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Blog Post

Florida Pharmacy Collaborative Practice Agreements: Defining the Scope of Practice

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While the COVID-19 pandemic made 2020 a trying year, one unintended benefit was that the Florida legislature allowed pharmacists to further expand their scope of practice to help patients with certain chronic conditions through collaborative practice agreements. Though, as discussed below, they did not make it easy.

The Board of Pharmacy ("the Board") "collaborated" with the Board of Medicine and the Board of Osteopathic Medicine to develop rules addressing both collaborative practice and the test and treat protocols. The rules set forth in Chapter 64B16-31, Florida Administrative Code, became final on October 20, 2020. We previously addressed the scope of these arrangements in a blog post titled, ***As COVID-19 Spreads, Florida Pharmacists' Scope of Practice Expands,*** so those will not be reviewed in detail here.

Collaborative practice requires that the pharmacist and physician enter into a collaborative practice agreement, or "CPA." The signed CPA has to be filed with the Board of Pharmacy before such services can begin, and there is a laundry list of other requirements related to these agreements in Section 465.1865, Florida Statutes, as well as Chapter 64B16-31, F.A.C. CPAs must include:

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

Further, the pharmacist's certification must be attached to the CPA, and the pharmacist, along with the collaborating physician, must maintain the CPA on file at his or her practice location and must make the agreement available to the Department of Health or Board of Pharmacy upon request or upon inspection.

The requirement that patient names be included in the CPA is especially problematic. Informed consent forms will need to be completed, and the patients need to be informed that their participation will be a public record when filed with the Board. Perhaps the Board will allow the parties to not attach the actual patient names and state in the CPA that the list of patient names is included in the CPA on file at the pharmacy and physician's practice and may be reviewed by the Board upon request, or perhaps the patients on the list could be identified by initials. Additionally, every time a new patient is added, the

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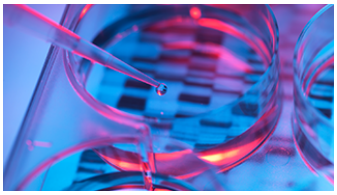

CPA will have to be updated and signed and re-filed with the Board. The CPA shall automatically terminate two years after execution if not renewed.

Additionally, the requirement that the CPA include "specific medicinal drug or drugs to be managed by the pharmacist for each patient" could be cumbersome. The parties will have to develop a streamlined mechanism for listing the drugs per patient, without having the scope of practice become overly broad.

So, what else should we address in these CPAs? One good source of information is the CDC's publication on collaborative practice agreements: *Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team*. But this resource should be supplemented with the requirements of the above Florida statutes and rules. Beyond the basics such as party names, authority, insurance, and other clauses, the most important clause will be the one spelling out exactly what the physician will allow and not allow the pharmacist to do. If this section is broad or vague, the pharmacist risks accidentally going beyond the CPA and thereby risking disciplinary action and civil liability.

The CDC document referenced above titles this section "Patient Care Functions Authorized." This is not one of those "close enough for government work" situations – each term in this section must be carefully considered and crafted.

For instance, the CPA should specify whether the pharmacist can initiate therapy for new patients or whether he or she is only allowed to continue therapy already started by the physician for existing patients or patients not yet needing this therapy. The therapy that is allowed should be clearly specified so the pharmacist is clear about the scope of his or her authority. If the physician wishes to limit the tests to be administered or drugs or dosages authorized by

the pharmacist, this needs to be clearly spelled out in the CPA.

Oftentimes the CPAs will incorporate medical standards to be followed by the pharmacist. These must be very specific, and they must be allowed by the Florida collaborative practice statute and rule. If the CPA says that the pharmacist has to follow "nationally recognized standards," then the agreement needs to identify what these are and who recognizes them. And, if a particular medical standard is identified, the exact title of the standard should be clearly stated as well as the date it was designated. Attaching and incorporating the document by reference in the CPA will help remove any doubt about what was intended. If the standard is later updated or modified, the CPA should be clear as to whether it automatically incorporates the change.

Pharmacists should not rely on the supervising physician to come to them with the CPA already completed. The pharmacists should take the initiative, discuss the scope of practice (and save a copy of the notes on this discussion), and develop these agreements on their own for presentation to the supervising physicians. Pharmacists should consider including their healthcare lawyer in the development of the CPA or, at a minimum, the review of the final CPA to make sure that the parties have addressed everything required.
