



Effective: June 4, 2015

Protecting, maintaining and improving the health of all Minnesotans

May 1, 2015

Wendy E. Davis
[REDACTED]

RE: MDH File Number: AUC13005

Dear Ms. Davis:

Based on the facts and law in this matter as described in the enclosed Staff Determination, the Minnesota Department of Health (MDH) has determined that you performed the services of an audiologist in a negligent manner and that falls below the community standard of care in audiology related to documentation of dispensing related services, in violation of Minnesota Statutes, section 148.5195, subdivision 3, clause (3) and (4); and that you failed to comply with the restrictions surrounding the recommendation and sales of hearing instruments, in violation of section 148.5195, subdivision 3, clause (20)(i) and (20)(iv). Therefore, the Department is reprimanding you and assessing you a civil penalty in the amount of \$1,110.00. This action is authorized pursuant to Minnesota Statutes, section 148.5195, subdivision 4.

This decision will be made final and effective 30 days from the date it is received by you. During that 30-day period, you have the right to challenge this decision in a contested-case hearing, as provided under Minnesota Statutes, Chapter 14. Requests for a hearing should be made in writing and include specific grounds for challenging the Department's decision. If you wish to request a hearing, please send a written hearing request, within 30 days of your receipt of this letter, to:

Gilbert Acevedo, Director
Health Occupations Program
Minnesota Department of Health
PO Box 64882
Saint Paul, MN 55164-0882

You may also deliver your request to 85 East Seventh Place, Suite 220, Saint Paul, MN; or fax it to Mr. Acevedo at (651)201-3839. If you have any questions about this matter, please contact Catherine Dittberner Lloyd at (651)201-3706.

Sincerely,

A handwritten signature in cursive script that reads "Darcy Miner".

Darcy Miner, Director
Health Regulation Division

Enclosure

cc: Anne Kukowski, Assistant Director, Health Occupations Program

**HEALTH OCCUPATIONS PROGRAM
MINNESOTA DEPARTMENT OF HEALTH**

**A Determination In the Matter of
Wendy E Davis, Audiologist, License Number 7170**

AUTHORITY

1. The Minnesota Department of Health (MDH) has the authority to discipline audiologists for violations of Minnesota Statutes, section 148.5195. Pursuant to section 148.5195, subdivision 4, the types of discipline MDH may impose include one or more of the following: impose, for each violation, a civil penalty not exceeding \$10,000 that deprives the licensee of any economic advantage gained by the violation and that reimburses MDH for the costs of the investigation and proceeding and any reasonable lesser action against an individual upon proof that the individual has violated sections 148.511 to 148.5198. Pursuant to Minnesota Statutes, section 13.41, disciplinary actions are public data.
2. Pursuant to Minnesota Statutes, section 148.5195, subdivision 3, clause (3), MDH may take disciplinary action against an audiologist for performing services in a negligent manner.
3. Pursuant to Minnesota Statutes, section 148.5195, subdivision 3, clause (4), MDH may take disciplinary action against an audiologist for violating sections 148.511 to 148.5198.
4. Pursuant to Minnesota Statutes, section 148.5195, subdivision 3, clause (20)(i), MDH may take disciplinary action against an audiologist for failure to provide the following information, in all capital letters of 12-point or larger boldface type, to the consumer: "THIS PRESCRIPTION OR RECOMMENDATION MAY BE FILLED BY, AND HEARING INSTRUMENTS MAY BE PURCHASED FROM, THE LICENSED AUDIOLOGIST OR CERTIFIED DISPENSER OF YOUR CHOICE."
5. Pursuant to Minnesota Statutes, section 148.5195, subdivision 3, clause (20)(iv), MDH may take disciplinary action against an audiologist for failure to comply with restrictions on sales of hearing instruments in section 148.5198.
6. Pursuant to Minnesota Statutes, section 148.5198, subdivision 1(c), an audiologist must provide the buyer with a written contract written in plain English and conforms to the Plain Language Contract Act. The contract must include, but is not limited to, the following: in immediate proximity to the space reserved for the signature of the buyer, a clear and conspicuous disclosure of the following specific statement in all capital letters of no less than 12-point boldface type: "MINNESOTA STATE LAW GIVES THE BUYER THE RIGHT TO CANCEL THIS PURCHASE FOR ANY REASON AT ANY TIME PRIOR TO MIDNIGHT OF THE 45TH CALENDAR DAY AFTER RECEIPT OF THE HEARING AID(S). THIS CANCELLATION MUST BE IN WRITING AND MUST BE GIVEN OR MAILED TO THE AUDIOLOGIST OR CERTIFIED DISPENSER. IF THE BUYER DECIDES TO RETURN THE HEARING AID(S) WITHIN THIS 45-CALENDAR-DAY

PERIOD, THE BUYER WILL RECEIVE A REFUND OF THE TOTAL PURCHASE PRICE OF THE AID(S) FROM WHICH THE AUDIOLOGIST OR CERTIFIED DISPENSER MAY RETAIN AS A CANCELLATION FEE NO MORE THAN \$250."

FINDINGS OF FACT

1. On June 1, 2006, Wendy Davis (hereinafter "Practitioner") was licensed as an audiologist in the State of Minnesota.
2. Practitioner owns and operates Soundgate Hearing Clinic.
3. Client 1 was referred to Practitioner's clinic by an organization that assists patients in purchasing hearing instruments at a reduced price.
4. On April 29, 2009, Practitioner evaluated Client 1's hearing loss, her medical evaluation, and recommended either a Unitron Moda II hearing instrument or a Nano Sonovation hearing instrument for her right ear. According to Practitioner, Client 1 was interested in the Unitron.
 - a. Practitioner gave client a form with the following statement: "As a participating provider with [Client 1's insurance provider] and its affiliated companies, we are obligated to notify you of services that are medically unnecessary. This notification will allow us to hold you financially responsible for the upgrade to the durable medical equipment you are purchasing." Following this statement, Practitioner offered Client 1 a "standard hearing aid with digital frequency" at a cost of \$2,244.00. The recommendation included a statement indicating Practitioner informed Client 1 that the least costly alternative under Client 1's insurance plan was \$1,632.00, and that the charge for the upgrade or deluxe feature was \$632.00. Client 1 signed and dated the document April 29, 2009.
 - b. MDH staff noted there was no evidence in the record that Practitioner provided Client 1 with a recommendation that included the following statement required by Minnesota Statutes, section 148.5195, subdivision 3, clause 20(i), "THIS PRESCRIPTION OR RECOMMENDATION MAY BE FILLED BY, AND HEARING INSTRUMENTS MAY BE PURCHASED FROM, THE LICENSED AUDIOLOGIST OR CERTIFIED DISPENSER OF YOUR CHOICE."
 - c. On April 29, 2009, Practitioner and Client 1 signed a purchase agreement. According to the purchase agreement, Practitioner recommended and Client 1 agreed to purchase a right Unitron Unison 3-Moda-DFC (frequency compression) hearing aid in the amount of \$2,200. Practitioner charged Client 1 \$32.00 tax, and discounted the hearing instrument by \$600.00 for a total amount due of \$1,632.00.
 - d. Other terms of the contract include:
 - i. Three-year repair warranty and a one-year loss and damage, with no deductible for submitting a loss or damage claim.
 - ii. Trial period start date of April 29, 2009 and end date of June 13, 2009.

- iii. Insurance: "Insurance will pay up to \$1,000. Patient has a 15% copay on allowable amount plus \$300 individual deductible. Patient is responsible for any amount insurance will not cover."
 - iv. MDH staff noted that Practitioner modified the 45-calendar-day guarantee and buyer right to cancel notice in violation of Minnesota Statutes, section 148.55198, subdivision 1(c). The notice on the purchase agreement states: "MINNESOTA STATE LAW GIVES THE BUYER THE RIGHT TO CANCEL THIS PURCHASE FOR ANY REASON AT ANY TIME PRIOR TO MIDNIGHT OF THE 45TH CALENDAR DAY AFTER RECEIPT OF THE HEARING AID(S). THIS CANCELLATION MUST BE IN WRITING AND MUST BE GIVEN OR MAILED TO THE SELLER. IF THE BUYER DECIDES TO RETURN THE HEARING AID(S) WITHIN THIS 45 DAY PERIOD, THE BUYER WILL ^ NOT RECEIVE A REFUND OF: -\$255."
5. On June 10, 2009, Practitioner sent a quotation in the amount of \$2,452.08 to a medical equipment distributor, with a reference to Client 1. The quotation was for one (monaural) digital, behind the ear (BTE) hearing aid in the amount of \$1,850, a dispensing fee of \$250.00, batteries at \$45.00; domes at \$4.00; slim tubes at \$34.00; a dry and store moisture removal system at \$219.00 and tax at \$45.08.
 6. On June 18, 2009, Client 1 signed a note in the amount of \$2,500.00 to finance the cost of the hearing instruments she purchased from Practitioner.
 7. In Practitioner's September 29, 2013 response to MDH staff in this matter, Practitioner stated she "gave Client 1 the opportunity to try two additional models of DFC hearing aids, including another Unitron and the Nano..... I wanted Client 1 to compare the hearing aids in her daily life. I knew she could not afford to put a deposit down on the other technologies so I let her take both the Unitron instrument per the purchase agreement and borrow the Sonovation Nano instrument. She ultimately decided to keep the more expensive hearing aid, Sonovation Nano, because it had a volume control." Practitioner stated she did not provide Client 1 with an updated purchase agreement because Client 1 did not return to her clinic.
 8. On February 18, 2010, Client 1 filed a claim against Practitioner in Anoka County Conciliation Court for certain products and services she alleged Practitioner charged, but she did not received. This included \$219 for a dry and store moisture removal system, a dispensing fee, and the fees for batteries she did not receive. Client 1's claim was denied and no judgement was ordered. Client 1 did not appeal.
 9. MDH staff noted the record indicates Client 1's insurance provider resolved billing-related issues.
 10. On January 15, 2015, the issues in the matter were presented to the Speech Language Pathologist and Audiologist Competency Review Committee (CRC). CRC members reviewed the issues in this matter and made the following comments:

- Practitioner's recordkeeping is poor and does not reflect all of the transactions that occurred regarding Client 1.
- There are no purchase agreements for the two hearing instruments Practitioner recommended and fit on Client 1 during the trial period.
- The purchase agreement violates the law regarding the 45-calendar-day guarantee and right to cancel.
- The Practitioner did not give Client 1 a written notice of her rights to take the recommendation to a dispenser or audiologist of her choice.
- Practitioner delivered and fit a different hearing instrument than what is memorialized on the signed purchase agreement.
- There are conflicting data between the Practitioner's quotation, insurance billing, and the purchase agreement.
- It does not appear the Practitioner provided sufficient counseling to Client 1.
- CRC members stated with Client 1's hearing loss, some audiologists may have fit the right ear, whereas other audiologists may have fit the left ear. Therefore, the CRC did not conclude Practitioner's decision to fit the right ear was incompetent.

11. The CRC recommended that MDH reprimand Practitioner and require that she pay for the cost of the investigation for providing services that violate the practice act and fall below the community standard of care in audiology. The CRC did not recommend Client 1 be reimbursed for the cost of the hearing aids because she did not appeal the Conciliation Court judgement.

CONCLUSION

Practitioner violated Minnesota Statutes, section 148.5195, subdivision 3, clause (3) and (4) when she failed to document and record a consistent and accurate description of the transactions, communications and dispensing related services and for providing services that fall below the community standards of care in audiology concerning Client 1; section 148.5195, subdivision 3, clause (20)(i) when she failed to include the required contract language giving Client 1 a notice of her right to bring Practitioner's recommendation to a hearing instrument dispenser or audiologist of her choice; and section 148.5195, subdivision 3, clause (20)(iv) when she failed to comply with the restrictions on hearing aid sales by omitting language on the required disclosure statement and by inserting the word "NOT" in reference to Client 1's right to a refund.

DETERMINATION

1. Practitioner is reprimanded.
2. Practitioner should pay a civil penalty of \$1,110.00, representing the economic advantage gained by the violation and to reimburse MDH for the costs of the investigation and proceedings to date.