

## **CHANGES TO THE RULES GOVERNING CLINICAL PHARMACIST PRACTITIONERS: WHAT DO THEY ENTAIL?**

The Medical and Pharmacy Boards recently collaborated on a series of changes to the rules governing Clinical Pharmacist Practitioners (21 N.C.A.C. 46.3101). The chief aims of the amendments are: (1) transfer primary administrative responsibility for CPP application, renewal, and monitoring to the Board of Pharmacy; (2) bring supervising physician consulting and oversight responsibilities in line with those for nurse practitioners and physician assistants; and (3) allow CPPs to designate “primary” and “back-up” supervising physicians, something particularly helpful for CPPs who service patients in a group practice.

This document answers some questions that are likely to arise immediately among presently-approved CPPs and CPP candidates currently seeking approval.

### **Effective Date and Amended Rule Language**

Q. When do the amendments to the CPP rules go into effect?

A. July 1, 2016

Q. Where can I obtain a copy of the amendments?

A. The amended rule .3101 may be found here:  
<http://www.ncbop.org/LawsRules/rules.3100.pdf>.

### **“Primary” and “Back-Up” Supervising Physicians**

Q. What are the roles of a “primary” supervising physician and “back-up” supervising physicians in a CPP protocol?

A. CPPs, and CPP applicants, must continue to include in their protocol every physician who supervises their work as a CPP.

The “primary supervising physician” means “the Supervising Physician who shall provide on-going supervision, collaboration, consultation, and evaluation of the drug therapy management performed by the CPP as defined in the CPP agreement.”

A “back-up supervising physician” means a “Supervising Physician who shall provide supervision, collaboration, consultation, and evaluation of the drug therapy management

performed by the CPP as defined in the CPP Agreement when the Primary Supervising Physician is not available.”

Importantly, with changes to required supervision meetings (discussed below), it is the Primary Supervising Physician with whom the CPP must meet for periodic review of the CPP’s practice under the CPP Agreement.

Prior to these amendments, CPPs in group practice settings were unsure whether they were required to meet periodically with every supervising physician. The amendments make clear that mandated meetings need only occur with the Primary Supervising Physician. Of course, CPPs should interact regularly with all supervising physicians. But one Primary Supervising Physician must be designated in the CPP Agreement for mandatory reviews of the CPP’s practice under the CPP Agreement.

As noted above, when a Primary Supervising Physician is “not available,” a designated Back-Up Supervising Physician may perform the “supervision” and “evaluation” of drug therapy management performed by the CPP. In such an event, the Primary Supervising Physician’s lack of availability and the Back-Up Supervising Physician who conducted the review should be documented.

- Q. What process do I need to follow for designating my Primary Supervising Physician and any Back-Up Supervising Physicians?
- A. All currently-approved CPPs will, in the coming weeks, receive an e-mail that will include a form for designating the Primary Supervising Physician and any Back-Up Supervising Physicians. The form will have instructions for completion, submission, and a deadline for doing so.

All new CPP applicants must include in their proposed CPP Agreement designation of the Primary Supervising Physician and any Back-Up Supervising Physicians.

- Q. What process do I need to follow for changing Primary and Back-Up Supervising Physicians in my CPP Agreement?
- A. Board of Pharmacy staff will be implementing a process for such notifications. CPPs will receive more information on that process in the coming weeks.

**Changes to Required Meetings with the Supervising Physician To Discuss Operation of the CPP Agreement**

Q. How often must the CPP meet with the Primary Supervising Physician “to discuss the operation of the CPP Agreement and quality improvement measures”?

A. Previously, such meetings were required weekly. Under the amended rule, the following schedule must be observed:

For the first six months of the CPP Agreement, the CPP and the Primary Supervising Physician must meet at least monthly.

After the first six months of the CPP Agreement, the CPP and the Primary Supervising Physician must meet at least once every six months.

Each required meeting must be documented, and that documentation must “identify clinical issues discussed and actions taken;” “be signed and dated by those who attended; and “be retained by both the CPP and Primary Supervising Physician and be available for review by members or agents of [the Medical and Pharmacy Boards] for five calendar years.”

Again, as noted above, when a Primary Supervising Physician is “not available,” a designated Back-Up Supervising Physician may perform the “supervision” and “evaluation” of drug therapy management performed by the CPP. In such an event, the Primary Supervising Physician’s lack of availability and the Back-Up Supervising Physician who conducted the review should be documented.

Q. I’m already practicing as a CPP. Beginning July 1, 2016, what schedule to I follow?

A. If, as of July 1, 2016, you are an approved CPP who has been operating under your CPP Agreement for more than six months, you are subject to the requirement that you meet with your Primary Supervising Physician at least every six months.

If, as of July 1, 2016, you are an approved CPP who has been operating under your CPP Agreement for less than six months, you must meet with your Primary Supervising Physician at least once a month until you have been operating under the CPP Agreement for more than six months, after which time you must satisfy the requirement that you meet with your Primary Supervising Physician at least every six months.

Q. What schedule must I follow if I change Primary Supervising Physician under my CPP Agreement?

A. If the new Primary Supervising Physician previously was a designated Back-Up Supervising Physician in the CPP Agreement, you may continue to follow the “at least every six months”

schedule.

If the new Primary Supervising Physician was not previously a designated Back-Up Supervising Physician in the CPP Agreement, you must follow the “at least monthly” schedule for six months.

### **Changes to Documentation Requirements**

- Q. Does a Supervising Physician still need to co-sign every order that a CPP writes?
- A. No. That requirement was deleted as part of the rule amendments. CPPs are reminded, however, that a primary purpose of the required CPP-Primary Supervising Physician meetings is review of the CPP’s practice under the CPP Agreement. Moreover, CPPs are expected to consult frequently with their Supervising Physicians as part of ordinary clinical practice.

### **Changes to Renewal Process**

- Q. Now that the Board of Pharmacy is responsible for administering renewals of the CPP credential, what changes will occur?
- A. CPPs are aware, of course, that CPP credential renewals through the Medical Board were keyed to the CPP’s birthday. The amended rule now provides that – consistent with all other licenses, permits, and registrations issued by the Pharmacy Board – “[e]ach CPP shall register annually on or before December 31.”

To facilitate this transition in renewal dates, any pharmacist holding a current CPP credential as of July 1, 2016 shall be deemed to hold a current CPP credential (for both renewal fee and continuing education requirements) through December 31, 2017.

Likewise, any pharmacist who newly acquires a CPP credential between July 1, 2016 and December 31, 2016 shall be deemed to hold a current CPP credential (for both renewal fee and continuing education requirements) through December 31, 2017.

This “extension” of the CPP credential is intended to fairly transition all CPPs onto an annual renewal cycle that coincides with all other Pharmacy Board renewals.

Board staff will implement an CPP credential on-line renewal process prior to the 2017 renewal period. More information will follow as that process is developed.

## **More Information To Follow**

Pharmacy Board licensing staff will be working with their Medical Board colleagues over the coming weeks and months to facilitate a transfer of primary administrative responsibilities for CPPs to the Pharmacy Board.

Pharmacy Board staff and the CPP Advisory Committee will be working over the coming weeks and months to consider changes and improvements in the application process.

Pharmacy Board staff will continue to provide CPPs, and CPP applicants, with updates as the transition unfolds.