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Final Order No. DOH-17-0607-DS-MQA

FILED DATE - APR 0 4 2017
Department of Health
By: Deputy Agency Clerk

STATE OF FLORIDA
BOARD OF CLINICAL LABORATORY PERSONNEL

IN RE: PETITION FOR DECLARATORY STATEMENT OF

CHARLES A. PELOQUIN, Pharm.D.

FINAL ORDER

THIS MATTER came before the Board of Clinical Laboratory Personnel (Board) pursuant to Section 120.565, Florida Statutes. At a duly-noticed public telephonic meeting held on March 10, 2017, the Board considered Charles A. Peloquin, Pharm.D.'s (Petitioner) Petition for Declaratory Statement. Petitioner was present. The Board was represented by Deborah Bartholow Loucks, Assistant Attorney General.

The Petition was filed with the Department of Health on January 19, 2017. Petitioner is requesting that the Board issue a Declaratory Statement interpreting Rule 64B3-10.005, Florida Administrative Code.

Having considered the Petition, the presentation of Petitioner, and relevant statutes and rules, the Board issues the following:

FINDINGS OF FACT

1. The Petition was duly filed and noticed in the Florida Administrative Register; Volume 43 Number 14 published on January 23, 2017.

2. The Petition is attached hereto and incorporated herein by reference.

3. Petitioner is seeking the Board's interpretation of Rule 64B3-10.005, F.A.C., as to whether using HPLC Technology with triple quadrupole mass spectrometry detection (also known as LC MS MS), as explained in the petition, is within the scope of petitioner's license.

4. Petitioner was issued a technologist license with conditions on or about August 14, 2009. As part of his licensure application, Petitioner submitted a petition for variance and/or waiver in which he described specialized laboratory tests that he was seeking licensure to perform. The Board granted his petition for variance and waiver and approved his technologist license with the condition that he perform the tests that he outlined in his petition for variance and/or waiver. The HPLC Technology was included in the original petition for variance and/or waiver.

CONCLUSIONS OF LAW

5. The Board has jurisdiction over this matter pursuant to section 120.565, and Chapter 483, Part II, Florida Statutes.

6. Because the Board granted him a license with the condition that he perform the tests that he outlined in his petition for variance and waiver, the Board voted that the scope of the testing is limited to the scope outlined in his initial petition for variance and waiver and declined to answer this petition for declaratory statement.

7. The Board declined to answer the petition.

This Order shall become effective upon filing with the Clerk of the Department of Health.

DONE AND ORDERED this 4th day of April, 2017.

BOARD OF CLINICAL LABORATORY PERSONNEL

Anthony B. Spivey, D.B.A., Executive Director
on behalf of Carleen P. Van Siclen, MS, MLS (ASCP), Chair

NOTICE OF RIGHT TO JUDICIAL REVIEW

A party who is adversely affected by this Final Order is entitled to judicial review pursuant to Section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing one copy of a Notice of Appeal with the Agency Clerk of the Department of Health and a second copy, accompanied by filing fees prescribed by law, with the District Court of Appeal, First District, or with the District Court of Appeal in the Florida Appellate District where the party resides. The Notice of Appeal must be filed within thirty (30) days of rendition of the order to be reviewed.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was furnished by U.S. Mail to: **Charles Peloquin, Pharm.D.,** University of Florida, 1600 SW Archer Road, Room P4-33, Gainesville, Florida 32640-0486; and by electronic mail to: **Deborah B. Loucks**, Assistant Attorney General, deborah.loucks@myfloridalegal.com, and **Angela Southwell**, Office of the Attorney General, angela.southwell@myfloridalegal.com, on April 4, 2017.

Amber Greene
Deputy Agency Clerk

6601-41909

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: Amy L Carraway
DATE: 1-19-17

UF UNIVERSITY of FLORIDA

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January 19, 2017

Petition for a Declaratory Statement before the Florida Board of Clinical Laboratory Personnel

Subject:
Whether the term HPLC technology, as used in the September 22, 2009 Order Granting Petition for Variance and Waiver and Granting License with Conditions, includes all relevant detectors for HPLC, including electrochemical, ultraviolet, fluorescence, and various mass spectrometers including triple quadrupole mass spectrometers (so called HPLC MS MS, UPLC MS MS, or LC MS MS), and any appropriate technology in order to perform TDM, as technology continues to evolve over time?

In November 2009, Dr. Charles Peloquin, was granted License Number TNL 42669, Control Number 199288, a Limited Clinical Lab Technologist license in the areas of Clinical Chemistry Limited, HPLC Technology, GC/MS Technology and Other Spectroscopy Equipment. Four additional individuals were granted identical licenses to work in Dr. Peloquin's lab.

Background:
In 2009, Dr. Peloquin and colleagues were recruited by the State of Florida (UF Emerging Pathogens Institute, UF College of Pharmacy, and the Florida Department of Health, TB Control Section). The goal of this recruitment was to bring a highly specialized clinical and research laboratory from National Jewish Health in Denver, Colorado to the State of Florida.

After a series of telephone, email, mail, and in person discussions, the Board of Clinical Laboratory Personnel (Board), through the Florida Department of Health, Division of Medical Quality Assurance, Bureau of Health Care Practitioner Regulation (Bureau) issued 5 individual licenses as listed above. This allowed the Infectious Disease Pharmacokinetics Lab (IDPL) to begin providing therapeutic drug monitoring (TDM) services. The focus of the lab is to monitor and to recommend adjustment of doses of antimicrobial agents for patients with serious, life-threatening conditions such as tuberculosis, HIV, and fungal infections. Dr. Peloquin and his IDPL now have 29 years of experience within this area of specialty, and are widely viewed as experts in this area.

It is understanding, through the various discussions with the Bureau in 2009, and based upon the very broad language chosen on the licenses themselves, that the intent of the license was to limit the IDPL technologists to TDM, and not to allow excursions into other areas of Clinical Chemistry, such as chemistry panels, urinalysis, etc.

Further, it is our understanding, through the same means listed above, that the Board specifically chose the terms "Other Spectroscopy Equipment," "GC/MS Technology," and "HPLC Technology" to provide the broadest spectrum of tools possible for us to conduct TDM. We note that specific types of detectors, either included or excluded, are not listed under "HPLC Technology." We also note that mass spectrometry (MS) is specifically included after gas chromatograph (GC). Since 2009, we have interpreted the wording on the licenses to mean that we are to choose the appropriate technology, including detection method, for the TDM task at hand.

Subsequent to our recent CAP self-inspection, some within the Department of Pathology raised the question about what functions are "Limited" in our license. Specifically, they posed that HPLC Technology with triple quadrupole mass spectrometry detection (also known as LC MS MS) may be beyond the scope of our licenses. Due to this interpretation, our HPLC testing was discontinued. We specialize in testing drugs for TB, HIV, fungal infections, and drug resistant bacterial infections. In some cases, no other lab in the country offers these tests with appropriate technology, as best as I can find.

At that point, we posed this questions to the Bureau's Regulatory Supervisor Brandi May, and she provided the following interpretation on December 23, 2016:

Mr. Peloquin,

HPLC detectors (UV, PDA, fluorescence, amperometric, electrochemical, etc.) are a basic component of HPLC technology and there are different types of mass spectrometers too including HPLC MS MS, UPLC MS MS, and LC MS MS. All of these would fall within the scope of practice for this limited clinical chemistry license.

Please let me know if you have any additional questions.

Sincerely,

Brandi May, Regulatory Supervisor
Department of Health | Division of Medical Quality Assurance
Bureau of Health Care Practitioner Regulation
4052 Bald Cypress Way Bin C-07
Tallahassee, FL 32399-1708
Phone 850.245.4395

However, in light of the questions raised from the Department of Pathology, and in an abundance of caution, we petition the Board for a Declaratory Statement regarding the scope of our Limited Clinical Lab Technologist licenses. Thank you for considering this petition.

Regards,

Charles Peloquin

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