

Effective: 6/15/2012

**HEALTH OCCUPATIONS PROGRAM
MINNESOTA DEPARTMENT OF HEALTH**

**In the Matter of Roger L. Alementi
Hearing Instrument Dispenser**

**STIPULATION AND
CONSENT ORDER**

IT IS HEREBY STIPULATED AND AGREED by Roger L. Alementi (hereinafter "Practitioner"), and the Minnesota Department of Health (hereinafter "MDH"), and that without trial or adjudication of any issue or fact or law herein;

This Stipulation and Consent Order (hereinafter "Stipulation"), investigative reports, and related documents shall constitute the entire record herein upon which this Stipulation is based and shall be filed with MDH. This Stipulation is public data pursuant to the Minnesota Government Data Practices Act, Minnesota Statutes, Chapter 13 (hereinafter "MGDPA"). All other data comprising the record shall not be considered a part of this Stipulation and shall maintain the data classifications to which they are entitled under the MGDPA.

I. LEGAL AUTHORITY

1. Pursuant to Minnesota Statutes, section 153A.14, subdivision 6, hearing instruments must be dispensed in compliance with state requirements and with the requirements of the United States Food and Drug Administration.

2. Pursuant to Minnesota Statutes, section 153A.15, subdivision 1(10), MDH may take enforcement action against a practitioner for failing to comply with the requirements of Chapter 153A as an employer, supervisor or trainee.

3. Pursuant to Minnesota Statutes, section 153A.15, subdivision 1(19), MDH may take enforcement action against a practitioner for violating any of the provisions of sections 148.5195, subdivision 3, clause (20); 148.5197; 148.5198; and 153A.13 to 153A.18.

4. MDH has statutory authority to discipline hearing instrument dispensing practitioners under Minnesota Statutes, section 153A.15. The types of disciplinary action MDH may impose include one or more of the following: deny the application for certification, revoke or suspend the certificate, impose for each violation a civil penalty that deprives the dispenser of any economic advantage gained by the violation and that reimburses MDH for the costs of the investigation and proceedings, censure or reprimand the dispenser, revoke or suspend the right to supervise or be a trainee, impose a civil penalty not to exceed \$10,000 for each separate violation or any other action reasonably justified by the individual case. Pursuant to Minnesota Statutes, Section 13.41, disciplinary actions are public data.

Practitioner and MDH hereby agree as follows:

II. FACTS

This agreement is based on the following facts:

1. Practitioner was approved and certified as a hearing instrument dispenser effective August 10, 1994 and renewed annually until October 31, 2011 when his certificate to dispense expired. On Practitioner's initial application and all subsequent renewals, Practitioner identified himself as self-employed under the business name, "Hearing Plus" in Duluth, Minnesota.

Practitioner has since sold the business entity.

2. On April 20, 2009, MDH received a complaint indicating Practitioner was not directly supervising a hearing instrument dispenser trainee (hereinafter "Trainee A"). The allegation indicated Trainee A was testing clients' hearing, recommending hearing instruments, selling and dispensing hearing instruments, fitting and adjusting hearing instruments, and otherwise holding himself out as a hearing instrument dispenser when his supervisor was not at the same business

location to supervise his duties. MDH Staff conducted an investigation that revealed the following:

a. On August 25, 2008, Practitioner signed a supervisor affirmation agreeing to supervise Trainee A. In the affirmation, Practitioner agreed to directly supervise Trainee A until he passed the practical examination.

b. On October 31, 2008, MDH approved Trainee A's status as a hearing instrument dispenser trainee under Practitioner's direct supervision.

c. From October 6, 2008 through November 27, 2008, Practitioner spent 72 hours training Trainee A in hearing instrument dispensing activities. Training activities included documentation of client hearing history, testing hearing and recording test results, performing otoscopy, evaluation of hearing test results, recommending hearing instruments, completing purchasing agreements, selling hearing instruments, fitting hearing instruments, making ear mold impressions, adjusting, and programming hearing instruments. Practitioner provided Trainee A with workbooks from the International Hearing Society, sent Trainee to training sessions, and paid for an instructor to prepare Trainee A for the hearing instrument examination.

d. Trainee A worked as a hearing instrument dispenser trainee in Practitioner's Virginia office from October 8, 2008 through October 14, 2009. Practitioner was not in the Virginia office to directly supervise Trainee A. During this period, Trainee was employed to test hearing, recommend, sell, and adjust hearing instruments for consumers four days per week, and five hours per day. Trainee worked a total of 260 hours as a dispenser trainee and was unsupervised.

e. Trainee A has never taken the hearing instrument dispensing examination and was not authorized to dispense hearing instruments independent of Practitioner's direct, on-site supervision.

3. On February 24, 2010, MDH convened the Hearing Instrument Dispenser Advisory Council Competency Review Committee (hereinafter "CRC") to review a sample of Trainee A's dispensing transactions including the client case histories, hearing tests, audiograms, and purchase agreements. Upon review of said documents, the CRC concluded Trainee A was incompetent in all aspects of hearing instrument dispensing. Trainee A did not complete client case hearing histories; he did not competently perform hearing tests in accordance with Minnesota hearing testing protocol and the U.S. Food and Drug Administration warnings; he started dispensing before he was an approved trainee, and he was not directly supervised by Practitioner as required by the law. CRC members also concluded Practitioner's dispensing contracts and forms were out-of-date with current Minnesota and FDA requirements. CRC members requested MDH obtain a sample of Practitioner's dispensing audiograms, hearing testes, recommendations and purchase agreements for review.

a. Between March 5, 2010 and April 30, 2010, Practitioner and MDH corresponded by U.S. mail, by facsimile, and discussed telephonically the state and federal regulations concerning minimum requirements for hearing instrument business contracts and forms. During this period, MDH reviewed and Practitioner updated his purchase agreement, including the 45-calendar-day guarantee and buyer right to cancel, the notice giving consumers the right to take their recommendation to a dispenser or audiologist of choice, the evidence of receipt of the MDH legal rights brochures for consumers of hearing instruments, the FDA waiver of medical evaluation, and the audiogram and related hearing test forms. On April 10, 2011, MDH

received, reviewed, and approved Practitioner's revised dispensing business contracts and forms.

b. On May 19, 2010, the CRC reviewed Practitioner's dispensing records and requested MDH staff to conduct an on-site inspection of Practitioner's business for review of original documents.

c. On August 24, 2010, MDH staff met with Practitioner at his place of business in Duluth and conducted an on-site inspection of Practitioner's dispensing records. MDH staff randomly reviewed 70 client files, including client case histories, audiograms, and related hearing tests. Practitioner provided copies of twenty-three client files for review by CRC members as requested by MDH staff.

d. Practitioner fully cooperated with MDH staff during the inspection process and provided access and copies of his business records.

e. Practitioner met with MDH staff before and after the review of his business dispensing records. Practitioner explained his business practices and the discrepancies in his contract forms and contract language regarding the 2005 legislative changes in Minnesota regulations surrounding the cancellation period and maximum cancellation fee. Practitioner also explained the discrepancies in his testing techniques and documentation.

f. During the random inspection of client files, MDH staff noted Practitioner's purchase agreements, signed and/or dated prior to about 2005, contained the correct contract language required by Minnesota Statutes (2004), section 153A.19, subdivision 2 which required a 30-calendar-day guarantee and buyer right to cancel and cancellation fee of no more than 10 percent of the purchase price. MDH staff also noted the client case histories were complete and included evidence Practitioner performed the FDA screen for potential medical conditions; there

was evidence consumers signed the FDA waiver, and the purchase agreements included language required by Minnesota Statutes (2004), section 153A.15, subdivision 1, clause (1), giving buyers the right to take the hearing instrument recommendation to a certified dispenser or licensed audiologist of their choice.

g. MDH staff also noted the randomly inspected purchase agreements and client records, signed and/or dated within the five years preceding the investigation did not contain the specific 45-calendar-day-guarantee and buyer right to cancel, and the cancellation had not been updated to a maximum of \$250. MDH staff also noted a lack of the consumers' initials indicating receipt of the MDH brochure, the language of choice was not included in the documents, and consumers did not sign the FDA waiver of medical evaluation.

h. Practitioner has been a certified hearing instrument dispenser since 1994 and admitted to not keeping up with the dispensing regulations. Practitioner conducted the audiometric testing using the methods Practitioner was trained in prior to his 1994 certification. Practitioner did not perform and document all hearing tests at the required frequencies because some of the required testing frequencies (250 Hz. and 8,000 Hz.) would not have changed his recommendation and believed the frequencies were not within the fitting range of a hearing instrument. Practitioner did not annotate the clients' response to the 25-word speech discrimination tests on the form because he was able to calculate the consumers' response in his head for documentation on the audiogram form. Practitioner referred consumers to an ear, nose, and throat specialists when there was an indication of an ear infection or other condition requiring a medical evaluation as required by the FDA. Practitioner stated he gave consumers a fair price on the hearing instruments, which included a 75-calendar day trial period and 100 percent refunds. Practitioner stopped documenting the test results on the client hearing history

forms in the last five years and consequently, Trainee A did not perform the required documentation because he was not trained to document test results.

i. Practitioner admitted he made mistakes by not keeping up with the documentation but did not believe he caused any patient harm. Practitioner stated he did not intentionally mislead clients when he did not conduct the required hearing tests.

j. MDH staff sent Practitioner the August 1, 2005 updated regulations and copies of the new MDH brochure; however, Practitioner believed MDH staff should have required he send a letter or document indicating he received the legislative updates due to the volume of his mail and the number of clients he serves.

4. On November 17, 2010, the records copied at Practitioner's place of business were reviewed by the CRC. MDH staff and CRC members concluded Practitioner's conduct did not comply with laws regarding supervision of trainees. Practitioner did not perform all required tests required by state and federal laws and regulations and his business documents and forms did not meet the minimum standards of dispensing practices in the industry.

III. ORDER

Under this Stipulation, and without any further notice of proceedings, the Division Director hereby ORDERS:

1. Upon the effective date of the Stipulation, the Commissioner's granting of certification to dispense hearing instruments is conditioned as follows:

a. Practitioner must meet the requirements for certification as required by Minnesota Statutes, Section 153A.14, subdivision 2g.

b. Within 30 days of the effective date of this Stipulation, Practitioner shall pay a civil penalty of \$550.00 to reimburse MDH for the costs of the investigations and proceedings to

date. Practitioner must make the payment by check made payable to "State of Minnesota, Treasurer" and mail the check to the attention of Catherine Dittberner Lloyd, P.O. Box 64882, Saint Paul, MN 55164-0882.

c. Practitioner shall successfully complete six continuing education (CE) course hours, pre-approved by MDH, as follows:

- i. Four CE course hours related to the techniques and methods of hearing instrument dispensing as defined by Minnesota Statutes, section 153A.14, subdivision 4b, hearing testing protocol.
- ii. Two CE course hours related to state and federal hearing instrument dispensing regulations.
- iii. The CE course hours required by this section shall be in addition to the continuing education requirements of Minnesota Statutes, sections 153A.14, subdivision 2g and 153A.14, subdivision 2i.
- iv. The CE course hours must be approved by the International Hearing Society, the American Speech-Language-Hearing Association, or the American Academy of Audiology.
- v. Practitioner shall submit evidence of completion of the CE course hours identified in paragraphs (i) and (ii) above, on forms provided by MDH.

2. Once all conditions as set forth in paragraph 1.a through 1.c above of this Stipulation have been met, Practitioner may petition the Commissioner for an unconditional certificate to dispense hearing instruments.

3. The civil penalty described in paragraphs 1(b) above may be referred to the Minnesota Collection Enterprise (MC), part of the Minnesota Department of Revenue, or any other source for collection, if Practitioner misses the payment by 14 calendar days after the established deadline. When this Order for a penalty becomes public and MDH refers the matter to MCE, MCE is authorized by Minnesota Statutes, section 16D.17, to obtain a judgment against Practitioner without further notice or proceedings.

4. Practitioner must provide any employer who hires him as a hearing instrument dispenser with a copy of this Stipulation for one year after the effective date of this Stipulation.

5. Within one year of the effective date of this Stipulation, MDH staff may conduct an on-site inspection of Practitioner's dispensing records, including but not limited to audiograms, client case histories, FDA waivers, recommendations and purchase agreements.

6. Practitioner's right to supervise hearing instrument dispense trainees, or otherwise provide training to hearing instrument dispenser trainees under any circumstance is revoked for twenty-four months after the effective date of this Stipulation.

7. In the event the Division Director in her discretion does not approve this settlement or a lesser remedy than specified herein, this Stipulation shall be of no evidentiary value and shall not be relied upon or used for any purpose by either party. If this should occur and thereafter an administrated contested case is initiated pursuant to Minnesota Statutes, Chapter 14 and Minnesota Statutes, Section 153a.15, Practitioner agrees to assert no claim that the Division Director was disqualified due to the review and consideration of this Stipulation or any records relating hereto.

8. This Stipulation shall not in any way or manner limit or affect the authority of MDH to proceed against Practitioner by initiating a contested-case hearing or by other appropriate means

on the basis of any, conduct, or omission of Practitioner, justifying action which occurred after or before the date of this Stipulation and which is not directly related to the specific facts and circumstances as set forth herein.

9. This Stipulation shall not in any way or manner limit or affect the authority of MDH to proceed against Practitioner by initiating a contested-case hearing or by other appropriate means on the basis of any act, conduct, or omission of Practitioner, justifying action which occurred after or before the date of the Stipulation and which is not directly related to the specific facts and circumstances as set forth herein.


10. This Stipulation contains the entire agreement between MDH and the Practitioner, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation. Practitioner understands that this agreement is subject to the Division Director's approval. If the Division Director either approves the Stipulation or makes changes acceptable to the Practitioner, the Division Director will issue the Stipulation. Upon this Stipulation and all other evidence made available to the Division Director, once the Division Director has approved it, the Division Director may issue the Stipulation to Practitioner at any time without further notice.

11. A copy of the Stipulation, when issued by the Division Director, shall be served by first class mail on Practitioner, at his designated address 931 Ebony Avenue, Duluth, MN 55811. Service via first class mail shall be considered as personal service upon Practitioner, at which time this Stipulation shall become effective. Any appropriate federal or state court shall, upon application of the Division Director, enter an order of enforcement of any or all of the terms of this Stipulation.

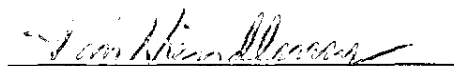
IV. CONSENT

Practitioner hereby acknowledges that he has read, understood, and agreed to this Stipulation and has freely and voluntarily signed it.

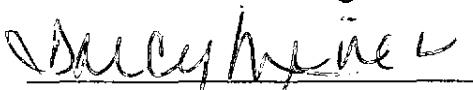
Dated: May 29th, 2012


Roger L. Alementi

Dated: 6/11, 2012


Tom Hiendlmayr, Director
Health Occupations Program

Upon consideration of this Stipulation and all the files, records, and proceedings herein by the Division Director, IT IS HEREBY ORDERED THAT THE TERMS OF THE Stipulation are adopted and implemented by the Division Director on this 7th, day of June, 2012.


Darcy Miner, Director
Compliance Monitoring Division