State of New Hampshire
Board of Registration in Podiatry

Concord, New Hampshire

In the Matter of:
Edward P. Newcott, D.P.M.
License No. 0147
(Adjudicatory Matter/Disciplinary Proceeding)

Docket No.: 14-06

FINAL DECISION AND ORDER

By the Board: Jennifer Sartori, DPM (Presiding Officer)
David Biss, DPM, Board Member
Matthew Burrell, DPM, Board Member

Not Participating: James Dolan, DPM, Recused Board Member

Appearances:

Hearing Counsel: Michelle Heaton, Esquire
Ryan Kuehne, Intern
Attorney General's Office

Hearing Counsel Witnesses: James Dolan, DPM
Todd Flanagan, Inspector, Attorney General's Office

For the Respondent: Brian M. Quirk, Esq.

Respondent Witnesses: None

Background Information

The New Hampshire Board of Podiatry ("Board") first granted a license to Edward P. Newcott, D.P.M. ("Dr. Newcott" or "Respondent") in 1981 to practice Podiatry in the state of New Hampshire. Respondent practices Podiatry in Concord, New London, and Peterborough, New Hampshire. On November 28, 2012, the Board issued an Unannounced Inspection Order for the practice of Dr. Edward Newcott after receiving information from the Administrative Prosecutions Unit ("APU"). On December 20, 2012, investigators Todd Flanagan and James Dolan, DPM conducted an unannounced inspection of the Respondent's Concord practice location. Using the checklist provided by the Centers for Disease Control ("CDC") titled Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care; multiple deficiencies were noted at this time. On May 31, 2013, APU Counsel sent Dr. Newcott a letter that outlined in formal detail the infection control areas of concern identified during the inspection. On June 7, 2013, investigators met with Respondent to review the inspection findings on an item-by-item basis. Respondent was strongly encouraged to retain an outside infection control consultant to assist his practice with implementing expected protocols and best practices. A few days after the meeting, Respondent was provided with the name of a consulting company that could assist his practice. He was also encouraged to conduct his own research with regard to retaining an appropriate consultant. On April 8, 2014, the Board received another complaint from a patient alleging concerns with Respondent's infection control practices. In May 2014, Respondent reported that he had not retained an outside consultant, but stated that he had implemented appropriate changes based on the previously outlined inspection findings. Investigators again encouraged Respondent to retain an outside infection control consultant and the Respondent agreed. On June 5, 2014 the consultant retained by Respondent evaluated his practice and provided investigators with a summary of the findings. On June 6, 2014 investigators discussed the evaluation results with Respondent. Respondent verbally agreed to take immediate corrective action with regard to the findings and stated that his staff was already ordering the necessary products and equipment. Respondent agreed to have the consultant return within thirty (30)

days to evaluate his corrective action. On August 12, 2014 the consultant retained by Respondent evaluated his practice again and provided investigators with a summary of the findings. Based upon the information gathered, the Board found that there was an imminent danger to life and/or health, and on September 11, 2014, issued an Order of Emergency License Suspension and Notice of Hearing.

The Hearing was held on October 24, 2014. The purpose of the hearing was to determine whether Respondent had engaged in professional misconduct contrary to RSA 315:9, II and RSA 315:10-b, that warrants the continued imposition of a temporary license suspension, the imposition of permanent disciplinary sanctions, or both. The specific issues to be determined in this proceeding were:

A. Whether Respondent committed professional misconduct by utilizing substandard infection control procedures, in violation of RSA 315:9, II(c); and/or

B. Whether Respondent has displayed a pattern of behavior incompatible with the basic knowledge and competence expected of persons licensed to practice podiatry by utilizing substandard infection control procedures, in violation of RSA 315:9, II(d); and/or

C. Whether Respondent committed professional misconduct by knowingly or willfully violating the rules by failing to address the deficiencies in his infection control procedures, in violation of RSA 315:9, II(f); and/or

D. Whether Respondent committed professional misconduct by failing to provide care consistent with established practice guidelines adopted by recognized podiatric medical organizations, in violation of RSA 315:9, II(c), and Pod 501.01; and/or

E. If any of the above allegations are proven, whether and to what extent, Respondent should be subjected to one or more of the disciplinary sanctions authorized by RSA 315:9, III.

Investigator Todd Flanagan and James Dolan, DPM testified as witnesses for Hearing Counsel. The Board found the testimony of both Mr. Flanagan and Dr. Dolan credible and unbiased. Respondent did not testify but introduced "Stipulation of Facts" into evidence.

Hearing Counsel introduced the following exhibits:

1. Centers for Disease Control ("CDC") Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care, May 2011
2. CDC Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care
3. Letter from Sarah Blodgett, Assistant Attorney General to Dr. Newcott, dated December 21, 2012
4. Letter from Jeff Cahill, Senior Assistant Attorney General to Dr. Newcott, dated May 31, 2013
5. Complaint from John Martell, received April 8, 2014
6. Response to complaint filed by Dr. Newcott, received April 21, 2014
7. Results from assessment of Dr. Newcott's practice conducted by Linda Doherty on June 5, 2014
8. Report of investigation dated June 6, 2014
9. Results from assessment of Dr. Newcott's practice conducted by Linda Doherty on August 12, 2014
10. CDC Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care completed by Lind Doherty on August 12, 2014
11. Addendum Report of Investigation, dated September 3, 2014
12. New Hampshire Board of Pharmacy Inspection Report dated September 9, 2014

13. Photographs from the New Hampshire Board of Pharmacy Inspection on September 9, 2014

14. Disinfection and Sterilization Guideline Recommendations for Podiatric Physicians

15. Memorandum from New Hampshire Division of Public Health Services (DPHS) to the Board, dated September 15, 2014

16. Fax from Monadnock Community Hospital to Penny Taylor, dated October 22, 2014.

Findings of Fact

The parties filed a Stipulation of Facts which is attached and incorporated herein as Appendix A. In light of the testimony, evidence presented by both parties, and the Stipulation of Facts, the Board finds the following facts:

In August 2012, the Board received an anonymous complaint alleging that Respondent's infection control practices were inadequate in that he did not routinely sanitize instruments between patients and did not routinely wash his hands between patients. Additionally, it was alleged that Respondent routinely used out-of-date medications. On December 20, 2012 Todd Flanagan and Dr. James Dolan (Board Member) conducted an unannounced inspection of Respondent's Concord practice location. Using the checklist provided by the Centers for Disease Control ("CDC") titled Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care, the following deficiencies were observed:

a. No practice manual was available documenting infection prevention policies and procedures.

b. No personal protective equipment, i.e.: disposable gowns, masks and protective eyewear were readily available to the staff.

c. No antimicrobial waterless foaming hand rubs were available, which should be strategically placed throughout the office to encourage hand cleaning before and after patients are examined. Antimicrobial soap and water should be used if visible debris is noted.

d. Out of date, multiuse, injectable vials were found. Some bottles had been expired for more than one year, and were not disposed of by their expiration date or within 28 days of opening. There was no system in place for tracking expiration dates.

e. Injectable medications were stored in a room with an orthotic grinder. Because an orthotic grinder creates significant airborne dust, these items should not be stored in close proximity.

f. Out of date syringes were noted, which should have been disposed of. There was no system in place for tracking expiration dates.

g. Out of date culture swabs were noted, which should have been disposed of. There was no system in place for tracking expiration dates.

h. Out of date topical medications were noted which should have been disposed of. There was no system in place for tracking expiration dates.

i. No tissues, masks or resources for hand hygiene were available in the waiting room for patients with a respiratory infection.

j. Bead sterilization was used to disinfect nail cutting instruments. Bead sterilizers are no longer approved by the United Stated Food & Drug Administration. Nailing cutting instruments are considered semi-critical instrumentation and require a minimum of chemical disinfection.

k. No spore testing was being performed on the autoclave.

l. No internal strips were used when processing instruments through the autoclave.

m. Used sharps, both a syringe with needle and scalpel blades, were observed left on the instrument tray for disposal by support staff. These items should be disposed of in a sharps container by the user immediately following their use.

n. No red hazardous waste bags were readily available.

On June 7, 2013, investigators met with Respondent to review the inspection findings on an item-by-item basis. Respondent was strongly encouraged to retain an outside infection control consultant to assist his practice with implementing expected protocols and best practices. A few days after the meeting, Respondent was provided with the name of a consulting company that could assist his practice. He was also encouraged to conduct his own research with regard to retaining an appropriate consultant. The Respondent failed to follow through with the recommendation to hire a consultant. On April 8, 2014, the Board received a complaint from a patient alleging concerns with the Respondent's infection control practices (Hearing Counsel's Exhibit 5). In May 2014, Respondent reported that he had not retained an outside consultant, but stated that he had implemented appropriate changes based on the previously outlined inspection findings. Investigators again encouraged Respondent to retain an outside infection control consultant and the Respondent agreed.

On June 5, 2014, a consultant hired by the Respondent evaluated his practice and provided investigators with a summary of the findings (Hearing Counsel's Exhibit 7). Using the same CDC checklist as described in the exhibits, the following deficiencies were observed:

a. No practice manual was available documenting infection prevention policies and procedures. More specifically, the following were noted:

i. There was no site specific practice manual, but a copy of the Infection Prevention & Control Guidelines, 2008 was available.

ii. There was no High Level Disinfection process in place.

iii. Respondent was not using the correct soaking solution for instrument reprocessing.

iv. There were no EPA-registered disinfectants available for surface disinfection.

b. There was no personal protective equipment, such as disposable gowns, masks and protective eyewear readily available to the staff.

c. Out of date, multiuse, injectable vials were found. In particular, expired vials of Bupivacaine (expired November, 2013) were found.

d. Out of date syringes were found. There was no system in place for tracking expiration dates.

e. Out of date culture swabs were found. There was no system in place for tracking expiration dates.

f. Out of date topical medications were found. There was no system in place for tracking expiration dates.

g. Respondent confirmed that the bead sterilizer was no longer being used.

h. No spore testing was being performed on the autoclave and there was no documentation regarding monthly autoclave maintenance.

i. It was observed that the scalpels were being left in the handles for disposal.

On June 6, 2014 investigators discussed the evaluation results with Respondent. Respondent verbally agreed to take immediate corrective action with regard to the findings and stated that his staff was already ordering the necessary products and equipment. Respondent also represented that he had not been using the expired medical supplies and claimed that he was implementing procedures so that his staff monitors expired supplies for discarding. He agreed to have the consultant return within thirty (30) days to evaluate his corrective action.

On August 12, 2014 the consultant retained by Respondent evaluated his practice again and provided investigators with a summary of the findings (Hearing Counsel's Exhibit 9). Using the above-referenced checklist provided by the CDC, the following observations were made:

j. A manual with written policies and procedures had been purchased and was made available in July 2014. However, the policies and procedures had not been completely implemented.

k. EPA-registered disinfectants were available for surface disinfection.

l. Personal protective equipment, such as gowns, eyewear and masks were available to the staff.

m. Antimicrobial waterless foaming hand rubs were available.

n. There was no High Level Disinfection process in place in that the wrong product, Glutaraldehyde, not an OPA solution, was being used. Test strips being used were for CIDEX OPA which is not compatible with the Glutaraldehyde product in use.

o. Enzymatic detergent was being used in Concord. However, instruments were not fully immersed. It was recommended that an appropriate sized container be used.

p. On July 9, 2014 Respondent had called the consultant wanting to remove the 28 day expiration provision for multi-dose vials from his policies. The consultant reviewed why that was not possible, provided Multi-Dose Vial 28 day expiration calendar to assist the practice with dating vials, and information from One and Only Campaign, "Single-Dose or Multi-Dose?" was also provided. Upon re-evaluation, two (2) multi-dose vials of Lidocaine with the same strength were found opened. It appeared that the vials had been used, were not dated, and had foil tops still left on.

q. There was a new process and checklist in Concord for out of date syringes, however the process needed to be improved to ensure nothing is outdated at each site.

r. Out of date topical medications were found in a drawer in one exam room, which were then disposed of by Dr. Newcott's staff.

s. No out of date culture swabs were noted.

t. Tissues, masks or resources for hand hygiene were available in the waiting room for patients with respiratory infections.

u. Bead sterilizer is no longer being used. Respondent's practice was using "Flash Sterilization" for convenience and to save time. However, time, temperature and pressure were not documented for each load, nor were indicators being used for each load.

v. Spore testing was being conducted in Concord effective June 18, 2014. The Peterborough office was missing spore testing documentation, and only had documentation for two weeks. The consultant suggested that the practice contact the mail away vendor and request copies of their records to ensure that spore testing is done weekly. Autoclave recordkeeping logs in Peterborough were not consistent with the Concord office. Staff competencies needed to be conducted.

w. Internal strips had been implemented in June 2014. However, no internal strips were used to verify that sterilization parameters were met when flash sterilizing instruments in the autoclave.

After contacting the CDC, Respondent was put in contact with the New Hampshire Division of Public Health Services ("DPHS"), a division of the New Hampshire Department of Health and Human Services ("DHHS"). Katrina Hansen, Dr. Elizabeth Talbot (Deputy State Epidemiologist), and Dr. Benjamin Chang (State Epidemiologist) participated in the site visit on September 4, 2014 (Hearing Counsel's Exhibit 15). During the visit, DPHS Representatives made the following observations:

a. Respondent would clean some instruments with only Saniwipes before re-using them when off-site. Respondent reported that when off-site, equipment used for more invasive procedures would not be reused, but brought back to the office to autoclave.

b. When asked what he would do if a small amount of blood was visible on a nail clipper, Respondent reported that he would wipe the instrument with a Saniwipe and reuse it.

c. Respondent reported only bringing 2-3 instrument sets with him to off-site visits.

d. Respondent indicated that he changes his infection control procedures when he treats a patient with a known blood-borne pathogen. Specifically, when asked what Respondent would do if he treated a patient known to be positive with Hepatitis C, Respondent stated that he would set all the instruments aside to be autoclaved and not reused.

e. Respondent was unresponsive to questions about whether or not he re-used vials of medication on different patients.

f. The medication storage room had several open, previously used vials of medication (including Kenalog and Bupivicane). All such vials appeared to be multi-dose vials. No single dose vials were found.

g. Respondent's staff voiced concerns about the ability to clean up a chemical spill.

h. Respondent was generally unknowledgeable about national infection control guidelines.

Analysis and Rulings of Law

In the Stipulation of Facts, the Respondent's response to the complaint filed April 8, 2014, results of the reevaluation by Ms Doherty, and the evaluation dated September 4, 2014 by the DPHS, the Respondent admitted using sterile wipes to disinfect instruments for nailcare. He also admitted in his response that it has never been necessary for him to use masks or gloves for nailcare. He continued violating the CDC guidelines for infection control even after he met with investigators on June 7, 2013 as

shown by the evaluation dated June 5, 2014. The evaluator, Linda Doherty observed continued multiple deficiencies including no practice manual documenting infection prevention policies and procedures, no personal protective equipment, expired injectable medications, expired syringes, expired culture swabs, expired topical medications, no spore testing on the autoclave. It was agreed that Ms. Doherty would return in 30 days for a reevaluation. Due to scheduling conflicts she was not able to return till August 12, 2014. This gave Dr. Newcott more time to address the issues. After conducting the resurvey Ms Doherty noted that while Dr. Newcott had made some improvements, they had not been made in a timely manner and some had still not been fully implemented. Additionally Ms Doherty noted that Dr. Newcott did not understand why he could not use environmental wipes to sterilize re-usable semi-critical items instead of a high level disinfectant. On September 4, 2014 the DPHS evaluation, showed that the Respondent was still unknowledgeable regarding infection control guidelines. It was apparent to them that Dr. Newcott had not dedicated time to have an in depth discussion, tour the facility, or demonstrate infection control practices. They concluded that Dr. Newcott demonstrated little understanding of basic infection control practice (e.g. injection safety, standard infection control guidance documents for Podiatrists). There were conflicting accounts on how Dr. Newcott processes (cleans and disinfects) equipment both on and off-site and whether patients may have been put at risk for infectious diseases.

The Board is concerned by the fact that between the time the Respondent met with investigators to review in detail the areas of concern identified during the unannounced inspection and the evaluations performed by Ms Doherty and DPHS, there was no immediacy in his efforts to remediate the issues with his practice and come into full compliance with RSA 315:9, the APMA Guidelines and the Podiatry administrative rules. The Respondent's failure to do more to rectify the violations in his practice leads the Board to believe that he does not understand the seriousness of these violations.

Respondent committed professional misconduct by utilizing substandard infection control procedures, in violation of RSA 315:9, II(c); Respondent displayed a pattern of behavior incompatible with the basic knowledge and competence expected of persons licensed to practice podiatry by utilizing substandard infection control procedures, in violation of RSA 315:9, II(d); and Respondent committed

professional misconduct by willfully violating the rules by failing to address the deficiencies in his infection control procedures, in violation of RSA 315:9, II(f), as described above. Specifically, Respondent failed to maintain basic infection control procedures, such as properly sterilizing instruments, failing to conduct spore testing, and failing to wear gloves.

Additionally, Respondent engaged in unprofessional conduct in practicing Podiatry by failing to keep up with CDC infection control guidelines and continuing to practice unsafe infection control procedures over the course of two years.

Respondent committed professional misconduct by failing to provide care consistent with established practice guidelines adopted by recognized podiatric medical organizations, such as the APMA Ethical Guidelines, in violation of RSA 315:9, II(c), and Pod 501.01. Specifically, when allowing his office conditions to jeopardize the health and welfare of his patients, Respondent violated APMA code of Ethics ME1.0 andME6.12 for failing to use professional judgment to facilitate patient care and not placing welfare and rights of the patients above all other considerations.

Respondent should have known that his conduct as set forth above were violations of either RSA 315:9 and/or APMA Code of Ethics. Respondent has clearly shown ignorance and incompetence with basic knowledge and skills expected of persons licensed to practice Podiatry. Respondent jeopardized the health and welfare of his patients by failing to keep abreast of infection control guidelines and continuing to practice unsafe infection control procedures.

Disciplinary Action

After making its finding of facts and rulings of law, the Board deliberated on the appropriate disciplinary action.

THEREFORE, IT IS ORDERED that Respondent's license remain suspended until the following conditions are met:

1. That the Respondent is fined $8,000, to be paid within 90 (ninety) days of the effective date of this Order; and

2. That Respondent shall, in addition to the 40 CEU's required for each Biennium, obtain 6 additional CEUs in infection control within 90 (ninety) days of the effective date of this order. The 6 CEU's shall be obtained by physically taking a course, rather than an online course, and the course must be approved by Board. Once completed, the certificate of completion must be provided to the Board; and

IT IS FURTHER ORDERED, that once the fine is paid and the additional course is completed, a further Order from the Board will be issued to lift the suspension; and

IT IS FURTHER ORDERED, that the Respondent is subject to unannounced inspections for a period of 5 years from the date of this Order; and

IT IS FURTHER ORDERED, when the license suspension is lifted, Respondent will have the following license restrictions for a period of 5 years:

A. Respondent will no longer perform surgeries in any setting;

B. Respondent will not seek reinstatement of his privileges at any hospital;

C. Respondent will no longer treat patients in nursing home settings; and

D. Respondent will have a Board-approved infection control supervisor that is a licensed New Hampshire Podiatrist, and will notify the Board if that Supervisor leaves or changes.

IT IS FURTHER ORDERED, that the Respondent's failure to comply with any terms or conditions imposed by this Final Decision and Order shall constitute unprofessional conduct pursuant to RSA 315:9, II(f) and a separate and sufficient basis for further disciplinary action by the Board against the Respondent.

IT IS FURTHER ORDERED, that this Final Decision and Order shall take effect as an Order of the Board on the date that an authorized representative of the Board signs it.

*/BY THE ORDER OF THE BOARD

DATED: 11-19-2014

Penny Taylor

Penny Taylor, Administrator
Authorized Representative of the
New Hampshire Board of Podiatry

*/Board member recused:
James Dolan, DPM