients for whom a pharmacist may provide services.
2. Each chronic health condition to be collaboratively managed.
3. Specific medicinal drug or drugs to be managed by the pharmacist for each patient.
4. Circumstances under which the pharmacist may order or perform and evaluate laboratory or clinical tests.
5. Conditions and events upon which the pharmacist must notify the collaborating physician and the manner and timeframe in which such notification must occur.
6. Beginning and ending dates for the collaborative pharmacy practice agreement and termination procedures, including procedures for patient notification and medical records transfers.
7. A statement that the collaborative pharmacy practice agreement may be terminated, in writing, by either party at any time.

The collaborative pharmacy practice agreement shall automatically terminate 2 years after execution if not renewed. The pharmacist, along with the collaborating physician, must maintain on file the collaborative pharmacy practice agreement at his or her practice location, and must make such agreements available to the department or board upon request or inspection.

A pharmacist who enters into a collaborative pharmacy practice agreement must submit a copy of the signed agreement to the board before the agreement may be implemented.

**8. SOCIAL SECURITY DISCLOSURE**

**This information is exempt from public records disclosure.**

Pursuant to Title 42 United States Code § 666(a)(13), the department is required and authorized to collect Social Security numbers relating to applications for professional licensure. Additionally, section (s.) 456.013(1)(a), Florida Statutes (F.S.), authorizes the collection of Social Security numbers as part of the general licensing provisions.

**Last Name:** \_\_\_\_\_

**First Name:** \_\_\_\_\_

**Middle Name:** \_\_\_\_\_

**Social Security Number:** \_\_\_\_\_

(Input without dashes)

**Social Security Information-** \* Under the Federal Privacy Act, disclosure of Social Security numbers is voluntary unless specifically required by federal statute. In this instance, Social Security numbers are mandatory pursuant to Title 42 United States Code § 653 and 654; and s. 456.013(1), 409.2577, and 409.2598, F.S. Social Security numbers are used to allow efficient screening of applicants and licensees by a Title IV-D child support agency to ensure compliance with child support obligations. Social Security numbers must also be recorded on all professional and occupational license applications and will be used for license identification pursuant to Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Welfare Reform Act. 104 Pub. L. Section 317). Clarification of the SSA process may be reviewed at [www.ssa.gov](http://www.ssa.gov) or by calling 1-800-772-1213.

Name: \_\_\_\_\_

**9. APPLICANT SIGNATURE**

I, the undersigned, state that I am the person referred to in this application for certification in the state of Florida.

I recognize that providing false information may result in disciplinary action against my license or criminal penalties pursuant to s. 456.067 and 775.083, Florida Statutes.

Florida law requires me to immediately inform the board of any material change in any circumstances or condition stated in the application which takes place between the initial filing and the final granting or denial of the license and to supplement the information on this application as needed.

Section 456.013(1)(a), Florida Statutes, provides that an incomplete application shall expire one year after the initial filing with the department.

Applicant Signature \_\_\_\_\_ Date \_\_\_\_\_  
*You may print out this application and sign it or sign it digitally.* MM/DD/YYYY

Documentation must be sent to the board office at [info@floridaspharmacy.gov](mailto:info@floridaspharmacy.gov), or mailed to:

**Board of Pharmacy**  
4052 Bald Cypress Way Bin C-04  
Tallahassee, FL 32399-3258



Application  
*for*  
Pharmacist Test and Treat Certification

**Board of Pharmacy**  
P.O. Box 6330  
Tallahassee, FL 32314-6330  
Website: <https://floridaspharmacy.gov/>  
Email: [info@floridaspharmacy.gov](mailto:info@floridaspharmacy.gov)  
Phone: (850) 245-4474  
Fax: (850) 921-5389



# Pharmacist Test and Treat Certification Application

Board of Pharmacy  
P.O. Box 6330  
Tallahassee, FL 32314-6330  
Fax: (850) 921-5389  
Email: info@floridaspharmacy.gov

All applicants must hold a current Florida Pharmacist license that is active and in good standing.

## Pharmacist Test and Treat Certification

Prior to testing or screening for and treating minor, nonchronic health conditions under a written protocol, a pharmacist must be certified by the board. Additionally, a pharmacist must practice within the framework of a written protocol with a supervising physician licensed under Chapter 458, Florida Statutes, or Chapter 459, Florida Statutes. Please refer to Section 465.1895, Florida Statutes, prior to submitting your application.

### 1. PERSONAL INFORMATION

Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_  
Last/Surname First Middle MM/DD/YYYY

Mailing Address: (This address is where mail and your certification should be sent)

\_\_\_\_\_  
Street/P.O. Box Apt. No. City  
\_\_\_\_\_  
State ZIP Country Home/Cell Telephone (Input without dashes)

Physical Location: (Required if mailing address is a P.O. Box – this address will be posted on the Department of Health’s website)

\_\_\_\_\_  
Street Apt. No. City  
\_\_\_\_\_  
State ZIP Country Business Telephone (Input without dashes)

Email Notification: To be notified of the status of your application by email, check the “Yes” box and fill in your email address on the line provided. If you choose to be notified via email you will be responsible for checking your email regularly and updating your email address with the board office.

Yes  No Email Address: \_\_\_\_\_

Under Florida law, email addresses are public records. If you do not want your email address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.

Name: \_\_\_\_\_

## 2. LICENSURE HISTORY

- A. What is your Florida Pharmacist (PS) license number? \_\_\_\_\_

## 3. CERTIFICATION TRAINING

To qualify for certification, an applicant must have completed an initial 20-hour certification course that meets the statutory and rule requirements of section 465.1895, Florida Statutes, and Rule 64B31.035, F.A.C.

- A. Have you successfully completed an initial 20-hour course approved by the Florida Board of Pharmacy?  Yes  No

If “Yes,” provide a copy of the certificate of completion and the following information.

Provider Name	Provider Number	Date of Completion	Certificate Number

## 4. PROFESSIONAL LIABILITY INSURANCE

To test or screen for and treat minor, nonchronic health conditions within the framework of a written protocol, a pharmacist must maintain at least \$250,000 of professional liability insurance coverage. A pharmacist who maintains professional liability coverage as a requirement of their Collaborative Practice Certification satisfies this requirement.

- A. Do you maintain at least \$250,000 of professional liability insurance?  Yes  No

If “Yes,” provide the following information:

Insurance Provider Name	Policy Number	Policy Expiration Date

## 5. REPORTING REQUIREMENTS

To test or screen for and treat minor, nonchronic health conditions within the framework of a written protocol, a pharmacist must report a diagnosis or suspected existence of a disease of public health significance to the Department of Health pursuant to section 381.0031, Florida Statutes.

- A. Have you reviewed the Disease Reporting and Management Information at <http://www.floridahealth.gov/diseases-and-conditions/index.html>?  Yes  No

## 6. SYSTEM TO MAINTAIN RECORDS

To test or screen for and treat minor, nonchronic health conditions within the framework of a written protocol, a pharmacist must furnish patient records to a health care practitioner designated by the patient upon request. Additionally, a pharmacist must maintain records of all patients receiving services for a period of five (5) years from each patient’s most recent provision of service.

- A. Have you established a system to maintain records of all patients receiving services within the framework of a written protocol?  Yes  No

Name: \_\_\_\_\_

## 7. SUPERVISING PHYSICIAN

If available, provide the following information for the physician licensed under chapter 458 or 459, Florida Statutes (F.S.), with whom you have entered into a protocol.

Physician Name: \_\_\_\_\_

Physician License #: \_\_\_\_\_

## 8. WRITTEN PROTOCOL INFORMATION

Each written protocol must include particular terms and conditions imposed by the supervising physician relating to the testing and screening for and treatment of minor, nonchronic health conditions. The terms and conditions must be appropriate to the pharmacist's training.

The written protocol must include, at a minimum, the following information:

1. Specific categories of patients who the pharmacist is authorized to test or screen for and treat minor, nonchronic health conditions.
2. The physician's instructions for obtaining relevant patient medical history for the purpose of identifying disqualifying health conditions, adverse reactions, and contraindications to the approved course of treatment.
3. The physician's instructions for the treatment of minor, nonchronic health conditions based on the patient's age, symptoms, and test results, including negative results.
4. A process and schedule for the physician to review the pharmacist's actions under the protocol.
5. A process and schedule for the pharmacist to notify the physician of the patient's condition, tests administered, test results, and course of treatment.

A pharmacist who enters into a written protocol must submit a copy of the protocol to the board.

## 9. SOCIAL SECURITY DISCLOSURE

**This information is exempt from public records disclosure.**

Pursuant to Title 42 United States Code § 666(a)(13), the department is required and authorized to collect Social Security numbers relating to applications for professional licensure. Additionally, section (s.) 456.013(1)(a), Florida Statutes (F.S.), authorizes the collection of Social Security numbers as part of the general licensing provisions.

**Last Name:** \_\_\_\_\_

**First Name:** \_\_\_\_\_

**Middle Name:** \_\_\_\_\_

**Social Security Number:** \_\_\_\_\_  
(Input without dashes)

**Social Security Information-** \* Under the Federal Privacy Act, disclosure of Social Security numbers is voluntary unless specifically required by federal statute. In this instance, Social Security numbers are mandatory pursuant to Title 42 United States Code § 653 and 654; and s. 456.013(1), 409.2577, and 409.2598, F.S. Social Security numbers are used to allow efficient screening of applicants and licensees by a Title IV-D child support agency to ensure compliance with child support obligations. Social Security numbers must also be recorded on all professional and occupational license applications and will be used for license identification pursuant to Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Welfare Reform Act. 104 Pub. L. Section 317). Clarification of the SSA process may be reviewed at [www.ssa.gov](http://www.ssa.gov) or by calling 1-800-772-1213.

Name: \_\_\_\_\_

## 10. APPLICANT SIGNATURE

I, the undersigned, state that I am the person referred to in this application for certification in the state of Florida.

I recognize that providing false information may result in disciplinary action against my license or criminal penalties pursuant to s. 456.067 and 775.083, F.S.

I am aware that my certification may be suspended or revoked if I violate any pharmacy law, rule or regulation, or the Florida Board of Pharmacy Code of Conduct.

Florida law requires me to immediately inform the board of any material change in any circumstances or condition stated in the application which takes place between the initial filing and the final granting or denial of the license and to supplement the information on this application as needed.

Section 456.013(1)(a), F.S., provides that an incomplete application shall expire one year after the initial filing with the department.

Applicant Signature \_\_\_\_\_ Date \_\_\_\_\_  
*You may print out this application and sign it or sign it digitally.* MM/DD/YYYY

Documentation must be sent to the board office at [info@floridaspharmacy.gov](mailto:info@floridaspharmacy.gov), or mailed to:

**Board of Pharmacy**  
4052 Bald Cypress Way Bin C-04  
Tallahassee, FL 32399-3258



Application  
*for*  
Initial Collaborative Practice Certification  
Course

**Board of Pharmacy**  
P.O. Box 6330  
Tallahassee, FL 32314-6330  
Website: <https://floridaspharmacy.gov/>  
Email: [info@floridaspharmacy.gov](mailto:info@floridaspharmacy.gov)  
Phone: (850) 245-4474  
Fax: (850) 921-5389



# Pharmacist Collaborative Practice Certification

## Provider Application

Board of Pharmacy  
4052 Bald Cypress Way Bin C-04  
Tallahassee, FL 32314-6330  
Fax: (850) 921-5389  
Email: info@floridaspharmacy.gov

The offering approval submitted must adhere to the Rules for Collaborative Pharmacy Practice Certification, Section 64B16-31.003, F.A.C., to be eligible for Provider Approval by the Board of Pharmacy.

Please read the following before completing this application:

1. All information must be legibly printed or typed.
2. Complete all sections.
3. Identify all attachments with your organization's name.

### 1. CONTACT INFORMATION

Contact Person Name: \_\_\_\_\_  
Last/Surname First Middle

Title: \_\_\_\_\_

Name of Organization, Institution or Agency (Do not use initials of abbreviations):  
\_\_\_\_\_

Mailing Address:

\_\_\_\_\_  
Street/P.O. Box Apt. No. City

\_\_\_\_\_  
Business Telephone (Input without dashes)

**Email Notification:** To be notified of the status of your application by email, check the "Yes" box and fill in your email address on the line provided. If you choose to be notified via email you will be responsible for checking your email regularly and updating your email address with the board office.

Yes No Email Address: \_\_\_\_\_

Under Florida law, email addresses are public records. If you do not want your email address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.

**1. ADMINISTRATION AND ORGANIZATION**

A. Administrative Authority:

Provide the name and title of the person in charge of the program of study. (If responsibilities are shared by more than one individual, please indicate responsibilities of each person using supplementary sheets.)

NAME \_\_\_\_\_ TITLE \_\_\_\_\_

NAME \_\_\_\_\_ TITLE \_\_\_\_\_

B. Please provide your Accreditation Council for Pharmacy Education (ACPE), American Medical Association (AMA), or Florida Osteopathic Medical Association (FOMA) provider number.

\_\_\_\_\_

C. Describe the nature of the applicant's role relative to the program of study and coursework.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**2. ADMINISTRATIVE REQUIREMENTS**

A. Please describe the nature of the system used for the maintenance and availability of records of participation in this program.

\_\_\_\_\_  
\_\_\_\_\_

B. Attach a sample certificate, letter or other document that is generally used as evidence to participants of satisfactory completion of the program of study for initial certification. Indicate the manner in which this document is distributed.

C. Indicate the number of course hours and type of study requested:

\_\_\_\_\_ Live \_\_\_\_\_ Home Study

**3. EDUCATIONAL CONTENT DEVELOPMENT**

A. Briefly describe the process for identifying educational needs and the manner in which topics for programs are usually determined.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

B. Describe the goals and objectives of your overall educational effort.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

- C. Briefly describe the usual planning process for an individual program. Indicate the time frame that may typically be involved.

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#### 4. METHODS OF DELIVERY

- A. What factors are taken into consideration in choosing the method of delivery for a particular program?

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- B. What is the review process that a home study program (audio-visual components, programmed learning, correspondence course, etc.) might undergo before it is offered to a new audience if utilized?

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#### 5. FACILITIES

- A. Name the facilities utilized for the past two programs presented.

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- B. What factors are considered in choosing facilities for programs?

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- C. If the preparation of educational offerings during the past year involved the production of audio-visual or other mediated materials such as programmed learning or correspondence course, etc., describe the facilities and equipment available and utilized for such preparations.

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#### 6. EVALUATION

- A. What opportunities are given for the participant to assess his/her evaluation of course objectives?

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B. Describe the methods employed to evaluate the effectiveness of the provider's programming and its presentation.

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C. Please attach a sample attendee evaluation instrument.

**Please submit completed application to CEBroker at [www.CEBroker.com](http://www.CEBroker.com)**



Application  
*for*  
Initial Test and Treat Certification  
Course

**Board of Pharmacy**  
4052 Bald Cypress Way Bin C-04  
Tallahassee, FL 32314-6330  
Website: <https://floridaspharmacy.gov/>  
Email: [info@floridaspharmacy.gov](mailto:info@floridaspharmacy.gov)  
Phone: (850) 245-4474  
Fax: (850) 921-5389



# Initial Test and Treat Certification Course Application

Board of Pharmacy  
4052 Bald Cypress Way Bin C-04  
Tallahassee, FL 32314-6330  
Fax: (850) 921-5389  
Email: info@floridaspharmacy.gov

The offering approval submitted must adhere to the Rules for Test and Treat Certification, Section 64B16-31.035, F.A.C., to be eligible for Provider Approval by the Board of Pharmacy.

Please read the following before completing this application:

1. All information must be legibly printed or typed.
2. Complete all sections.
3. Identify all attachments with your organization's name.

## 1. CONTACT INFORMATION

**Contact Person Name:** \_\_\_\_\_  
Last/Surname First Middle

**Title:** \_\_\_\_\_

**Name of Organization, Institution or Agency (Do not use initials of abbreviations):**  
\_\_\_\_\_

**Mailing Address:**

\_\_\_\_\_  
Street/P.O. Box Apt. No. City

\_\_\_\_\_  
Business Telephone (Input without dashes)

**Email Notification:** To be notified of the status of your application by email, check the "Yes" box and fill in your email address on the line provided. If you choose to be notified via email you will be responsible for checking your email regularly and updating your email address with the board office.

Yes No Email Address: \_\_\_\_\_

Under Florida law, email addresses are public records. If you do not want your email address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.

**1. ADMINISTRATION AND ORGANIZATION**

A. Administrative Authority:

Provide the name and title of the person in charge of the program of study. (If responsibilities are shared by more than one individual, please indicate responsibilities of each person using supplementary sheets.)

NAME \_\_\_\_\_ TITLE \_\_\_\_\_

NAME \_\_\_\_\_ TITLE \_\_\_\_\_

B. Please provide your Accreditation Council for Pharmacy Education (ACPE), American Medical Association (AMA), or Florida Osteopathic Medical Association (FOMA) provider number.

\_\_\_\_\_

C. Describe the nature of the applicant's role relative to the program of study and coursework.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**2. ADMINISTRATIVE REQUIREMENTS**

A. Please describe the nature of the system used for the maintenance and availability of records of participation in this program.

\_\_\_\_\_  
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B. Attach a sample certificate, letter or other document that is generally used as evidence to participants of satisfactory completion of the program of study for initial certification. Indicate the manner in which this document is distributed.

C. Indicate the number of course hours and type of study requested:

\_\_\_\_\_ Live \_\_\_\_\_ Home Study

**3. EDUCATIONAL CONTENT DEVELOPMENT**

A. Briefly describe the process for identifying educational needs and the manner in which topics for programs are usually determined.

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\_\_\_\_\_

B. Describe the goals and objectives of your overall educational effort.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

- C. Briefly describe the usual planning process for an individual program. Indicate the time frame that may typically be involved.

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- A. What factors are taken into consideration in choosing the method of delivery for a particular program?

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- B. What is the review process that a home study program (audio-visual components, programmed learning, correspondence course, etc.) might undergo before it is offered to a new audience if utilized?

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#### 5. FACILITIES

- A. Name the facilities utilized for the past two programs presented.

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- C. If the preparation of educational offerings during the past year involved the production of audio-visual or other mediated materials such as programmed learning or correspondence course, etc., describe the facilities and equipment available and utilized for such preparations.

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#### 6. EVALUATION

- A. What opportunities are given for the participant to assess his/her evaluation of course objectives?

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B. Describe the methods employed to evaluate the effectiveness of the provider's programming and its presentation.

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C. Please attach a sample attendee evaluation instrument.

**Please submit completed application to CEBroker at [www.CEBroker.com](http://www.CEBroker.com).**

**BOARD OF PHARMACY  
RULE DEVELOPMENT WORKSHOP  
JOINT RULES COMMITTEE  
DRAFT MINUTES  
July 29, 2020  
9:00 A.M. ET  
Call In Number: (888) 585-9008  
Conference Code: 599-196-982(#)**

Participants in this public meeting should be aware that these proceedings are being recorded and that an audio file of the meeting will be posted to the board's website.

**I. CALL TO ORDER/ROLL CALL**

Dr. Mesaros called the meeting to order at 9:00 a.m. ET.

**MEMBERS PRESENT**

Jeffrey Mesaros, PharmD, JD, Chair  
Jeenu Philip, BPharm,  
Jonathan Hickman, PharmD  
Mark Mikhael, PharmD  
David Wright, BPharm

**STAFF PRESENT**

Jessica Sapp, Executive Director  
Traci Zeh, Program Administrator

**BOARD COUNSEL**

David Flynn, Esq.  
Senior Assistant Attorney General  
Christopher Dierlam, Esq.  
Assistant Attorney General

**BOARD OF MEDICINE MEMBERS:**

Hector Vila, MD

**BOARD OF OSTEOPATHIC MEDICINE MEMBERS:**

Joel B. Rose, DO  
Michelle R. Mendez, DO

**ABSENT MEMBERS:**

Sarvam TerKonda, MD

**COURT REPORTER**

For the Record  
150 Mahan Drive, Suite 140  
Tallahassee, FL 32308  
(850) 222-5491  
(850) 224-5316 (Fax)

**II. RULES DEVELOPMENT WORKSHOP**

- a. 64B16-31.007, F.A.C., Collaborative Practice Certification: Chronic Health Conditions

On June 29, 2020 the Board of Pharmacy received a request for a Rules Workshop from the Florida Chapter of the American College of Physicians and the Florida Academy of Family Physicians as well as the Florida Medical Association on rules 64B16-31.007 Collaborative Practice Certification: Chronic Health Conditions and 64B16-31.039 Test and Treat Certification: Formulary of Medical Drugs.

**64B16-31.007 Collaborative Practice Certification: Chronic Health Conditions.**

Pursuant to Section 465.1865, F.S., the Board hereby adopts the following list of chronic health conditions for which a pharmacist certified pursuant to section 465.1865, F.S., can provide specified patient care services to patients of a collaborating physician pursuant to a pending Collaborative Pharmacy Practice Agreement:

- 1) Hyperlipidemia;
- 2) Hypertension;
- 3) Anti-coagulation management;
- 4) Smoking cessation;
- 5) Osteoporosis and Osteoarthritis;
- 6) Opioid use disorder; and
- 7) Those chronic health conditions enumerated in section 465.1865(1)(b), F.S.
- 8) Any disease state that is expected to last greater than one (1) year or more and will require ongoing medical treatment and drug therapy services.

Dr. Mesaros summarized the changes made to subsection 5 and 8 of Rule 64B16-31.007, F.A.C., and opened the matter for discussion.

Dr. Vila addressed the Committee and stated the term “arthritis” is already enumerated in s. 465.1865(1)(b), F.S; therefore, the inclusion of osteoarthritis in the rule may be duplicative. Dr. Vila also expressed concern regarding the management of opioid use disorder as a chronic health condition. His concern lies with utilizing controlled substances as a treatment mechanism for opioid use disorder as pharmacists are not authorized to prescribe controlled substances under a collaborative practice agreement.

Dr. Rose commented that it may be beneficial for a pharmacist to manage opioid use disorder as some treatments, e.g. Narcan/naloxone, do not require the use of controlled substances.

Dr. Hickman and Mr. Philip concur with Dr. Rose. Mr. Philip also expressed that other states, e.g. Kentucky, have protocols in place to manage opioid use disorders without the prescription of controlled substances.

Mr. Wright addressed the Committee in agreeance with Dr. Vila to strike subsection 5 from proposed Rule 64B16-31.007, F.A.C. He also concurred with Dr. Rose, Dr. Hickman, and Mr. Philip regarding treatment for opioid use disorder without controlled substances. Mr. Wright disagreed with striking subsection 8 from the rule. He expressed concern that if the subsection is removed, then the Board will be continually adding conditions to the list. He also stated that heart disease should be added to the list of conditions as patients with congestive heart failure benefit from a pharmacist adjusting the dosage of their medication as that could prevent hospitalization.

Dr. Mikhael agreed with striking subsection 5 from the rule and stated that he would be in support of striking subsection 8 for now and revisiting it at a later date.

Mr. Philip stated that he would like to discuss further disease states at the August Rules Committee meeting and is in favor of adding heart disease to the list enumerated in Rule 64B16-31.007, F.A.C.

Dr. Mendez addressed the Committee and expressed that pharmacists already have an obligation to counsel patients and inquired if the intent of the legislation was to facilitate a practice that is already in place.

Angela Garcia from the University of South Florida (USF) addressed the Committee and confirmed that collaborative practice agreements are already being utilized in the ambulatory care setting.

Dr. Mesaros agreed that subsection 5 should be stricken from the rule and opened the floor for public comment.

Michael Jackson, Executive Vice-President of the Florida Pharmacy Association (FPA), addressed the Committee and stated that the language utilized in subsection 8 of the rule appears to be derived from the Centers of Disease Control and Prevention (CDC) verbiage regarding the definition of chronic health conditions. He also expressed that it is not uncommon for regulations to reference outside entities. The goal is to provide a range of services to patients that pharmacists can help manage. The FPA is in support of subsection 8 of the rule, however, the list needs more work, as it is not comprehensive for all chronic conditions.

Dan Buffington, Clinical Pharmacology Services, addressed the Committee and expressed that subsection 8 would allow for pharmacists and physicians to actively collaborate and manage conditions effectively.

Gore Alvarez from Nova Southeastern University addressed the Committee and stated the goal of a collaborative practice agreement is to manage patients. Subsection 8 works in conjunction with this goal and limits excessive rulemaking.

Dr. Rose stated that it was the legislative intent to have each condition be vetted and added to the list on its merits. If the legislature wanted there to be a catchall phrase in the rule, they would have indicated so in the statute. Dr. Rose indicated that additional conditions can be added at a later date.

Christopher Nuland, representing the Florida Chapter, American College of Physicians, addressed the Committee and concurs with the deletion of subsection 8 from the rule.

Toni Large, representing the Florida Society of Rheumatology, addressed the Committee and agrees with Dr. Rose and stated medication management is complex, and each condition should be added on its own merits. Ms. Large expressed opposition to the inclusion of specific conditions in the rule, aside from osteoarthritis.

Mr. Flynn addressed the Committee and reiterated that the term "arthritis" is already enumerated in s. 465.1865(1)(b), F.S; therefore, the inclusion of osteoarthritis in the rule may be duplicative and restrictive so subsection 5 should be stricken from the rule. Mr. Flynn believes that subsection 8 is likely to be challenged as it likely exceeds the rulemaking authority outlined in the statute.

Mr. Philip addressed the Committee indicating he would be in favor of adding heart disease or heart failure to the list of chronic conditions enumerated in the rule.

Dr. Vila stated the importance of considering other disease states; however, this should be done in consultation with other physician groups. He also expressed concern with being too broad with the rule language; it is better to be more specific so that collaboration can occur.

Dr. Mikhael expressed that the intent is a collaboration between the physician, who diagnoses the condition, and the pharmacist, who manages the condition. Subsection 8 would still allow for the physician to have a relationship with the patient; the physician is always in control of the diagnosis. The pharmacist would be following the collaborative practice agreement that is in place.

Dr. Mesaros summarized the discussion.

Dr. Hickman addressed the Committee and agreed with Mr. Wright regarding the inclusion of heart disease to the list

Dr. Mendez addressed the Committee in opposition of subsection 8.

Mr. Flynn addressed the committee and shared that 1 in every 3 deaths in the United States is related to cardiovascular disease. It is an important condition to consider, however, we should consult specialists prior to finalizing its inclusion in the rule language. Subsection 8 will need to be further discussed and revised accordingly.

Dr. Hickman agreed that an open-ended definition is not the legislative intent of the statute. He suggested striking subsection 8 and revisiting it at a later date.

Mr. Philip stated that the Committee is trying to strike a balance between being too open-ended and too restrictive. The language should not exclude comorbid conditions. Any comorbid disease states tied to the conditions listed in subsection 7 should be added to the rule language. He also agreed that heart disease or heart failure should also be added to the list of conditions going forward.

Dr. Vila expressed that physicians are not against this collaboration, but it is important to consult with other physicians prior to finalizing the list of conditions. He recommended giving advance notice for the disease states that will be discussed, so that all interested parties may provide comment. He stated this collaboration is important in order to have the best product for patient safety.

Dr. Mikhael addressed the Committee and agreed with the deletion of subsection 5 and with amending subsection 8. The goal is to move the rule forward and build trust with physicians. He also stated that there is no evidence out there that says a pharmacist cannot safely manage medications. It is better to start cautiously.

Mary Thomas, representing the Florida Medical Association (FMA), supports the elimination of subsection 8.

Vanessa Goodnow, representing Jackson Health System in Miami, addressed the Committee and indicated that there is quite a bit of literature that supports a pharmacist's collaboration in specialty areas.

Nicole Garrett, Clinical Ambulatory Pharmacist in Florida, addressed the Committee in favor of rewording subsection 8 to include language for comorbid and cardiovascular conditions.

Mr. Flynn addressed the Committee and summarized the discussion indicating subsections 5 and 8 will be deleted and that heart disease and behavioral health conditions will be added. These additional conditions will be discussed at the next Board of Pharmacy Rules Committee meeting in August.

- b. 64B16-31.039, F.A.C., Test and Treat Certification: Formulary of Medicinal Drugs

**64B16-31.039 Test and Treat Certification: Formulary of Medical Drugs**

(1) Pursuant to section 465.1895, F.S., the Board hereby incorporates all medicinal drugs approved by the United States Food and Drug Administration (“FDA”) as the formulary of medicinal drugs that a pharmacist may prescribe pursuant to a written test and treat protocol.

~~(b) All compounded medicinal drugs that utilize only active pharmaceutical ingredients approved by the FDA.~~

(2) A pharmacist may not prescribe controlled substances as described in s. 893.03 or 21 U.S.C. s. 812.

Dr. Mesaros summarized the changes made to Rule 64B16-31.039, F.A.C. and opened the floor for discussion.

Mr. Wright addressed the Committee and expressed that eliminating subsection (1)(b) may be too limiting, as compounding medicine to treat minor, non-chronic conditions can be useful.

Dr. Rose inquired with Mr. Flynn regarding compounding medication.

Mr. Flynn indicated that s. 465.1895(3), F.S., provides that “the formulary must include medicinal drugs approved by the United States Food and Drug Administration which are indicated for treatment of the minor, nonchronic health condition. The formulary may not include any controlled substance as described in s. 893.03 or 21 U.S.C. s. 812.” Compounded drugs could be included in the formulary so long as the ingredients are approved by the FDA; the statutory language does not exclude compounded drugs.

Dr. Vila inquired how compounding would translate into a written protocol.

Mr. Flynn stated that pharmacists must follow federal law. Federal law has certain requirements for compounded drugs. The compounding language could only be applicable in emergency situations.

Richard Montgomery, Florida Board of Pharmacy Chair, addressed the Committee confirming there are current regulations in place that restrict a pharmacist’s ability to compound certain drugs.

Mr. Flynn indicated that there are no legal concerns with adding back the stricken language.

Dr. Vila has no objections to adding back the stricken language.

No additional Committee comments were received.

No public comment was received.

### III. RULES DISCUSSION

- a. HB 389 Practice of Pharmacy
  - i. Chapter 64B16-31, F.A.C., Collaborative Practice and Test and Treat Certifications

#### **64B16-31.001 Collaborative Practice Certification (CPC).**

Applicants for CPC shall submit an application using Form DH-MQA XXXX (eff. 0X/20), "Application for Pharmacist Collaborative Practice Certification<sup>1</sup>" that is hereby incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX> or <http://floridapharmacy.gov>. Applicants for certification shall must meet and comply with all requirements in Section 465.1865, F.S.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

#### **64B16-31.003 Collaborative Practice Certification: Initial Certification Course.**

(1) Applicants for Initial Certification Course approval shall submit an application using Form DH-MQA XXX (eff. XX/20) "Application for Initial Collaborative Practice Certification Course<sup>2</sup>" that is hereby incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX> or <http://floridapharmacy.gov>.

(2) Initial collaborative practice certification courses shall be a minimum of 20 hours in duration, and shall meet all the following mandatory requirements:

(a) The course may only be offered by a program provider who is accredited by the Accreditation Council for Pharmacy Education (ACPE), or a program provider who is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit, or a program provider approved by the American Osteopathic Association ~~Category 1-A~~ to offer continuing medical education credits.

(b) The course content and objectives offered by an approved provider shall be developed in conjunction with an individual licensed to practice pharmacy and an individual who is a licensed allopathic or osteopathic physician, or an individual who is dual licensed in both pharmacy and allopathic medicine or osteopathic medicine.

(c) The course content shall include all those areas enumerated in section 465.1865 (2)(c), F.S., and shall also cover the following areas:

1. Laws and rules applicable to the collaborative practice for the treatment of chronic health care conditions; and
2. Writing and entering into a collaborative practice agreement.

(d) No less than 12 hours of the course shall be offered through a live seminar or a live video teleconference.

(3) A pharmacist who successfully completes a board approved collaborative practice certification course shall be awarded 20 hours of general continuing education credits.

Place holder for consultation with BOM and BOOM.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

**64B16-31.005 Collaborative Practice Certification: Collaborative Pharmacy Practice Agreement Submission.**

(1) Prior to providing or implementing patient care services under a Collaborative Pharmacy Practice Agreement or immediately after the renewal of such an Agreement, the Pharmacist shall submit the executed Agreement to the Board Office through the pharmacist's online licensure account at <http://www.flhealthsource.gov> or via U.S. Mail to 4052 Bald Cypress Way, Bin C-04, Tallahassee, FL 32399.

(2) In the event of an addendum to the material terms of an existing collaborative pharmacy practice agreement, the pharmacist shall maintain a copy of the addendum and the initial agreement pursuant to Section 465.1865(3)(c), F.S. Material terms shall be defined as those terms enumerated in Section 465.1865(3)(a), F.S.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

**64B16-31.007 Collaborative Practice Certification: Chronic Health Conditions.**

Pursuant to Section 465.1865, F.S., the Board hereby adopts the following list of chronic health conditions for which a pharmacist certified pursuant to section 465.1865, F.S., can provide specified patient care services to patients of a collaborating physician pursuant to a pending Collaborative Pharmacy Practice Agreement:

- 1) Hyperlipidemia;
- 2) Hypertension;
- 3) Anti-coagulation management;
- 4) Smoking cessation;
- 5) Osteoporosis and Osteoarthritis;
- 6) Opioid use disorder; and
- 7) Those chronic health conditions enumerated in section 465.1865(1)(b), F.S.
- 8) Any disease state that is expected to last greater than one (1) year or more and will require ongoing medical treatment and drug therapy services.

Place holder for discussion with Board to determine appropriate list of chronic health conditions in consultation with BOM and BOOM.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

**64B16-31.009 Collaborative Practice Certification: Mandatory Continuing Education.**

A licensee shall not be required to complete the 8-hour continuing education related to collaborative pharmacy practice if the initial certificate was issued less than 12 months prior to the expiration date of the license.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

**64B16-31.033 Test and Treat Certification (TTC)**

Applicants for TTC shall submit an application using Form DH-MQA XXXX (eff. 0X/20), “Application for Pharmacist Test and Treat Certification”<sup>3</sup> that is hereby incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX> or <http://floridapharmacy.gov>. Applicants for certification shall must meet and comply with all requirements in Section 465.1895, F.S.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

**64B16-31.035 Test and Treat Certification: Initial Certification Course**

(1) Applicants for Initial Certification Course approval shall submit an application using Form DH-MQA XXX (eff. XX/20) “Application for Initial Test and Treat Certification Course”<sup>4</sup> that is hereby incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX> or <http://floridapharmacy.gov>.

(2) Initial test and treat certification courses shall be a minimum of 20 hours in duration, and shall meet all the following mandatory requirements:

(a) The course may only be offered by a program provider who is accredited by the Accreditation Council for Pharmacy Education (ACPE), or a program provider who is accredited to provide educational activities designated for the American Medical Association Physician’s Recognition Award Category 1 credit, or a program provider approved by the American Osteopathic Association Category 1-A to offer continuing medical education credits.

(b) The course content and objectives offered by an approved provider shall be developed in conjunction with an individual licensed to practice pharmacy and an individual who is a licensed allopathic or osteopathic physician, or an individual who is dual licensed in both pharmacy and allopathic medicine or osteopathic medicine.

(c) The course content shall include all those areas enumerated in section 465.1895 (2)(b), F.S., and shall also cover the following areas:

1. Laws and rules applicable to test and treat certifications; and
2. Writing and entering into a written protocol.

(d) No less than 12 8 hours of the course shall be offered through a live seminar or a live video teleconference.

(3) A pharmacist who successfully completes a board approved test and treat certification course shall be awarded 20 hours of general continuing education credits.

Place holder for consultation with BOM and BOOM.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

**64B16-31.037 Test and Treat Certification: Written Protocol and Written Protocol Submission**

(1) Within 5 business days of entering into a written protocol with a supervising physician pursuant to section 465.1895, F.S., the pharmacist shall submit a copy of the written agreement to the Board Office through the pharmacist's online licensure account at <http://www.flhealthsource.gov> or via U.S. Mail to 4052 Bald Cypress Way, Bin C-04, Tallahassee, FL 32399.

(2) In the event of an addendum to the material terms of an existing written protocol, the pharmacist shall maintain a copy of the addendum and the initial agreement. Material terms shall be defined as those terms enumerated in Section 465.1895(5)(a), F.S.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

#### **64B16-31.039 Test and Treat Certification: Formulary of Medical Drugs**

(1) Pursuant to section 465.1895, F.S., the Board hereby incorporates all medicinal drugs approved by the United States Food and Drug Administration ("FDA") as the formulary of medicinal drugs that a pharmacist may prescribe pursuant to a written test and treat protocol.

~~(b) All compounded medicinal drugs that utilize only active pharmaceutical ingredients approved by the FDA.~~

(2) A pharmacist may not prescribe controlled substances as described in s. 893.03 or 21 U.S.C. s. 812.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

#### **64B16-31.041 Test and Treat Certification: Patient Records**

Upon receipt of a patient request, a pharmacist shall furnish patient records to a health care practitioner designated by the patient within a reasonable time frame, not to exceed 5 business days.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

#### **64B16-31.043 Test and Treat Certification: Follow-up Care**

A pharmacist must provide written information to the patient advising the patient when to seek follow-up care from his or her primary care physician. A pharmacist shall provide follow-up care written information:

(1) Immediately prior to performing testing, screening, or treatment services on a patient for the first time;

(2) As outlined in the written protocol; and

(3) When the pharmacist determines in his or her judgment that the patient should follow-up with his or her primary care provider.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

#### **64B16-31.045 Test and Treat Certification: Mandatory Continuing Education.**

A licensee shall not be required to complete the 3-hour continuing education related to minor, nonchronic health conditions if the initial certificate was issued less than 12 months prior to the expiration date of the license.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

**64B16-31.050 Mandatory Review of Rule Chapter 64B16-31, F.A.C.**

(1) No later than 90 days prior to December 31, 2025, the Board shall review each rule in this Chapter and amend, modify or repeal any rule that creates barriers to entry for private business competition, is duplicative, outdated, obsolete, overly burdensome, or imposes excessive costs.

(2) In the event the Board fails to complete this review, the board, for any rule that has not been reviewed in accordance with subsection (1), shall begin the rule repeal process in accordance with the Administrative Procedures Act.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

The Joint Committee reviewed the proposed draft rule language that was amended based on comments following the June 25, 2020 Joint Rules Committee Meeting and decided to discuss Rules 64B16-31.003 and 64B16-31.043, F.A.C.

Dr. Mesaros summarized the proposed changes to Rule 64B16-31.003, F.A.C.

Dr. Villa addressed the Committee and suggested striking subsection (2)(b), which states “or an individual who is dual licensed in both pharmacy and allopathic medicine or osteopathic medicine.” This language may prevent collaboration between practitioners.

Dr. Hickman echoed Dr. Villa’s sentiments to ensure collaboration from both sides. Dr. Hickman inquired if the language requires the practitioners to function in a consultant or in an instructor role.

Mr. Flynn indicated that the intent is for the practitioners be involved in the development of the course.

Mr. Wright addressed the Committee with no opposition with the change and agreed with Dr. Vila to strike (2)(b).

Mr. Philip would like to amend the language in subsection (2)(d) of Rule 64B16-31.003, F.A.C., to the following: (d) No less than 8 1/2 hours of the course shall be offered through a live seminar or a live video teleconference.

Dr. Rose addressed the Committee regarding allowing a period of time for the courses to be provided through distance learning given our current pandemic.

Dr. Vila has no objection to modifying the hours requirement.

Michael Jackson, Executive Vice-President of the FPA, addressed the Committee and expressed the FPA is making their best effort to collaborate with colleagues to develop a course; however, there could be a delay to bringing a course to fruition and he inquired if the collaboration must take place with a Florida licensed physician or a physician licensed outside of the state.

Dr. Hickman and Dr. Rose agreed that the language should not exclude out-of-state practitioners.

Dr. Mendez addressed the Committee in opposition and stated the legislative intent was for Florida practitioners only.

Mr. Flynn stated that there is nothing that prohibits consultation from practitioners licensed outside of Florida.

Dr. Vila expressed that the language should be left as proposed and offered his consultative services for course development.

Nicole Garrett, Clinical Ambulatory Pharmacist in Florida, addressed the Committee and sought clarification regarding the content of the certification course. Ms. Garrett inquired as to whether pre-existing content could be submitted for approval.

Mr. Flynn stated that there is nothing that limits utilizing pre-existing content; however, this must be done in consultation with a pharmacist.

Mr. Dierlam indicated that a pre-existing course could be submitted for approval so long as it meets the statutory and regulatory requirements.

Mary Thomas, representing the Florida Medical Association, addressed the Committee and expressed concern over consulting with practitioners licensed in other states.

Mr. Philip stated that as collaborative practice begins to evolve, national programs may be created. It would be prudent to allow for national certification courses to be submitted in Florida.

Dr. Mendez addressed the Committee regarding the definition of a supervising physician and inquired if limits would be put in place to restrict the pharmacists to physician ratio.

Dr. Hickman alluded to the current structure set in place for the immunization certification for pharmacists.

Ms. McNulty and Mr. Tellechea indicated that there is no rulemaking authority to allow for a cap at this time. Mr. Tellechea indicated any standard of care issues down the road would be handled appropriately by each regulatory board.

Dr. Vila addressed the Committee and suggested the Board of Medicine and the Board of Osteopathic Medicine provide samples of protocol templates to physicians.

Kathy Baldwin, representing the Florida Society of Health-System Pharmacists (FSHP), addressed the Committee and offered to share examples of protocols utilized by other states.

Mr. Philip addressed the Committee and suggested to amend the language in Rule 64B16-31.043, F.A.C., to the following:

- A pharmacist must provide written information to the patient advising the patient when to seek follow-up care from his or her primary care physician. A pharmacist shall provide follow-up care written information:
  - (1) Immediately prior to performing testing, screening, or treatment services on a patient for the first time; or
  - (2) As outlined in the written protocol; and
  - (3) When the pharmacist determines in his or her judgment that the patient should follow-up with his or her primary care provider.

Dr. Mesaros expressed no opposition to this amendment.

Dr. Mesaros opened for public comment.

No public comments were received.

#### **IV. ADJOURNMENT**

There being no further discussion, the meeting adjourned at 12:20 p.m.

**BOARD OF PHARMACY  
JOINT RULES COMMITTEE  
DRAFT MINUTES  
June 25, 2020  
9:00 A.M. ET  
Call In Number: (888) 585-9008  
Conference Code: 599-196-982(#)**

Participants in this public meeting should be aware that these proceedings are being recorded and that an audio file of the meeting will be posted to the board's website.

**I. CALL TO ORDER/ROLL CALL**

Dr. Mesaros called the meeting to order at 9:00 a.m. ET.

**MEMBERS PRESENT**

Jeffrey Mesaros, PharmD, JD, Chair  
Jeenu Philip, BPharm,  
Jonathan Hickman, PharmD  
Mark Mikhael, PharmD  
David Wright, BPharm

**STAFF PRESENT**

Jessica Sapp, Executive Director  
Traci Zeh, Program Administrator

**BOARD COUNSEL**

David Flynn, Esq.  
Senior Assistant Attorney General  
Christopher Dierlam, Esq.  
Assistant Attorney General

**BOARD OF MEDICINE MEMBERS:**

Hector Vila, MD  
Sarvam TerKonda, MD

**BOARD OF OSTEOPATHIC MEDICINE MEMBERS:**

Joel B. Rose, DO  
Michelle R. Mendez, DO

**COURT REPORTER**

For the Record  
150 Mahan Drive, Suite 140  
Tallahassee, FL 32308  
(850) 222-5491  
(850) 224-5316 (Fax)

**II. RULES DISCUSSION**

- a. HB 389 Practice of Pharmacy
  - i. Chapter 64B16-31, F.A.C., Collaborative Practice and Test and Treat Certifications

This bill was enrolled and signed into law with an effective date of July 1, 2020. This adds to the definition of the practice of pharmacy the ability to initiate, modify, discontinue drug therapy under a collaborative practice agreement with a physician, for patients with chronic illnesses. It also allows a pharmacist to test for and treat certain nonchronic health conditions. The bill requires additional education and training requirements that will create two certification types: Collaborative Practice Certification (CPC) and the Test and Treat Certification (TTC). The bill outlines the requirements to

obtain the certifications as well as terms and conditions are to be included in a collaborative practice pharmacy agreement and in the written protocol between a pharmacist and a physician. The bill requires continuing education to maintain the certifications and it requires the Board to adopt by rule a formulary of medicinal drugs that a pharmacist may prescribe for the treatment of non-chronic health conditions.

The Board of Pharmacy Rules Committee held a meeting on June 2, 2020 to review and discuss draft rule language for Chapter 64B16-31, F.A.C. Subsequent to the Rules Committee Meeting, Ms. Sapp sent out invitations to the Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM) to request representatives from each Board in order to form a Joint Rules Committee to review the draft rule language.

The BOM reviewed and discussed the draft rule language during their June 3, 2020 Board Meeting and determined that Dr. Vila and Dr. TerKonda would represent the BOM. The BOOM held a meeting on June 9, 2020 to discuss and review the language and determined that Dr. Rose and Dr. Mendez would represent BOOM.

The Joint Committee reviewed the below proposed draft rule language.

The Committee along with BOM and BOOM determined to only discuss the rules that require collaboration between the three Boards.

**64B16-31.001 Collaborative Practice Certification (CPC).**

Applicants for CPC shall submit an application using Form DH-MQA XXXX (eff. 0X/20), "Application for Pharmacist Collaborative Practice Certification<sup>1</sup>" that is hereby incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX> or <http://floridapharmacy.gov>. Applicants for certification must meet and comply with all requirements in Section 465.1865, F.S.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

**64B16-31.003 Collaborative Practice Certification: Initial Certification Course.**

(1) Applicants for Initial Certification Course approval shall submit an application using Form DH-MQA XXX (eff. XX/20) "Application for Initial Collaborative Practice Certification Course<sup>2</sup>" that is hereby incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX> or <http://floridapharmacy.gov>.

(2) Initial collaborative practice certification courses shall be a minimum of 20 hours in duration, and shall meet all the following mandatory requirements:

(a) The course may only be offered by a program provider who is accredited by the Accreditation Council for Pharmacy Education (ACPE) or a program provider who is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit or the American Osteopathic Association Category 1-A continuing medical education credit.

(b) The course content shall include all those areas enumerated in section 465.1865 (2)(c), F.S., and shall also cover the following areas:

1. Laws and rules applicable to the collaborative practice for the treatment of chronic health care conditions;

2. Writing and entering into a collaborative practice agreement;

3. Place holder for discussion with Board to determine appropriate content list in consultation with BOM and BOOM.

(c) No less than 12 hours of the course shall be offered through a live seminar or a live video teleconference.

Place holder for discussion with Board to determine appropriate format of specific hour requirements with BOM and BOOM.

(3) A pharmacist who successfully completes a board approved collaborative practice certification course shall be awarded 20 hours of general continuing education credits.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

**64B16-31.005 Collaborative Practice Certification: Collaborative Pharmacy Practice Agreement Submission.**

(1) Prior to providing or implementing patient care services under a Collaborative Pharmacy Practice Agreement or immediately after the renewal of such an Agreement, the Pharmacist shall submit the executed Agreement to the Board Office through the pharmacist's online licensure account at <http://www.flhealthsource.gov> or via U.S. Mail to 4052 Bald Cypress Way, Bin C-04, Tallahassee, FL 32399.

(2) In the event of an addendum to the material terms of an existing collaborative pharmacy practice agreement, the pharmacist shall maintain a copy of the addendum and the initial agreement pursuant to Section 465.1865(3)(c), F.S. Material terms shall be defined as those terms enumerated in Section 465.1865(3)(a), F.S.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

**64B16-31.007 Collaborative Practice Certification: Chronic Health Conditions.**

Pursuant to Section 465.1865, F.S., the Board hereby adopts the following list of chronic health conditions for which a pharmacist certified pursuant to section 465.1865, F.S., can provide specified patient care services to patients of a collaborating physician pursuant to a pending Collaborative Pharmacy Practice Agreement:

1) Hyperlipidemia;

2) Hypertension;

3) Anti-coagulation management;

4) Smoking cessation;

5) Osteoporosis and osteo-arthritis;

6) Opioid use disorder;

7) Those chronic health conditions enumerated in section 465.1865(1)(b), F.S.; and

8) Any disease state that is expected to last greater than one (1) year or more and will require ongoing medical treatment and drug therapy services.

Place holder for discussion with Board to determine appropriate list of chronic health conditions in consultation with BOM and BOOM.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

**64B16-31.009 Collaborative Practice Certification: Mandatory Continuing Education.**

A licensee shall not be required to complete the 8-hour continuing education related to collaborative pharmacy practice if the initial certificate was issued less than 12 months prior to the expiration date of the license.

*Rulemaking Authority 465.1865, FS. Law Implemented 465.1865, FS. History – New XX-XX-20.*

#### **64B16-31.033 Test and Treat Certification (TTC)**

Applicants for TTC shall submit an application using Form DH-MQA XXXX (eff. 0X/20), “Application for Pharmacist Test and Treat Certification<sup>3</sup>” that is hereby incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX> or <http://floridapharmacy.gov>. Applicants for certification must meet and comply with all requirements in Section 465.1895, F.S.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

#### **64B16-31.035 Test and Treat Certification: Initial Certification Course**

(1) Applicants for Initial Certification Course approval shall submit an application using Form DH-MQA XXX (eff. XX/20) “Application for Initial Test and Treat Certification Course<sup>4</sup>” that is hereby incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX> or <http://floridapharmacy.gov>.

(2) Initial test and treat certification courses shall be a minimum of 20 hours in duration, and shall meet all the following mandatory requirements:

(a) The course may only be offered by a program provider who is accredited by the Accreditation Council for Pharmacy Education (ACPE) or a program provider who is accredited to provide educational activities designated for the American Medical Association Physician’s Recognition Award Category 1 credit or the American Osteopathic Association Category 1-A continuing medical education credit.

(b) The course content shall include all those areas enumerated in section 465.1895 (2)(b), F.S., and shall also cover the following areas:

1. Laws and rules applicable to test and treat certifications;

2. Writing and entering into a written protocol;

3. Place holder for discussion with Board to determine appropriate content list in consultation with BOM and BOOM.

(c) No less than 12 hours of the course shall be offered through a live seminar or a live video teleconference.

(3) A pharmacist who successfully completes a board approved test and treat certification course shall be awarded 20 hours of general continuing education credits.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

#### **64B16-31.037 Test and Treat Certification: Written Protocol and Written Protocol Submission**

(1) Within 5 business days of entering into a written protocol with a supervising physician pursuant to section 465.1895, F.S., the pharmacist shall submit a copy of the written

agreement to the Board Office through the pharmacist's online licensure account at <http://www.flhealthsource.gov> or via U.S. Mail to 4052 Bald Cypress Way, Bin C-04, Tallahassee, FL 32399.

(2) In the event of an addendum to the material terms of an existing written protocol, the pharmacist shall maintain a copy of the addendum and the initial agreement. Material terms shall be defined as those terms enumerated in Section 465.1895(5)(a), F.S.

Place holder for discussion with Board to determine if it wants to provide additional requirements for the written protocol in consultation with BOOM and BOM pursuant to Section 465.1895(5)(a)6.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

#### **64B16-31.039 Test and Treat Certification: Formulary of Medical Drugs**

(1) Pursuant to section 465.1895, F.S., the Board hereby incorporates the following as the formulary of medicinal drugs that a pharmacist may prescribe pursuant to a written test and treat protocol:

(a) All medicinal drugs approved by the United States Food and Drug Administration ("FDA");

(b) All compounded medicinal drugs that utilize only active pharmaceutical ingredients approved by the FDA.

(2) A pharmacist may not prescribe controlled substances as described in s. 893.03 or 21 U.S.C. s. 812.

Placeholder for discussion with Boards regarding additional drugs that should be excluded.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

#### **64B16-31.041 Test and Treat Certification: Patient Records**

Upon receipt of a patient request, a pharmacist shall furnish patient records to a health care practitioner designated by the patient within a reasonable time frame, not to exceed 5 business days.

Place holder for discussion with Board regarding reasonable time frame for production of records.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

#### **64B16-31.043 Test and Treat Certification: Follow-up Care**

A pharmacist must provide written information to the patient advising the patient when to seek follow-up care from his or her primary care physician. A pharmacist shall provide follow-up care written information:

(1) Immediately prior to performing testing, screening, or treatment services on a patient for the first time;

(2) As outlined in the written protocol; and

(3) When the pharmacist determines in his or her judgment that the patient should follow-up with his or her primary care provider.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

**64B16-31.045 Test and Treat Certification: Mandatory Continuing Education.**

A licensee shall not be required to complete the 3-hour continuing education related to minor, nonchronic health conditions if the initial certificate was issued less than 12 months prior to the expiration date of the license.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

**64B16-31.050 Mandatory Review of Rule Chapter 64B16-31, F.A.C.**

(1) No later than 90 days prior to December 31, 2025, the Board shall review each rule in this Chapter and amend, modify or repeal any rule that creates barriers to entry for private business competition, is duplicative, outdated, obsolete, overly burdensome, or imposes excessive costs.

(2) In the event the Board fails to complete this review, the board, for any rule that has not been reviewed in accordance with subsection (1), shall begin the rule repeal process in accordance with the Administrative Procedures Act.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

The Joint Committee reviewed and began discussion on 64B16-31.003, F.A.C., Collaborative Practice Certification.

Dr. Rose addressed the Committee regarding (2)(a) and suggested to strike “category” in subsection (2)(a): American Osteopathic Association Category 1 A as they are subject to change.

Dr. Hickman addressed the Committee and inquired if taking the course by one of these associations listed in the rule, meet the requirements for the certification, or would the pharmacist need to complete a course that is specifically ACPE accredited.

Mr. Flynn confirmed that yes, this would apply in the state of Florida for general education credit hours if taken by one of the listed providers.

Dr. Vila addressed the Committee regarding the content of the course and suggested requiring specific hours in evaluation and management of chronic diseases and suggested those hours be completed on a human simulator.

Dr. Hickman confirmed that when the BOP reviews courses for approval, the course content will be reviewed to assure all requirements are being captured.

Mr. Philip addressed the Committee and agreed with Dr. Vila that the requirements of the evaluation and management is outlined in the statute and will be included in the approved course.

Dr. Mendez addressed the Committee regarding the intent of the certification and what setting it would be utilized in.

Mr. Philip stated the bill does not specify what setting the certification is to be utilized in and the intent is to be available to any practitioners whom qualify for the certifications.

Dr. Mendez stated that laboratory testing can be very different depending on what setting the pharmacist and collaborating physician are practicing.

Dr. Mikhael addressed the Committee and Dr. Mendez and confirmed that the intent is to increase patient access.

Dr. TerKonda addressed the Committee regarding the provider of the course and suggested the highlighted change in subsection (2)(a): The course may only be offered by a program provider who is accredited by the Accreditation Council for Pharmacy Education (ACPE) or and a program provider who is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit or the American Osteopathic Association Category 1-A continuing medical education credit as he would like to see the course be offered in conjunction with ACPE, AMA and AOMA.

Mr. Wright addressed the Committee regarding the benefits of the course being offered in conjunction with multiple accrediting bodies but was not sure if historically had ever been done.

Dr. Vila suggested splitting up the required course hours between the accrediting bodies and requiring specific hours per entity.

Mr. Flynn addressed the Committee and suggested requiring the instructor of the course be a licensed physician.

Dr. Mesaros summarized the discussion.

Dr. Villa inquired with the Committee regarding how the rule will capture the requirement of the patient's medical records and the communication between the pharmacist and the collaborating physician.

Mr. Philip addressed Dr. Villa's inquiry and stated the rule should not be prescriptive, as that would be outlined in the collaborative practice agreement and the certification should capture if a pharmacist has the knowledge, skills, and ability to enter into an agreement.

Dr. Mesaros opened the floor to additional Board Members.

No additional Board Member comments were provided.

Dr. Mesaros opened the floor for public comment.

Nicole Garrett, Clinical Ambulatory Pharmacist in Florida, addressed the Committee regarding the term CPA and that the statute requires the delegation be appropriate to the pharmacist's education and training and to the physician's scope of practice. She indicated pharmacists and physicians will only enter into an agreement in which both parties feel comfortable.

Mary Thomas, representing the Florida Medical Association (FMA) and the Florida Osteopathic Medical Association (FOMA), addressed the Committee regarding the continuing education requirements for physicians in order to diagnose patients and inquired what the process will be for approving the continuing education courses.

Ms. Sapp addressed the Committee regarding the process of approving continuing education courses and indicated that through this rulemaking the process, the rule shall outline who the course will be given by and what requirements will be included in the course. Courses will be reviewed by our staff pharmacist to ensure they meet the requirements in the statute and rule.

Mr. Flynn confirmed that the course will be approved by the Board of Pharmacy.

Dr. Vila suggested having multiple courses depending on the subject area.

Mr. Dierlam addressed the Committee indicating the bill requires a 20-hour course and outlines the requirements of the course and suggested the course be widely applicable.

Dr. Schwimmer, Vice-Chair of the BOOM, addressed the Committee and asked Mr. Flynn if anything in the statute prohibits the physician from requiring additional training for the pharmacists.

Mr. Flynn addressed Dr. Schwimmer and the Committee and confirmed, the CPA is a contractual agreement that is driven by the physician. A physician has the authority to select, create, and enter into an agreement with their pharmacist of choice. A pharmacist may not enter into an agreement unless they are appropriately qualified. Mr. Flynn indicated that requiring additional training would strictly be up to the physician when entering into an agreement.

Dr. Hickman indicated this agreement is between one practitioner and one pharmacist for the specific patient and the agreement could not be applied to multiple patients.

Louis Adams addressed the Committee regarding if a consultant license would qualify a pharmacist for this certification.

Mr. Flynn stated this statute stands independently and would be a separate certification.

Mr. Dierlam addressed the Committee regarding the requirements of a Consultant Pharmacist.

Dr. Villa addressed the Committee regarding how the course would be presented, either live, online, or otherwise and suggested no less than three hours of the course be live with interactive patient scenarios.

Dr. Mikhael addressed Dr. Vila regarding the human simulator.

Dr. Hickman and Dr. Mikhael addressed the Committee and agree with Dr. Vila for a live interaction requirement within the course.

Dr. Rose and Dr. Schwimmer suggested to be cognizant of COVID-19 and the difficulties with live hours during these times.

Dr. Mesaros thanked everyone for the discussion and stated that the Committee would take the comments into consideration when amending the draft rule language.

The Joint Committee began discussion on Rule 64B16-31.007, F.A.C., Collaborative Practice Certification: Chronic Health Conditions.

Dr. Mesaros summarized the proposed rule language and opened the floor for discussion.

Mr. Philip addressed the Committee regarding the chronic health conditions outlined in the rule. He indicated the agreement entered will be between a single physician and single pharmacist to manage a specific patient. The goal is to work together to ensure that the patient's quality of care is improved. Terms and conditions must be appropriate to a pharmacist's education and training to assure the pharmacist participating in the agreement be educated and prepared for that specific condition of the patient.

Mr. Wright addressed the Committee and agrees with, (7) Those chronic health conditions enumerated in section 465.1865(1)(b), F.S.; and stated this lets the physician determine states of the disease that can be covered.

Dr. Hickman addressed the Committee and agreed with Mr. Philip regarding evidence based in improving patient care and advised that, (8) Any disease state that is expected to last greater than one (1) year or more and will require ongoing medical treatment and drug therapy services., is necessary as there are a lot of additional chronic medical conditions that are not listed within the proposed rule.

Dr. Rose addressed the Committee regarding subsection 8 and expressed the intent of the legislature was not to put a catch all. He stated this option would bypass the ability for the Boards to collaborate on what chronic diseases could listed and would prefer to only list what is outlined in the bill.

Dr. Mendez addressed the Committee and would prefer to start slow and be deliberate when considering additional chronic conditions.

Dr. TerKonda addressed the Committee and agreed with Dr. Rose regarding his concerns with subsection 8.

Dr. Vila addressed the Committee and stated he has no opposition with the six additional diseases listed; however, would like to remove subsection 8.

Chris Nuland, representing the Florida Chapter, American College of Physicians, addressed the Committee and recommended the deletion of subsection 8.

Dr. Schwimmer, addressed the Committee and agreed with the deletion of subsection 8 and suggested adding behavioral health conditions.

Dr. Mikhael addressed the Committee regarding becoming too restrictive and expressed he believes the intent of subsection 8 was to fall back on the physician's responsibility with the pharmacist to determine what conditions are appropriate. Deleting this addition could be doing a disservice to accessing patient care.

Toni Large, representing the Florida Society of Rheumatology, addressed the Committee in opposition to (5) Osteoporosis and osteo-arthritis and expressed that most patients who go to a rheumatologist have potentially been treated by several physicians prior to being under the care a specialist to manage their conditions.

Mary Thomas, FMA, addressed the Committee in opposition of subsection 8 and suggested the bill does not authorize a catchall provision.

Kathy Baldwin, representing the Florida Society of Health-System Pharmacists (FSHP), addressed the Committee regarding the benefits of physicians collaborating with pharmacists as pharmacists can effectively manage medications and create an efficient path for patient access.

Jason Wynn, representing the Florida Osteopathic Medical Association, addressed the Committee in opposition of subsection 8.

Dr. Vila addressed the Committee regarding what items should be listed in the CPA.

Mr. Philip addressed Dr. Villa and the Committee and confirmed that the requirements of the CPA are outlined in the statute and those are also identified in the proposed application.

Mr. Flynn addressed the Committee regarding the statutory requirements of rulemaking and confirmed a statute should not be duplicated in rule.

Dr. TerKonda dismissed himself from the call.

Dr. Mendez dismissed herself from the call.

The Joint Committee began discussion on Rule 64B16-31.035, F.A.C., Test and Treat Certification: Initial Certification Course

Dr. Mesaros addressed the Committee and indicated that comments and suggestions from the discussion regarding the Collaborative Practice Certification will be incorporated in the Test and Treat Certification proposed rule language.

Mr. Philip addressed the Committee and stated he had no additional content areas to be added to the list as they are outlined in the statute and suggested lowering the requirement for live hours from twelve to eight.

Dr. Vila addressed the Committee regarding adopting the philosophy of not being too broad as that will delay the implementation of the proposed rules.

Dr. Rose addressed the Committee regarding the follow up care requirement.

Mr. Flynn indicated that the follow up requirement will be outlined within Rule 64B16-31.043, F.A.C., Test and Treat Certification: Follow-up Care.

Dr. Rose commented on the authority for compounded drugs within the drug formulary outlined in (b) All compounded medicinal drugs that utilize only active pharmaceutical ingredients approved by the FDA.

Dr. Hickman addressed the Committee and confirmed (b) was outlined due to the Tamiflu shortage.

Mr. Flynn confirmed the rule will be dictated by what is in the written protocol and indicated he indicated the current language will be clarified to specifically exclude controlled substances. The formulary shall include a list of US FDA approved active ingredients as the proposed language could be open for potential abuse of compounded drugs.

Dr. Rose dismissed himself from the meeting.

Dr. Schwimmer addressed the Committee regarding the formulary to Medicaid patients and should the rule address a Medicaid formulary.

Mr. Wright addressed the Committee regarding the formulary and how it may potentially alleviate the concern with compounding.

Dr. Hickman agreed with Mr. Wright and volunteered to work with Mr. Flynn on amending the proposed language to address the concerns.

Dr. Vila addressed the Committee and inquired about the electronic medical records.

Mr. Philip addressed Dr. Vila's concerns and confirmed this would depend on how communication is set up between each physician.

Dr. Mikhael addressed the Committee and extended his gratitude for the open discussion today.

Dr. Mesaros opened for public comment.

No public comments were received.

Ms. Sapp addressed the Committee and confirmed the comments from the discussion will be taken into consideration and amendments to the proposed rules will be presented at the next Committee Meeting.

### **III. ADJOURNMENT**

There being no further discussion, the meeting adjourned at 12:45 p.m.



# Florida House of Representatives

## Representative Tyler Sirois

### District 51

**District Office:**  
2460 North Courtenay Parkway  
Suite 108  
Merritt Island, FL 32953  
(321) 449-5111

**Tallahassee Office:**  
1301 The Capitol  
402 South Monroe Street  
Tallahassee, FL 32399-1300  
(850) 717-5051

August 7, 2020

Dr. Jeffery J. Mesaros, Chair  
Florida Department of Health  
Board of Pharmacy  
4052 Bald Cypress Way, Bin C-04  
Tallahassee, Florida 32399-3258

Dear Dr. Mesaros,

Following my review of the commentary at the joint meeting of the Board of Pharmacy, Board of Medicine, and Board of Osteopathic Medicine regarding House Bill 389, I am writing to offer my view on the intended goals of the legislation and the questions currently being considered. The primary purpose of this law is to increase patient access to quality and affordable healthcare options. This access provides Floridians with more choices to receive treatment for routine medical conditions, including influenza and streptococcus, under a protocol established with a supervising physician. Given the current COVID-19 pandemic and approaching cold and flu season, I am confident that you share my belief that we must move quickly to prepare Florida for the months ahead. Recognizing this very issue, Governor DeSantis issued an emergency order directing the Surgeon General to allow Florida's pharmacists to test for COVID-19 and to begin the rulemaking process for implementation of House Bill 389.

The law provides that the Board of Pharmacy will establish the requirements and approval for the certification course in *consultation* with the Board of Medicine and Osteopathic Medicine. The law states that a pharmacist who tests and treats minor, non-chronic health conditions must "hold a certification issued by the board to test and screen for and treat minor, non-chronic health conditions in accordance with requirements established by the board in rule in consultation with the Board of Medicine and Osteopathic Medicine." The law goes on to provide that "the certification must require a pharmacist to complete, on a one-time basis, a 20-hour education course approved by the board in *consultation*" with the medical boards. The course, at a minimum, must address guidelines related to patient assessments, testing procedures, patient safety, and treatment.

Based on differences in the proposed language offered between the June 25<sup>th</sup> and June 29<sup>th</sup> meetings, I am concerned that the inclusion of additional requirements not specifically mentioned by law will overcomplicate and slow the urgent need to implement this legislation. Specifically, by assigning coursework and certification development to occur in *conjunction* with the medical boards, I fear pursuit

Dr. Jeffery J. Mesaros, Chair  
August 7, 2020  
Page 2

of a consensus will slow the implementation of this straightforward legislation. *Consultation* suggests discussion or seeking of advice; *conjunction* suggests agreement—two entirely different things.

Again, with flu season approaching, time is of the essence and Florida's healthcare system will require a surge of all available resources—including pharmacies. It is critical to establish and finalize this process so that Floridians will have more options to access care. I strongly recommend that the Board of Pharmacy strike this additional requirement and adopt rules following consultation with the medical boards as provided by law. Local pharmacists need as much time as possible to prepare to offer these new services to Floridians.

On behalf of my constituents, thank you for the important work that you are doing during this ongoing and unprecedented public health emergency.

Sincerely,

A handwritten signature in black ink, appearing to read 'Tyler I. Sirois', with a stylized, cursive script.

Tyler I. Sirois

CC: Stephanie Kopelousos, Executive Office of the Governor  
Jessica Sapp, Executive Director, Florida Board of Pharmacy  
Richard Montgomery, Chair, Florida Board of Pharmacy

## Zeh, Traci

---

**From:** Kemp, Claudia J  
**Sent:** Tuesday, July 28, 2020 8:47 AM  
**To:** Sapp, Jessica  
**Cc:** Zeh, Traci  
**Subject:** FW: Rule draft for Board of Pharmacy Rule Committee July 29 meeting/Collaborative practice

---

**From:** TerKonda, Sarvam P., M.D. <TerKonda.Sarvam@mayo.edu>  
**Sent:** Monday, July 27, 2020 6:56 PM  
**To:** Kemp, Claudia J <Claudia.Kemp2@flhealth.gov>  
**Cc:** Ed Tellechea <Ed.Tellechea@myfloridalegal.com>; Donna McNulty <Donna.McNulty@myfloridalegal.com>; Sarvam TerKonda <terkonda.sarvam@mayo.edu>  
**Subject:** RE: Rule draft for Board of Pharmacy Rule Committee July 29 meeting/Collaborative practice

Claudia:

Please have the following reviewed at BOP meeting:

1. I agree with Dr. London regarding the timely communication of changes made to medications from the pharmacist to the physician.
2. Under Chronic Health Conditions, we need a better definition of Opioid Use Disorder or remove this from the Chronic Health Conditions. Also in the Statue line numbers 261-263, the pharmacist is not allowed to prescribe controlled substances.

### **64B16-31.007 Collaborative Practice Certification: Chronic Health Conditions.**

Pursuant to Section 465.1865, F.S., the Board hereby adopts the following list of chronic health conditions for which a pharmacist certified pursuant to section 465.1865, F.S., can provide specified patient care services to patients of a collaborating physician pursuant to a pending Collaborative Pharmacy Practice Agreement:

- 1) Hyperlipidemia;
- 2) Hypertension;
- 3) Anti-coagulation management;
- 4) Smoking cessation;
- 5) Osteoporosis and Osteoarthritis;
- 6) Opioid use disorder; and
- 7) Those chronic health conditions enumerated in section 465.1865(1)(b), F.S.
- 8) Any disease state that is expected to last greater than one (1) year or more and will require ongoing medical treatment and drug therapy services.

256 | (3) The board shall adopt, by rule, a formulary of  
257 | medicinal drugs that a pharmacist may prescribe for the minor,  
258 | nonchronic health conditions approved under subsection (1). The  
259 | formulary must include medicinal drugs approved by the United  
260 | States Food and Drug Administration which are indicated for  
261 | treatment of the minor, nonchronic health condition. The  
262 | formulary may not include any controlled substance as described  
263 | in s. 893.03 or 21 U.S.C. s. 812.

3. Similar to the Collaborative Practice Form (as per Dr. Villa). We need Written Form for the Test and Treat Certification: Formulary of Medical Drugs

### **64B16-31.039 Test and Treat Certification: Formulary of Medical Drugs**

(1) Pursuant to section 465.1895, F.S., the Board hereby incorporates all medicinal drugs approved by the United States Food and Drug Administration (“FDA”) as the formulary of medicinal drugs that a pharmacist may prescribe pursuant to a written test and treat protocol.

~~(b) All compounded medicinal drugs that utilize only active pharmaceutical ingredients approved by the FDA.~~

(2) A pharmacist may not prescribe controlled substances as described in s. 893.03 or 21 U.S.C. s. 812.

3. We need to add: The Pharmacist may not delegate responsibilities to a pharmacy tech or another individual.

Thank you

Sarvam TerKonda

---

**From:** Kemp, Claudia J [<mailto:Claudia.Kemp2@flhealth.gov>]

**Sent:** Wednesday, July 22, 2020 4:17 PM

**To:** Kemp, Claudia J

**Cc:** Ed Tellechea; Donna McNulty; Sanford, Crystal; 'Hector Vila Jr MD'

**Subject:** [EXTERNAL] Rule draft for Board of Pharmacy Rule Committee July 29 meeting/Collaborative practice

Members:

The public book for this meeting is available on our website and contains the attached rule draft along with other materials. Dr. Vila requested that I send you just the rule draft for review. As the board’s representative at the meeting, Dr. Vila wants to have any input you would like to provide. Send comments/input to me and copy Ed and Donna. I will provide the comments/input to Dr. Vila and the Board of Pharmacy.

**Claudia Kemp, JD**

**Executive Director, Board of Medicine**

Department of Health | Division of Medical Quality Assurance | Health Care Practitioner Regulation

4052 Bald Cypress Way Bin C-03

Tallahassee, FL 32399-1708

Phone 850-245-4130



**Mission:** To protect, promote and improve the health of all people in Florida through integrated state, county and community efforts.

July 27, 2020

Pg 13 Further evidence of the need for prompt timely communication between the participating pharmacist and the sponsoring physician in the CPPA:

83 | authorized by the patient, regarding the drug therapy; and  
84 | initiating, modifying, or discontinuing drug therapy for a  
85 | chronic health condition under a collaborative pharmacy practice  
86 | agreement. ~~However,~~ Nothing in this subsection may be

The physician needs to be kept up to date with adjustments to treatments as described herein.

116 | (b) "Chronic health condition" means:  
117 | 1. Arthritis;  
118 | 2. Asthma;  
119 | 3. Chronic obstructive pulmonary diseases;  
120 | 4. Type 2 diabetes;  
121 | 5. Human immunodeficiency virus or acquired immune  
122 | deficiency syndrome;  
123 | 6. Obesity; or  
124 | 7. Any other chronic condition adopted in rule by the  
125 | board, in consultation with the Board of Medicine and Board of

Pg 16 Reference to medical records limited to:

150 | (e) Have established a system to maintain records of all  
151 | patients receiving services under a collaborative pharmacy  
152 | practice agreement for a period of 5 years from each patient's  
153 | most recent provision of service.

And

174 | 6. Beginning and ending dates for the collaborative  
175 | pharmacy practice agreement and termination procedures,  
176 | including procedures for patient notification and medical  
177 | records transfers.

Pg 16 Examples of Terms and conditions of CPPA:

161       (a) A collaborative pharmacy practice agreement must  
162 include the following:  
163       1. Name of the collaborating physician's patient or  
164 patients for whom a pharmacist may provide services.  
165       2. Each chronic health condition to be collaboratively  
166 managed.  
167       3. Specific medicinal drug or drugs to be managed by the  
168 pharmacist for each patient.  
169       4. Circumstances under which the pharmacist may order or  
170 perform and evaluate laboratory or clinical tests.  
171       5. Conditions and events upon which the pharmacist must  
172 notify the collaborating physician and the manner and timeframe  
173 in which such notification must occur.  
174       6. Beginning and ending dates for the collaborative  
175 pharmacy practice agreement and termination procedures,

Agree with Dr. Vila's recommendation that this be formatted much as in the same manner as are current standardized order sets where the physician chooses from a selection of options, from which the pharmacist can then manage the patient

Simple Example (final formatting would have to include options relating to parameters for laboratory and clinical testing (line 169), circumstances for physician notification (171), etc.

Chronic Medical conditions/treatment options Check all that apply:

1. \_\_\_\_ Asthma

Medications:

A

B

C

2. \_\_\_\_ DM T2

Medications:

A

B

C

3. \_\_\_\_ COPD

Medications

A

B

C

4. \_\_\_\_ Etc.,

Pg 17 Since the Board of Pharmacy regulatory authority is restricted to Pharmacists, can the BOM and the BOOM regulate the components of the CPPA as it relates to physician medical practice (e.g. similar to below, physicians must make such agreements available to their Board)?

183 |           (c) The pharmacist, along with the collaborating  
184 | physician, must maintain on file the collaborative pharmacy  
185 | practice agreement at his or her practice location, and must  
186 | make such agreements available to the department or board upon  
187 | request or inspection.

See next page

Pg 18 Minor non-chronic health conditions: Same comments as fort chronic conditions with regards to medical record keeping and timely communication with the CPPA physician of any interventions, testing, changes, treatments

216        465.1895 Testing or screening for and treatment of minor,  
217 nonchronic health conditions.-  
218        (1) A pharmacist may test or screen for and treat minor,  
219 nonchronic health conditions within the framework of an  
220 established written protocol with a supervising physician  
221 licensed under chapter 458 or chapter 459. For purposes of this  
222 section, a minor, nonchronic health condition is typically a  
223 short-term condition that is generally managed with minimal  
224 treatment or self-care, and includes:  
225        (a) Influenza.

Page 9 of 14

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

hb0389-03-er

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F L O R I D A   H O U S E   O F   R E P R E S E N T A T I V E S

ENROLLED

CS/HB 389, Engrossed 1

2020 Legislature

226        (b) Streptococcus.  
227        (c) Lice.  
228        (d) Skin conditions, such as ringworm and athlete's foot.  
229        (e) Minor, uncomplicated infections.

Pg 20 Same language regarding medical record and documentation as which chronic medical conditions referenced above.

251 | (e) Upon request of a patient, furnish patient records to  
252 | a health care practitioner designated by the patient.  
253 | (f) Maintain records of all patients receiving services  
254 | under this section for a period of 5 years from each patient's  
255 | most recent provision of service.

Pg 21 The following is found in the section for acute, non-chronic conditions. I did not find similar language in the section for chronic conditions. It should be there as well.

292 | 4. A process and schedule for the physician to review the  
293 | pharmacist's actions under the protocol.  
294 | 5. A process and schedule for the pharmacist to notify the  
295 | physician of the patient's condition, tests administered, test  
296 | results, and course of treatment.

Pg 65 Individual pharmacy letter to BOP. Could not disagree more with the following:

The legislature's actions were promising and progressive in the best interest of the patient, and I believe that the board's rulemaking process should be as well. Therefore, I make the following suggestions:

1. Allow individual protocols, rather than preconstructed blank forms which must be followed strictly.

Pg. 65 Standards for pharmacists should be identical as for those regulating physicians (EHRs, CPOE, etc.) Else invite two standards of patient care.

- c. Certain procedures outlined in the protocol may be impossible for some practitioners to meet.
  - i. For example, if it is obligated that the protocol is transmitted electronically only, and a physician and/or pharmacists does not have the technology available to do so, or is financially not in the position to spend hefty sums of money to upgrade to said technology for this purpose, why would the rule compel them to do so? If they are unable and thus cannot collaborate and provide

expertise for the benefit of Florida's public, that is a disservice to the citizens and not at all what the legislature had intended. There should not be any substantial financial limitations to a pharmacist being able to implement this in their practice.

Pg 67 Disagree strongly with the following:

2. Do not limit to only conditions specifically outlined in statute.

Additional comments:

CPPA should be restricted to physicians currently and actively treating the patient for the specified condition. Corporate physicians employed by pharmacies who are not directly involved in treating the individual patient should be prohibited from entering into CPPAs.

CPPA should clearly prohibit a participating pharmacist from delegating any aspect of the patient interactions as described herein to a pharmacy tech, pharmacist assistant or other healthcare extender.

Respectfully Submitted for consideration.

Robert A. London MD



*Unifying and strengthening the voice of pharmacy  
while advancing pharmacy practice through  
education, advocacy collaboration, and relationships*

July 26, 2020

Florida Board of Pharmacy  
Attention: Jessica Sapp, Executive Director  
4052 Bald Cypress Way, Bin C-04  
Tallahassee, Florida 32399

**Re: Draft Rules Implementing HB389 and FPA Provided Comments**

Dear Ms. Sapp:

This correspondence is provided on behalf of the Florida Pharmacy Association, Inc. (FPA), a not-for-profit corporation which seeks to preserve and advance the practice of pharmacy and serves the professional needs of all pharmacists, pharmacy students, and pharmacy technicians in Florida. The FPA is committed to improving public health and patient care, enhancing professional development, and advocating for the interests of the profession. The purpose of this letter to provide the Board of Pharmacy with comments relating to the Board's most recent draft rules implementing HB 389.

The Board's most recent draft rules implementing HB 389 include several revisions to the prior version. We will focus our comments on two of the revisions. First, the Board has removed the chronic health condition "catch-all" from proposed rule 64B16-31.007 Collaborative Practice Certification: Chronic Health Conditions. This may have been done, in part, in response to concerns raised by the Florida Medical Association, the Florida Osteopathic Medical Association, and the Florida Society of Rheumatology. Each of these associations suggests that the Board may not have sufficient rulemaking authority to include a catch-all in the chronic health conditions rule.

We disagree. HB 389 specifically provides that the Board has the authority to include any other chronic condition adopted in rule. HB 389 does not limit the number or type of chronic conditions that the Board may include in the rule. Thus, the Board has the authority to include any and all chronic conditions, if it so chooses. Additionally, the Board's catch-all language nearly mirrors CDC's definition of chronic disease. Any suggestion that the language is arbitrary or capricious is without merit.

Pharmacists and supervising physicians should have the discretion and flexibility to determine which chronic conditions are best suited for collaborative pharmacy practice agreements based on the unique circumstances of their practice and expertise. The removal of the catch-all limits this discretion and significantly restricts the use of collaborative pharmacy practice agreements in Florida. We feel that this is contrary to the legislative intent behind HB 389 of increasing access to healthcare. With that said, we recognize the importance of expediting the adoption of rules relating to collaborative pharmacy practice agreements so that pharmacists and supervising physician can begin utilizing the agreements as soon as possible. However, as noted above, we believe the Board has the necessary authority for the catch-all and ask that the Board consider adding the language back to the rule.

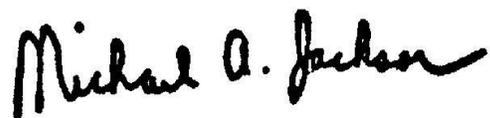
Second, the Board has included a requirement in proposed rule 64B16-31.003 Collaborative Practice Certification: Initial Certification Course and proposed rule 64B16-31.035 Test and Treat Certification: Initial Certification Course that each course must be developed in conjunction with a licensed pharmacist and a licensed physician. We are concerned that this requirement will unnecessarily delay the process of developing a certification course. It has been our experience that requiring a pharmacy course to be developed in conjunction with another profession will inevitably lead to a long, drawn out development process. For example, section 465.1893's 8-hour continuing education course to administer long-acting antipsychotic medications by injection is required to be developed by a statewide association of physicians and a statewide association of pharmacists. It took years for the course to be developed, thus delaying the implementation of the law. We are concerned that the requirement in the certification course rules could have a similar effect. In light of the current strain on the healthcare system, it is imperative that pharmacists and physicians have the ability to enter into collaborative pharmacy practice agreements and written protocols as soon as possible and any unnecessary requirements that could delay this should be avoided.

Additionally, it is not necessary for the certification course rules to require that the courses be developed in conjunction with other licensed practitioners. The rules already require that only certain accredited providers of continuing education may provide the certification courses. This

ensures the courses will only be offered by providers that have been approved by national accrediting organizations as meeting strict continuing education standards. With this requirement in place, there should be no concern that the course providers will not offer high quality content. It should also be noted that nothing in HB 389 requires that the certification courses must be developed in conjunction with licensed physicians. For these reasons, we ask that the Board remove the requirement that the certification courses must be developed in conjunction with licensed pharmacists and licensed physicians.

Thank you for the opportunity to submit these comments and we look forward to continuing to work with the Board on the development of these important rules.

With kindest regards,

A handwritten signature in black ink that reads "Michael A. Jackson". The signature is written in a cursive, flowing style.

Michael A. Jackson, BPharm, CPh  
Executive Vice President and CEO



*Unifying and strengthening the voice of pharmacy  
while advancing pharmacy practice through  
education, advocacy collaboration, and relationships*

August 13, 2020

Jessica Sapp  
Executive Director  
Florida Board of Pharmacy  
4052 Bald Cypress Way, C-04  
Tallahassee Florida 32399

**Re: Supplemental Comment Letter Re Rulemaking for HB389**

Dear Ms. Sapp:

This correspondence is provided on behalf of the Florida Pharmacy Association, Inc. (FPA), a not-for-profit corporation which seeks to preserve and advance the practice of pharmacy and serves the professional needs of all pharmacists, pharmacy students, and pharmacy technicians in Florida. The FPA is committed to improving public health and patient care, enhancing professional development, and advocating for the interests of the profession. The purpose of this letter is to supplement our prior comments regarding the Board of Pharmacy's most recent rules implementing HB 389.

As the scope of the practice of pharmacy continues to expand, pharmacists are provided with greater opportunities to share their knowledge and training with Florida patients. We are fully in support of this and are confident this will increase patient access to care, lower healthcare costs, and improve healthcare outcomes. However, we are concerned that as pharmacists are authorized to provide more services some pharmacies will require employee pharmacists to perform more services without providing the pharmacists with the necessary resources and staffing to ensure there is no reduction in the standard of care. This is a very real concern that could negatively impact both a pharmacist's quality of life and the safety and welfare of patients.

As you know, HB 389 requires a pharmacist seeking to enter into a collaborative pharmacy practice agreement or a written protocol to test and treat for minor, nonchronic health conditions to obtain the written approval of his or her pharmacy before entering into such agreement. This requirement ensures

that the decision to enter into such agreements is a joint decision between the pharmacy and the pharmacist. A pharmacy should only provide its approval if it fully supports the pharmacist and will provide the necessary resources so that the pharmacist can perform his or her obligations under the agreement. A pharmacy that is unwilling to provide these assurances is not truly “approving” a pharmacist to enter into such agreements. Rather, it is allowing (or requiring) the pharmacist to provide services under such agreements with no assurance that the pharmacist will have the resources needed to protect themselves and adequately care for the patients.

In order to address the concerns raised in this letter and to ensure that the decision to enter into an agreement is a joint decision between the pharmacy and the pharmacist, we believe the Board should adopt a rule requiring a pharmacy to affirmatively confirm in writing that it has or will have sufficient staffing and resources, including personal protective equipment and testing equipment, before approving a pharmacist to enter into a collaborative pharmacy practice agreement or a written protocol. The written confirmation should be maintained on file at the pharmacy. We believe such a rule is within the Board’s rulemaking authority included in HB 389, as well as the Board’s existing authority in sections 465.005, 465.0155, and 465.022, Florida Statutes.

Thank you for the opportunity to submit these comments and we look forward to continuing to work with the Board on the development of these important rules.

With kindest regards,

A handwritten signature in black ink that reads "Michael A. Jackson". The signature is written in a cursive, flowing style.

Michael A. Jackson, BPharm, CPh  
Executive Vice President and CEO

## Zeh, Traci

---

**From:** Sapp, Jessica  
**Sent:** Monday, June 29, 2020 4:07 PM  
**To:** Zeh, Traci  
**Subject:** FW: Proposed Rule 64B16-31.007

---

**From:** Sapp, Jessica  
**Sent:** Monday, June 29, 2020 4:06 PM  
**To:** 'Mary Thomas' <MThomas@flmedical.org>; nulandlaw@aol.com; David.Flynn@myfloridalegal.com  
**Cc:** Winn, Jason D. <jwinn@jwinnlaw.com>  
**Subject:** RE: Proposed Rule 64B16-31.007

Hi Mary,

Thank you for your request. Once we have scheduled a rules workshop, I will notify you of the date and time.

Regards,

**Jessica Sapp**

**Executive Director**

Department of Health | Division of Medical Quality Assurance  
Bureau of Health Care Practitioner Regulation  
4052 Bald Cypress Way Bin C-04  
Tallahassee, FL 32399-1708  
Phone 850/245-4463  
[www.FloridasDentistry.gov](http://www.FloridasDentistry.gov)  
[www.FloridasPharmacy.gov](http://www.FloridasPharmacy.gov)



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---

**From:** Mary Thomas <MThomas@flmedical.org>  
**Sent:** Monday, June 29, 2020 12:34 PM  
**To:** [nulandlaw@aol.com](mailto:nulandlaw@aol.com); Sapp, Jessica <[Jessica.Sapp@flhealth.gov](mailto:Jessica.Sapp@flhealth.gov)>; [David.Flynn@myfloridalegal.com](mailto:David.Flynn@myfloridalegal.com)

Cc: Winn, Jason D. <[jwinn@jwinnlaw.com](mailto:jwinn@jwinnlaw.com)>

Subject: RE: Proposed Rule 64B16-31.007

Ms. Sapp,

On behalf of the Florida Medical Association and the Florida Osteopathic Medical Association, I would like to echo Mr. Nuland's comments and concerns and formally request a rule development workshop on the proposed rules within Chapter 64B16-31, F.A.C.

Thank you,

Mary



Mary Thomas, Esq.  
Assistant General Counsel  
1430 Piedmont Dr. E  
Tallahassee, FL 32308  
850.224.6496  
[www.flmedical.org](http://www.flmedical.org)  
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---

**From:** CHRIS NULAND <[nulandlaw@aol.com](mailto:nulandlaw@aol.com)>

**Sent:** Monday, June 29, 2020 11:56 AM

**To:** [Jessica.Sapp@flhealth.gov](mailto:Jessica.Sapp@flhealth.gov); [David.Flynn@myfloridalegal.com](mailto:David.Flynn@myfloridalegal.com)

**Subject:** Proposed Rule 64B16-31.007

**This message came from an external source. Please do not click LINKS if unexpected or unusual.**

**Law Offices of Christopher L. Nuland, P.A.**  
4427 Herschel Street  
Jacksonville, FL 32210  
(904) 355-1555  
[nulandlaw@aol.com](mailto:nulandlaw@aol.com)

Dear Ms. Sapp:

Thank you for the opportunity to have spoken briefly at last week's Board of Pharmacy Rules Committee meeting with regard to the above rule.

As I and my clients believe that questions still remain as to whether the existence of subsection (8) is supported by sufficient statutory authority, is arbitrary and capricious in its wording, as well as whether the addition of certain diseases has been supported by competent substantial evidence, the Florida Chapter of the American College of Physicians and the Florida Academy of Family Physicians would like to request a formal workshop on the proposed rule.

Thank you for your time and consideration of this request, and I hope you all stay well.

Sincerely,

CHRIS NULAND  
[nulandlaw@aol.com](mailto:nulandlaw@aol.com)

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**Zeh, Traci**

---

**Subject:** FW: Proposed Rule 64B16-31.007

**From:** CHRIS NULAND <[nulandlaw@aol.com](mailto:nulandlaw@aol.com)>

**Sent:** Monday, June 29, 2020 11:56 AM

**To:** [Jessica.Sapp@flhealth.gov](mailto:Jessica.Sapp@flhealth.gov); [David.Flynn@myfloridalegal.com](mailto:David.Flynn@myfloridalegal.com)

**Subject:** Proposed Rule 64B16-31.007

**This message came from an external source. Please do not click LINKS if unexpected or unusual.**

**Law Offices of Christopher L. Nuland, P.A.**  
4427 Herschel Street  
Jacksonville, FL 32210  
(904) 355-1555  
[nulandlaw@aol.com](mailto:nulandlaw@aol.com)

Dear Ms. Sapp:

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Thank you for your time and consideration of this request, and I hope you all stay well.

Sincerely,

CHRIS NULAND  
[nulandlaw@aol.com](mailto:nulandlaw@aol.com)

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## Zeh, Traci

---

**Subject:** FW: Proposed Rule 64B16-31.007

**From:** Sapp, Jessica

**Sent:** Thursday, July 2, 2020 12:29 PM

**To:** 'Mary Thomas' <[MThomas@flmedical.org](mailto:MThomas@flmedical.org)>; [nulandlaw@aol.com](mailto:nulandlaw@aol.com); [David.Flynn@myfloridalegal.com](mailto:David.Flynn@myfloridalegal.com)

**Cc:** Winn, Jason D. <[jwinn@jwinnlaw.com](mailto:jwinn@jwinnlaw.com)>

**Subject:** RE: Proposed Rule 64B16-31.007

Good afternoon,

This is to inform you that a rule development workshop on proposed rules 64B16-31.007, F.A.C. and 31.039, F.A.C. has been scheduled in conjunction with our joint rules committee meeting for Wednesday, July 29, 2020 at 9:00 a.m.

Regards,

**Jessica Sapp**

**Executive Director**

Department of Health | Division of Medical Quality Assurance

Bureau of Health Care Practitioner Regulation

4052 Bald Cypress Way Bin C-04

Tallahassee, FL 32399-1708

Phone 850/245-4463

[www.FloridasDentistry.gov](http://www.FloridasDentistry.gov)

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**From:** Mary Thomas <[MThomas@flmedical.org](mailto:MThomas@flmedical.org)>

**Sent:** Monday, June 29, 2020 12:34 PM

**To:** [nulandlaw@aol.com](mailto:nulandlaw@aol.com); Sapp, Jessica <[Jessica.Sapp@flhealth.gov](mailto:Jessica.Sapp@flhealth.gov)>; [David.Flynn@myfloridalegal.com](mailto:David.Flynn@myfloridalegal.com)

**Cc:** Winn, Jason D. <[jwinn@jwinnlaw.com](mailto:jwinn@jwinnlaw.com)>

**Subject:** RE: Proposed Rule 64B16-31.007

Ms. Sapp,

On behalf of the Florida Medical Association and the Florida Osteopathic Medical Association, I would like to echo Mr. Nuland's comments and concerns and formally request a rule development workshop on the proposed rules within Chapter 64B16-31, F.A.C.

Thank you,

Mary



Mary Thomas, Esq.  
Assistant General Counsel  
1430 Piedmont Dr. E  
Tallahassee, FL 32308  
850.224.6496  
[www.flmedical.org](http://www.flmedical.org)  
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**From:** CHRIS NULAND <[nulandlaw@aol.com](mailto:nulandlaw@aol.com)>  
**Sent:** Monday, June 29, 2020 11:56 AM  
**To:** [Jessica.Sapp@flhealth.gov](mailto:Jessica.Sapp@flhealth.gov); [David.Flynn@myfloridalegal.com](mailto:David.Flynn@myfloridalegal.com)  
**Subject:** Proposed Rule 64B16-31.007

**This message came from an external source. Please do not click LINKS if unexpected or unusual.**

**Law Offices of Christopher L. Nuland, P.A.**  
4427 Herschel Street  
Jacksonville, FL 32210  
(904) 355-1555  
[nulandlaw@aol.com](mailto:nulandlaw@aol.com)

Dear Ms. Sapp:

Thank you for the opportunity to have spoken briefly at last week's Board of Pharmacy Rules Committee meeting with regard to the above rule.

As I and my clients believe that questions still remain as to whether the existence of subsection (8) is supported by sufficient statutory authority, is arbitrary and capricious in its wording, as well as whether the addition of certain diseases has been supported by competent substantial evidence, the Florida Chapter of the American College of Physicians and the Florida Academy of Family Physicians would like to request a formal workshop on the proposed rule.

Thank you for your time and consideration of this request, and I hope you all stay well.

Sincerely,

CHRIS NULAND  
[nulandlaw@aol.com](mailto:nulandlaw@aol.com)

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## Zeh, Traci

---

**From:** Sapp, Jessica  
**Sent:** Wednesday, July 1, 2020 1:36 PM  
**Subject:** Board of Pharmacy Joint Rules Committee Meeting

Good afternoon,

The Board of Pharmacy has scheduled a second Joint Rules Committee meeting for **July 29, 2020 at 9:00 a.m.** to review draft rules based on the discussion during the June 25 meeting. We have received a request for a Rules Workshop on proposed rules 64B16-31.007 and 31.039 which will also take place during this meeting. The meeting materials will be published to you approximately 10 days prior to the meeting. Please let me know if you have any questions or concerns.

All committee members, board counsels and staff have been blind copied on this email.

Regards,

**Jessica Sapp**

**Executive Director**

Department of Health | Division of Medical Quality Assurance

Bureau of Health Care Practitioner Regulation

4052 Bald Cypress Way Bin C-04

Tallahassee, FL 32399-1708

Phone 850/245-4463

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## **64B16-31.007 Collaborative Practice Certification: Chronic Health Conditions.**

Pursuant to Section 465.1865, F.S., the Board hereby adopts the following list of chronic health conditions for which a pharmacist certified pursuant to section 465.1865, F.S., can provide specified patient care services to patients of a collaborating physician pursuant to a pending Collaborative Pharmacy Practice Agreement:

- 1) Hyperlipidemia;
- 2) Hypertension;
- 3) Anti-coagulation management;
- 4) Smoking cessation;
- 5) Osteoporosis and Osteoarthritis;
- 6) Opioid use disorder; and
- 7) Those chronic health conditions enumerated in section 465.1865(1)(b), F.S.
- 8) Any disease state that is expected to last greater than one (1) year or more and will require ongoing medical treatment and drug therapy services.

## **64B16-31.039 Test and Treat Certification: Formulary of Medical Drugs**

(1) Pursuant to section 465.1895, F.S., the Board hereby incorporates all medicinal drugs approved by the United States Food and Drug Administration (“FDA”) as the formulary of medicinal drugs that a pharmacist may prescribe pursuant to a written test and treat protocol.

~~(b) All compounded medicinal drugs that utilize only active pharmaceutical ingredients approved by the FDA.~~

(2) A pharmacist may not prescribe controlled substances as described in s. 893.03 or 21 U.S.C. s. 812.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

## Zeh, Traci

---

**From:** Kemp, Claudia J  
**Sent:** Thursday, July 23, 2020 8:08 AM  
**To:** Sapp, Jessica  
**Cc:** Zeh, Traci  
**Subject:** FW: Rule draft for Board of Pharmacy Rule Committee July 29 meeting/Collaborative practice

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Comment.

**From:** Robert London <rlondon10.bom@gmail.com>  
**Sent:** Thursday, July 23, 2020 7:47 AM  
**To:** Kemp, Claudia J <Claudia.Kemp2@flhealth.gov>  
**Cc:** Ed Tellechea <Ed.Tellechea@myfloridalegal.com>; Donna McNulty <Donna.McNulty@myfloridalegal.com>  
**Subject:** Re: Rule draft for Board of Pharmacy Rule Committee July 29 meeting/Collaborative practice

All,

Nothing in the following requires timely communication from the pharmacist to the treating physician of changes made to medications (dose, ,med changes), or new diagnoses and treatments. Deferring to the individual collaboration agreements invites inconsistencies in such communications, which may be at the expense of patient care.

Robert London MD.

### **64B16-31.041 Test and Treat Certification: Patient Records**

Upon receipt of a patient request, a pharmacist shall furnish patient records to a health care practitioner designated by the patient within a reasonable time frame, not to exceed 5 business days.

*Rulemaking Authority 465.1895, FS. Law Implemented 465.1895, FS. History – New XX-XX-20.*

### **64B16-31.043 Test and Treat Certification: Follow-up Care**

A pharmacist must provide written information to the patient advising the patient when to seek follow-up care from his or her primary care physician. A pharmacist shall provide follow-up care written information:

- (1) Immediately prior to performing testing, screening, or treatment services on a patient for the first time;
- (2) As outlined in the written protocol; and
- (3) When the pharmacist determines in his or her judgment that the patient should follow-up with his or her primary care provider.

On Wed, Jul 22, 2020 at 4:17 PM Kemp, Claudia J <[Claudia.Kemp2@flhealth.gov](mailto:Claudia.Kemp2@flhealth.gov)> wrote:

Members:

The public book for this meeting is available on our website and contains the attached rule draft along with other materials. Dr. Vila requested that I send you just the rule draft for review. As the board's representative at the meeting, Dr. Vila wants to have any input you would like to provide. Send comments/input to me and copy Ed and Donna. I will provide the comments/input to Dr. Vila and the Board of Pharmacy.

**Claudia Kemp, JD**

**Executive Director, Board of Medicine**

Department of Health | Division of Medical Quality Assurance | Health Care Practitioner Regulation

4052 Bald Cypress Way Bin C-03

Tallahassee, FL 32399-1708

Phone 850-245-4130



**Mission:** To protect, promote and improve the health of all people in Florida through integrated state, county and community efforts.

Collaborative Pharmacy Practice Agreement  
Chronic Health Conditions

Physician name:  
Florida License #

Physician's Patient Name:  
DOB  
Contact info:  
    Address  
    Tel. number

Pharmacist Name:  
Florida License Number:  
Collaborative Practice Certification: Attach copy as required by Statute

Chronic Health Condition to Be Collaborated (circle):

1. Arthritis
2. Asthma
3. COPD
4. Type 2 Diabetes
5. HIV
6. Obesity

Drug or Drugs to be managed by pharmacist:

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_
4. \_\_\_\_\_

Circumstances that require ordering of laboratory or clinical tests:

Conditions and events that require physician notification within \_\_\_\_\_ days:

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_
4. \_\_\_\_\_

Above notification should go to (email or physical address):

Beginning date \_\_\_\_\_ and Ending date \_\_\_\_\_. Procedure for notifying patient and transferring records:

This agreement may be terminated at any time by either party in writing and will automatically terminate in 2 years if not renewed.

This agreement must be submitted to the board before implementation.

Physician signature \_\_\_\_\_ Date: \_\_\_\_\_

Pharmacist signature \_\_\_\_\_ Date: \_\_\_\_\_

## Zeh, Traci

---

**From:** Kemp, Claudia J  
**Sent:** Thursday, July 23, 2020 11:26 AM  
**To:** Sapp, Jessica  
**Cc:** Zeh, Traci  
**Subject:** FW: draft CPA  
**Attachments:** Collaborative Pharmacy Practice Agreement.docx

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Comment.

---

**From:** Ed Tellechea <Ed.Tellechea@myfloridalegal.com>  
**Sent:** Thursday, July 23, 2020 10:58 AM  
**To:** Kemp, Claudia J <Claudia.Kemp2@flhealth.gov>  
**Subject:** FW: draft CPA

See attachment. Dr. Vila wants to have it added to the 7/29 agenda of the Pharm Committee meeting. I know it's a bit late but I guess we can ask.

**Edward A. Tellechea**  
Chief Assistant Attorney General  
Administrative Law Bureau  
Office of the Attorney General  
PL-01, The Capitol  
Tallahassee, Florida 32399-1050  
Office: (850) 414-3754  
Fax: (850) 922-6425  
[Ed.Tellechea@myfloridalegal.com](mailto:Ed.Tellechea@myfloridalegal.com)



---

**From:** Hector Vila <[drhvila@gmail.com](mailto:drhvila@gmail.com)>  
**Sent:** Thursday, July 23, 2020 9:54 AM  
**To:** Ed Tellechea <[Ed.Tellechea@myfloridalegal.com](mailto:Ed.Tellechea@myfloridalegal.com)>; Donna McNulty <[Donna.McNulty@myfloridalegal.com](mailto:Donna.McNulty@myfloridalegal.com)>  
**Subject:** draft CPA

Do you see anything not consistent with statute?

Collaborative Pharmacy Practice Agreement

Chronic Health Conditions

Physician name:

Florida License #

Physician's Patient Name:

DOB

Contact info:

Address

Tel. number

Pharmacist Name:

Florida License Number:

Collaborative Practice Certification: Attach copy as required by Statute

Chronic Health Condition to Be Collaborated (circle):

1. Arthritis
2. Asthma
3. COPD
4. Type 2 Diabetes
5. HIV
6. Obesity

Drug or Drugs to be managed by pharmacist:

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_
4. \_\_\_\_\_

Circumstances that require ordering of laboratory or clinical tests:

Conditions and events that require physician notification within \_\_\_\_ days:

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_
4. \_\_\_\_\_

Above notification should go to (email or physical address):

Beginning date \_\_\_\_\_ and Ending date \_\_\_\_\_. Procedure for notifying patient and transferring records:

This agreement may be terminated at any time by either party in writing and will automatically terminate in 2 years if not renewed.

This agreement must be submitted to the board before implementation.

Physician signature \_\_\_\_\_ Date: \_\_\_\_\_

Pharmacist signature \_\_\_\_\_ Date: \_\_\_\_\_





# FLORIDA SOCIETY OF RHEUMATOLOGY

4909 Lannie Road, Suite B | Jacksonville, FL 32218

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Executive Director

TEENA DIOTTE  
Executive Manager

Thursday, July 2, 2020

Florida Board of Pharmacy  
4052 Bald Cypress Way Bin C-04  
Tallahassee, FL 32399-3258

## RE: Rule Making Authority 465.1865, 64B16-31.007 Collaborative Practice Certification – Chronic Health Conditions

Dear Board of Pharmacy Committee Members,

The Florida Society of Rheumatology (FSR) represents the physicians and other medical professionals practicing rheumatology in the state of Florida and facilitates the recognition of the role of the rheumatologist as the provider of choice for patients with arthritis, chronic pain, osteoporosis, and musculoskeletal disease.

We manage a select, specific group of highly complex autoimmune diseases that require specialized medications that modulate the immune system - much like oncologists who use chemotherapy, immunomodulatory and at times immunosuppressive medications to treat cancer. These medications have specific indications, target the immune system, and have to prescribe with great care and consideration to the appropriate patient, in order to maximize effectiveness and minimize side effects.

In response to the Collaborative Practice Certification – Chronic Health Conditions, the FSR respectfully requests that **section (8) eight, “any disease state that is expected to last greater than (1) year or more and will require ongoing medical treatment and drug therapy services”** be deleted from the proposed rule. The FSR agrees that the Board of Pharmacy has the authority to approve certain chronic health conditions, but to unilaterally allow all chronic health conditions to be subjected to this agreement raises serious concerns for the care and safety of our patient community.

FSR believes the Board of Pharmacy shares our concern to protect the health, safety and welfare of our unique patient population, and each condition should be considered prior to inclusion. Just because a health condition is expected to last greater than (1) year, does nothing in the consideration as to if the disease state lends itself well to a written constraints of collaborative practice and if comorbidities outside the chronic condition also need to be part of the management of the drug therapies in question.



@FloridaRheums

After all, the pharmacist is not managing the disease, but the drug therapies to be used in treating that disease, and the pharmacist does not go to school or have the required training to be a specialist in any one disease type, so we believe training must be added to the CME requirements for each disease state added.

Furthermore, the FSR opposes the BOP from including **“osteoporosis” in section (5) five of the Collaborative Practice Certification – Chronic Health Conditions**. There are many choices in the treatment of osteoporosis. The choice of the right treatment depends on the severity of the disease as well as comorbidities. It is not a simple decision in many cases whether the patient should or should not receive treatment. There are many drug choices for therapy in osteoporosis. The choice of which drug should be used not only depends on the severity of disease but also other additional diseases the patient may have, or comorbidities. So, the choice of which drug to use in a specific patient is a complex decision, within a mostly elder and fragile patient population.

The diagnosis must be verified by thorough review of the patient’s history, bone mineral density scan results and often, imaging study. Cognitive evaluation is also done by the physician to verify the diagnosis and severity of disease to select the right drug. After verifying that the diagnosis is, in fact, osteoporosis, the patient’s history of related comorbidities is determined and the severity of each of those must be ascertained to select the medication which will not only be the most effective, but importantly, the safest for that unique patient.

Osteoporosis is complex to manage and could result in permanent negative patient outcomes if treated improperly. There are a number of underlying causes/contributing factors for osteoporosis which must be evaluated and treated differently for optimal treatment results. We oppose the management of this condition by consulting pharmacists, and this disease does not fit into a simple algorithm of care such as the other conditions contemplated under a collaborative agreement.

We do not object to **“osteoarthritis” being included in section (5) five**. When treating osteoarthritis, care pathways are more straightforward algorithms of care, conducive to a collaborative agreement.

However, many of our patients have arthritis that represents an inflammatory and/or autoimmune disease. These are complex diseases that even physicians outside of our specialty do not manage. These diseases require complex assessments to ascertain whether the current treatment is effective and safe. Conducting these assessments is not simple and straightforward. It is often not obvious whether a treatment regimen should be changed. It takes specialized training and experience to be skilled enough to conduct these assessments competently.

In the case of the best known of these diseases, rheumatoid arthritis, such assessment includes obtaining validated patient reported outcomes, conducting a physical exam including a swollen and tender joint count, as well as review of radiology and laboratory findings. Synthesizing this information and then making the decision whether treatment should be changed is something that is beyond the scope of a consulting pharmacist. After the decision is made to change therapy, the decision of what the next best treatment regimen is also complex. This capacity takes experience and specialized training, beyond the scope of a consulting pharmacist.

Other examples of complex inflammatory and autoimmune diseases that FSR believes should not be managed by a consulting pharmacist include systemic lupus erythematosus and psoriatic arthritis. This is not an inclusive list as there are many more diseases in this category of inflammatory and autoimmune

arthritis. It is the firm opinion of FSR that Consulting Pharmacists should not be allowed to manage these forms of inflammatory and autoimmune diseases.

FSR stands committed in working with the Florida Board of Pharmacy in helping provide the best treatment options for Floridians with chronic conditions. Toward that end, please include us as an interested party in any future communications regarding the proposed rule. Thank you for your consideration.

Respectfully,

A handwritten signature in black ink, appearing to read 'G. Valenzuela', is positioned above the typed name.

Guillermo J. Valenzuela, MD  
President  
Florida Society of Rheumatology

PHARM/DEN  
JUL 09 2020

July 3rd, 2020

Richard Montgomery, BPharm, MBA  
Chair  
Florida Board of Pharmacy  
4052 Bald Cypress Way Bin C-04  
Tallahassee, FL 32399-3258

Re: Rulemaking process regarding CS/HB 389

Dear Mr. Montgomery,

I write to you today as a concerned pharmacist and very interested party in regards to the rulemaking surrounding FL CS/HB 389. My name is Kevin Duane, and I am a pharmacist and pharmacy owner in Jacksonville, FL.

The legislature made a very bold step in empowering pharmacists in this state to be able to aid in the management of chronic disease states, as well as to be able to provide a means for testing and treatment of certain acute conditions. While this was a bold step, it was certainly not one taken lightly by the legislature or the governor. Indeed, as we have seen these past few months we are in uncharted territory, and we must provide our practitioners with any and all tools possible to implement this legislation to the best of our ability for the betterment of patient care and health management.

As the owner of two pharmacies which are located within physician office buildings, I see this bill as a very good opportunity to bring care to patients who sorely need it. My pharmacies are located in very poor parts of Jacksonville, and many patients come to us for care because the primary care landscape poses many barriers to proper care whether that be financial, or personal. My rural colleagues express the same barriers to care, and these barriers are ones that this bill aims to begin to solve. Above all, the bill allows us to better care for our patients than we are able to do so currently.

The legislature's actions were promising and progressive in the best interest of the patient, and I believe that the board's rulemaking process should be as well. Therefore, I make the following suggestions:

1. Allow individual protocols, rather than preconstructed blank forms which must be followed strictly.

- a. Florida is a diverse state of over 21,000,000 people. We have densely populated city centers with dozens of pharmacies and physicians within walking distance. We have rural areas where oftentimes the pharmacy is the only health care entity for miles. Simply put, it is not a state that lends itself to a one-size-fits-all approach to this practice.
- b. Different pharmacy practice settings will have different goals for implementation - restricting the practice to a single protocol for each acute condition listed under 465.1895 (1)(a)-(e) F.S. will stifle the entrepreneurial aspirations of self-employed pharmacists like myself, and may provide perverse incentives for chain-pharmacies who do not have to share the profits with their pharmacist employees.
  - i. In this state we have consistently seen chain pharmacists that are being asked to do more and more work with less and less help. They have no decision making input into their staffing levels and no ability to enjoy their share of revenue generation they have created. Only allowing a single protocol eliminates the ability for such a pharmacist to be able to tailor their practice limitations or situations to suit their current employment circumstances. Furthermore, a single protocol will limit the ability of pharmacy owners such as myself to change their practice to fit the needs of their own business or their specific patient population. Ultimately, if a physician is to sign on to any protocol under this statute, whether or not it is standardized, they understand what is written within the protocol is what they are signing off on. The physician has the professional discretion to make responsible medical decisions concerning the collaborative programs in a way that is in the best interest of their patients' health management.
- c. Certain procedures outlined in the protocol may be impossible for some practitioners to meet.
  - i. For example, if it is obligated that the protocol is transmitted electronically only, and a physician and/or pharmacists does not have the technology available to do so, or is financially not in the position to spend hefty sums of money to upgrade to said technology for this purpose, why would the rule compel them to do so? If they are unable and thus cannot collaborate and provide

expertise for the benefit of Florida's public, that is a disservice to the citizens and not at all what the legislature had intended. There should not be any substantial financial limitations to a pharmacist being able to implement this in their practice.

2. Do not limit to only conditions specifically outlined in statute.

- a. The legislature recognized the need for pharmacists to be involved in this aspect of patient care. They also recognized the need to add in language to protect and preserve the pharmacist's and physician's ability to choose and augment those conditions with new or evolving conditions as time progressed.
  - i. Indeed, when this bill was filed in the fall no one had even considered a threat to Florida such as Covid-19, and yet it is now at the forefront of everyone's daily routine. To deny pharmacists and physicians the ability to agree to collaborate on conditions that the legislature was not able to contemplate is counter to what is in the public's interest, and frankly a disservice to the health of the citizens of the state of Florida. New progressions in treatment for conditions are developed constantly, and legislation and rulemaking will always lag behind. The rules must be left open for pharmacists and physicians to adopt protocols for new unforeseen illnesses and treatments. We know that leaving the inclusivity of conditions up to rule amendments by the board may take valuable time to implement. Time which could be spent helping patients with such a disease reach better outcomes and potentially save their quality of life.
  - ii. Additionally, being that a physician and a pharmacist are collaborating regarding the scope of services able to be provided, I feel it an unnecessary and improper intrusion by the government into the private agreement between these two parties.
  - iii. Finally, I believe that most of the commentary regarding the need to slow the development and limit the list of conditions eligible for collaboration under this protocol stems from physician discomfort surrounding the intrusion of pharmacy upon their scope of practice. Many physicians are not accepting of the vital role pharmacists can

play in the healthcare system due to their own personal reservations, rather than genuine concern for the patient. They do not seem to mind other physician extenders such as CNAs and MAs to play a large role in their patient care, and after all, they can always choose not to enter into such a collaborative agreement with pharmacists or other midlevel practitioners such as APRNs or PAs if they do not feel comfortable doing so. It was clearly the legislature's intent to allow other conditions to be collaborated on, and rulemaking (or delaying rulemaking) regarding such is counter to the body's intent.

3. Allow drug formularies to be defined by class, and do not allow negative drug formularies.
  - a. In the same way the landscape of disease has shifted so drastically in our lives, so too have treatments - and they will continue to do so! We need again to only look to the COVID-19 pandemic to see how a rigidly defined drug formulary could absolutely impede expert patient care from being delivered. Remdesivir was a drug initially designed for the ebola virus outbreak, and was found to be ineffective. Had a rigid formulary been in place, we would not have had the power to pick it back up and have it find its home as the mainstay of treatment in critically ill COVID-19 patients. Drugs that are the current mainstay of therapy for certain diseases may soon be discovered to have a certain side effect that makes it undesirable to use, or a previously unknown benefit that brings it from the last line of therapy to the first line. A defined drug formulary in rule makes changes like this very inflexible to do, and again impedes the collaborative aspect of the physician and the pharmacist. If the physician wishes for the pharmacist to use or not to use certain drugs for certain conditions, it should be left to them to decide that collaboratively rather than to rely on the long and arduous process of board rulemaking.
  - b. Limited formularies in rule do not consider that not all patients are the same. A certain first line treatment the patient may have an allergic reaction to. The FDA is notoriously slow and has often no impetus to change certain approvals. It is again only serving to hurt patient care by doing so. An APRN or PA does not have a formulary restriction, and in the same way the physician and the pharmacist should be the ones to be able to make these decisions collaboratively.

4. Do not allow exclusivity of initial training CE or renewal CE to one body
  - a. Currently, pharmacists are permitted to immunize patients, but only in the framework of a protocol in collaboration with a physician. In order to renew his or her license, though, the pharmacist must complete a continuing education program that "...shall be offered by a statewide professional association of physicians in this state accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award (AMA PRA) Category I credit...". I believe that CS/HB 389 is a bill that fosters collaboration with pharmacists and physicians, and as such neither group should have a monopoly on the ability to offer continuing education. Allowing only one of the stakeholders to have full authority on the continuing education offerings necessarily tips the balance of control unfavorably away from the other stakeholders.

This bill adds a wonderful opportunity for pharmacists to be able to collaborate with physicians for the betterment of healthcare delivery to the citizens of the state. The theme of collaboration is well evidenced throughout the bill. I hope that this same theme carries itself well throughout the rulemaking process, and that the private collaborative agreement process between physician and pharmacists is respected and upheld. The above points serve to point out potential pitfalls that I hope the rulemaking process avoids. I am available via e-mail at [Kevin@PanamaRX.com](mailto:Kevin@PanamaRX.com) for any further input if it is needed. I appreciate the efforts of the Boards of Pharmacy, Medicine, and Osteopathic Medicine, and I am hopeful that the legislature's bold vision embodied in this bill carries forward and is evidenced in the final rulemaking product.

Respectfully,

A handwritten signature in black ink, appearing to read 'Kevin J. Duane', with a long horizontal line extending to the right.

Kevin J. Duane, Pharm.D.  
President, Panama Pharmacy

## Pharmacist Education and Training

Pharmacists are medication experts who enhance patient care and promote wellness. Pharmacists use their professional knowledge to prepare and dispense prescriptions, ensure medicines and doses are correct, prevent harmful drug interactions, and assist other health care professionals to select, monitor, and administer medications to improve patient health and outcomes. Below is a summary of minimum education requirements for a pharmacist as well as post-graduate education opportunities which are pursued by many pharmacy graduates today.

- **Minimum Education Requirements for a Pharmacist**

- To enter practice in the United States, the Doctor of Pharmacy (Pharm.D.) degree must be earned from a college or school accredited by the American Council for Pharmacy Education (ACPE). The Pharm.D. became the required entry-level degree into the profession in 2000.
- The minimum program length is 6 years including at least 2 years of undergraduate pre-requisite course work plus 4 years in the Doctor of Pharmacy program.
  - While a minimum of 2 years of undergraduate course work is required, many students complete bachelor's degrees prior to entry into pharmacy school. Approximately 60% of student pharmacists earn a bachelor's degree prior to entry into pharmacy school.
- Pharmacy school is typically comprised of at least 2 to 3 years of pre-clinical course work which includes foundational sciences, pharmaceutical and clinical sciences, and introductory pharmacy practice experiences (up to 300 hours split between institutional, community, and other practice settings).
- During the final year of the Pharm.D. program, students complete a minimum of 1440 hours (36 weeks) of clinical rotations. ACPE, the pharmacy education accrediting body, similar to the Liaison Committee for Medical Education (LCME) mandates that required rotation settings include:
  - 1) community pharmacy,
  - 2) hospital/health-system pharmacy,
  - 3) ambulatory patient care, and
  - 4) general inpatient medicine.
  - The remaining rotations should be a mix of patient care (e.g. clinical electives such as oncology, pediatrics, etc.) and non-patient care rotations (e.g. administration, research, etc.).
- The ACPE 2016 Standards for pharmacy education emphasize that pharmacy graduates must be "practice-ready" and "team-ready."
  - Practice-ready = provide direct-patient care in a variety of healthcare settings
  - Team-ready = contribute as a member of an interprofessional collaborative patient care team.
  - These standards emphasize early exposure to clinical care through practice skills laboratories, introductory pharmacy practice experiences, and intensive courses focused on optimal use of medications.

- In order to practice pharmacy in the state of Florida, graduates from an accredited college/school of pharmacy must pass two examinations – 1) The North American Pharmacists Licensure Examination (NAPLEX) and the 2) Multistate Pharmacy Jurisprudence Examination (MPJE) which evaluates candidates knowledge of state and national laws governing the practice of pharmacy. Both examinations are administered by the National Association of Boards of Pharmacy (NABP).

**Table 1. Comparison of Pharmacy with Medical Curricula**

	Pharmacy	Medical
<b>Accreditation Standards</b>	1. Foundational Knowledge 2. Essentials for Practice and Care 3. Approach to Practice and Care 4. Personal and Professional Development	1. Medical Knowledge 2. Patient Care 3. Systems-based practice 4. Interpersonal communication and skills 5. Professionalism 6. Practice-based learning and improvement
<b>Requirement for Team-Based Care</b>	YES – defined accreditation standard	YES – (2017-2018)
<b>Education on medications</b>	3 didactic years	Portion of body system curriculum OR 1 semester concentrated course

- **Post-Graduate Education**

- While not required, many pharmacy graduates pursue post-graduate training in residency programs. Pharmacy residency programs are 1 to 2 years in length and are accredited by the American Society of Health-System Pharmacists (ASHP).
- PGY-1 (post-graduate year 1) residency programs are 12-months in length and include goals and objectives to ensure graduates can care for patients in a broad variety of practice settings. Accredited program types for PGY-1 residencies include: Pharmacy Practice, Managed Care, and Community Practice
- PGY-2 (post-graduate year 2) residency programs are 12-months in length and allow the graduate to focus in a specialized area of practice. Types of PGY-2 residency programs include – ambulatory care, infectious disease, cardiology, critical care, and pediatrics, among others.
- Pharmacy graduates match into residency programs similar to the process for medical students to match into medical residencies.
- In 2020
  - 2118 residency programs (PGY-1 and PGY-2) participated in the ASHP match.
  - 7364 applicants participated in the match.
  - 4768 applicants matched into residency programs.

- **Additional post-graduate education**

- Pharmacists can also pursue additional certifications following graduation or completion of a residency program. Examples of these certifications include:
  - Board Certification through the Board of Pharmacy Specialties (BPS). Certification includes passing a competency examination and additional continuing education hours to maintain certification. As of 2019, there are 46,000 BPS Board Certified Pharmacists. Current specialties for board certification include:
    - Ambulatory Care
    - Cardiology Pharmacy
    - Compounded Sterile Preparations Pharmacy
    - Critical Care Pharmacy
    - Geriatric Pharmacy
    - Infectious Disease Pharmacy
    - Nuclear Pharmacy
    - Nutrition Support Pharmacy
    - Oncology Pharmacy
    - Pediatric Pharmacy
    - Pharmacotherapy
    - Psychiatric Pharmacy
    - Solid Organ Transplantation
- Pharmacists can also pursue disease or condition specific certification opportunities. These include:
  - Certified Diabetes Care & Education Specialists (CDCES) (formerly a certified diabetes educator)
  - Board Certified Advanced Diabetes Manager (BC-ADM)
  - American Society of Hypertension (ASH) Certified Hypertension Clinician (ASH-CHC)
  - Certified Anticoagulation Care Provider (CACP)
  - Certified Tobacco Treatment Specialists (CTTS)

# SELF-CARE CONDITIONS PROTOCOL: DIABETES TESTING SUPPLIES

Approved 12/11/2019

## PURPOSE

This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of diabetes testing supplies for diabetes self-care/management.

## PHARMACIST EDUCATION AND TRAINING

Prior to initiating the dispensing of diabetes testing supplies under this protocol, pharmacist(s) must have received education and training in diabetes and the supplies necessary to test blood glucose levels, including review of the most current American Diabetes Association (ADA) Standards of Medical Care in Diabetes and the monitoring parameters associated with pharmacologic therapies for the treatment of diabetes. The education of pharmacist(s) must be conducted by a provider accredited by the Accreditation Council for Pharmacy Education, or by a comparable provider approved by the Kentucky Board of Pharmacy.

Provider of Training: \_\_\_\_\_

Date Training Completed: \_\_\_\_\_

## CRITERIA

Pharmacist(s) authorized to dispense diabetes testing supplies will follow the most current ADA Standards of Medical Care in Diabetes for pharmacologic options and the associated blood glucose monitoring guidelines.

### *Inclusion criteria:*

- Any individual who currently has a diagnosis of diabetes, as defined by the ADA Standards of Medical Care for Diabetes, and is interested in obtaining diabetic testing supplies for self-care purposes in an outpatient setting.

### *Exclusion criteria:*

- Any individual who exhibits symptoms of hyperglycemic crisis. For both diabetic ketoacidosis (DKA) and hyperosmolar hyperglycemic state (HHS), the classic clinical picture includes a history of polyuria, polydipsia, weight loss, vomiting, dehydration,

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Resources

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Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S13-S27. Web. 27 Dec. 2017.

Glycemic Targets: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S55-S64. Web. 27 Dec. 2017.

weakness, and mental status change. These individuals should be referred to a setting where they can receive immediate medical attention.

### **DIABETES TESTING SUPPLIES**

This protocol authorizes pharmacist(s) to initiate the dispensing of the following diabetes testing supplies for self-care purposes in quantities sufficient to provide adequate testing based upon patient history, including refills for up to 12 months.

- Glucometer
- Glucometer test strips
- Lancet devices
- Lancets
- Blood glucose control solutions
- Alcohol wipes

### **PROCEDURES FOR INITIATING DISPENSING OF DIABETES TESTING SUPPLIES**

Diabetes testing supply initiation will be individualized based on the diagnosis and pharmacologic treatment of diabetes as defined by the ADA Standards of Medical Care in Diabetes and individual preferences:

- Intensive insulin therapy: 4-10 tests per day
- Basal insulin and/or oral antidiabetic agents: 1-3 tests per day
- Non-pharmacologically managed diabetes: 1-4 tests per day

### **PROCEDURES FOR MONITORING AND CONTINUATION OF DISPENSING DIABETES TESTING SUPPLIES**

Follow-up monitoring and evaluation shall occur at a minimum of every 90 days to determine:

- Changes in pharmacologic treatment for diabetes
- How the individual is utilizing testing supplies and efficacy of performing self-monitoring of blood glucose (SMBG)

If pharmacist(s) believes that SMBG is being performed incorrectly, education is to be provided to the individual in regard to proper use of diabetic testing supplies, as well as education on interpretation of blood glucose levels. If pharmacist(s) suspects an individual is consistently hyperglycemic or periodically hypoglycemic, the primary care provider of the individual is to be contacted. If the individual does not have primary care provider, other healthcare provider with prescribing privilege shall be contacted.

#### Resources

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Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S13-S27. Web. 27 Dec. 2017.

Glycemic Targets: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S55-S64. Web. 27 Dec. 2017.

Should follow-up evaluation and monitoring indicate an adjustment in therapy is warranted, all procedures as outlined for initiation of therapies, including education, documentation and notification, will be followed.

### **EDUCATION REQUIREMENTS**

Individuals, or their parent/guardian/caregiver, receiving diabetes testing supplies under the protocol will receive education regarding:

- Monitoring technique both initially and at regular intervals, using dispensed test strips, lancets, and meter
- Proper review and interpretation of the data provided by the blood glucose meter
- Signs and symptoms of hypoglycemia and instructions on steps to take if blood glucose level is 70 mg/dL or less

### **DOCUMENTATION**

Pharmacist(s) shall document via prescription record each person who receives any diabetes testing supplies under this protocol, including:

- Documentation as required in 201 KAR 2:170 for the dispensing of prescription medication
- Documentation that the individual receiving the diabetes testing supplies was provided with the required education pursuant to this protocol
- Documentation of the diagnosis and pharmacologic treatment of diabetes, the plan of care implemented, and follow-up monitoring and evaluation

### **NOTIFICATION**

Pharmacist(s) shall ask all individuals receiving diabetes testing supplies under this protocol for the name and contact information of the individual's primary care provider and shall provide notification of the diabetes testing supplies dispensed under the protocol to the identified primary care provider within two (2) business days. Any individual affirmatively stating that the individual does not have a primary care provider may still receive diabetes testing supplies under this protocol provided all other applicable requirements of the protocol are met.

[If directed by the authorizing prescriber, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing prescriber of persons receiving diabetes testing supplies under this protocol within 7 days of initiating dispensing.]

### **TERMS**

This protocol is effective as of the date parties execute this document. It shall remain in effect for a period of one year and shall automatically renew for successive one year periods unless

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Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2018." Diabetes Care 41.

Supplement 1 (2018): S13-S27. Web. 27 Dec. 2017.

Glycemic Targets: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S55-S64. Web. 27 Dec. 2017.

otherwise terminated by any party, with or without cause. Any termination without cause shall require prior notice to all parties of no less than sixty (60) days.

Resources

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Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2018." *Diabetes Care* 41. Supplement 1 (2018): S13-S27. Web. 27 Dec. 2017.

Glycemic Targets: Standards of Medical Care in Diabetes—2018." *Diabetes Care* 41. Supplement 1 (2018): S55-S64. Web. 27 Dec. 2017.

## SIGNATURES

_____	_____	_____
Prescriber Name	Prescriber Signature	Date
_____	_____	_____
Pharmacist Name	Pharmacist Signature	Date

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Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S13-S27. Web. 27 Dec. 2017.

Glycemic Targets: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S55-S64. Web. 27 Dec. 2017.

## Resources

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Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2018." *Diabetes Care* 41. Supplement 1 (2018): S13-S27. Web. 27 Dec. 2017.

Glycemic Targets: Standards of Medical Care in Diabetes—2018." *Diabetes Care* 41. Supplement 1 (2018): S55-S64. Web. 27 Dec. 2017.

Physician-Pharmacist Collaborative Practice Agreements (CPA) Overview  
This legislation has passed.

**What would Physicians like pharmacists to do for their patients?**

- **Physician reimbursement opportunities can be created** through *Collaborative Practice Agreements (CPA)* with pharmacists by *optimizing physician practice time*, to allow physicians more time for patients to be seen, diagnosed, and prescribed.
  - By referring medication therapy management for complex chronic patients to the **pharmacist of the physician's choosing, through a physician pre-approved protocol**, physicians can replace those medication therapy appointments with new patients.
  - The use of a Collaborative Practice Agreement allows for improved patient medication outcomes and higher value-based payment for Physicians.
- A Collaborative Practice Agreement is a formal agreement established **voluntarily** between a Florida licensed physician and a Florida licensed pharmacist to perform **physician pre-approved** patient care functions for the physician's patients.
  - A physician pre-approved protocol agreement with the pharmacist *specifies what patient care functions may be provided for the patients of the collaborating physician.*
- **Pharmacists are not trained to perform a differential diagnosis.** Collaborative practice agreements **DO NOT** allow a pharmacist to perform a differential diagnosis.
- Encouraged by the AMA Steps Forward Programming, most physicians in the United States already have established collaborative practice legislation.
  - The American Medical Association (AMA), Centers for Disease Control, American College of Physicians and CMS support Physician directed pharmacist CPAs.
  - The AMAs Steps Forward program encourages implementing “*Embedding Pharmacists into the Practice – Collaborating with Pharmacists to Improve Patient Outcomes*” as physician continuing education programs.

# FLORIDA BOARD OF PHARMACY



June 8, 2020

Dear Dr. Rose,

On March 11, 2020, CS/HB 389 Practice of Pharmacy was approved by the Governor and is effective July 1, 2020. This bill authorizes a pharmacist, who meets certain qualifications, to enter into a collaborative pharmacy practice agreement with a physician to manage chronic health conditions. It also authorizes a pharmacist, who meets certain qualifications, to test or screen for and treat minor, non-chronic health conditions within the framework of a written protocol with a supervising physician.

The Board of Pharmacy must consult with the Boards of Medicine and Osteopathic Medicine to develop rules to implement certain provisions of the bill. The first draft of the proposed rules has been provided to your Board identifying the sections in which consultation is required. The Board of Pharmacy will hold a Rules Committee meeting on June 25, 2020 at 1:00 p.m. ET wherein we invite two representatives from the Board of Osteopathic Medicine to participate in rulemaking discussion. Multi-board collaboration will ensure quality rules are produced. Please inform the Board of Pharmacy, through your Executive Director, of your chosen representatives so that we may provide them with the meeting materials.

The Board of Pharmacy looks forward to working with the Board of Osteopathic Medicine to implement this bill. Together, we will continue to protect, promote, and improve the health of all people in Florida.

Sincerely,

Jessica Sapp, Executive Director  
*on behalf of*

Jeffrey Mesaros, PharmD, J.D., Rules Committee Chair

**Richard Montgomery, BPharm, MBA,**  
Chair  
Orlando, FL

**Jonathan Hickman, PharmD,**  
Vice-Chair  
Tallahassee, FL

**Mark Mikhael, PharmD**  
Orlando, FL

**Blanca R. Rivera, PharmD, MBA**  
Miami, FL

**Jeffrey J. Mesaros, PharmD, JD**  
Orlando, FL

**Jeenu Philip, BPharm**  
Jacksonville, FL

**David Wright, BPharm**  
Fort Pierce, FL

**Gavin Meshad**  
Consumer Member  
Jacksonville, FL

# FLORIDA BOARD OF PHARMACY

June 8, 2020



Dear Dr. Zachariah,

On March 11, 2020, CS/HB 389 Practice of Pharmacy was approved by the Governor and is effective July 1, 2020. This bill authorizes a pharmacist, who meets certain qualifications, to enter into a collaborative pharmacy practice agreement with a physician to manage chronic health conditions. It also authorizes a pharmacist, who meets certain qualifications, to test or screen for and treat minor, non-chronic health conditions within the framework of a written protocol with a supervising physician.

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Sincerely,

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Orlando, FL

**Jeenu Philip, BPharm**  
Jacksonville, FL

**David Wright, BPharm**  
Fort Pierce, FL

**Gavin Meshad**  
Consumer Member  
Jacksonville, FL

**From:** [Sapp, Jessica](#)  
**To:** [Monroe, Kama](#); [Taylor, Carol](#)  
**Cc:** [Kemp, Claudia J](#)  
**Subject:** BOOM Representatives  
**Date:** Tuesday, June 9, 2020 2:26:20 PM

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Hi Kama and Carol,

From your call today, I understand that Dr. Mendez and Dr. Schwemmer were selected as your Board's representatives. Please let them know, as well as the rest of your Board, that our June 25 meeting begins at 9:00 a.m., not 1:00 p.m. We discussed two different times and I did not amend the letter when 9:00 a.m. was finalized so I apologize for the typo.

Claudia- Will you also let your Board know as you all are still deciding on your representatives?

Thank you!

**Jessica Sapp**

**Executive Director**

Department of Health | Division of Medical Quality Assurance

Bureau of Health Care Practitioner Regulation

4052 Bald Cypress Way Bin C-04

Tallahassee, FL 32399-1708

Phone 850/245-4463

[www.FloridasDentistry.gov](http://www.FloridasDentistry.gov)

[www.FloridasPharmacy.gov](http://www.FloridasPharmacy.gov)



**Mission:** To protect, promote and improve the health of all people in Florida through integrated state, county and community efforts.

**Note:** Florida has a very broad public records law. Most written communications to or from state officials regarding state business are public records available to the public and media upon request. Your email communication may therefore be subject to public disclosure.

General comments: I listened to the BOOM conference call on 6-9-29 and agree with the comments and discussion. My two general suggestions are:

1. The BOP should adopt rules that mirror and are limited to the legislation wording and examples only at this time. Expansion to diseases not listed as examples can occur later via a process that allows for proposals from pharmacists followed by input from the BOM/BOOM. Formulary should be limited to FDA approved first line treatment for these diseases and specified in the CPA.
2. The BOP should provide a sample blank CPA that contains each of the elements required by the legislation. I also suggest this process become fully electronic online and updated in real time with reporting that can be used to fulfill the legislative requirements.

Comments to sections identified by BOP for consultation with BOM

1. CPC Initial Certification Course -20 hrs
  - a. Performance of patient assessments – I recommend in-person with human simulator no less than 3 hours of content for this portion
  - b. Testing, evaluation and management portions should include content specific to the diseases requested to be covered in the Collaborative practice agreement.
2. Collaborative practice agreement

I suggest providing a sample blank agreement. I also suggest this process become fully electronic online and updated in real time with reporting that can be used to fulfill the legislative requirements
3. Chronic health condition
  - a. I would limit the conditions initially to those examples listed in the legislation.
  - b. I would limit formulary to medications considered to be first line or initial treatments most commonly used in treatment of the listed chronic conditions consistent with the FDA labeling of the medications
  - c. Very important that the formulary be limited to medications that are considered initial treatments of the illnesses and not secondary or tertiary treatments without a consultation with the collaborating physician.
4. Test and treat certification
  - a. I would limit the conditions initially to those examples listed in the legislation.
  - b. I would limit formulary to medications considered to be first line or initial treatments most commonly used in treatment of the listed minor illnesses consistent with the FDA labeling of the medications
  - c. Very important that the formulary be limited to medications that are considered initial treatments of the illnesses and not secondary or tertiary treatments without a consultation with primary care physician.

5. Test and treat an initial certification course must cover the specific disease and treatments specified by the rule with examples of diseases that are similar clinically and often misdiagnosed and mistreated.

June 9, 2020

RE; CS/HB 389

Dear Ed and Claudia,

Below are some thoughts offered for further elaboration, clarification, discussion and consideration.

Respectfully Submitted.

Robert London MD

1. Standards of Care: Clarify that participating pharmacists, their practice, employees and agents held to the same standards as physicians with regards to:
  - a. Existing Florida Statutes and Administrative Rules (Ex. See Appendix A for medical record documentation)
  - b. HIPAA compliance
  - c. Medicare/Medicaid compliance
  - d. Requirements for electronic medical record keeping
  
2. Practice Model: The intent of the law is to expand the current pharmacy-based scope of practice. Are the following models of practice permissible?
  - a. Pharmacist independently practices in an office setting indistinguishable to that of a physician or ARNP.
  - b. Pharmacist owns the medical practice, and employs physicians, who enter into a collaborative agreement with the pharmacist.
  - c. The pharmacist restricts their professional activity solely/exclusively to the expanded scope of practice established by the law.
  - d. Pharmacist is hired by a participating physician as a physician-extender to work in their office.
  
3. Collaborative Agreements:
  - a. Standardization/simplification: Creation of individualized agreements for each patient, potentially by multiple providers and pharmacists, invites the risk of error, where a pharmacist inadvertently treats a patient outside of their particular agreement, or duplication or contrary managements are put in place.
  - b. Creating a small number of standardized agreements based on the specific disease, severity of disease, or existence of patient co-morbidities may mitigate risk. An example of a risk stratification method based on disease states and comorbidity is the American Society of Anesthesiologists (ASA) Risk Classes (ASA I, II, III, IV, V) (See Appendix B)

- c. Implementation of a process whereby overlapping CPAs (more than one Collaborative Practice Agreement for a single patient) can be identified and reviewed or eliminated if needed.
  - d. Patient centric/control:
    - i. Consider documentation of patient's informed consent to allow the pharmacist's provision of care and physician/pharmacist sharing of protected health information.
    - ii. Consider patient acknowledgement, and approval of expanded role of pharmacist in their personal care
    - iii. Consider the patient's signature on the collaborative agreement
  - e. Clarification of physician/pharmacist liability in such arrangements
    - i. If pharmacist treats the patient outside of the terms of the collaborative agreement,
    - ii. If changes to the patient's care/treatment are not reported back to the physician in a timely fashion,
    - iii. Delays in diagnosis due to a patient not feeling the need to follow-up with a physician.
    - iv. If patient follows pharmacist care against the medical advice of the physician?
  - f. If patient leaves physician's practice?
  - g. Clarification of the number of times or the duration of time a pharmacist can manage a patient for a particular condition without improvement or resolution before having to refer the patient to a physician.
  - h. Clarification of the number of supervising physicians and pharmacists who can be involved with CPAs with regard to a specific patient. Example, any prohibition on an internist, family physician, and pulmonologist each having a CPA with their preferred pharmacist (multiple) regarding the same patient.
4. Continuing Medical Education:
- a. The 20-hour CME is one time. Are continuing medical education requirements to be included to assist the pharmacist in maintaining competency over time?
  - b. Objective assessment of competency? Testing? Evaluations? Auditing? Other?
5. Are BOM and BOOM able to create standards for rules applying to physicians for entering into a collaborative practice agreement with a pharmacist?
- a. Establishment of clear communication protocols
  - b. Avoid the confusion of multiple physicians and pharmacists managing the same patient for the same condition
  - c. Standards of care
  - d. Liability
  - e.

## Appendix A: Documentation requirements for medical record keeping

### Example FS 458.331(1)(m):

(m) Failing to keep legible, as defined by department rule in consultation with the board, medical records that identify the licensed physician or the physician extender and supervising physician by name and professional title who is or are responsible for rendering, ordering, supervising, or billing for each diagnostic or treatment procedure and that justify the course of treatment of the patient, including, but not limited to, patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations.

## Appendix B: ASA Risk Classes

### Current Definitions and ASA-Approved Examples

ASA PS Classification	Definition	Adult Examples, Including, but not Limited to:
<b>ASA I</b>	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
<b>ASA II</b>	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30 < BMI < 40), well-controlled DM/HTN, mild lung disease
<b>ASA III</b>	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Examples include (but not limited to): poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, premature infant PCA < 60 weeks, history (>3 months) of MI, CVA, TIA, or CAD/stents.
<b>ASA IV</b>	A patient with severe systemic disease that is a constant threat to life	Examples include (but not limited to): recent (< 3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis
<b>ASA V</b>	A moribund patient who is not expected to survive without the operation	Examples include (but not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction
<b>ASA VI</b>	A declared brain-dead patient whose organs are being removed for donor purposes	

\*The addition of "E" denotes Emergency surgery: (An emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part)

### References

For more information on the ASA Physical Status Classification system and the use of examples, the following publications are helpful. Additionally, in the reference section of each of the articles, one can find additional publications on this topic.

1. Abouleish AE, Leib ML, Cohen NH. ASA provides examples to each ASA physical status class. *ASA Monitor* 2015; 79:38-9 <http://monitor.pubs.asahq.org/article.aspx?articleid=2434536> 
2. Hurwitz EE, Simon M, Vinta SR, et al. Adding examples to the ASA-Physical Status classification improves correct assignments to patients. *Anesthesiology* 2017; 126:614-22
3. Mayhew D, Mendonca V, Murthy BVS. A review of ASA physical status – historical perspectives and modern developments. *Anaesthesia* 2019; 74:373-9





**Florida Board of Medicine  
Rules/Legislative Committee Meeting**

**Meet-Me-Number: 888-585-9008  
Conference Room Number: 432-162-565  
(Please login and mute your phone)**

**Wednesday, June 3, 2020**

**MINUTES**

Roll call 1:00 pm

**Members Present:**

Shailesh Gupta, MD, Vice Chair  
Kevin Cairns, MD  
Hector Vila, MD  
Zachariah P. Zachariah, MD  
Eleonor Pimentel, MD

**Members Absent:**

Sarvam TerKonda, MD, Chair  
Nicholas Romanello, Consumer Member

**Staff Present:**

Claudia Kemp, JD, Executive Director  
Edward Tellechea, Board Counsel  
Donna McNulty, Board Counsel  
Nancy Murphy, Certified Paralegal  
Crystal Sanford, Program Operations Administrator (850) 222-5491  
Shaila Washington, Regulatory Supervisor  
Rebecca Hewett, Regulatory Specialist III

**Others Present:**

For the Record Court Reporting  
Lindsey Sampson  
1500 Mahan Drive, Suite 140  
Tallahassee, FL 32308

**Legislative Discussion**

**Legislative Summary ..... 1**

Ms. Kemp addressed the Committee and provided a brief summary of the bills. She said the Governor signed HB 389 (Practice of Pharmacy) and HB 607 (Direct Care Workers). She added that HB 743 (Nonopioid Alternatives) has been presented to the Governor but is pending his signature. She said the rest of the bills have not yet been presented to the Governor.

**No action necessary**

**May 2020 Rules Report ..... 3**

The Rules Report, prepared by Ms. Murphy, provided updates on rules currently in development.

**No action necessary.**

**House Bill 389 ..... 2 and Addendum V3**

Ms. Kemp presented the bill and the draft work completed by the Board of Pharmacy on the rule language. She explained she sent updated information to the members that morning from the Board of Pharmacy (attached). She said they plan to meet on the rule again on June 25, 2020.

Dr. Vila expressed concerns over the process because there were issues to talk about like the timing, the items for consultation in the rule, and how the Board of Medicine can provide consultation to the Board of Pharmacy.

Ms. Kemp suggested a couple of ways to proceed, such as having a medical doctor on the call with the Board of Osteopathic Medicine when they consider the rule at their June 9, 2020 conference call. She also suggested presenting this to the entire Board at Friday's meeting.

Dr. Vila felt full Board participation was necessary.

Mr. Tellechea said he has spoken with counsel to the Board of Pharmacy, David Flynn. He said the language being presented today was preliminary language and they would be solidifying the language at their June 25<sup>th</sup> meeting. He said the Pharmacy Board wanted to hear the Board's input and concerns including meeting with a member and are waiting to hear from us and the Osteopathic Board before their June 25<sup>th</sup> meeting.

Ms. Kemp confirmed Mr. Tellechea's statement and said she has been in direct contact with the Executive Director of the Board of Pharmacy, Jessica Sapp, and in other conversations about the rule and the Board's input.

Dr. Zachariah said he was happy to hear the Pharmacy Board wanted to their input. He suggested conducting a joint committee meeting.

Mr. Tellechea suggested the members write down their comments and concerns and send those to Ms. Kemp. Ms. Kemp could then provide that information to Ms. Sapp to include in the agenda materials for the June 25<sup>th</sup> meeting. He explained the Pharmacy Board is being asked to have this rule in place by August 1, 2020 so Florida is ready for the Fall when COVID-19 is expected to flare again.

Dr. Vila said this was a big change and going slow and deliberate equals success. He suggested starting with a few conditions, see how that goes, then expand to other conditions. He said he was willing to meet at any time and would send his comments to Mr. Tellechea.

Ms. Kemp suggested taking this discussion to the full Board during Friday's meeting.

Dr. Gupta said the Board should offer to meet and work with the Pharmacy Board.

Mr. Tellechea reminded the members about the Sunshine Law. He suggested the members send their comments. He said there is no action yet and today was a good discussion.

Dr. Zachariah advised for members to send their comments to Ms. Kemp and Mr. Tellechea.

**Action taken:** members to submit comments to Ms. Kemp and Mr. Tellechea; discuss at Friday's Board Meeting



Florida Board of Medicine  
Board Meeting

**Meet-Me Number:**  
Toll Free Number: 1-888-585-9008  
Conference Room Number: 432 162 565

June 5, 2020

**Meeting Minutes**

8:00 a.m. Roll call

**Members Present:**

Zachariah P. Zachariah, MD, Chair  
Hector Vila, MD, Vice Chair  
Eleonor Pimentel, MD  
Scot Ackerman, MD  
Sarvam TerKonda, MD  
Kevin Cairns, MD  
Jorge Lopez, MD  
Robert London, MD  
Nicholas Romanello, Consumer Member  
(was present for initial roll call, but not present for the second roll call)  
Andre Perez, Consumer Member  
David Diamond, MD  
Shailesh Gupta, MD  
Luz Pages, MD

**Members Absent:**

Barbara Fonte, Consumer Member

**Staff Present:**

Claudia Kemp, JD, Executive Director  
Edward Tellechea, Board Counsel  
Donna McNulty, Board Counsel  
Nancy Murphy, Certified Paralegal  
Crystal Sanford, CPM, Program Operations Administrator (850) 222-5491  
Wendy All, Program Operations Administrator  
Shaila Washington, Regulatory Supervisor  
Rebecca Hewett, Regulatory Specialist III

**Others Present:**

For the Record Court Reporting  
Lindsey Sampson  
1500 Mahan Drive, Suite 140  
Tallahassee, Florida 32308

**Department Prosecutors Present:**

Allison Dudley, Esquire  
Jamal Burk, Esquire  
Geoffrey Christian, Esquire  
Sarah Corrigan, Esquire  
Cynthia Nash-Early, Esquire  
Corynn Alberto, Esquire  
Michael Williams, Esquire  
Andrew Perrin, Esquire  
Major Thompson, Esquire

**Rules/Legislative Committee ..... No tab**

Dr. Gupta provided the report for the meeting held June 3, 2020. He explained the Committee discussed HB 389 and the best way to consult with the Board of Pharmacy on their rule. He

encouraged all members to send their comments to Mr. Tellechea and Ms. Kemp who would share the comments with the Board of Pharmacy members.

Ms. Kemp reminded the members the rule language is still being drafted. She said the Board of Pharmacy's Rules Committee will be conducting another meeting on June 25, 2020 and encouraged members to listen in to the call.

Dr. Pages asked if the law differentiates between adults and pediatric patients.

Mr. Tellechea said the law did not differentiate between them.

Dr. Zachariah said the process should be methodical, thoughtful and should not be rushed. He suggested asking for members of the Boards of Medicine, Osteopathic Medicine and Pharmacy hold a joint meeting to work on the rule language.

Dr. Pimentel asked if there was a similar law in other states.

Mr. Tellechea said he was not aware of other states.

Ms. Kemp said she could find out and let the members know.

Dr. Gupta asked how the Board asks for a joint meeting.

Ms. Kemp said she and Mr. Tellechea could talk to their Executive Director and Board Counsel.

Dr. TerKonda said there are a lot of questions and the members need a better understanding. He said he would be on the call on June 25<sup>th</sup>.

Dr. London said this is a significant increase in scope of practice.

Dr. Vila said he had concerns but glad to have the opportunity to work with the Board of Pharmacy so patients have more access to care.

Dr. Gupta brought up the next topic from the meeting which concerned Telehealth by Electrologists doing Laser Hair Removal.

Dr. Zachariah called speakers to address the Board.

Jolynn Greenhalgh, DNP, ARNP, Electrology Council Chair, addressed the Board in support of their rule.

Judy Adams, Legislative Liaison with the Electrolysis Society of Florida, addressed the Board in support of the rule language.

Tali Arviv was called but was not on the call.

Christopher Nuland, Esquire, representing the Florida Society of Dermatology and Dermatologic Surgeons and the Florida Society of Plastic Surgeons, addressed the Board in opposition to the rule language. He said Chapters 456 and 458, F.S. define direct supervision requiring the onsite presence of the physicians. He said the Legislature specifically put supervision in the law.

Lawrence Gonzalez, Counsel to the Electrolysis Society of Florida and the Electrolysis Association of Florida, addressed the Board in support of the language. He said the language

would allow supervision under telehealth and direct supervision and responsibility was within the Board's scope to define. He reminded the Board the profession has a superior safety record.

A motion was made and seconded to accept the report.

Mr. Tellechea read the language into the record.

Dr. Vila asked if the rule would now go into rule making.

Mr. Tellechea confirmed.

The motion passed unanimously.

**Action taken:** report accepted; send comments to Ms. Kemp and Mr. Tellechea regarding the Pharmacy rule, members encouraged to attend June 25<sup>th</sup> Pharmacy meeting, Mr. Tellechea and Ms. Kemp to discuss a joint meeting with Pharmacy's Executive Director and Board Council, Electrology telehealth rule language approved

# FLORIDA | Board of Osteopathic Medicine

June 9, 2020



**DRAFT MEETING MINUTES**  
**Board of Osteopathic Medicine**  
**Teleconference Business Meeting**  
**June 9, 2020**  
**1:00 p.m.**

The meeting was called to order by Dr. Joel Rose, Chair, at approximately 1:00 p.m.

Those present for all or part of the meeting included the following:

**MEMBERS PRESENT:**

Joel B. Rose, DO, Chair  
Sandra Schwemmer, DO, Vice-Chair  
Anna Hayden, DO  
Michelle R. Mendez, DO  
Bridget Bellinger, DO.

**MEMBERS ABSENT**

Valerie Jackson, Consumer Member

**COURT REPORTER:**

For the Record Reporting  
(850) 222-5491  
Julie Pulver

**OTHERS PRESENT:**

Jessica Sapp, Board of Pharmacy Executive Director  
Claudia Kemp, Board of Medicine Executive Director  
Ed Tellachea, Board of Medicine Board Counsel  
David Fynn, Board of Pharmacy Board Counsel  
Dr. Terkonda, Board of Medicine  
Dr. Gupta, Board of Medicine  
Dr. London, Board of Medicine  
Dr. Mesaros, Board of Pharmacy

**BOARD STAFF PRESENT:**

Kama Monroe, Executive Director  
Carol Taylor, Program Administrator

**BOARD COUNSEL**

Donna McNulty, Board Counsel  
Nancy Murphy, Paralegal

*Please note that the meeting minutes reflect the actual order that agenda items were discussed during the meeting and may differ from the agenda outline*

## **TAB 1: Discussion of Board of Pharmacy's Draft Rules Related to HB389 Informational Materials for Review for Discussion**

Board Chair, Dr. Joel Rose, called the meeting to order and welcomed all attendees.

Program Administrator, Carol Taylor, noted that the purpose of the meeting was to discuss House Bill 389 (HB 389). Dr. Rose provided a brief overview of HB 389 and the items the board would discuss.

Dr. Rose asked for volunteers from the Osteopathic board who would be interested in serving as the board's second member of the joint committee with the Board of Pharmacy and the Board of Medicine. He also stated that he would serve as the first member. The first Joint Committee meeting is scheduled for June 25, 2020.

Dr. Bellinger nominated Dr. Mendez to serve as the second member of the Joint Committee. Dr. Hayden seconded the nomination. The nomination passed.

Direction was given to the board to provide any comments or questions they might have, following the meeting, to the Board of Osteopathic Medicine board office.

Discussion ensued with input from the board and meeting attendees. Discussion included the desire from an attendee, that there be a single standard of care that is no less than the standard currently in place. There was a further desire that the term "interactive computer based" when discussing a course, be better defined. Several questions and comments arose during discussion of Rule 64B16-0035. A desire to see in rule something that specifies what modification entails was conveyed. Discussion regarding the Collaborative Agreement resulted in much input from all present, including concerns with HIPAA compliance. Board of Pharmacy board counsel noted HIPAA concerns would be further discussed at the June 25<sup>th</sup> joint meeting. In discussion of test and treat, there was concern that movement forward should be in a safe and responsible manner. Much discussion entailed regarding concerns with sharing of information, records, and a failure to specify which board when referencing the board. This discussion generated much input and many concerns.

Direction was again provided for osteopathic physicians to provide comments or questions to Board of Osteopathic Medicine board office and for medical physicians to provide comments or questions to Board of Medicine board staff.

A Joint Committee Meeting with representation from the Board of Osteopathic Medicine, Board of Pharmacy and Board of Medicine is scheduled for June 25, 2020.

### **ADJOURN**

Motion: by Dr. Hayden, to adjourn the meeting.

Meeting adjourned at 2:00 pm.

### **ADJOURN**

**Next Meeting: June 22, 2020  
Teleconference**

**64B16-26.XXXX Collaborative Pharmacy Practice Certification.**

(1) An application for certification to provide services under a collaborative pharmacy practice agreement shall be made on Board approved form DH-MQA XXXX, "Board of Pharmacy Collaborative Pharmacy Practice Certification Application," dated XX/20, which is hereby incorporated by reference. To obtain an application go to XXXXXX, or contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254 or (850)488-0595, or download the application from the web at <http://www.doh.state.fl.us/mqa/pharmacy>.

(2) The Board shall approve a 20-hour education course offered by an Accreditation Council of Pharmacy Education (ACPE) accredited provider for initial certification to provide services under a collaborative pharmacy practice agreement. The course shall cover all of the following:

- (a) Performance of patient assessments;
- (b) Ordering, performing, and interpreting clinical and laboratory tests related to collaborative pharmacy practice;
- (c) Evaluating and managing diseases and health conditions in collaboration with other health care practitioners; and
- (d) Review of applicable state and federal laws and rules.

(3) The 20-hours of education for initial certification may be applied to the 30 hours of continuing education required under section 465.009, F.S.

(4) The Board shall approve an 8-hour continuing education course offered by an ACPE accredited provider to be completed by a pharmacist who practices under a collaborative pharmacy practice each biennial license renewal period. The course shall provide a review of the material covered in the initial certification course and any applicable updated information.

**64B16-27.XXXX Collaborative Pharmacy Practice for Chronic Health Conditions.**

In addition to the chronic health conditions listed in section 465.1865, F.S., “chronic health condition” means any chronic condition to be collaboratively managed by a pharmacist and a collaborating physician under a collaborative pharmacy practice agreement that meets the requirements of 465.1865(3), F.S.

**64B16-26.XXXX Certification for Testing or Screening for and Treating Minor, Nonchronic Health Conditions.**

(1) An application for certification to test or screen for and treat minor, nonchronic health conditions shall be made on Board approved form DH-MQA XXXX, "Board of Pharmacy Test and Treat Certification Application," dated XX/20, which is hereby incorporated by reference. To obtain an application go to XXXXXX, or contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254 or (850)488-0595, or download the application from the web at <http://www.doh.state.fl.us/mqa/pharmacy>.

(2) The Board shall approve a 20-hour education course offered by an Accreditation Council of Pharmacy Education (ACPE) accredited provider for initial certification to test or screen for and treat minor, nonchronic health conditions. The course, at a minimum, shall cover all of the following:

- (a) Patient assessments;
- (b) Point-of-care testing procedures;
- (c) Safe and effective treatment of minor, nonchronic health conditions;
- (d) Identification of contraindications;
- (e) Applicable state and federal laws and rules.

(3) The 20-hours of education for initial certification may be applied to the 30 hours of continuing education required under section 465.009, F.S.

(4) The Board shall approve a 3-hour continuing education course offered by an ACPE accredited provider to be completed by a pharmacist providing services under section 465.1895, F.S., each biennial license renewal period. The course shall provide a review of the material covered in the initial certification course and any applicable updated information.

**64B16-27.XXXX Formulary of Drugs for Treating Minor, Nonchronic Health Conditions**

A pharmacist certified to treat minor, nonchronic health conditions in accordance with section 465.1895, F.S., may prescribe any medicinal drug for the treatment of a minor, nonchronic health condition that is:

- (1) Not a controlled substance as described in section 893.03, F.S., or 21 U.S.C. section 812;
- (2) Approved by the United States Food and Drug Administration; and
- (3) Indicated for treatment of the minor, nonchronic health condition.

**64B16-27.XXXX Guidelines for Providing Patients with Written Information Advising Patients to Seek Followup Care**

A pharmacist who tests or screens for and treats minor, nonchronic health conditions in accordance with section 465.1895, F.S., must provide a patient with written information advising the patient to followup with his or her primary care provider when:

- (1) The written protocol between the pharmacist and the supervising physician requires the pharmacist to advise the patient to followup with his or her primary care provider.
- (2) The pharmacist determines in his or her professional judgment that the patient should followup with his or her primary care provider.



March 30, 2020

Richard Montgomery, BPharm, MBA  
Chair  
Florida Board of Pharmacy  
4052 Bald Cypress Way Bin C-04  
Tallahassee FL, 32399-3258

***Re: HB 389 - Boards of Pharmacy, Medicine and Osteopathic Medicine Joint Committee***

Dear Mr. Montgomery,

On March 11, 2020, Governor Ron DeSantis signed into law House Bill 389 which greatly expands the role pharmacists play in Florida's healthcare system. HB 389 is best characterized as having two major pieces of legislation wrapped up in one. First, it creates a collaborative pharmacy practice agreement between a physician and pharmacist for the management of chronic conditions and second, establishes a protocol for pharmacists that may test and treat for minor, nonchronic conditions.

HB 389 calls for the promulgation of several rules by the Board of Pharmacy in consultation with the Boards of Medicine and Osteopathic Medicine. It is the role of all three boards to protect the public and to assure competency and safety to practice in their respective service for the people of Florida. In order for that mission to be accomplished in regard to HB 389, it is imperative that all three boards have a seat at the table so that the proper expertise can be shared. Rules that must be developed in consultation include the following:

Chronic conditions under a collaborative pharmacy practice agreement –

- **Chronic conditions** – HB 389 defines “chronic health conditions” as arthritis, asthma, COPD, type 2 diabetes, HIV/AIDS, obesity, or any other chronic condition adopted in rule by the Board of Pharmacy (BOP), in consultation with the Board of Medicine (BOM) and Board of Osteopathic Medicine (BOOM).
- **Certification Criteria** – In order to provide services under a collaborative pharmacy practice agreement, the BOP must certify the pharmacist according to rules adopted in consultation with the BOM and BOOM.
- **Educational Requirements** – In order to be certified to provide services under a collaborative pharmacy practice agreement, the pharmacist must complete an initial 20-hour course approved by the BOP in consultation with the BOM and BOOM.
- **Implementation** – all other rules required to implement this section shall be done in consultation with the BOM and BOOM.

Minor, non-chronic conditions under a protocol –



- **Certification Criteria** – In order to provide services under a protocol agreement to test and treat for minor, non-chronic conditions, the BOP must certify the pharmacist in accordance to requirements established by rule in consultation with the BOM and BOOM.
- **Educational Requirements** – In order to be certified to test and treat for minor, nonchronic health conditions, the pharmacist must complete an initial 20-hour course approved by the BOP in consultation with the BOM and BOOM.
- **Protocol Requirements** – HB 389 sets the minimum requirements for what a protocol must contain and allows for other requirements as established by rule in consultation with the BOM and BOOM.

While HB 389 does not mandate the Board of Pharmacy adopt rules in consultation in other areas of the legislation, such as establishing the drug formulary and guidelines for providing medical record information to patients for physician follow-up, it would be best practice for the three boards to continue to collaborate. The FMA believes that the BOP would benefit from the presence of BOM and BOOM members throughout the rulemaking process.

The Florida Medical Association hereby respectfully requests that the Board of Pharmacy create a Joint Committee with the Boards of Medicine and Osteopathic Medicine in order to collaborate and streamline the rulemaking process.

Thank you for your consideration in this matter. If you have any questions, please do not hesitate to contact me via email at [MThomas@flmedical.org](mailto:MThomas@flmedical.org) or by telephone at 850-224-6496.

Sincerely,

Mary Thomas, Esq.  
Assistant General Counsel  
Florida Medical Association

Cc: Zachariah Zachariah, M.D., Chair, Board of Medicine  
Joel Rose, D.O., Chair, Board of Osteopathic Medicine

# WINN LAW

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Tallahassee, FL 32309  
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Jason D. Winn, Esq.  
*Administrative, Association  
and Governmental Law*

[jwinn@jwinnlaw.com](mailto:jwinn@jwinnlaw.com)  
850.222.7199(w)  
850.222.1562(f)

April 7, 2020

Richard Montgomery, BPharm, MBA  
Chair Florida Board of Pharmacy  
4052 Bald Cypress Way, Bin C-04  
Tallahassee, FL 32399-3258

Re: HB 389 – Board of Pharmacy, Medicine and Osteopathic Medicine Joint Committee

Dear Mr. Montgomery,

As General Counsel to the Florida Osteopathic Medical Association (FOMA), please accept this letter on behalf of the FOMA requesting the Board of Pharmacy create a Joint Committee with the Boards of Medicine and Osteopathic Medicine for rulemaking regarding HB389.

As you are aware, HB389 passed during the 2020 Legislative Session, and Governor DeSantis signed the bill into law on March 11, 2020, expanding the role of pharmacists in Florida. There are two major components to this new law: creating a collaborative pharmacy practice agreement between a physician and pharmacist for the management of chronic conditions; and, establishing a protocol for pharmacists that may test and treat for minor, non-chronic conditions.

## **CHRONIC HEALTH CONDITIONS**

HB389 defines **chronic health conditions** as: Arthritis, Asthma, Chronic obstructive pulmonary diseases, type 2 diabetes, human immunodeficiency virus or acquired immune deficiency syndrome, obesity, or any other chronic condition adopted in rule by the board, in consultation with the Boards of Medicine and Board of Osteopathic Medicine. (465.1865(1)(b), (FS)).

Also, HB389 requires the Board of Pharmacy to collaborate with the Boards of Medicine and Osteopathic Medicine to: 1. certify pharmacists under a collaborative agreement; 2. Provide an approved 20-hour course; and, 3. Any other rules required to implement HB389.

## **NON-CHRONIC & MINOR CONDITIONS**

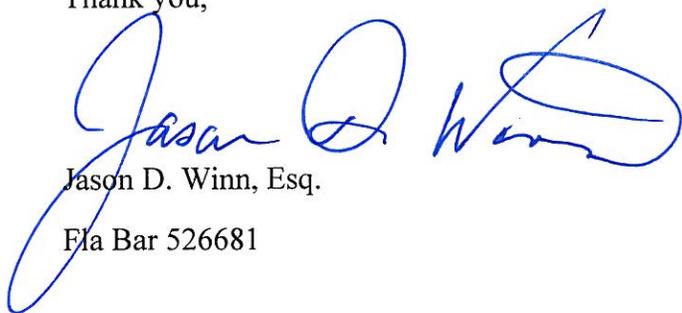
HB389 defines non-chronic & minor conditions as: Influenza, Streptococcus, lice, skin conditions such as ringworm and athlete's foot, and minor uncomplicated infections. Again, this new law requires consultation by this Board with the Boards of Medicine and Osteopathic Medicine to: 1. Set requirements for certification of pharmacists to test and treat for non-chronic and minor conditions; 2. Provide an approved 20-hour course; 3.

Set the minimum requirements for what a protocol must contain; and, 4. Any other requirements established by rule.

The FOMA supports the FMA's letter dated March 30, 2020 in requesting the Board of Pharmacy create a Joint Committee with the Boards of Medicine and Osteopathic Medicine in order to collaborate during the rulemaking process. The FOMA supports the position that the Board of Pharmacy would benefit from the inclusion of members from the Board of Medicine and Board of Osteopathic Medicine.

Thank you for your time in this matter, and please contact me via email at [jwinn@jwinnlaw.com](mailto:jwinn@jwinnlaw.com) or by phone at 850/519-5876.

Thank you,

A handwritten signature in blue ink, reading "Jason D. Winn, Esq.", with a large, stylized flourish at the end.

Jason D. Winn, Esq.

Fla Bar 526681

CC: Zachariah Zachariah, MD, Chair of Board of Medicine

Joel Rose, DO, Chair of Board of Osteopathic Medicine

ENROLLED

CS/CS/HB 599

2020 Legislature

1  
2 An act relating to consultant pharmacists; amending s.  
3 465.003, F.S.; revising the definition of the term  
4 "practice of the profession of pharmacy"; amending s.  
5 465.0125, F.S.; requiring a pharmacist to complete  
6 additional training to be licensed as a consultant  
7 pharmacist; authorizing a consultant pharmacist to  
8 perform specified services under certain conditions;  
9 prohibiting a consultant pharmacist from modifying or  
10 discontinuing medicinal drugs prescribed by a health  
11 care practitioner under certain conditions; revising  
12 the responsibilities of a consultant pharmacist;  
13 requiring a consultant pharmacist and a collaborating  
14 practitioner to maintain written collaborative  
15 practice agreements; requiring written collaborative  
16 practice agreements to be made available upon request  
17 from or upon inspection by the Department of Health;  
18 prohibiting a consultant pharmacist from diagnosing  
19 any disease or condition; defining the term "health  
20 care facility"; providing an effective date.

21  
22 Be It Enacted by the Legislature of the State of Florida:

23  
24 Section 1. Subsection (13) of section 465.003, Florida  
25 Statutes, is amended to read:

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CS/CS/HB 599

2020 Legislature

26 465.003 Definitions.—As used in this chapter, the term:  
27 (13) "Practice of the profession of pharmacy" includes  
28 compounding, dispensing, and consulting concerning contents,  
29 therapeutic values, and uses of any medicinal drug; consulting  
30 concerning therapeutic values and interactions of patent or  
31 proprietary preparations, whether pursuant to prescriptions or  
32 in the absence and entirely independent of such prescriptions or  
33 orders; and conducting other pharmaceutical services. For  
34 purposes of this subsection, the term "other pharmaceutical  
35 services" means ~~the monitoring of~~ the patient's drug therapy and  
36 assisting the patient in the management of his or her drug  
37 therapy, and includes reviewing, and making recommendations  
38 regarding, review of the patient's drug therapy and health care  
39 status in communication with the patient's prescribing health  
40 care provider as licensed under chapter 458, chapter 459,  
41 chapter 461, or chapter 466, or a similar statutory provision in  
42 another jurisdiction, or such provider's agent or such other  
43 persons as specifically authorized by the patient, ~~regarding the~~  
44 ~~drug therapy~~. However, ~~nothing in~~ this subsection may not be  
45 interpreted to permit an alteration of a prescriber's  
46 directions, the diagnosis or treatment of any disease, the  
47 initiation of any drug therapy, the practice of medicine, or the  
48 practice of osteopathic medicine, unless otherwise permitted by  
49 law. The term "practice of the profession of pharmacy" also  
50 includes any other act, service, operation, research, or

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CS/CS/HB 599

2020 Legislature

51 transaction incidental to, or forming a part of, any of the  
 52 foregoing acts, requiring, involving, or employing the science  
 53 or art of any branch of the pharmaceutical profession, study, or  
 54 training, and shall expressly permit a pharmacist to transmit  
 55 information from persons authorized to prescribe medicinal drugs  
 56 to their patients. The practice of the profession of pharmacy  
 57 also includes the administration of vaccines to adults pursuant  
 58 to s. 465.189 and the preparation of prepackaged drug products  
 59 in facilities holding Class III institutional pharmacy permits.  
 60 The term also includes the ordering and evaluating of any  
 61 laboratory or clinical testing; conducting patient assessments;  
 62 and modifying, discontinuing, or administering medicinal drugs  
 63 pursuant to s. 465.0125 by a consultant pharmacist.

64 Section 2. Section 465.0125, Florida Statutes, is amended  
 65 to read:

66 465.0125 Consultant pharmacist license; application,  
 67 renewal, fees; responsibilities; rules.—

68 (1) The department shall issue or renew a consultant  
 69 pharmacist license upon receipt of an initial or renewal  
 70 application that ~~which~~ conforms to the requirements for  
 71 consultant pharmacist initial licensure or renewal as adopted  
 72 ~~promulgated~~ by the board by rule and a fee set by the board not  
 73 to exceed \$250. To be licensed as a consultant pharmacist, a  
 74 pharmacist must complete additional training as required by the  
 75 board.

ENROLLED

CS/CS/HB 599

2020 Legislature

76        (a) A consultant pharmacist may provide medication  
77 management services in a health care facility within the  
78 framework of a written collaborative practice agreement between  
79 the pharmacist and a health care facility medical director or a  
80 physician licensed under chapter 458 or chapter 459, a podiatric  
81 physician licensed under chapter 461, or a dentist licensed  
82 under chapter 466 who is authorized to prescribe medicinal  
83 drugs. A consultant pharmacist may only provide medication  
84 management services, conduct patient assessments, and order and  
85 evaluate laboratory or clinical testing for patients of the  
86 health care practitioner with whom the consultant pharmacist has  
87 a written collaborative practice agreement.

88        (b) A written collaborative practice agreement must  
89 outline the circumstances under which the consultant pharmacist  
90 may:

91            1. Order and evaluate any laboratory or clinical tests to  
92 promote and evaluate patient health and wellness, and monitor  
93 drug therapy and treatment outcomes.

94            2. Conduct patient assessments as appropriate to evaluate  
95 and monitor drug therapy.

96            3. Modify or discontinue medicinal drugs as outlined in  
97 the agreed upon patient-specific order or preapproved treatment  
98 protocol under the direction of a physician. However, a  
99 consultant pharmacist may not modify or discontinue medicinal  
100 drugs prescribed by a health care practitioner who does not have

ENROLLED

CS/CS/HB 599

2020 Legislature

101 a written collaborative practice agreement with the consultant  
 102 pharmacist.

103 4. Administer medicinal drugs.

104 (c) A ~~The~~ consultant pharmacist shall maintain ~~be~~  
 105 ~~responsible for maintaining~~ all drug, patient care, and quality  
 106 assurance records as required by law and, with the collaborating  
 107 practitioner, shall maintain written collaborative practice  
 108 agreements that must be available upon request from or upon  
 109 inspection by the department.

110 (d) This subsection does not authorize a consultant  
 111 pharmacist to diagnose any disease or condition.

112 (e) For purposes of this subsection, the term "health care  
 113 facility" means an ambulatory surgical center or hospital  
 114 licensed under chapter 395, an alcohol or chemical dependency  
 115 treatment center licensed under chapter 397, an inpatient  
 116 hospice licensed under part IV of chapter 400, a nursing home  
 117 licensed under part II of chapter 400, an ambulatory care center  
 118 as defined in s. 408.07, or a nursing home component under  
 119 chapter 400 within a continuing care facility licensed under  
 120 chapter 651 ~~for establishing drug handling procedures for the~~  
 121 ~~safe handling and storage of drugs. The consultant pharmacist~~  
 122 ~~may also be responsible for ordering and evaluating any~~  
 123 ~~laboratory or clinical testing when, in the judgment of the~~  
 124 ~~consultant pharmacist, such activity is necessary for the proper~~  
 125 ~~performance of the consultant pharmacist's responsibilities.~~

ENROLLED

CS/CS/HB 599

2020 Legislature

126 ~~Such laboratory or clinical testing may be ordered only with~~  
127 ~~regard to patients residing in a nursing home facility, and then~~  
128 ~~only when authorized by the medical director of the nursing home~~  
129 ~~facility. The consultant pharmacist must have completed such~~  
130 ~~additional training and demonstrate such additional~~  
131 ~~qualifications in the practice of institutional pharmacy as~~  
132 ~~shall be required by the board in addition to licensure as a~~  
133 ~~registered pharmacist.~~

134 (2) Notwithstanding ~~the provisions of~~ subsection (1), a  
135 consultant pharmacist or a doctor of pharmacy licensed in this  
136 state may also be responsible for ordering and evaluating any  
137 laboratory or clinical testing for persons under the care of a  
138 licensed home health agency when, in the judgment of the  
139 consultant pharmacist or doctor of pharmacy, such activity is  
140 necessary for the proper performance of his or her  
141 responsibilities and only when authorized by a practitioner  
142 licensed under chapter 458, chapter 459, chapter 461, or chapter  
143 466. In order for the consultant pharmacist or doctor of  
144 pharmacy to qualify and accept this authority, he or she must  
145 receive 3 hours of continuing education relating to laboratory  
146 and clinical testing as established by the board.

147 (3) The board shall adopt ~~promulgate~~ rules necessary to  
148 implement and administer this section.

149 Section 3. This act shall take effect July 1, 2020.

**64B16-26.300 Consultant Pharmacist Licensure.**

(1) No person shall serve as consultant pharmacist as defined in Section 465.003(3), F.S., unless that person holds a license as a consultant pharmacist.

(2) Application for consultant pharmacist licensure shall be made on form DOH-MQA 1109, (Rev. 12/15 xx/2020), Consultant Pharmacist Application and Information, which is hereby incorporated by reference, and which can be obtained from <http://www.flrules.org/Gateway/reference.asp?No=Ref-06933> and the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or from the website located at <http://floridaspharmacy.gov/Applications/app-consultant-pharmacist.pdf>. The application shall be accompanied by an application fee.

(3) In order to be licensed as a consultant pharmacist, a person must meet the following requirements:

(a) Hold a license as a pharmacist which is active and in good standing; and

(b) Successfully complete a consultant pharmacist course of no fewer than ~~twelve~~ twenty (1220) hours, sponsored by an accredited college of pharmacy, and approved by the Florida Board of Pharmacy Tripartite Continuing Education Committee which is based on the Statement of the Competencies Required in Institutional Pharmacy Practice and covers the subject matter set forth in rule 64B16-26.301, F.A.C. The course shall be instructionally designed to include a cognitive test on which the applicant must score a passing grade for certification of successful completion of the course.

(c) ~~Successfully complete a period of assessment and evaluation under the supervision of a preceptor within one (1) year of completion of the course set forth in paragraph (b), above. This period of assessment and evaluation shall be completed over no more than three (3) consecutive months and shall include at least 40 hours of training in the following practice areas, 60% of which shall occur on-site at an institution that holds a pharmacy permit. The training shall include:~~

	Percent of Time	Hours
Minimum Skills Required		
Minimum of 40 Hours in Maximum of Three Months		
1. Regimen review, documentation and communication.	60%	24
a. Demonstrate ability to carry out process and understand documentation functions.		
b. Understand and perform drug regimen review. Communicate findings to appropriate individuals or groups.		
c. The applicant is responsible for learning other skills needed to perform in his/her type of facility where he/she is or will be the consultant Pharmacist of Record.		
2. Facility review.	20%	8
Demonstrate areas that should be evaluated, documentation, and reporting procedures.		
3. Committee and Reports.	5%	2
Review quarterly Quality of Care Committee minutes and preparation and delivery of pharmacist quarterly report.		
4. Policy and Procedures.	5%	2
Preparation, review, updating Policy and Methods.		
5. Principles of formulary management.	5%	2
Demonstrate ability to manage formulary.		
6. Professional Relationships.	5%	2
Knowledge and interaction of facility administration and professional staff.		

(4) In order to act as a preceptor, a person shall:

(a) Be a consultant pharmacist of record at an institutional pharmacy which is required to have a consultant pharmacist under the provisions of chapter 465, F.S., and these rules.

(b) Have a minimum of one (1) year of experience as a consultant pharmacist of record.

~~(c) Maintain all pharmacist licenses in good standing with the Board.~~

~~(d) Not act as a preceptor to more than two (2) applicants at the same time.~~

~~(5) Upon completion of the requirements set forth above, the applicant's preceptor shall confirm that the applicant's assessment and evaluation have met the requirements and that the applicant has successfully completed all required assignments under the preceptor's guidance and supervision.~~

~~(6) After licensure a consultant pharmacist's license shall be renewed biennially upon payment of the fee set forth in rule 64B16-26.1003, F.A.C., and upon completing twenty-four (24) hours of board approved continuing education based upon the provisions of rule 64B16-26.302, F.A.C.~~

~~(7) The number of hours earned in recertification programs by a consultant pharmacist, if applied to the twenty-four (24) hours required for consultant pharmacist license renewal, may not be used toward the thirty (30) hours of continued professional pharmaceutical education credits as set forth in rule 64B16-26.103, F.A.C.~~

~~(8) An applicant who applies for a consultant pharmacist license after the effective date of this rule shall be required to complete the assessment and evaluation required in paragraph (3)(c), prior to being licensed as a consultant pharmacist.~~

*Rulemaking Authority 456.013, 465.005, 465.0125 FS. Law Implemented 456.013, 465.0125 FS. History—New 5-19-72, Revised 4-19-74, Repromulgated 12-18-74, Amended 10-17-79, 4-8-80, 7-29-81, 7-1-83, 4-10-84, 4-30-85, Formerly 21S-1.26, 21S-1.026, Amended 7-31-91, 10-14-91, Formerly 21S-26.300, 61F10-26.300, Amended 9-19-94, 3-28-95, 3-10-96, Formerly 59X-26.300, Amended 5-22-01, 5-5-05, 11-29-06, 3-29-10, 6-23-16.*

**64B16-26.301 Subject Matter for Consultant Pharmacist Course Training Program.**

(1) Jurisprudence.

(a) Laws and regulations, state and federal, pertaining to institutional pharmacy and health care facilities.

(b) Laws and regulations, state and federal, pertaining to the safe and controlled storage of alcohol and other related substances, and relating to fire and health-hazard control.

(c) Laws and regulations, state and federal, pertaining to collaborative practice agreements.

(2) Policy and Procedures.

(a) Written procedures for outlining the medication system in effect.

1. Traditional systems.

2. Unit-dose systems.

a. Centralized.

b. Decentralized.

c. Automated medication systems.

3. Routine and emergency use of drugs.

4. After hours procedure for medication dispensing.

5. Managing drug shortages.

(b) Record keeping and reports.

1. Controlled substance control and record-of-usage.

2. Alcohol inventory and record-of-usage.

3. Patient drug use control and records.

a. Recalls.

b. Medication use evaluation.

c. Medication errors.

4. Drug charges, methods, accountability, and reports.

5. Statistical reports of usage, volume, etc.

6. Written collaborative practice agreement records.

(c) Regimen review, documentation and communication

1. Performing drug regimen review.

2. Documentation of drug regimen review.

3. Communication of findings to appropriate individuals or groups.

(3) Administrative Responsibilities.

(a) Fiscal Control.

1. Perpetual and traditional inventory systems.

2. Application of EDP techniques.

(b) Personnel Management, orientation and training.

(c) Intra-professional relations pertaining to medication use.

(d) Inter-professional relations with other members of the institutional health care team.

1. Pharmacy & Therapeutic Committee.

a. Rational drug therapy; review of medication use and prescribing.

b. Formulary development – evaluation, appraisal, selection, procurement, storage, distribution, medication safety, criteria for use development and safety.

c. Automatic stop orders on potent and dangerous drugs.

d. Controls on storage and use of investigational drugs.

2. In-service education of nurses and other health-related personnel.

3. Infectious Disease Committee.

(e) Facility Review

1. Areas appropriate for evaluation

2. Documentation of evaluations

### 3. Reporting of evaluations

(4) Professional Responsibilities.

(a) Drug information retrieval and methods of dispersal.

(b) Development of pharmacy practice.

(c) Development of an IV Admixture service.

(d) Procedures to enhance medication safety.

1. Availability of equipment, technique, etc., to prepare special dosage forms for pediatric and geriatric patients.

2. Preparation of sterile dosage forms.

3. Proper writing, transcribing and initiating and/or transferring patient medication orders; development of physician's chart order copy system.

4. Safety of patient self-medication and control of drugs at bedside.

5. Reporting and trending adverse drug reactions.

6. Screening for potential drug interactions.

7. Development and maintenance of up-to-date emergency kits.

(e) Maintain drug quality and safe storage.

1. Procedures for eliminating out-dated drugs.

2. Requirements for safe and appropriate storage conditions.

(f) Maintain drug identity.

1. Procedures for labeling, transferring of bulk medications, etc.

2. Manufacturing and packaging procedures.

3. Pre-packaging control and supervision.

(g) Conducting patient assessments.

(h) Ordering and evaluating laboratory or clinical tests.

(i) Administration of medicinal drugs.

(5) The Institutional Environment.

(a) The institution's pharmacy function and purpose.

(b) Interdepartmental relationships important to the institutional pharmacy.

(c) Understanding of scope of service and in-patient care mission of the institution.

(d) Special training with respect to the operation of nursing homes and Extended Care Facilities (ECF)/pharmacy relationship and special procurement procedures.

(6) Nuclear pharmacy.

(a) Procurement.

(b) Compounding.

(c) Quality control procedures.

(d) Dispensing.

(e) Distribution.

(f) Basic radiation protection and practices.

(g) Consultation and education to the nuclear medicine community; including patients, pharmacists, other health professionals, and the general public.

(h) Research and development of new formulations.

(i) Record keeping.

(j) Reporting adverse drug reactions and medication errors.

(k) Screening for potential drug interaction.

The Bureau of Health Care Practitioner Regulation has been working to standardize the format of all licensure applications. The enclosed application has been amended to include the redesign as well as required amendments based on proposed rule language in 64B16-26.300 Consultant Pharmacist Licensure and 64B16-26.301 Subject Matter for Consultant Pharmacist Course.

**The changes are as followed:**

- Title change, Striking “And Information”
- Updated the citation in the Equal Opportunity Data section.
- The Preceptor Evaluation Form has been removed from the application.
- The required board approved consultant pharmacist course, has been amended to 20 hours and the requirement for the course to be sponsored by an accredited college of pharmacy, located with the state of Florida as been removed and proposed verbiage added.
- Verbiage relating to the 40-hour period of evaluation and assessment has been stricken from the application.
- The applicant signature statement has been amended.

**Additional Redesign Features Include:**

- Custom designed cover page.
- Directions are embedded throughout the application in their corresponding sections, instead of in the beginning.
- The applications are fillable and tab-able.
- If applicants try to answer both “Yes” and “No” the fields will reset and only keep the last answer.
- Once the applicant’s name is filled in one time, it will populate in the applicable fields throughout the application.
- Board office logos are included on documents that will be mailed to the board. This is to ensure that the forms are received by the correct Board office.
- There are formatting rules set for the following types of fields: SSN, dates, and phone numbers.
- There may be drop-down menus to help limit the types of answers that can be given.
- Most signature fields are able to be digitally signed, unless stated otherwise.
- Font size goes down when data is longer than the field can accommodate at the original font.
- Format will be standard.
- We will meet with board staff to ensure that we have correctly interpreted applications and to make any changes they feel will help make it easier for the applicant.
- Each application goes through multiple reviews to check for accuracy.



# Consultant Pharmacist Application

**Board of Pharmacy**

P.O. Box 6330

Tallahassee, FL 32314-6330

Website: <https://floridaspharmacy.gov/>

Email: [info@floridaspharmacy.gov](mailto:info@floridaspharmacy.gov)

Phone: (850) 245-4474

Fax: (850) 921-5389



# Consultant Pharmacist Application

Board of Pharmacy  
P.O. Box 6330  
Tallahassee, FL 32314-6330  
Fax: (850) 921-5389  
Email: info@floridaspharmacy.gov

Do Not Write in this Space  
For Revenue Receiving Only

All applicants must hold a current Florida Pharmacist license that is active and in good standing.

Consultant Pharmacist (1020) \$55.00

Total fee of \$55.00 includes the following:

Application Fee \$55.00

Fees must be paid in the form of a cashier's check or money order, made payable to the Department of Health. The \$55.00 application fee is not refundable.

## 1. PERSONAL INFORMATION

Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_  
Last/Surname First Middle MM/DD/YYYY

Mailing Address: (The address where mail and your license should be sent)

Street/P.O. Box Apt. No. City

State ZIP Country Home/Cell Telephone (Input without dashes)

Business Telephone (Input without dashes)

### EQUAL OPPORTUNITY DATA:

We are required to ask that you furnish the following information as part of your voluntary compliance with 41 CFR Part 60-3 Uniform Guidelines on Employee Selection Procedure (1978); 43 FR 38295 and 38296 (August 25, 1978). This information is gathered for statistical and reporting purposes only and does not in any way affect your candidacy for licensure.

Gender: Male Race: Native Hawaiian or Pacific Islander Hispanic or Latino White  
Female American Indian or Alaska Native Black or African American Asian  
Two or More Races

Email Notification: To be notified of the status of your application by email, check the "Yes" box and fill in your email address on the line provided. If you choose to be notified via email you will be responsible for checking your email regularly and updating your email address with the board office.

Yes No Email Address: \_\_\_\_\_

Under Florida law, email addresses are public records. If you do not want your email address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.

## 2. LICENSURE HISTORY

A. Do you have a Florida Pharmacist (PS) license that is active and in good standing? Yes No

If "Yes," what is the license number? \_\_\_\_\_

B. Have you ever held a Consultant Pharmacist License in Florida? Yes No

If "Yes," what was the license number? \_\_\_\_\_

**3. SOCIAL SECURITY DISCLOSURE**

**CONFIDENTIAL AND EXEMPT FROM  
PUBLIC RECORDS DISCLOSURE**

**Last Name:** \_\_\_\_\_

**First Name:** \_\_\_\_\_

**Middle Name:** \_\_\_\_\_

**Social Security Number:** \_\_\_\_\_

(Input without dashes)

This page is exempt from public records disclosure. The Department of Health is required and authorized to collect Social Security Numbers relating to applications for professional licensure pursuant to Title 42 USCS § 666 (a)(13). For all professions regulated under chapter 456, Florida Statutes, the collection of Social Security Numbers is required by section 456.013 (1)(a), Florida Statutes.

Name: \_\_\_\_\_

All applicants must complete a board approved consultant pharmacist course of no fewer ~~12 hours, sponsored by an accredited college of pharmacy, located with the state of Florida.~~ 20 hours as outlined in rule 64B16-26.300(3)(b), F.A.C.

**All applicants must provide a copy of the initial course certificate for the consultant pharmacist course.**

Documentation must be sent to the board office at [info@floridaspharmacy.gov](mailto:info@floridaspharmacy.gov), or mailed to:

**Board of Pharmacy**  
4052 Bald Cypress Way Bin C-04  
Tallahassee, FL 32399-3258

#### 4. APPLICANT SIGNATURE

I, the undersigned, state that I am the person referred to in this application for licensure in the state of Florida.

I recognize that providing false information may result in disciplinary action against my license or criminal penalties pursuant to s. 456.067 and 775.083, F.S.

I am aware that my Consultant Pharmacist license may be suspended or revoked if I violate any pharmacy law, rule or regulation, or the Florida Board of Pharmacy Code of Conduct.

Florida law requires me to immediately inform the board of any material change in any circumstances or condition stated in the application which takes place between the initial filing and the final granting or denial of the license and to supplement the information on this application as needed.

Section 456.013(1)(a), F.S., provides that an incomplete application shall expire one year after the initial filing with the department.

Applicant Signature \_\_\_\_\_ Date \_\_\_\_\_  
*You may print out this application and sign it or sign it digitally.* MM/DD/YYYY



**Subject:** FW: Recommended Change in Consultant Pharmacists Licensure Requirements:

**From:** Dan Buffington <[danbuffington@cpshealth.com](mailto:danbuffington@cpshealth.com)>

**Date:** June 2, 2020 at 7:48:28 AM EDT

**Subject: Recommended Change in Consultant Pharmacists Licensure Requirements:**

**Recommended Change in Consultant Pharmacists Licensure Requirements:**

Update the Consultant Pharmacist training course to include the background and application of Collaborative Practice Agreements (CPA)

Eliminate and remove the 40-hour requirement for "preceptorship" or "mentorship"

Alternatively add an additional targets component to the CP course training content that promotes the demonstration of "best practice" (i.e., features practice overviews and examples of established practices and FAQ and bank of mentors ) which would accomplish the same historical goal of precepting, but in a broader, more diverse, and more efficient manner that utilizes the benefits of current technology and adult learning methods.

Possibly increase the 12-hour training course to include additional hours for the mentoring and best practice applications (possibly 14-16 hours total), per the board's discretion.

Acknowledge advanced post graduate training (i.e., residency and fellowship training)

Change the requirement for CP continuing education to acknowledge a smaller "CP Update" (required) but allow traditional pharmacists continuing education programming to be included in the 24-hour CE renewal (not creating a limitation that it has to be separate and distinct from standard continuing education).

**Daniel Buffington, PharmD, MBA**  
Clinical Pharmacology Services, Inc.  
6285 E. Fowler Ave  
Tampa, FL 33617

813-983-1500 Office  
813-983-1501 Fax  
813-679-0792 Cell

[DanBuffington@cpshealth.com](mailto:DanBuffington@cpshealth.com)  
[www.cpshealth.com](http://www.cpshealth.com)

**Subject:** FW: Drug Therapy Management (64B16.27.830) and Consultant Pharmacists Licensure (465.0125)

**From:** Dan Buffington <[drdanbuffington@gmail.com](mailto:drdanbuffington@gmail.com)>

**Date:** June 2, 2020 at 7:46:34 AM EDT

**Subject: Drug Therapy Management (64B16.27.830) and Consultant Pharmacists Licensure (465.0125)**

Please note that both **Drug Therapy Management (DTM) (64B16.27.830)** and **Consultant Pharmacist Licensure (465.0125)** are separate and distinct descriptions of established and appropriate pharmacy practice models that benefit from physician delegated authority and that they have always co-existed and still have their own vignettes and practice instruments.

They have not and do not conflict with either other, but rather both underscore the value and impact of physicians and pharmacists working together to optimized medication therapy and improve patient care and safety.

The revisions to 465.0125 are cleaner and more articulate than the prior language and are focused on the "Consultant Pharmacist," and individual who by nature was already practicing in unique settings with unique services and responsibilities including administrative and patient care. The revisions just add contemporary descriptions to established process like orders and protocols. The revisions do not create a conflict, nor do they impinge upon other roles or models of pharmacy practice, but rather update the Consultant Pharmacist description.

There are many healthcare practice settings, practice roles, and healthcare documentation systems. The future of healthcare will continue to evolve and see new and emerging therapies and conditions. These two elements that regulate professional practice are not mutually exclusive and each promote improved care and patient safety.

**Drug Therapy Management (DTM)**  
-----

Established scope of practice model (since 2000)

Does not require additional testing or licensure

A collaborative healthcare service provided by physicians and pharmacists working together to optimize a patient's medication therapy and health outcomes.

Based on a patient-specific written agreement/instrument, "**Prescriber Care Plan**"

May be provide in any practice setting.

Delegates authorities and responsibilities and communication plan via a physician defined care plan.

### **Consultant Pharmacist License**

-----

2020 revision/update to the Consultant Pharmacists Practice licensure model (Since 1983)

Requires additional testing & licensure

Describes advanced care services provided by a pharmacist in a healthcare facility

Based on a written agreement/instrument, "**Collaborative Practice Agreement**"

Designated to be delivered within specific-types of **healthcare facilities**, specific-types of **ambulatory care centers**, or **nursing homes**

Delegated authority from physician to pharmacist utilizing either a "patient-specific order" or "treatment protocol"

Legal Reference: FS 465.0125

### **Interpretation:**

Both Consultant Pharmacists (465.0125) and DTM (64B16.27.830) are long standing established pharmacy practice models that have acknowledge physician delegation of authority with distinct typical vignettes.

Physician delegation of authority supersedes all types of practitioners and support staff.

The new revisions to FS 465.003(13) and 465.0125 do no conflict, but rather merely describe two different models for healthcare practitioner collaboration with different vignettes and criteria and written instruments.

Consultant Pharmacists (CP & CPA) and Drug Therapy Management (DTM & Prescriber Care Plans) are distinct established and functional models of pharmacy practice that merely facilitate two different types of practice models and instruments.

The revisions to CP just articulate the application of a secondary licensure for healthcare facilities, ambulatory care facilities, and nursing homes, as defined in the revision. Those by no means describe the full scope of health care settings. So, CP is for specific settings and applications.



Florida Society of Health System Pharmacists, Inc  
2910 Kerry Forest Parkway D4, Suite 376  
Tallahassee, FL 32309  
(850) 906-9333  
[www.fshp.org](http://www.fshp.org)

August 11, 2020

Dear Executive Director Jessica Sapp,

Re: 64B16-26.302 Subject Matter for Consultant Pharmacist Licensure Renewal Continuing Education

On behalf of FSHP, please accept our request regarding updated language for Consultant Pharmacist license renewal, 64B16-26.302. Specifically we would request that the Board of Pharmacy allow Pharmacy Specialty (BPS) credits be accepted for consultant pharmacist license renewal. (See attachment)

Our rationale is that these credits are rigorous to accomplish and other states have incorporated the BPS credentialing into their expanded scope of practice regulation - please see attachment.

Additionally, we are enclosing a collaborative practice chronic care management protocols for the BOP's consideration.

And finally, in response to Rep Sirois letter dated August 7, 2020, we request that HB 599 and the subsequent new consultant pharmacist language along with and Non Chronic Health Conditions regulation be finalized and allowed to move through the next committee without delay while the BOP continues to write regulations on collaborative practice chronic health conditions.

We request this be an agenda item of the rules committee on August 24<sup>th</sup>.

Sincerely,

William Kernan, PharmD, MBA, FASHP  
FSHP Immediate Past President

CC: Richard Montgomery, Chairman of the BOP

# BPS Board Certification

Recognition by States, March 2020

*Board certification through the Board of Pharmacy Specialties is recognized as the gold standard for determining which pharmacists are qualified to contribute at advanced practice levels.*



# BPS Board Certification

Recognition by States, March 2020

## *About the Board of Pharmacy Specialties*

The Board of Pharmacy Specialties (BPS) was established as an autonomous division of the American Pharmacists Association (APhA) in 1976. Nuclear Pharmacy was approved as the first specialty in 1978 and Emergency Medicine Pharmacy was approved as the most recent specialty in 2020, with a total of 14 specialties now approved. The other available specialties are:

- Ambulatory Care Pharmacy
- Cardiology Pharmacy
- Compounded Sterile Preparations
- Critical Care Pharmacy
- Geriatric Pharmacy
- Infectious Diseases Pharmacy
- Nutrition Support Pharmacy
- Oncology Pharmacy
- Pediatric Pharmacy
- Pharmacotherapy
- Psychiatric Pharmacy
- Solid Organ Transplantation Pharmacy

Specialty certifications offered by BPS are accredited by the National Commission for Certifying Agencies (NCCA). NCCA uses a peer review process to establish accreditation standards, evaluate compliance with these standards, recognize programs which demonstrate compliance, and serve as a resource on quality certification. NCCA accreditation is an important benchmark of quality and demonstrates a commitment to excellence in administering a professional certification program on the part of the certifying agency. BPS is strongly committed to the NCCA accreditation process and their certification standards because BPS has an obligation to the public, board-certified pharmacists and other stakeholders to administer a program that utilizes best practices.

## *Overview*



The Board of Pharmacy Specialties (BPS) was established in 1976 as an autonomous division of the American Pharmacists Association (APhA). The mission of BPS is to improve patient care by positioning BPS Board-Certified Pharmacists as integral members of multidisciplinary healthcare teams, through recognition and promotion of specialized training, knowledge and skills for pharmacists. BPS is accredited by the National Commission for Certifying Agencies and upholds rigorous standards for board certification and recertification. BPS currently recognizes more than 45,000 pharmacist certifications with 14 approved specialties.



The Board of Pharmacy Specialties currently certifies over 45,000 pharmacists in twelve specialties. The first examination in Solid Organ Transplantation Pharmacy will be offered in Fall 2020, and the first examination in Emergency Medicine Pharmacy is anticipated in Fall 2022. BPS continues to explore opportunities for new specialties. A role delineation study has been conducted in pain management and this topic is being explored as a possible future specialty.

The mission of the Board of Pharmacy Specialties is to improve patient care and increase awareness of the need for BPS Board Certified Pharmacists as integral members of multidisciplinary healthcare teams through recognition and promotion of specialized training, knowledge, and skills in pharmacy and specialty board certification and recertification of pharmacists throughout the world.

The BPS Board of Directors, with assistance from several professional organizations and their members, has continued to provide vital leadership and support for the recognition of specialties and certification of pharmacist specialists. Each of the BPS Specialty Councils works diligently with our Examination Development and Psychometrics team to ensure that the certification process is psychometrically sound and legally defensible. BPS also collaborates with other national organizations and professional societies to promote specialty recognition and board certification to a variety of stakeholders, including the profession, other health care professionals, employers, and the public.

### *About Board Certification*

The primary purpose of specialization in any health care profession is to improve the quality of care individual patients receive, to promote positive treatment outcomes, and ultimately, to improve the patient's quality of life. Each specialty approved by the Board of Pharmacy Specialties is defined by a content outline, which serves as a "map" for the board certification examination for that specialty. Candidates for each specialty must qualify for all the specified eligibility criteria for that specialty, which includes practice experience in that specialty and passing the board certification examination for that specialty. Upon successful qualification, the term of initial certification is seven years.

Each specialty is guided by a Specialty Council composed of nine pharmacists, seven of which are board-certified in the designated specialty and two of which are not specialists in that specialty. The Specialty Council makes recommendations to the BPS Board of Directors on eligibility criteria and recertification criteria for the specialty, and has responsibility as subject matter experts for the board-certification examination.

Recertification is required every seven years to maintain certification. This may be accomplished by passing the recertification examination or by completion of the minimum number of professional development credits from a provider approved by BPS. Recertification assures the public and the profession that certified practitioners undergo periodic evaluation. Participating in continuing education opportunities or preparing for the recertification exam also offers the opportunity for certificants to stay up to date with current developments in the field.



## *Recognition of BPS Credential by States*

The Board of Pharmacy Specialties has a long history of collaborating with Boards of Pharmacy. The first specialty approved by BPS was Nuclear Pharmacy. At the time, there was a perceived need for a way to identify pharmacists with the requisite skills and expertise to manage this complex task. Boards of Pharmacy quickly began to require that Nuclear Pharmacists obtain BPS certification to demonstrate expertise and help reduce risk. Since that time, the Nuclear Regulatory Commission has introduced the Authorized Nuclear Pharmacist credential.

In recent years, the role of the pharmacist has evolved to become more focused on patient-centered activities. Many states have recognized BPS credentials as a way to identify pharmacists with expertise needed for collaborative drug therapy management and more advanced clinical activities. Appendix A provides a comprehensive listing with excerpts of text of applicable statutes and regulations.

In summary, eight states plus the District of Columbia recognize BPS credentials as an option or pathway toward collaborative drug therapy management:

- Colorado
- Connecticut
- District of Columbia
- Maine
- Maryland
- Massachusetts
- New Jersey
- Rhode Island
- West Virginia

Two states recognize BPS credentials as an option toward Clinical Pharmacist Practitioner recognition:

- Montana
- North Carolina

One state includes BPS credentials as an option toward Advanced Practice Pharmacist recognition:

- California

One state recognizes BPS credentials toward a certificate of medication therapeutic authority:

- Missouri

One state recognizes BPS credentials as an indication of ongoing competence for licensure as a pharmacist in the state:

- Nebraska

## BPS Board Certification



In summary, board-certification from the Board of Pharmacy Specialties is widely recognized by Boards of Pharmacy and established in many states as a pathway for pharmacists to qualify for collaborative drug therapy management. BPS would be pleased to respond to questions or inquiries on this topic.

Respectfully submitted,

Thomas R. Clark, RPh, MHS, BCGP

Senior Advisor, Government & Regulatory Affairs

Board of Pharmacy Specialties

Phone: 202-558-2724

E-mail: [tclark@aphanet.org](mailto:tclark@aphanet.org)



## Appendix A

### Recognition of BPS Board-Certification in Pharmacy Practice

#### NOTES:

1. The search of the legislation and regulations below was conducted in July 2019 and is current as of that date.
2. In some of the language quoted below, the Board of Pharmacy Specialties is referred to as the “Board of Pharmaceutical Specialties”, a former name of the organization.
3. The Commission for Certification in Geriatric Pharmacy merged with the Board of Pharmacy Specialties in January 2017 and the Certified Geriatric Pharmacist credential was moved under the BPS umbrella as the “Board Certified Geriatric Pharmacist” (BCGP).

#### *Recognition of BPS as a Criterion for Eligibility for Collaborative Drug Therapy Management*

##### *Colorado [Regulation]*

Any pharmacist engaged in drug therapy management shall meet the following qualifications:

- a. Have and maintain an unrestricted license in good standing to practice pharmacy in Colorado; and
- b. Meet one of the following qualifications:
  1. Proof of completion of a pharmacy residency accredited by the American Society of Health Systems Pharmacists or the American Pharmacists Association in the specialty being practiced; or
  2. Proof of completion of one (1) year of practice experience in pharmacotherapy, and 40 hours of onsite supervised clinical practice and training in each area in which the pharmacist is choosing to practice; or
  3. Completion of a certificate program accredited by the Accreditation Council for Pharmacy Education in each area of practice, and 40 hours of on-site supervised clinical practice and training in each area in which the pharmacist is choosing to practice; or
  4. Completion of at least 40 hours of ACPE approved continuing education regarding clinical practice and 40 hours of onsite supervised clinical practice and training in the area in which the pharmacist is choosing to practice; or
  5. **Current Board specialty certification from the Board of Pharmaceutical Specialties**, current certification from the National Institute for Standards in Pharmacist Credentialing, or current certification from the Commission for Certification in Geriatric Pharmacy. Such credentials must be in the area of pharmacy practice undertaken in the drug therapy management; or
  6. In an inpatient or group model integrated closed HMO setting, all of the following criteria shall be met in order to practice drug therapy management:
    - a. Forty (40) hours of onsite supervised clinical practice and training in the area(s) in which the pharmacist is choosing to practice;



b. Protocols must be approved by the health-system's medical committee, or pharmacy and therapeutics committee; and

c. Documented competency of each area of practice in which the pharmacist is choosing to practice shall be maintained on site.

c. Licensed Colorado pharmacists practicing drug therapy management prior to August 1, 2005, must attest and certify that they were provided clinical training, experience, and oversight practicing in the disease state(s) that they work in, and the physician with whom they are currently practicing must attest that they are practicing to the standard of care required for management of the specific disease. Such attestations must be on file at the site of practice. Documentation of their employment dates must be on file as proof of practice prior to August 2, 2005.

1. Colorado ADC 10-2505-10-8.800.18 Prescription Drug Consumer Information and Technical Assistance Program [Regulation]

8.800.18.A The Prescription Drug Consumer Information and Technical Assistance

Program provides Medical Assistance Program clients the opportunity to meet with a pharmacist to review the client's medications, receive information on the prudent use of prescription drugs and, with the approval of the appropriate prescribing health care provider, how to avoid dangerous drug interactions, improve client outcomes, and save the state money for the drugs prescribed.

8.800.18.B. REQUIREMENTS FOR PARTICIPATION IN THE PROGRAM

1. The Department shall refer clients to pharmacists based on location.

2. Pharmacists shall:

a. Have and maintain an unrestricted license in good standing to practice pharmacy in Colorado; and

b. Maintain liability insurance; and

c. Complete an application; and

d. Enter into a contract with the Department; and

e. Meet one of the following qualifications:

i) Provide proof of completion of a pharmacy practice residency accredited by the American Society of Health Systems Pharmacists or the American Pharmaceutical Association; or

ii) Earned a bachelor of pharmacy degree and completed a certificate program accredited by the Accreditation Council for Pharmacy Education (ACPE) in each area of practice, and 40 hours of on-site supervised clinical practice and training in each area in which the pharmacist is choosing to practice; or

iii) Earned a Doctor of Pharmacy degree and completed at least 40 hours of ACPE-approved continuing education regarding clinical practice and 40 hours of on-site supervised clinical practice and training in the area in which the pharmacist is choosing to practice; or

iv) **Possess current board specialty certification from the Board of Pharmaceutical Specialties**, current certification from the National Institute for Standards in Pharmacist Credentialing, or current certification from the Commission for Certification in Geriatric Pharmacy. Such credentials must be in the area of pharmacy practice undertaken in the drug



therapy management

3. Clients may participate in the program if they are a fee-for-service client who receives prescription drug benefits, is at high risk of complications from drug interactions and who otherwise lacks access to informational consultation with a pharmacist.

#### 8.800.18.C. SERVICES

1. Pharmacists participating in the program shall:
  - a. Schedule a face-to-face meeting with the client within ten days of the referral. If the client is unable or refuses to participate in a face-to-face meeting, the pharmacist may conduct the consultation by telephone.
  - b. Collect and review client drug histories.
  - c. Hold face-to-face or telephonic consultations with clients.
  - d. Notify clients that they will provide clinical recommendations to the client, the prescribing health care provider and the Department.
  - e. Provide the client with information regarding:
    - i) The prudent use of prescription drugs.
    - ii) How to avoid dangerous drug interactions.
    - iii) The appropriate use of medication to optimize therapeutic outcomes.
    - iv) How to reduce the risk of adverse events, including adverse drug interactions.
2. The Department shall notify clients participating in the program in writing that a pharmacist has been assigned to review the client's records and that the pharmacist will contact the client within ten days from the date of notification.

#### 8.800.18.D. REPORTING

Within ten days following the consultation, the pharmacist shall provide a letter to the client, all appropriate health-care providers and the Department outlining the face-to-face meeting. The letter shall include the pharmacist's recommendations for possible alternatives available for the client.

#### 8.800.18.E. REIMBURSEMENT

The Department shall pay each pharmacist participating in the program a predetermined amount.

### *Connecticut [Regulation]*

To qualify for participation in a collaborative drug therapy management agreement, a pharmacist shall be licensed in this state and shall meet at least one of the following qualifications:

- a. Ten years of clinical experience;
- b. Certification by the Board of Pharmaceutical Specialties;**
- c. Certification by the Commission for Certification in Geriatric Pharmacy;
- d. A credential in disease state management from the National Institute for Standards in Pharmacist Credentialing;
- e. Pharmacy residency accredited by the American Society of Health-System Pharmacists; or



f. Completion of a disease state management certification program approved by the Accreditation Council for Pharmacy Education.

*District of Columbia [Regulation]*

- 10001.1 A pharmacist shall only participate in a collaborative practice agreement in accordance with this chapter.
- 10001.2 A licensed physician shall have a valid patient-physician relationship with a patient that he or she refers to a pharmacist for participation in a collaborative practice agreement under this chapter.
- 10001.3 For purposes of this chapter, an internet-based or telephone consultation or questionnaire evaluation is not adequate to establish a valid patient-physician relationship unless and except as otherwise specifically permitted by District law.
- 10001.4 The licensed physician and pharmacist who are parties to a collaborative practice agreement shall hold an active license in good standing in the District of Columbia.
- 10001.5 The Boards may deny approval of a physician or pharmacist to participate in a collaborative practice agreement if the physician or pharmacist has:
- (a) A final order by the governing Board disciplining the physician or pharmacist's license for a practice issue within the five (5) years immediately preceding the formation of the agreement; or
  - (b) Limitations placed on the physician or pharmacist's license by the governing board.
- 10001.6 The collaborative practice agreement shall be within the scope of the licensed physician's current practice.
- 10001.7 To be eligible to participate in a collaborative practice agreement, a pharmacist:
- (a) Shall possess relevant advanced training as indicated by one of the following:
    - (1) **Certification as a specialist by:**
      - (A) **The Board of Pharmaceutical Specialties;**
      - (B) The Commission for Certification in Geriatric Pharmacy; or
      - (C) Another credentialing body approved by the Board of Pharmacy; or
    - (2) Successful completion of:
      - (A) A residency accredited by the American Society of Health-Systems Pharmacists, a body approved by the Board of Pharmacy or offered by a body accredited by the Accreditation Council for Pharmacy Education; or
      - (B) A certificate program approved by the Board of Pharmacy; and
  - (b) Shall have successfully completed:
    - (1) A minimum of three (3) years of relevant clinical experience, if the pharmacist holds an academic degree of Doctor of Pharmacy; or
    - (2) A minimum of five (5) years of relevant clinical experience, if the pharmacist holds an academic degree of Bachelor of Science in Pharmacy; and
  - (c) Shall have documented training related to the area of practice covered by the collaborative practice agreement.

*Maine [Statute]*

In order to enter into a collaborative practice agreement with a practitioner under this subchapter, a pharmacist must:

## BPS Board Certification



1. License. Hold a valid unrestricted pharmacist license in this State;
2. Training. Submit evidence acceptable to the board that the pharmacist:
  - A. Possesses certification from **the Board of Pharmacy Specialties** or successor organization or has completed an accredited residency program. If the residency program is not in the area of practice covered by the agreement, the pharmacist must complete a continuing education certificate program of at least 15 hours of continuing education in each clinical area of practice covered by the agreement;
  - B. Has graduated with a Doctor of Pharmacy degree from a college of pharmacy accredited by the American Council on Pharmaceutical Education, has 2 years of professional experience and has completed a continuing education certificate program of at least 15 hours of continuing education in each clinical area of practice covered by the agreement; or
  - C. Has graduated with a Bachelor of Science in Pharmacy degree from a college of pharmacy accredited by the American Council on Pharmaceutical Education, has 3 years of professional experience and has completed a continuing education certificate program of at least 15 hours of continuing education in each clinical area of practice covered by the agreement.

### *Maryland [Regulation]*

In order to enter into a therapy management contract, a pharmacist: (1) Shall be licensed by and in good standing with the Board of Pharmacy; (2) Shall possess a Doctor of Pharmacy degree or equivalent training as established in §B of this regulation; (3) May not have: (a) A public final order by the Board of Pharmacy disciplining the pharmacist's license within the 5 years immediately before the application is submitted; or (b) Limitations placed on the pharmacist's license by the Board of Pharmacy in a public order; (4) Shall possess relevant advanced training as indicated by one of the following: (a) **Certification as a specialist related to the disease state specified by the protocol by:** (i) **The Board of Pharmacy Specialties;** (ii) The American Society of Consultant Pharmacist's Certified Geriatric Practitioner certification program; or (iii) Another credentialing body approved by the Board of Pharmacy; or (b) Successful completion of: (i) A residency accredited by the American Society of Health-Systems Pharmacists, a body approved by the Board of Pharmacy or offered by a body accredited by the Accreditation Council for Pharmacy Education; (ii) A certificate program approved by the Board of Pharmacy; (iii) A National Association of Boards of Pharmacy credentialing examination; or (iv) An examination approved by the Board of Pharmacy; (5) Shall have successfully completed: (a) 1,000 hours of relevant clinical experience; or (b) 320 hours in a structured experience program approved by the Board of Pharmacy; and (6) Shall document training related to the disease state specified in the protocol.

The Board of Pharmacy shall determine whether the pharmacist meets the requirements of §§A and B of this regulation.

A licensed pharmacist who has entered into a prescriber-pharmacist agreement shall submit to the Board of Pharmacy a copy of: (1) The prescriber-pharmacist agreement; (2) Subsequent amendments made to the: (a) Prescriber-pharmacist agreement; or (b)



Protocols specified in the prescriber-pharmacist agreement; and (3) Changes to participants of the: (a) Prescriber-pharmacist agreement; or (b) Protocols specified in the prescriber-pharmacist agreement.

The Board of Pharmacy shall determine whether a pharmacist added under §F of this regulation meets the requirements of §§A and B of this regulation.

The Board of Pharmacy shall notify the pharmacist of any additional information needed within 30 days of the receipt of the submitted information.

*Massachusetts [Regulation]*

I. Introduction

The Massachusetts Board of Registration in Pharmacy (“Board”) would like to advise licensees of the educational qualifications that would be considered equivalent to 5 years of experience as a licensed pharmacist in order to participate in a Collaborative Drug Therapy Management agreement (CDTM) pursuant to M.G.L. c. 112, § 24B½ and 247 CMR 16.00.

II. Requirements

For the educational qualifications to be considered equivalent to 5 years of experience as a licensed pharmacist, the following requirements must be met:

A. One of the following conditions must be met:

**1. The pharmacist holds a current board certification from the Board of Pharmacy Specialties (BPS).**

2. The pharmacist must have completed an ASHP-accredited PGY-1 residency and:

i. Must have completed an additional 2 years of experience as a practicing pharmacist; or

ii. Must complete 12 months of CDTM practice under the direction of a practicing CDTM pharmacist. The facility must have a policy and procedure describing the manner by which the CDTM pharmacist is monitored. Documentation of the monitoring must be maintained by the facility and available for Board review upon request.

3. The pharmacist must have completed an ASHP-accredited PGY-2 residency and:

i. Must have completed an additional 1 year of experience as a practicing pharmacist; or

ii. Must complete 6 months of CDTM practice under the direction of a practicing CDTM pharmacist. The facility must have a policy and procedure describing the manner by which the



CDTM pharmacist is monitored. Documentation of the monitoring must be maintained by the facility and available for Board review upon request.

B. Pharmacists must also complete a comprehensive CDTM credentialing and training program developed and administered by the clinical site. The credentialing and training program must include at least the following elements:

1. Assessment of the understanding of national and site specific clinical guidelines;

2. Assessment of clinical skills relevant to the practice area: e.g. vital signs, height/weight, respiration, peak flow, glucose testing, specialty specific training if applicable (e.g. standard depression and anxiety clinical assessment scales for behavioral health); and

3. Current Basic Life Support (BLS) certification.

III. A pharmacist who does not meet the qualifications as set forth in 247 CMR 16.00 or this advisory, but would like for the Board to consider other education or residency criteria to participate in a CDTM program, may submit a petition to be considered by the Board.

*New Jersey [Regulation]*

(a) In order to enter into an agreement to engage in the collaborative drug therapy management of a patient with a physician licensed in this State, a licensed pharmacist shall be pre-approved by the Board to engage in such activity. In order to obtain Board approval, a pharmacist shall submit a collaborative practice application and documentation that establishes that he or she has successfully completed one of the following:

1. A certificate training program offered by an American Council of Pharmaceutical Education-approved provider;

2. A post-graduate residency program accredited by the American Society of Health-System Pharmacists; or

3. A certification program from the **Board of Pharmacy Specialties**.

(b) The Board shall issue an authorization to engage in collaborative drug therapy management to a pharmacist who, upon application to the Board, demonstrates satisfaction of the requirements of (a) above.

(c) A pharmacist granted authorization to engage in collaborative drug therapy management pursuant to this section shall complete a minimum of 10 credits of continuing education every biennial renewal period in the area covered by the collaborative practice agreement to which he or she is a party, consistent with the requirements of NJAC 13:39-3A.

*Rhode Island [Regulation]*

A. A pharmacist may engage in collaborative pharmacy practice pursuant to a collaborative practice agreement.



- B. Any pharmacist desiring to engage in collaborative pharmacy practice shall execute an agreement which shall include, but not be limited to, the following:
1. Identification and signatures of parties to the agreement, as well as dates of signing;
  2. A provision that allows either party to cancel the agreement by written notification;
  3. Site and setting where the collaborative practice is to take place;
- a. The agreement shall specify the site and setting where the collaborative practice occurs. All services provided pursuant to a collaborative practice agreement shall be performed in a setting that ensures patient privacy and confidentiality.
- C. Informed Consent Procedures
1. The agreement shall specify the procedures for obtaining an informed consent from each patient involved in services pursuant to a collaborative practice agreement.
  2. Informed consent shall include patients' consent to release all minimum necessary medical information between the parties.
  3. Informed consent shall include provision to allow the patient to withdraw from collaborative practice at any time.
- D. Qualification of Pharmacist and Participating Practitioners
1. The agreement shall specify the qualifications of all participants in the collaborative practice agreement. Any pharmacist participating in the collaborative pharmacy practice shall comply with § 1.13(L) of this Part.
  2. Role of any employed healthcare professional with prescriptive privileges participating in the collaborative practice shall include, but not be limited to, initiating, adjusting, monitoring, or discontinuing drug therapy.
- E. Scope of Conditions or Diseases to be Managed
1. A detailed description of the types of diseases, drugs or drug categories involved, drug therapies management allowed in each case;
  2. Agreements may only be used for conditions or diseases with generally accepted standards of care;
  3. The scope of the agreement shall not include research, clinical or investigational trials;
  4. The agreement shall include only the conditions or diseases to be managed that meet the qualifications and scope of practice for each party to the agreement.
- F. Practice Protocols
1. The practice protocol shall contain a statement by the physician that describes the activities a pharmacist is authorized to engage in, including:
    - a. The procedures, decision criteria, or plan a pharmacist shall follow when providing drug therapy management;
    - b. The procedures a pharmacist shall follow for documentation; and
    - c. The procedures a pharmacist shall follow for reporting activities and results to the physician or the prescribing healthcare provider caring for the patient.
  2. A provision that allows the physician to override a collaborative practice decision made by the pharmacist when appropriate
  3. A provision for regular review and revision to reflect changes in standards of care
  4. A provision that allows either party to cancel the agreement by written notification
  5. An effective date.
- G. Risk Management Activities
1. The agreement shall provide for a plan for measuring and ensuring quality.



2. The agreement shall include proof that liability insurance is maintained by all parties.
- H. Outcomes Measurements
1. The agreement shall include a method to monitor compliance and clinical outcomes.
    - a. A pharmacist shall submit a copy of the agreement to the Board prior to the commencement of collaborative pharmacy practice.
- I. Amendments to the agreement must be documented, signed, and dated.
- J. A pharmacist shall initiate drug therapy management for a particular patient.
- K. A pharmacist shall have adequate access to the patient's history, vital signs including pulse, height, weight, temperature, blood pressure, and respiration, disease states, drug therapy and laboratory and procedure results.
- L. A pharmacist with advanced training and experience relevant to the scope of collaborative practice shall be a licensed pharmacist in the State of Rhode Island with a bachelor of science degree in pharmacy and post-graduate educational training or a doctor of pharmacy degree. Such training shall include, but not be limited to, residency training, board certification, certification from an accredited professional organization, educational institution, or any other continuing education provider approved by the Department relevant to the proposed scope of the collaborative practice agreement. The pharmacist shall meet one of the following qualifications:
1. **Has successfully completed certification from the Board of Pharmaceutical Specialties**, or has completed an American Society of Health System Pharmacists (ASHP) or other accredited residency program in the area of practice covered by the agreement. If the residency program is not in the area of practice covered by the agreement, the pharmacist shall complete a continuing education provider certificate program in the area of practice covered by the agreement; or
  2. Has successfully completed the course of study and holds the academic degree of Doctor of Pharmacy and has two (2) years of professional experience and has completed an Accreditation Council for Pharmaceutical Education (ACPE), Continuing Medical Education (CME), or other continuing education provider certificate program in the area of practice covered by the agreement; or
  3. Has successfully completed the course of study and holds the academic degree Bachelor of Science in Pharmacy and has three (3) years of professional experience and has completed one (1) ACPE or other continuing education provider certificate programs with at least one (1) program in the area of practice covered by the agreement.
- M. Any pharmacist participating in a collaborative pharmacy practice agreement shall earn at least five (5) additional contact hours or 0.5 continuing education units of board-approved continuing education that addresses areas of practice generally related to collaborative practice agreements each year and shall maintain documentation of these hours at the practice site to be made available for inspection by the Boards of Medical Licensure and Discipline and Pharmacy
- N. Any pharmacist who has not participated in a collaborative pharmacy practice arrangement for a period of two (2) years and seeks to enter into such an arrangement, must have obtained and/or maintained the certification set forth in §§ 1.13(L)(2) or (3) of this Part, as applicable, or have earned fifteen (15) hours of relevant continuing education within the prior year in the area of practice covered by the agreement.



For a pharmacist to participate in a collaborative pharmacy practice agreement, the pharmacist shall:

- (a) Have an unrestricted and current license to practice as a pharmacist in West Virginia;
- (b) Personally have or have employer coverage of at least \$1 million of professional liability insurance coverage;
- (c) Meet one of the following qualifications, at a minimum:

(1) **Earned a Certification from the Board of Pharmaceutical Specialties**, is a Certified Geriatric Practitioner, or has completed an American Society of Health System Pharmacists (ASHP) accredited residency program, which includes two years of clinical experience approved by the board; or

(2) Successfully completed the course of study and holds the academic degree of Doctor of Pharmacy and has three years of clinical experience approved by the board and has completed an Accreditation Council for Pharmacy Education (ACPE) approved practice based continuing pharmacy education activity in the area of practice covered by the collaborative pharmacy practice agreement; or

(3) Successfully completed the course of study and hold the academic degree of Bachelor of Science in Pharmacy and has five years of clinical experience approved by the board and has completed two ACPE approved practice based continuing pharmacy education activity with at least one program in the area of practice covered by a collaborative pharmacy practice agreement.

### *Recognition of Clinical Pharmacist Practitioner*

#### *Montana [Regulation]*

(1) An applicant for a Clinical Pharmacist Practitioner registration shall: (a) submit an application on a form prescribed by the board; (b) pay a registration fee as prescribed by the board; (c) hold an active, unrestricted Montana pharmacist license; (d) have completed the years of clinical practice experience that meet the requirements for **Board of Pharmacy Specialties (BPS) certification** or other equivalent national certification, and hold one of the following active certifications: (i) **BPS certification**; or (ii) nationally recognized certification equivalent to BPS certification standards in an area of practice as approved by the board and the Board of Medical Examiners (BME).

(e) submit a signed collaborative practice agreement to the board that includes a description of the type of supervision the collaborating practitioner will exercise over the clinical pharmacist practitioner; (f) following approval of the board, submit the application and collaborative practice agreement to the BME for approval; and (g) appear before the board and/or BME if requested

(2) Within ten days of discontinuing work under an approved collaborative drug therapy agreement, the pharmacist shall notify the board and the clinical pharmacist practitioner's registration shall be inactive, until such time as a new application is approved.

#### *North Carolina [Regulation]*



- (1) The requirements for application for CPP (Clinical Pharmacist Practitioner) approval include that the pharmacist:
  - (A) has an unrestricted and current license to practice as a pharmacist in North Carolina;
  - (B) meets one of the following qualifications:
    - (i) has earned **Certification from the Board of Pharmaceutical Specialties**, is a Certified Geriatric Pharmacist as certified by the Commission for Certification in Geriatric Pharmacy, or has completed an American Society of Health System Pharmacists (ASHP) accredited residency program with two years of Clinical Experience approved by the Boards;

### ***Recognition of Advanced Practice Pharmacist***

#### *California [Statute]*

4210. (a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements:

- (1) Hold an active license to practice pharmacy issued pursuant to this chapter that is in good standing.
- (2) Satisfy any two of the following criteria:
  - (A) **Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy**, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.
  - (B) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.
  - (C) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.
- (3) File an application with the board for recognition as an advanced practice pharmacist.
- (4) Pay the applicable fee to the board.

*[NOTE: The list of certification topics in the legislation matched the list of topics available from BPS and CCGP at the time the legislation was passed.]*

### ***Certificate of Medication Therapeutic Authority***

#### *Missouri [Regulation]*

- (1) A pharmacist shall obtain a certificate of medication therapeutic authority from the Missouri State Board of Pharmacy to provide medication therapy services that include initiating or implementing a modification of a patient's medication therapy or device usage.  
Applications shall be submitted on forms provided by the Missouri State Board of Pharmacy and shall be accompanied by the certificate of medication therapeutic plan authority fee and proof the applicant—
  - (A) Holds a doctor of pharmacy (PharmD) degree earned from a school, accredited by the Accreditation Council for Pharmacy Education (ACPE); or
  - (B) Has



successfully completed a postgraduate medication therapy certificate course or program accredited or granted by the APCE, American Society of Health-System Pharmacists, American Society of Consultant Pharmacists, or the American Pharmacists Association; or (C) **Holds a current certification from the Board of Pharmaceutical Specialties**, the Commission for Certification in Geriatric Pharmacy, or the National Certification Board for Diabetes Educators; or (D) Has completed a post-graduate medication therapy certificate course that, at a minimum, included training in the following areas: 1.

For purposes of renewal, six (6) of the continuing education hours required for renewing the certificate holder's Missouri pharmacist license shall be earned in courses/programs related to medication therapy management.

The continuing education required by this rule shall be governed by the rules of the Missouri State Board of Pharmacy governing pharmacist continuing education

(4) The Missouri State Board of Pharmacy may discipline or terminate a pharmacist's certificate of medication therapeutic plan authority if the Missouri State Board of Pharmacy determines that the pharmacist has violated the terms of a protocol, the requirements of Chapter 338, RSMo, or rules of the board governing medication therapy services or any other state or federal drug law.

### *Eligibility for Licensure*

#### *Nebraska [Statute]*

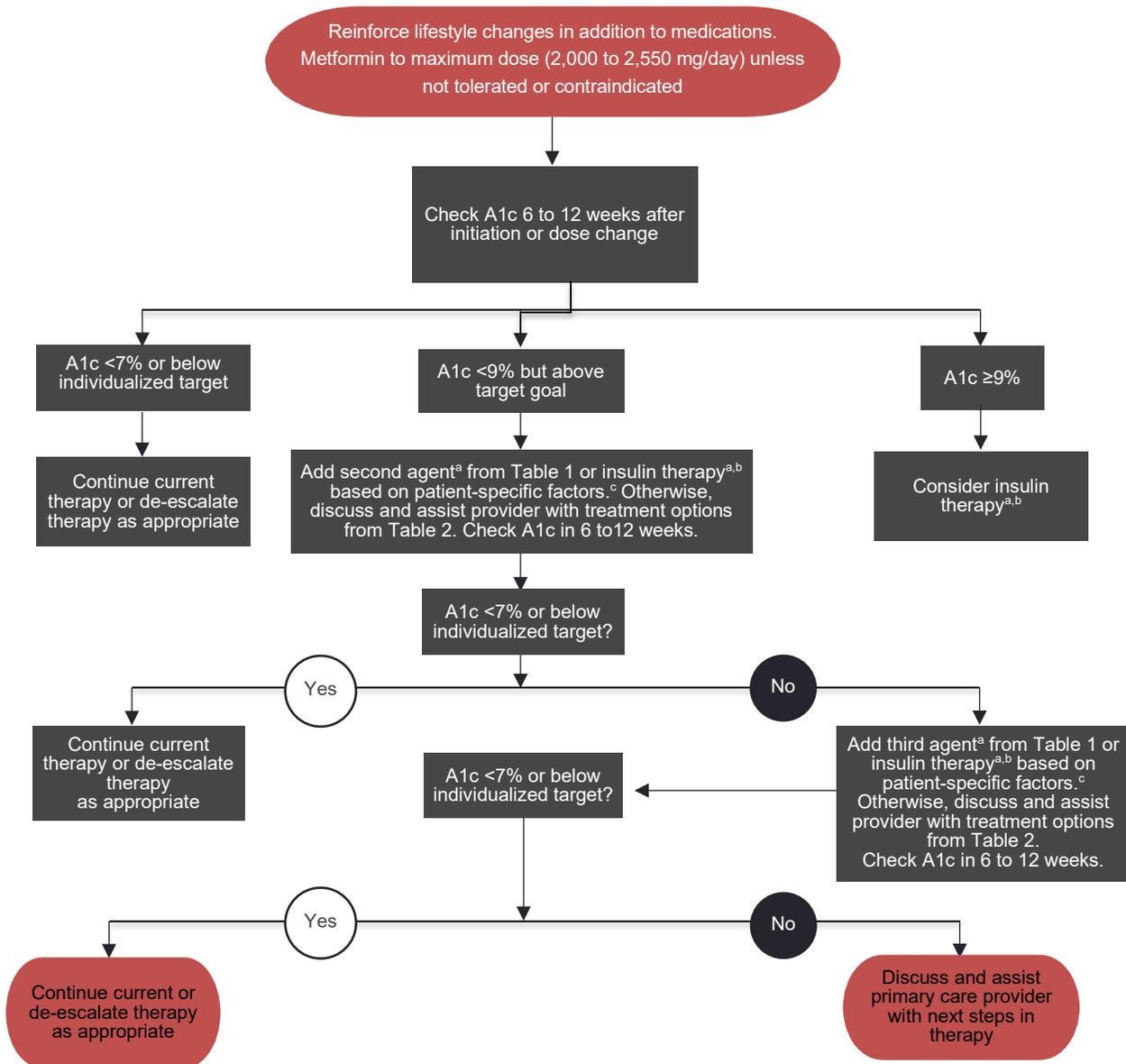
- (1) To be eligible to take the pharmacist licensure examination, every applicant must present proof of graduation from an accredited pharmacy program. A graduate of a pharmacy program located outside of the United States and which is not accredited shall be deemed to have satisfied the requirement of being a graduate of an accredited pharmacy program upon providing evidence satisfactory to the department, with the recommendation of the board, of graduation from such foreign pharmacy program and upon successfully passing an equivalency examination approved by the board.
- (2) Every applicant for licensure as a pharmacist shall
  - (a) pass a pharmacist licensure examination approved by the board,
  - (b) have graduated from a pharmacy program pursuant to subsection (1) of this section, and
  - (c) present proof satisfactory to the department, with the recommendation of the board, that he or she has met one of the following requirements to demonstrate his or her current competency:
    - (i) Within the last three years, has passed a pharmacist licensure examination approved by the board;
    - (ii) has been in the active practice of the profession of pharmacy in another state, territory, or the District of Columbia for at least one year within the three years immediately preceding the application for licensure;
    - (iii) **has become board certified in a specialty recognized by the Board of Pharmacy Specialties or its successor within the seven years immediately preceding the application for licensure;**
    - (iv) is duly licensed as a pharmacist in some other state, territory, or the District of Columbia in which, under like conditions, licensure as a pharmacist is granted in this state; or

## BPS Board Certification



- (v) has completed continuing competency in pharmacy that is approved by the Board of Pharmacy.
- (3) Proof of the qualifications for licensure prescribed in this section shall be made to the satisfaction of the department, with the recommendation of the board. Graduation from an accredited pharmacy program shall be certified by the appropriate school, college, or university authority by the issuance of the degree granted to a graduate of such school, college, or university.

# Example of Therapeutic Management of Type 2 Diabetes



<sup>a</sup> Primary care provider (PCP) will be notified via notes in EMR; PCP will co-sign prescriptions.

<sup>b</sup> Refer to insulin initiation and insulin adjustment protocols, below.

<sup>c</sup> Patient-specific factors include anticipated efficacy of antihyperglycemic agents at achieving A1c goal, hypoglycemia risk, weight gain, side effects, and costs.

**Table 1. Noninsulin antihyperglycemic agents for the treatment of type 2 diabetes**

<b>Generic (Brand Name)</b>	<b>Strength (mg)</b>	<b>Initial Dose (mg)</b>	<b>Max Dose (mg)</b>	<b>Usual Dose (mg)</b>
<i>Biguanide</i>				
Metformin (Glucophage)	500, 850, 1000	500 or 850 daily	2550 daily	1500-2000 divided (BID)
Metformin extended-release (Glucophage XR/Fortamet)	500, 750	500 daily with evening meal	2500 daily	1500-2000 daily or divided
<i>DPP-4 inhibitors</i>				
Sitagliptin (Januvia)	25, 50, 100	50-100 daily	100 daily	100 daily
Saxagliptin (Onglyza)	2.5, 5	2.5-5 daily	5 daily	2.5-5 daily
Linagliptin (Trajenta)	5	5 daily	5 daily	5 daily
Alogliptin (Nesina)	6.25, 12.5, 25	25 daily	25 daily	25 daily
<i>GLP-1 agonists</i>				
Liraglutide (Victoza)	Multidose pen	0.6 daily	1.8 daily	1.8 daily
Albiglutide (Tanzeum)	30, 50	30 weekly	50 weekly	30-50 weekly
Dulaglutide (Trulicity)	0.75, 1.5	0.75 weekly	1.5 weekly	0.75-1.5 mg weekly
Exenatide (Byetta)	5 mcg, 10 mcg	5-10 mcg BID	10 mcg BID	10 mcg BID
Exenatide extended-release (Bydureon)	2	2 weekly	2 weekly	2 weekly
Lixisenatide <sup>a</sup> (Adlyxin)	10 mcg, 20 mcg	10 mcg daily	20 mcg daily	20 mcg daily
<i>Sulfonylureas (Second Generation)</i>				
Glimepiride (Amaryl)	1, 2, 4	1-2 daily	8 daily	4 daily
Glipizide (Glucotrol)	5, 10	2.5, 5 daily	40 divided (BID)	10-20 divided (BID)
Glipizide ER (Glucotrol XL)	2.5, 5, 10	5 daily	20 daily or divided (BID)	5-20 daily or divided (BID)
Glyburide <sup>b</sup> (Diabeta, Micronase)	1.25, 2.5, 5	2.5-5 daily	20 daily or divided (BID)	5-20 daily or divided (BID)

BID, twice daily.

<sup>a</sup> Expected to be available late 2016.

<sup>b</sup> Use glyburide with caution (higher risk of prolonged hypoglycemia in older adults and those with renal impairment).

**Table 1 continued. Noninsulin antihyperglycemic options for the treatment of type 2 diabetes**

<b>Generic (Brand Name)</b>	<b>Strength (mg)</b>	<b>Initial Dose (mg)</b>	<b>Max Dose (mg)</b>	<b>Usual Dose (mg)</b>
<i>Thiazolidinedione</i>				
Pioglitazone (Actos)	15, 30, 45	15-30 daily	45	15-45 daily
<i>Alpha-glucosidase inhibitor</i>				
Acarbose (Precose)	25, 50, 100	25 daily with meal	300	50-100 TID before meals
Miglitol (Glyset)	25, 50, 100	25 daily with meal	300	25-100 TID
<i>Non-sulfonylurea insulin secretagogues</i>				
Repaglinide (Prandin)	0.5, 1.2	0.5 with meals	16	0.5-4 AC to QID
Nateglinide (Starlix)	60, 120	60-120 with meal	360	60-120 AC
<i>Sodium-glucose cotransporter 2 (SGLT-2) inhibitors</i>				
Empagliflozin (Jardiance)	10, 25	10 daily	25	10-25 daily
Canagliflozin (Invokana)	100, 300	100 daily	300	300 daily
Dapagliflozin (Farxiga)	5, 10	5 daily	10	5 in morning

AC, *ante cibum* before meals; QID, four times a day; TID, three times a day.

**Table 3. Combination noninsulin antihyperglycemic agents for the treatment of type 2 diabetes**

Generic (Brand Name)	Strength (mg)	Initial Dose (mg)	Max Daily Dose (mg)	Usual Dose (mg)
Glipizide/metformin (Metaglip)	2.5/250, 2.5/500, 5/500	2.5/250 daily-2.5/500 BID or 2.5/500-5/500 BID	10/2000 or 20/2000	Titrate to effective dose (not over max)
Glyburide/metformin (Glucovance)	1.25/250, 2.5/500, 5/500	1.25/250 daily-BID or 2.5/500-5/500 BID	10/2000 or 20/2000	2.5/500-10/1000 daily-BID
Repaglinide/metformin (PrandiMet)	1/500, 2/500	1/500 BID within 15 min prior to meal	10/2500	Titrate to effective dose (not over max)
Pioglitazone/metformin (Actoplus Met)	15/500, 15/850	15/500-15/850 daily-BID	45/2550	Titrate to effective dose (not over max)
Pioglitazone/metformin ER (Actoplus Met XR)	15/1000, 30/1000	15/1000-30/1000 daily	45/2000	Titrate to effective dose (not over max)
Sitagliptin/metformin (Janumet)	50/500, 50/1000	50/500 BID or 50/1000 BID	100/2000	Titrate to effective dose (not over max)
Sitagliptin/metformin ER (Janumet XR)	50/500, 50/1000, 100/1000	50/500 BID or 50/1000 BID or 100/1000 daily	100/2000	Titrate to effective dose (not over max)
Linagliptin/metformin (Jentaduetto)	2.5/500, 2.5/850, 2.5/1000	2.5/500 BID or 2.5/850 BID or 2.5/1000 BID	5/2000	2.5-5/2000 mg daily
Linagliptin/metformin ER (Jentaduetto XR)	2.5/1000, 5/1000	2.5/1000 daily or 5/1000 daily	5/1000	2.5-5/1000 mg daily
Saxagliptin/metformin ER (Kombiglyze XR)	2.5/1000, 5/500, 5/1000	2.5/1000 daily or 5/500 daily or 5/1000 daily	5/2000	2.5-5/2000 mg daily
Alogliptin/metformin (Kazano)	12.5/500, 12.5/1000	12.5/500 BID or 12.5/1000 BID	25/2000	25/2000 mg daily
Canagliflozin/metformin (Invokamet)	50/500, 150/500, 50/1000, 150/1000	50/500 BID or 150/500 BID or 50/1000 BID or 150/1000 BID	300/2000	100-300/2000 mg daily
Dapagliflozin/metformin ER (Xigduo XR)	5/500, 10/500, 5/1000, 10/1000	5/500 daily-BID or 5/1000 daily-BID or 10/500 daily or 10/1000mg daily	10/2000	5-10/2000 mg daily
Empagliflozin/metformin (Synjardy)	5/500, 5/1000, 12.5/500, 12.5/1000	5/500 BID or 5/1000 BID or 12.5/500 BID or 12.5/1000 BID	25/2000	10-25/2000 mg daily

## Example protocol for initiating insulin

1. Start with NPH, detemir, or glargine.
2. The choice may vary depending on endogenous insulin secretion, need for mealtime insulin coverage, cost and convenience.
3. All patients started on insulin should demonstrate use of a glucometer and be educated about recognizing and treating hypoglycemia.

### NPH, detemir, or glargine insulin

- a. Continue metformin ± sulfonylurea depending on preprandial glucose.
- b. Add 10-20 units of NPH, detemir, or glargine insulin daily.
- c. Then increase insulin by 10% or 2-4 units every 3 days until attaining the goal fasting blood glucose of <130 mg/dL without hypoglycemia.
- d. Once fasting glucose is at goal, check post-prandial glucose; if >180 mg/dL, consider adding either rapid-acting or regular insulin before meals.

### NPH or detemir insulin (BID)

- a. Continue metformin, discontinue sulfonylurea.
- b. Add 5-10 units of NPH or detemir insulin at breakfast and dinner (or bedtime).
- c. Then increase insulin by 10% or at least 2 units every 3 days until attaining the goal fasting blood glucose and pre-dinner glucose of <130 mg/dL without hypoglycemia.
- d. Once fasting glucose is at goal, check post-prandial glucose; if >180 mg/dL, consider adding either rapid or regular insulin before meals.

### Premixed insulin (intermediate and short-acting or rapid-acting mixtures)

- a. Continue metformin, discontinue sulfonylurea.
- b. Add 10 units of pre-mixed insulin at breakfast and dinner.
- c. Then increase pre-breakfast and/or pre-dinner insulin by 10% or at least 2 units every 3 days until attaining the goal fasting and pre-meal glucose level of <130 mg/dL without hypoglycemia.

## Sample protocol for adjusting insulin

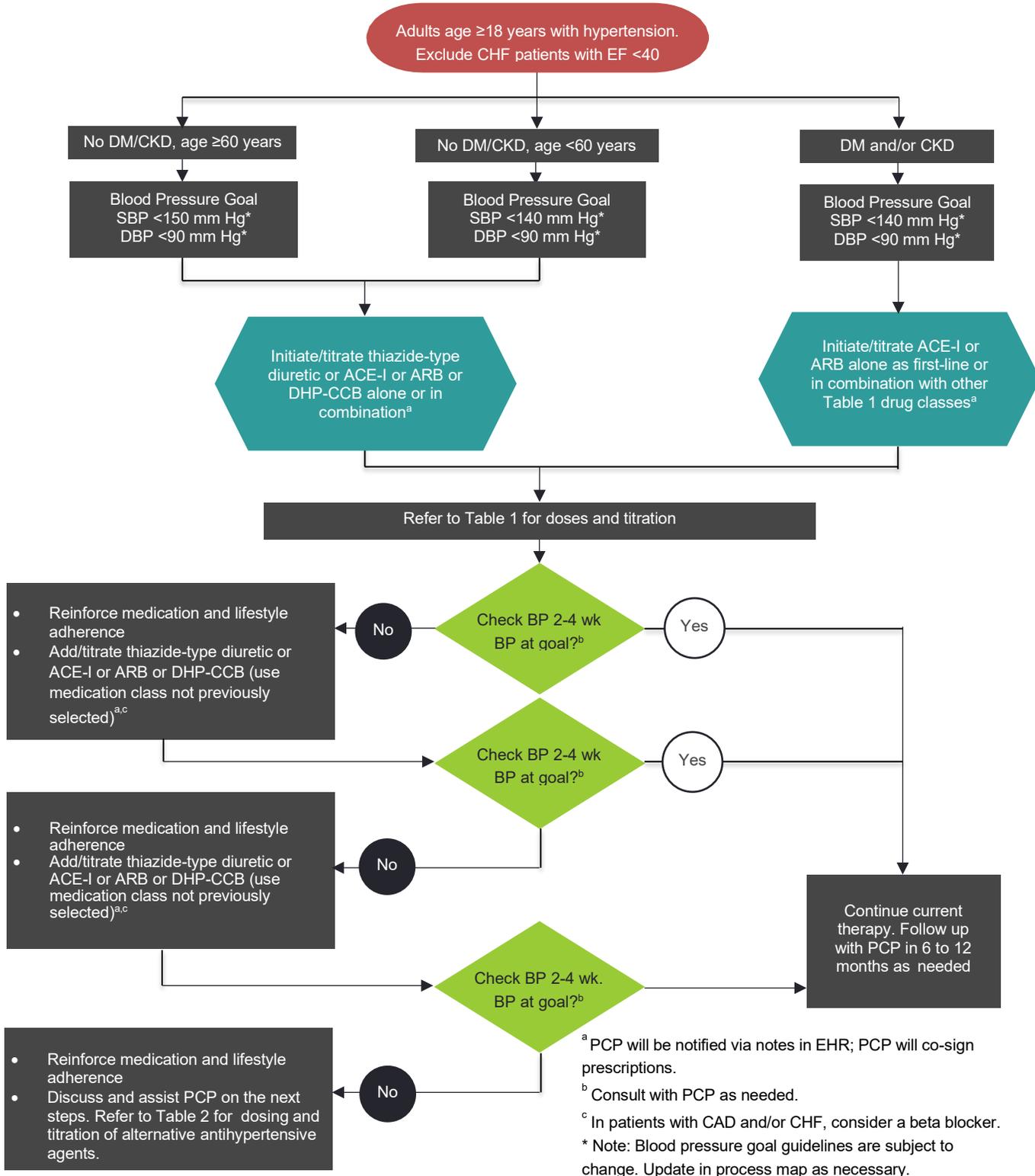
If overnight or before breakfast glucose is above/below target...	Adjust the dinner or bedtime dose of NPH or glargine
If before lunch glucose is above/below target...	Adjust the breakfast dose of regular or rapid-acting insulin
If before dinner glucose is above/below target...	Adjust the breakfast dose of NPH or adjust the lunch dose of regular or rapid-acting insulin
If before bedtime glucose is above/below target...	Adjust the dinner dose of regular or rapid-acting insulin
If fasting glucose levels are significantly higher than bedtime levels (i.e., twice as high), consider nocturnal hypoglycemia. Have the patient check glucose levels around 3:00 a.m. for two days during the week. If the glucose levels are:	
Normal in the middle of the night...	Increase the NPH dinner dose
Low in the middle of the night...	Decrease the NPH dinner dose

*Disclaimer: Please note that clinical guidelines change frequently and this document is meant to serve as an example only. The therapeutic management of type 2 diabetes protocol flow chart can be modified so you can update it based on your patient population and current guidelines. This content is provided for informational purposes only and is not intended as medical advice, or as a substitute for the medical advice of a physician.*

Example provided courtesy of the University of Michigan Medical Group.

Source: AMA. *Practice transformation series: improve care for patients with type 2 diabetes. 2017.*

# Example of Therapeutic Management of Hypertension



**Table 1: First-line antihypertensive medications**

Drug Class and Generic Name	Brand Name	Usual Dosage Regimens				
<b>Thiazide Diuretics</b>						
hydrochlorothiazide		12.5 mg daily	25 mg daily	50 mg daily		
chlorthalidone					25 mg daily	
indapamide		1.25 mg daily		2.5 mg daily		
<b>ACE Inhibitors</b>						
benazepril	Lotensin	5 mg daily	10 mg daily	20 mg daily	40 mg daily	
quinapril	Accupril	10 mg daily		20 mg daily	40 mg daily	
lisinopril	Prinivil/Zestril	5 mg daily	10 mg daily	20 mg daily	40 mg daily	
enalapril	Vasotec	2.5 mg daily	5 mg daily	10 mg daily	10 mg BID	
fosinopril	Monopril	10 mg daily		20 mg daily	40 mg daily	
trandolapril	Mavik Univasc	1 mg daily	2 mg daily	4 mg daily		
moexipril	Altace				7.5 mg daily	15 mg daily
ramipril	Aceon	2.5 mg daily	5 mg daily	10 mg daily		
perindopril		4 mg daily		8 mg daily		
<b>Angiotensin Receptor Blockers</b>						
telmisartan	Micardis			40 mg daily	80 mg daily	
olmesartan	Benicar				20 mg daily	40 mg daily
valsartan	Diovan	80 mg daily	160 mg daily	320 mg daily		
irbesartan	Avapro				150 mg daily	300 mg daily
candesartan	Atacand	8 mg daily	16 mg daily	32 mg daily		
eprosartan	Teveten				400 mg daily	600 mg daily
losartan	Cozaar	50 mg daily	100 mg daily	50 mg BID		
<b>Dihydropyridine Calcium Channel Blockers</b>						
amlodipine	Norvasc			5 mg daily	10 mg daily	
felodipine	Plendil				5 mg daily	10 mg daily
nifedipine CC	Adalat CC Procardia XL	30 mg daily	60 mg daily	90 mg daily		
nisoldipine	Sular	20 mg daily	30 mg daily	40 mg daily		
isradipine	Dynacirc CR			2.5 mg BID	5 mg BID	

**Table 2: Alternative antihypertensive medications**

Drug Class and Generic Name	Brand Name	Usual Dosage Regimens			
<b>Aldosterone Antagonists</b>					
spironolactone	Aldactone			25 mg daily	50 mg daily
eplerenone	Inspira			50 mg daily	50 mg BID
<b>Potassium Sparing/Thiazide Combination Diuretics</b>					
amiloride /HCTZ				5 mg/50 mg daily	
triamterene/HCTZ				37.5 mg/25 mg daily	
spironolactone/HCTZ				25 mg/25 mg daily	
<b>Beta Blockers</b>					
atenolol	Tenormin		25 mg daily	50 mg daily	100 mg daily
metoprolol tartrate	Lopressor			50 mg BID	100 mg BID
propranolol	Inderal LA			40 mg BID	80 mg BID
propranolol	Inderal XL		60 mg daily	80 mg daily	120 mg daily
labetalol	Trandate/Normodyne		100 mg BID	200 mg BID	300 mg BID
nadolol	Corgard		40 mg daily	80 mg daily	160 mg daily
metoprolol succinate	Toprol XL			100 mg daily	200 mg daily
nebivolol	Bystolic		2.5 mg daily	10-20 mg daily	40 mg daily
carvedilol	Coreg			3.125 BID	12.5-25 mg BID
	Coreg CR	10 mg daily	20 mg daily	40 mg daily	80 mg daily
<b>Non-Dihydropyridine Calcium Channel Blockers</b>					
verapamil SR	Calan SR				240 mg daily
diltiazem	Cardizem	30 mg QID	60 mg TID	60 mg QID	90 mg TID
diltiazem CD	Cardizem CD	120 mg daily	180 mg daily	240 mg daily	300 mg daily
<b>Central Acting Agents</b>					
clonidine	Catapres		0.1 mg BID	0.2 mg BID	0.3 mg BID
clonidine patch	Catapres-TTS		0.1 mg/24 hr	0.2 mg/24 hr	0.3 mg/24 hr
methyldopa			250 mg TID	500 mg TID	1000 mg TID
<b>Vasodilators</b>					
isosorbide dinitrate			10 mg TID	20 mg TID	40 mg TID
hydralazine			25 mg TID	50 mg TID	100 mg TID

**Table 2: Alternative antihypertensive medications, continued**

Alpha Blockers					
doxazosin	Cardura		1 mg daily	2 mg daily	4 mg daily
terazosin	Hytrin		1 mg daily	2 mg daily	5 mg daily
prazosin	Minipress		1 mg BID	2 mg BID	5 mg BID
Renin Inhibitors					
aliskiren	Tekturra			150 mg daily	300 mg daily
Other Diuretics					
furosemide	Lasix			20 mg BID	40 mg BID
toremide	Demadex			5 mg daily	10 mg daily

*Disclaimer: Please note that clinical guidelines change frequently and this document is meant to serve as an example only. The therapeutic management of hypertension protocol flow chart can be modified so you can update it based on your patient population and current guidelines. This content is provided for informational purposes only and is not intended as medical advice, or as a substitute for the medical advice of a physician. This content does not constitute a recommendation or endorsement of any specific tests, products, procedures, practices or medical opinions.*

Example provided courtesy of the University of Michigan Medical Group.

Source: AMA. Practice transformation series: maximizing the role of a pharmacist in your practice. 2017.

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2020 Legislature

1  
2 An act relating to automated pharmacy systems;  
3 amending s. 465.0235, F.S.; authorizing a community  
4 pharmacy to use an automated pharmacy system under  
5 certain circumstances; providing that certain  
6 medicinal drugs stored in an automated pharmacy system  
7 for outpatient dispensing are part of the inventory of  
8 the pharmacy providing services through such system;  
9 requiring community pharmacies to adopt certain  
10 policies and procedures; authorizing, rather than  
11 requiring, the Board of Pharmacy to adopt specified  
12 rules; deleting an obsolete date; providing an  
13 effective date.

14  
15 Be It Enacted by the Legislature of the State of Florida:

16  
17 Section 1. Section 465.0235, Florida Statutes, is amended  
18 to read:

19 465.0235 Automated pharmacy systems used by long-term care  
20 facilities, hospices, or state correctional institutions, or for  
21 outpatient dispensing.-

22 (1) A pharmacy may provide pharmacy services to a long-  
23 term care facility or hospice licensed under chapter 400 or  
24 chapter 429 or a state correctional institution operated under  
25 chapter 944 through the use of an automated pharmacy system that

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26 | need not be located at the same location as the pharmacy.

27 |       (2) A community pharmacy, as defined in s. 465.003 and  
28 | licensed in this state, may provide pharmacy services for  
29 | outpatient dispensing through the use of an automated pharmacy  
30 | system that need not be located at the same location as the  
31 | community pharmacy if:

32 |       (a) The automated pharmacy system is under the supervision  
33 | and control of the community pharmacy.

34 |       (b) The automated pharmacy system is housed in an indoor  
35 | environment area and in a location to increase patients' access  
36 | to their prescriptions, including, but not limited to, medical  
37 | facilities or places of business where essential goods and  
38 | commodities are sold or large employer workplaces or locations  
39 | where access to a community pharmacy is limited.

40 |       (c) The community pharmacy providing services through the  
41 | automated pharmacy system notifies the board of the location of  
42 | the automated pharmacy system and any changes in such location.

43 |       (d) The automated pharmacy system has a mechanism that  
44 | provides live, real-time patient counseling by a pharmacist, as  
45 | defined in s. 465.003 and licensed in this state, before the  
46 | dispensing of any medicinal drug.

47 |       (e) The automated pharmacy system does not contain or  
48 | dispense any controlled substance listed in s. 893.03 or 21  
49 | U.S.C. s. 812.

50 |       (f) The community pharmacy maintains a record of the

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51 medicinal drugs dispensed, including the identity of the  
52 pharmacist responsible for verifying the accuracy of the dosage  
53 and directions and providing patient counseling.

54 (g) The automated pharmacy system ensures the  
55 confidentiality of personal health information.

56 (h) The community pharmacy maintains written policies and  
57 procedures to ensure the proper, safe, and secure functioning of  
58 the automated pharmacy system. The community pharmacy shall  
59 annually review the policies and procedures and maintain a  
60 record of such policies and procedures for a minimum of 4 years.  
61 The annual review must be documented in the community pharmacy's  
62 records and must be made available to the board upon request.  
63 The policies and procedures must, at a minimum, address all of  
64 the following:

65 1. Maintaining the automated pharmacy system and any  
66 accompanying electronic verification process in good working  
67 order.

68 2. Ensuring the integrity of the automated pharmacy  
69 system's drug identifier database and its ability to identify  
70 the person responsible for making database entries.

71 3. Ensuring the accurate filling, stocking, restocking,  
72 and verification of the automated pharmacy system.

73 4. Ensuring the sanitary operation of the automated  
74 pharmacy system and the prevention of cross-contamination of  
75 cells, cartridges, containers, cassettes, or packages.

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76        5. Testing the accuracy of the automated pharmacy system  
77 and any accompanying electronic verification process. The  
78 automated pharmacy system and accompanying electronic  
79 verification process must, at a minimum, be tested before the  
80 first use of the system, upon restarting the system, and after a  
81 modification of the system or electronic verification process  
82 which alters the filling, stocking, or restocking of the system  
83 or the electronic verification process.

84        6. Training of persons authorized to access, stock,  
85 restock, or use the system.

86        7. Conducting routine and preventative maintenance of the  
87 automated pharmacy system, including calibration of the system,  
88 if applicable.

89        8. Removing expired, adulterated, misbranded, or recalled  
90 medicinal drugs from the automated pharmacy system.

91        9. Preventing unauthorized persons from accessing the  
92 automated pharmacy system, including assigning, discontinuing,  
93 or modifying security access.

94        10. Identifying and recording persons responsible for  
95 filling, stocking, and restocking the automated pharmacy system.

96        11. Ensuring compliance with state and federal law,  
97 including, but not limited to, all applicable labeling, storage,  
98 and security requirements.

99        12. Maintaining an ongoing quality assurance program that  
100 monitors and records performance of the automated pharmacy

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101 system and any accompanying electronic verification process to  
102 ensure proper and accurate functioning, including tracking and  
103 documenting system errors. A community pharmacy must maintain  
104 such records for a minimum of 4 years and must make such records  
105 available to the board upon request.

106 (3)~~(2)~~ Medicinal drugs stored in bulk or unit of use in an  
107 automated pharmacy system servicing a long-term care facility,  
108 hospice, or correctional institution, or for outpatient  
109 dispensing, are part of the inventory of the pharmacy providing  
110 pharmacy services to that facility, hospice, or institution, or  
111 for outpatient dispensing, and medicinal drugs delivered by the  
112 automated pharmacy system are considered to have been dispensed  
113 by that pharmacy.

114 (4)~~(3)~~ The operation of an automated pharmacy system must  
115 be under the supervision of a ~~Florida-licensed~~ pharmacist  
116 licensed in this state. To qualify as a supervisor for an  
117 automated pharmacy system, the pharmacist need not be physically  
118 present at the site of the automated pharmacy system and may  
119 supervise the system electronically. The ~~Florida-licensed~~  
120 pharmacist shall be required to develop and implement policies  
121 and procedures designed to verify that the medicinal drugs  
122 delivered by the automated pharmacy ~~dispensing~~ system are  
123 accurate and valid and that the machine is properly restocked.

124 (5)~~(4)~~ The Legislature does not intend for this section to  
125 limit the current practice of pharmacy in this state. This

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126 section is intended to allow automated pharmacy systems to  
 127 enhance the ability of a pharmacist to provide pharmacy services  
 128 in locations that do not employ a full-time pharmacist. This  
 129 section does not limit or replace the use of a consultant  
 130 pharmacist.

131 (6) ~~(5)~~ The board may ~~shall~~ adopt rules governing the use  
 132 of ~~an~~ automated pharmacy systems. If adopted, such rules ~~system~~  
 133 ~~by January 1, 2005, which~~ must include all of the following  
 134 specify:

- 135 (a) Recordkeeping requirements. ~~†~~
- 136 (b) Security requirements. ~~†~~ ~~and~~
- 137 (c) Labeling requirements that permit the use of unit-dose  
 138 medications if the facility, hospice, or institution maintains  
 139 medication-administration records that include directions for  
 140 use of the medication and the automated pharmacy system  
 141 identifies:

- 142 1. The dispensing pharmacy. ~~†~~
- 143 2. The prescription number. ~~†~~
- 144 3. The name of the patient. ~~†~~ ~~and~~
- 145 4. The name of the prescribing practitioner.

146 Section 2. This act shall take effect July 1, 2020.

#### **64B16-28.141 Requirements for use of an Automated Pharmacy System by a Community Pharmacy.**

##### (1) Definitions:

(a) "Automated pharmacy system (APS)" means a mechanical system that performs operations or activities, other than compounding or administration, relative to storage, packaging, dispensing, or distribution of medication, and which collects, controls, and maintains all transaction information.

(b) "Establishment" means one general physical location that may extend to one or more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and control. Where multiple buildings are under common ownership, operation, and control, an intervening thoroughfare does not affect the contiguous nature of the buildings.

(c) "Pharmacist" means a pharmacist as defined by section 465.003, FS.

##### (2) General Requirements. A pharmacy may use an automated pharmacy system provided that:

(a) The automated pharmacy system is located within the prescription department, adjacent to the prescription department, or is located on the establishment of the licensed pharmacy, and the operation of the automated pharmacy system is under the supervision of a pharmacist. An automated pharmacy system that is not located within the prescription department shall be operated as an extension of the licensed pharmacy and the automated pharmacy system shall not require an independent and separate community pharmacy permit. An automated pharmacy system that is not located within the prescription department shall have conspicuously displayed on the automated pharmacy system the name, address, contact information and the permit number of the community pharmacy that is responsible for the operation of the automated pharmacy system.

(b) The pharmacy develops and maintains a policy and procedure manual that includes:

1. The type or name of the system including a serial number or other identifying nomenclature.
2. A method to ensure security of the system to prevent unauthorized access. Such method may include the use of electronic passwords, biometric identification (optic scanning or fingerprint) or other coded identification.
3. A process of filling and stocking the system with drugs; an electronic or hard copy record of medication filled into the system including the product identification, lot number, and expiration date.
4. A method of identifying all the registered pharmacy interns or registered pharmacy technicians involved in the dispensing process.
5. Compliance with a Continuous Quality Improvement Program.
6. A method to ensure that patient confidentiality is maintained.
7. A process to enable the prescription department manager or designee to revoke, add, or change access at any time.

(c) The system ensures that each prescription is dispensed in compliance with the definition of dispense as defined by section 465.003, F.S., and the practice of the profession of pharmacy. The system shall include a mechanism to ensure that the patient or an authorized agent of the patient has a means to communicate with a pharmacist responsible for dispensing the medical drug product. The means of communication may include in person, electronic, digital, or telephonic.

(d) The system shall maintain a readily retrievable electronic record to identify all pharmacists, pharmacy interns, registered pharmacy technicians, or other personnel involved in the dispensing of a prescription.

(e) The system shall provide the ability to comply with product recalls generated by the manufacturer, distributor, or pharmacy. The system shall have a process in place to isolate affected lot numbers including an intermix of drug product lot numbers.

(3) Additional Requirements for Patient Accessed Automated Pharmacy Systems. A pharmacy may use a patient accessed automated pharmacy system, provided that:

(a) The requirements in subsection (2), above, are met.

(b) Except as provided in paragraph (d), below, the stocking or restocking of a medicinal drug shall only be completed by the following:

1. A pharmacist;
2. A pharmacy intern under the direct and immediate personal supervision of a pharmacist; or
3. A registered pharmacy technician under the direct supervision of a pharmacist.

(c) Access to the Automated Pharmacy System in the absence of a pharmacist for purposes of servicing and

maintenance by non-pharmacy licensed personnel shall be permitted provided that the system is capable of tracking individual access and preventing unauthorized access, and the system employs user based access or other technology that will prevent access to areas of the dispensing cabinet where drugs are stored. If the system does not employ such technology, access to the system for servicing and maintenance is permitted only under the direct supervision of a pharmacist.

(d) If the automated pharmacy system uses removable cartridges or containers to store the drug or uses unit of use packages, the stocking or restocking of the cartridges, containers or unit of use packages may occur at a licensed repackaging facility and may be sent to the provider pharmacy to be loaded by personnel designated by the pharmacist if:

1. A pharmacist verifies the cartridge, container or unit of use packages have been properly filled and labeled.
2. The individual cartridge, container or unit of use package is transported to the provider pharmacy in a secure, tamper-evident container.
3. The automated pharmacy system uses a bar code verification, electronic verification, weight verification, radio frequency identification (RFID) or similar process to ensure that the cartridge, container or unit of use package is accurately loaded into the automated pharmacy system.

4. The pharmacist verifying the filling and labeling retains responsibility if the cartridge, container or unit of use package is stocked or restocked incorrectly by the personnel designated to load the cartridges or containers.

(e) The automated pharmacy system must use at least two separate verifications, such as bar code verification, electronic verification, weight verification, radio frequency identification (RFID), visual verification or similar process to ensure that the proper medication is being dispensed from the automated system.

(f) The medication shall bear a patient specific label that complies with rule 64B16-28.108, F.A.C.

(g) The record of transactions with the patient accessed automated pharmacy system shall be available to authorized agents of the Department of Health. The record of transactions shall include:

1. Name of the patient.
2. Name, strength, and dosage form of the drug product dispensed.
3. Quantity of drug dispensed.
4. Date and time of dispensing.
5. Name of provider pharmacy.
6. Prescription number.
7. Name of prescribing practitioner.
8. Identity of the pharmacist who approved the prescription or order.
9. Identity of the person to whom the drug was released.

(4) The pharmacist responsible for filling, verifying, loading or supervising the automated pharmacy system shall be responsible for her or his individual action.

(5) A prescription dispensed pursuant to the requirements of this rule shall be deemed to have been certified by the pharmacist.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.018, 465.022 FS. History—New 11-29-04, Amended 12-30-07, 1-1-10, 7-5-18.*



*Unifying and strengthening the voice of pharmacy  
while advancing pharmacy practice through  
education, advocacy collaboration, and relationships*

July 26, 2020

Jessica Sapp  
Executive Director  
Florida Board of Pharmacy  
4052 Bald Cypress Way, C-04  
Tallahassee Florida 32399

Re: Rulemaking for HB59

Dear Ms. Sapp

This correspondence is provided on behalf of the Florida Pharmacy Association, Inc. ("FPA"), a not-for-profit corporation organized under the laws of this state which seeks to preserve and advance the practice of pharmacy and serves the professional needs of all pharmacists, pharmacy students, and pharmacy technicians in Florida. The FPA is the state's largest and oldest professional society representing Florida pharmacists and pharmacies with over 3,500 members. The FPA is committed to improving public health and patient care, enhancing professional development, and advocating for the interests of the profession.

As you know, Governor DeSantis signed CS/CS/HB 59 – Automated Pharmacy Systems into law on June 30, 2020 (the "Bill"). The Bill, which went into effect July 1, 2020, amends section 465.0235, Florida Statutes, to allow community pharmacies to provide pharmacy services for outpatient dispensing through automated pharmacy systems. The purpose of this letter is to notify the Board of Pharmacy (the "Board") of the FPA's continuing concerns with the Bill and to respectfully request that the Board promptly initiate rulemaking to mitigate these concerns.

Prior to the passage of the Bill, the use of automated pharmacy systems in Florida was extremely limited. Automated pharmacy systems could only be located in long term care facilities, hospices, and state correctional institutions. The Bill significantly expands the use automated pharmacy systems by authorizing community pharmacies to use automated pharmacy systems "housed in an indoor environment area and in a location to increase patients' access to their prescriptions, including, but not

limited to, medical facilities or places of business where essential good and commodities are sold or large employer workplaces or locations where access to a community pharmacy is limited.” CS/CS/HB 59 at lines 34-39. The Bill does not define “indoor environment area” or “location to increase patient access to their prescription”. It is our belief that this broad language potentially allows the systems to be located inside any building in Florida.

This is at odds with what the Bill’s proponents stated was the intent of the Bill. Throughout the legislative process, the Bill’s proponents indicated that the Bill limits where automated pharmacy systems can be located and does not allow for the broad deployment of these systems across the state. However, as noted, this is contrary to the plain language of the Bill. The Bill allows for these systems to be placed at any indoor environment area that increases patient access to prescriptions. Of course, any location would increase access to prescriptions for at least one patient.

The proponents also stated that the Bill gives the Board rulemaking authority to determine suitable locations for automated pharmacy systems. While the Bill does not directly state that the Board may adopt rules restricting locations where automated pharmacy systems may be placed, the Bill authorizes the Board to adopt rules addressing “security requirements” for the system. CS/CS/HB 59 at lines 131-136.

The FPA strongly supports increasing patient access to prescriptions. However, it must be done in a manner that ensures the public health and safety is not compromised. Allowing automated pharmacy systems to be located in virtually any building (no matter how structurally unsound or unsecure) poses a serious risk to the public health and safety. Thus, we ask that the Board exercise its “security requirements” rulemaking authority to establish minimum requirements for structures which house the systems. This will ensure that the pharmacy systems are located in safe and secure environments while furthering the Bill’s intent to increase patient access to prescriptions in underserved locations. The FPA is committed to working with the Board to assist in drafting language that will achieve these goals.

Additionally, the Bill requires that an automated pharmacy system must be under the supervision and control of a community pharmacy (although later in the Bill it provides that the system must be under the supervision of a pharmacist). CS/CS/HB 59 at lines 32-33, 114-116. The Bill does not provide any guidance as to how many systems a pharmacy or pharmacist may supervise at any given time or where the supervising pharmacy or pharmacist must be located. The lack of any restriction on the number of systems a pharmacy or pharmacist can supervise eliminates any meaningful supervision as a single pharmacy or pharmacist could oversee thousands of systems. Further, the supervising pharmacy or pharmacist could be thousands of miles from Florida while conducting this “supervision”. These systems should not be allowed to operate throughout the state without any meaningful oversight.

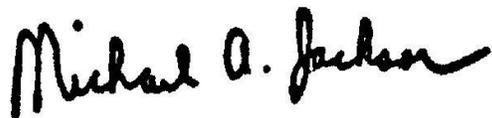
The Bill’s proponents were made aware of these concerns before the Bill was passed and indicated that the Board could address the issues through rulemaking. The Bill authorizes the Board to adopt rules relating to the “use” of automated pharmacy systems. CS/CS/HB 59 at lines 131-132. The Board also has the authority to adopt by rule standards of practice relating to the practice of pharmacy. §465.0155(1),

Fla. Stat. We believe the Board has the necessary authority under these provisions to adopt rules regulating the supervision and control of automated pharmacy systems and we ask that the Board initiate rulemaking to consider these concerns. As always, the FPA is committed to working with the Board to assist in the creation of the rules.

While we are unable to determine whether the Board of Pharmacy has any rulemaking authority on pharmacy network access standards, we wish to bring to the Board's attention that it is not clear whether the adoption of the provisions of this legislation prohibits pharmacy benefit managers (PBMs) from using this technology to meet such purposes. We are concerned that the unregulated deployment of these systems could unbalance the pharmacy market and perhaps even have an impact on existing full service pharmacy providers in medically underserved and economically disadvantaged areas. We ask that the Board monitor this issue very carefully and if there is evidence of the decline in full service pharmacies that affect access, this may be considered a symptom of a deeper problem making a review of existing rules necessary to protect the public and improve standard of practices.

As the Bill has already gone into effect, we respectfully ask that the Board act promptly to begin the rulemaking process so that automated pharmacy systems are not deployed in large numbers without any meaningful oversight. Thank you for your time and consideration and please let me know if you have any questions or need any additional information.

With kindest regards,

A handwritten signature in black ink that reads "Michael A. Jackson". The signature is written in a cursive, flowing style.

Michael A. Jackson, BPharm, CPh  
Executive Vice President and CEO