EFFECTIVE 08-18-2009

BEFORE THE MINNESOTA DEPARTMENT OF HEALTH HEALTH OCCUPATIONS PROGRAM

In the Matter of Rodney J. Guza Hearing Instrument Dispenser STIPULATION AND CONSENT ORDER

IT IS HEREBY STIPULATED AND AGREED by Rodney J Guza, (hereinafter "Practitioner"), and the Minnesota Department of Health (hereinafter "Department"), and that without trial or adjudication of any issue of fact or law herein:

Except as otherwise specified 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 the Department. This Stipulation is public data pursuant to the Minnesota Government Data Practices Act, Minnesota Statutes, Chapter 13 ("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.

LEGAL AUTHORITY

- 1. Pursuant to Minnesota Statutes, section 153A.13, subdivision 10, "direct supervision" or "directly supervised" means the on-site and contemporaneous location of a supervisor and trainee, when the supervisor observes the trainee engaging in hearing instrument dispensing with a consumer.
- 2. Pursuant to Minnesota Statutes, section 153A.13, subdivision 11, "indirect supervision" or "indirectly supervised" means the remote and independent performance of hearing instrument dispensing by a trainee when authorized.
- 3. Pursuant to Minnesota Statutes, section 153A.14, subdivision 2h, paragraph (a), clause (2), an applicant for certification as a hearing instrument dispenser must pass the practical tests of proficiency in the following techniques as they pertain to hearing instrument selling:
 - (i) Pure tone audiometry, including air conduction testing and bone conduction testing;
 - (ii) Live voice or recorded voice speech audiometry including speech recognition (discrimination) testing, most comfortable loudness level, and uncomfortable loudness measurements of tolerance thresholds;
 - (iii) Masking when indicated;
 - (iv) Recording and evaluation of audiograms and speech audiometry to determine proper selection and fitting of a hearing instrument;
 - (v) Taking ear mold impressions;

- (vi) Using an otoscope for the visual observation of the entire ear canal; and
- (vii) State and federal laws, rules and regulations.
- 4. Pursuant to Minnesota Statutes, section 153A.14, subdivision 4b, when conducting a hearing test for the purpose of hearing instrument dispensing, a dispenser must:
 - a. Comply with the United States Food and Drug Administration (FDA) warning regarding potential medical conditions required by Code of Federal Regulations, title 21, section 801.420;
 - b. Complete a case history of the client's hearing;
 - c. Inspect the client's ears with an otoscope; and
 - d. Conduct the following tests on both ears of the client and document the results, and if for any reason one of the following tests cannot be performed pursuant to the FDA guidelines, an audiologist shall evaluate the hearing and the need for a hearing instrument:
 - (i) Air conduction at 250, 500, 1,000, 2,000, 4,000 and 8,000 Hertz (Hz). When a difference of 20 decibels (dB) or more occurs between adjacent octave frequencies the interoctave frequency must be tested;
 - (ii) Bone conduction at 500, 1,000, 2,000 and 4,000 Hz for any frequency where the air conduction threshold is greater than 15 dB HL;
 - (iii) Monaural word recognition (discrimination), with a minimum of 25 words presented for each ear; and
 - (iv) Loudness discomfort level, monaural, for setting a hearing instrument's maximum output; and
 - e. Include masking in all tests whenever necessary to ensure accurate results.
- 5. Pursuant to Minnesota Statutes, section 153A.15, subdivision 1(9), a hearing instrument dispenser is prohibited from performing the services of a certified hearing instrument dispenser in an incompetent or negligent manner.
- 6. Minnesota Statutes, Section 153A.15, subdivision 2 authorizes the Department to take disciplinary action against hearing instrument dispensers. The types of disciplinary action the Department may impose include censure or reprimand, revocation, suspension or impose, for each violation, a civil penalty not to exceed \$10,000 that deprives the dispenser of any economic advantage gained by the violation and that reimburses the Department for the costs of the investigation and proceedings resulting in the discipline, and any other action reasonably justified by the individual case. Pursuant to Minnesota Statutes, Section 13.41, disciplinary actions are public data.
- Regarding Federal Laws Applicable to Hearing Instrument Dispensers

 Pursuant to FDA Code of Federal Regulations, title 21, section 801.420, a hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

- (i) Visible congenital or traumatic deformity of the ear.
- (ii) History of active drainage from the ear within the previous 90 days.
- (iii) History of sudden or rapidly progressive hearing loss within the previous 90 days.
- (iv) Acute or chronic dizziness.
- (v) Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- (vi) Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1,000 Hz, and 2,000 Hz.
- (vii) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- (viii) Pain or discomfort in the ear.

FACTS

The Department alleges and Practitioner unconditionally admits for the purposes of these and any future disciplinary proceedings the following allegations:

- 1. Rodney Guza (hereinafter "Practitioner") was approved as a hearing instrument dispenser trainee effective April 5, 2004 and held this status until expiration on April 30, 2005.
- 2. On July 8, 2004, Practitioner took the Hearing Instrument Dispenser Certification Examination (hereinafter "examination"). On August 12, 2004, the Department informed Practitioner he did not receive a passing score on the written practicum, Minnesota Law and portions of the practical examination. On December 10, 2004 and March 3, 2005, Practitioner took portions of the examination he did not pass in July 2004. By letters dated January 4, 2004 and March 24, 2005, respectively, the Department notified Practitioner he did not receive a passing score on the portions he was required to retake. In its March 24, 2005 letter, the Department advised Practitioner he could not take any part of the examination more than three times in a two year period and advised Practitioner he could apply to take the entire examination after July 8, 2006.
- 3. By electronic mail dated August 22, 2005, Practitioner asked the Department to make an exception to the examination requirements since he was able to pass the South Dakota hearing instrument dispenser examination. By letter dated September 8, 2005, the Department denied Practitioner's request and advised Practitioner that under Minnesota law, he was restricted from taking any part of the examination more than three times in a two-year period and that he would be eligible to take the entire examination after July 8, 2006 because he had already taken the Minnesota examination three times.
- 4. On November 2, 2006, Practitioner took the examination and by letter dated November 21, 2006, the Department notified Practitioner he passed the examination and provided instructions about the process for applying for certification as a hearing instrument dispenser.

- 5. On November 29, 2006, the Department received Practitioner's application for certification as a hearing instrument dispenser. In his response to application question nineteen (19), which asked Practitioner to describe hearing instrument dispensing education and training, Practitioner answered, in part, "7-18-05 attained South Dakota license. Sept. 06 attained BC-HIS status."
- 6. Practitioner was certified as a Minnesota hearing instrument dispenser effective December 12, 2006. Practitioner's certificate to dispense hearing instruments was renewed on November 1, 2007 and November 1, 2008.
- 7. Between November 2004 and February 2005, the Department received information indicating Practitioner tested Client 1's hearing and recommended hearing instruments. Client 1 did not purchase hearing instruments from Practitioner. The Department learned Practitioner was testing clients, recommending and dispensing hearing instruments during his trainee status when his supervisor was not on site and not directly observing Practitioner's dispensing practices. In February 2005, the Department received information that Practitioner was dispensing hearing instruments after his status as a trainee expired and before he was certified to dispense hearing instruments.
- 8. By letter dated March 14, 2007, the Department requested Practitioner to provide information about the types of hearing instrument related services he provided to consumers during his trainee status from April 5, 2004 to March 24, 2005, including copies of audiograms and purchase agreements for all hearing instruments he dispensed with or without direct supervision. The Department also requested Practitioner to provide information and documentation concerning Client 1 and the Department asked Practitioner for information and documents related to his duties and employment, including whether he dispensed hearing instruments in Minnesota between May 1, 2005 and December 11, 2006.
- 9. By letter received April 13, 2007, Practitioner responded to the Department's request for information. Practitioner provided a copy of all audiograms and related hearing tests, including the clients' case histories, ear inspection records, recommendations and purchase agreements he performed during his trainee status. Practitioner provided records which represented hearing tests he performed under direct supervision and hearing tests he performed under indirect supervision. Practitioner stated he understood appropriate supervision meant his supervisor was not on site, but available for consultation by phone, electronic mail or fax. Regarding Client 1, Practitioner stated he performed a case history, performed a hearing evaluation and made a recommendation, but Client 1 did not purchase hearing instruments. Regarding supervision, Practitioner stated he acted under appropriate supervision concerning Client 1. Regarding work duties he performed after his trainee status expired and before obtaining a certificate to dispense, Practitioner stated his duties included hearing aid cleaning, adjusting hearing aids, processing repair orders and selling batteries. Practitioner stated his supervisor performed the hearing tests and ear mold impressions between May 1, 2005 and December 11, 2006.
- 10. On July 26, 2007 and again on June 16, 2008, the Hearing Instrument Dispenser Advisory Council Competency Review Committee (CRC) reviewed thirty-two of

Practitioner's client files (Clients A through L and Clients 1 through 20). The files represented clients for whom Practitioner tested, recommended, and dispensed hearing instruments to under indirect supervision between August 2004 and March 2005. The CRC identified the following trends in Practitioner's dispensing practices during his trainee status:

- There is uncertainty in how the Practitioner came up with word or speech recognition scores. Except for a few exceptions, all client test scores are divisible by five and usually the score is more precise. Most scores are based on a word list of 25; therefore, if the client missed two words, the score is 92% and not 90% as documented by Practitioner. In addition, some of the scores are not accurate based on the hash marks, which indicates the number of words the client missed.
- Many of the tests indicate that only one ear was tested for bone conduction, the bone was not tested at all, the bone was not tested at all required frequencies, or there are no bone conduction responses. Also, the common rule in the industry is the bone conduction scores are always higher than air conduction scores, except in rare cases, because the Practitioner is testing the nerve. Practitioner's bone conduction scores are consistently worse than the pure tone air scores, which is likely not accurate.
- Many of the tests indicate Practitioner did not mask, did not mask at required frequencies, or the ear was masked when it was not necessary.
- Practitioner did not check the box indicating whether he/she performed the otoscopy examination, which determines whether the client has cerumen accumulation or a foreign body in the ear canal, visible congenital or traumatic deformity of the ear or active drainage from the ear.
- The UCL and MCL scores are unusual and the dynamic range as documented by the Practitioner is frequently wrong based on the hearing loss. The dynamic range, in all clients reviewed, is either 10 dB or 15 dB, which indicates the Practitioner does not know how to establish the correct UCL and MCL.
- Practitioner fit clients with hearing instruments when the client case history indicated the client should have been referred for a medical evaluation to rule out possible medical conditions, as exampled below:
 - O Client D checked "yes" to "Has [sic] hearing in one ear rapidly decreased within the previous 90 days" and checked "ear pain" and "buzzing" to the question "Are you currently experiencing any of the following?"
 - O Client F and 17 answered "yes" to the question, "Have you experienced acute or recurring dizziness within the last 90 days?"
 - O Clients L and 6 answered "yes" to the question, "Has the hearing in one ear rapidly decreased within the previous 90 days?"

- O Client 10 should have been referred to a medical doctor because the test for the right ear indicates normal hearing and the test for the left ear indicates profound hearing loss.
- 11. Based on review of Practitioner's trainee records, the CRC recommended the Department obtain twenty client files, including the audiograms and related hearing tests, to sample Practitioner's current practices as a certified hearing instrument dispenser. By letter received August 21, 2008, Practitioner submitted twenty-one client files including the client case history, audiograms and related hearing tests, and purchase agreements representing Practitioner's clients as a certified hearing instrument dispenser. In each case, Practitioner provided an explanation of the basis of his recommendation. Practitioner also provided an explanation of his hearing testing techniques related to bone conduction testing, masking, word recognition (discrimination) testing and UCL and MCL scores.
- On November 20, 2008, the CRC reviewed the client files and Practitioner's explanation of his techniques related to the performance, calculation and documentation of hearing tests. Upon review of the records and Practitioner's explanation of testing techniques, the CRC determined Practitioner is performing hearing tests and documenting the results of the hearing tests in an incompetent manner and Practitioner does not understand the concepts of hearing testing techniques regarding: 1) bone conduction testing; 2) masking techniques; 3) word (speech) discrimination; 4) UCL and MCL; and 5) Practitioner is not referring clients for a medical evaluation when required. The CRC recommended the Department take disciplinary action, which may include suspension of Practitioner's certificate to dispense hearing instruments, supervision and retaking the practical examination.

ORDER

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

- 1. Upon the effective date of this Stipulation, Practitioner's certificate to dispense hearing instruments is conditioned as follows:
 - (a) Within six months, Practitioner shall pay a civil penalty of \$2,400 that deprives Practitioner of any economic advantage gained by the violation and that reimburses the Department for costs of investigations and proceedings to date.
 - (b) Practitioner must be indirectly supervised by a supervisor approved by the Department for six months. Practitioner shall meet monthly with the pre-approved supervisor.

- (c) Practitioner must maintain a daily log of all consumer transactions for review with Practitioner's pre-approved supervisor. Review must include Practitioner's analysis of the consumer's hearing health history, the consumer's hearing and audiometry test results, and all other information relevant to Practitioner's recommendation.
- (d) Practitioner's supervisor will submit monthly reports to the Department for the six-month supervisory period about Practitioner's hearing testing techniques and methods used for dispensing hearing instruments and specifically, Practitioner's ability to screen for potential medical conditions, evaluation, calculation and documentation of tests scores and a recommended course of action. The time spent in supervision will be recorded by the supervisor.
- (e) Within twelve months, Practitioner shall successfully complete six continuing education (CE) course hours, pre-approved by the Department, related to the techniques and methods of hearing instrument dispensing, as defined by Minnesota Statutes, section 153A.14, subdivision 4b, hearing testing protocol. These CE requirements are in addition to the ten course hours Practitioner is required to complete within the 12-month period preceding renewal of his certificate.
- (f) Upon completion of the conditions and restrictions set forth in paragraphs (a) through (e) above, Practitioner may petition for reinstatement of an unconditional certificate.
- 2. Regarding the penalty described in paragraph 1(a) above, Practitioner may pay the \$2,400.00 civil penalty in monthly installments of up to six months after the effective date of this action. If Practitioner chooses to make installments, he must notify the Department in writing about his intentions, including how many installments he intends to make, in what amount, and over which time period. Practitioner must send this information to: Catherine Dittberner Lloyd, PO Box 64882, Saint Paul, MN 55164-0882, within 30 days of receipt of this document. Each payment will be made by check payable to "State of Minnesota, Treasurer", and mailed to Catherine Dittberner Lloyd, PO Box 64882, Saint Paul, MN 55164-0882, or any other address specified by the Department. Each payment is due by the last day of each month; however, Practitioner may prepay at any time.
- 3. The civil penalty described in paragraphs 1(a) and 2 above may be referred to the Minnesota Collection Enterprise (MCE), part of the Minnesota Department of Revenue, or any other source for collection, if Practitioner misses a monthly 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 shall sign whatever releases are necessary for the supervisor to report Practitioner's work directly to the Department and Practitioner shall cooperate fully during the process of the Department's enforcing and monitoring compliance with this Stipulation.
- 5. Practitioner's failure to adhere to the terms of this Stipulation shall result in immediate suspension of Practitioner's certificate to dispense hearing instruments.
- 6. Practitioner must provide any employer who hires him as a hearing instrument dispenser with a copy of this Stipulation for two years after the effective date of this Stipulation.

 The Department may extend this period if the Department receives complaints alleging facts similar to those identified in the facts stated above.
- 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 administrative 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 the Department 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 this Stipulation and which is not directly related to the specific facts and circumstances as set forth herein.
- 9. This Stipulation contains the entire agreement between the Department 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.
- 10. A copy of this Stipulation, when issued by the Division Director, shall be served by first class mail on Practitioner, at his designated address of 3856 170th Avenue, Minneota, Minnesota 56264. 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.

CONSENT

understood, and agreed to this Stipulation and
Rodney J Guza
Tom Hiendlmey, Director Health Occupations Program
at the terms of this Stipulation are adopted day of,
STATE OF MINNESOTA DEPARTMENT OF HEALTH
Darcy Miner, Director Division of Compliance Monitoring