Blog Post

Updated for Expanded DDC Interpretation: New Help for the Florida Healthcare Transaction Attorney-Temporary Drug, Device, and Cosmetic Permits

August 30, 2021
By Martin R. Dix

Whoever authored this new legislation (Chapter 2021-135, Laws of Florida) deserves a pat on the back for an idea whose time has come. When an applicant files for a change of ownership (CHOW) or change of location for one of the permits authorized by the Florida Department of Business Professional Regulation, Division of Drugs, Devices, and Cosmetics (affectionately, DDC) under Part 1 of Chapter 499, FS, they can now also request a temporary permit for 90 days.

Having the option to request a temporary permit is especially important when pursuing a CHOW. In a typical healthcare CHOW process, the parties are hammering out the terms of the agreement while the healthcare regulatory team coordinates with state agency personnel to arrange issuance of the healthcare entity permit exactly on the effective date of the transaction. The problem is that the parties' preferred closing schedule may not coincide with statutory time frames and the schedules of the state agency permit processors. So, prior to this new legislation, if, for example, the parties want to close in 10 days, but the state can't process the application

Related People

Martin R. Dix

Related Work

Healthcare
Pharmacy, Drugs, and Medical Devices

Related Offices

Tallahassee

Health Law Rx

Akerman Perspectives on the Latest Developments in Healthcare Law

Visit this Akerman blog

for 30 days, then the parties would be left with no permit for 20 days after the scheduled closing.The new owner loses business and the provider's patients struggle to find a provider to serve them while the buyer awaits the new permit. Also, if there are drugs on the premises, what happens to them when the permit is no longer in effect?

The transaction/regulatory legal community has developed all kinds of legal machinations and fictions to tide them over while they wait for the healthcare permit to issue. These might include "bridge" or management agreements or powers of attorney where the buyer takes over running the business while the parties await permit issuance. During this period, the seller remains on the hook for liability that may occur while the buyer operates the business under the seller's permit. And, while the parties can address civil liability through contractual indemnity by the buyer, there is really nothing to protect the seller against regulatory violations by the buyer while the buyer operates the seller's healthcare business.

Enter our hero, the new DDC temporary operating permit. Under the new temporary permit, the buyer can apply for and receive its own temporary permit for 90 days pending receipt of the actual permit. The temporary permit will allow the buyer to step in early and operate the seller's business while DDC works on issuing the actual permit. The only big downside is that once the temporary permit issues, the seller's permit is immediately null and void. Thus, sellers should only allow buyers to apply for a temporary permit when they are really, really, really positively sure that the deal will go through. If the deal doesn't go through, the temporary permit expires in 90 days and the seller is left with a business it can't operate and no money from the buyer, though an astute seller will require some money before allowing the buyer to file for a temporary permit. You should note that when the DDC says 90 days, they really mean 90 days – the temporary permit becomes null and void on the

91st day and it cannot be extended. If the temporary permit expired or was about to expire and the CHOW application had not been approved, the seller could quickly file a new license application (or maybe file one upon issuance of the temporary permit just in case and withdraw the application if not needed) and hope it can be processed quickly and perhaps before the 91st day.

The permit will also help with change of location applications when a licensee moves. Because the DDC permits are facility permits, the new facility generally has to be inspected before the new permit can issue. As with CHOWs, timing the move for a change in location with the DDC's permit processing and inspections can be tricky. Once again, the temporary permit steps in to make things easier for the relocating healthcare provider by allowing it to operate sooner under the temporary permit.

This is the list of DDC permits eligible under Part 1 of Chapter 499, FS:

- A prescription drug manufacturer;
- A prescription drug repackager;
- A nonresident prescription drug manufacturer;
- A nonresident prescription drug repackager;
- A prescription drug wholesale distributor;
- An out-of-state prescription drug wholesale distributor;
- A retail pharmacy drug wholesale distributor;
- A restricted prescription drug distributor;
- A complimentary drug distributor;
- A freight forwarder;
- A veterinary prescription drug retail establishment;
- A veterinary prescription drug wholesale distributor;

- A limited prescription drug veterinary wholesale distributor;
- An over-the-counter drug manufacturer;
- A device manufacturer;
- A cosmetic manufacturer;
- A third party logistics provider; or
- A healthcare clinic establishment.

While you may think that these permits are all drug and drug distribution permits only important to Florida's pharmacy law geeks, the last permit on the list, the healthcare clinic establishment permit (or HCCE), is actually very common among a variety of healthcare providers including physician practices, clinics, urgent care centers, veterinary clinics, hospital owned providers, and others. The HCCE permit allows business entities to purchase and hold drugs in their own names.

And, DDC has decided to extend the temporary permit process to include the medical gas permits, including the medical oxygen retailer permit even though they are not in Part 1 of Chapter 499, F.S. The introductory language to Part III of the statute, dealing with medical gases, states that the law is "cumulative" and DDC has informally determined that this provides a legal basis for the extension of the temporary permits to Part III licensees. We applaud the extension of the law to medical gas permits and note that it will be especially helpful with sale of DME businesses as they often also hold a medical oxygen retailer permit. Overall, the allowance of temporary permits provides a continuity of operations and care that was much needed in Florida's healthcare community.

This blog post, originally published on July 29, 2021, has been updated to include analysis of recent guidance provided by the Florida Department of Business Professional Regulation, Division of Drugs, Devices, and Cosmetics on the following legislation: Chapter 2021-135, Laws of Florida.

This information is intended to inform firm clients and friends about legal developments, including recent decisions of various courts and administrative bodies. Nothing in this Practice Update should be construed as legal advice or a legal opinion, and readers should not act upon the information contained in this Practice Update without seeking the advice of legal counsel. Prior results do not guarantee a similar outcome.