

HEARING INSTRUMENT FITTERS AND DISPENSERES LICENSING REPORT January 3rd, 2019

HEARING INSTRUMENTS FITTERS AND DISPENSERS

	TOTAL FY 2017	4th Quarter FY 2018	TOTAL FY2018	Sept.-Oct. FY2019
New Licenses Issued	52	20	66	3
Renewed Licenses Issued	324	42	252	41
Online Renewals	215	35	195	36
% Renewed Online	66%	83%	77%	89%
Total Population	646	686	686	688

APPRENTICE PERMIT

	TOTAL FY 2017	4th Quarter FY 2018	TOTAL FY2018	Sept.-Oct. FY2019
New Licenses Issued	55	11	34	6
Renewed Licenses Issued	7	1	4	2
Online Renewals	0	0	0	0
% Renewed Online	0	0	0	0
Total Population	61	36	36	39

TEMPORARY TRAINING PERMIT

	TOTAL FY 2017	4th Quarter FY 2018	TOTAL FY2018	Sept.-Oct. FY2019
New Licenses Issued	72	29	100	22
Renewed Licenses Issued	21	5	33	2
Online Renewals	0	0	0	0
% Renewed Online	0	0	0	0
Total Population	95	112	112	126

Hearing Instrument Fitter and Dispenser Advisory Board

Enforcement Division Staff Report

January 3, 2019

Case Highlights

- On September 4, 2018, an Agreed Order was signed imposing a voluntary revocation of Respondent’s HFD temporary training permit for performing hearing aid fitting and dispensing without being supervised by a licensee. No monetary penalty was assessed, only revocation of the permit.

Key Statistics Fiscal Year 2018

Shown below are key statistics for the Hearing Instrument Fitter and Dispenser program and for all TDLR programs for Fiscal Year 2018.

<u>Statistic</u>	<u>HFD</u>	<u>TDLR</u>
• Number of cases opened:	27	10,585
• Number of cases resolved:	32	9,833
• Number of Agreed Orders:	0	1,295
• Total amount of penalties assessed:	\$0	\$3,209,055
• Total amount of penalties collected:	\$0	\$1,528,594

Key Statistics Fiscal Year 2019

Shown below are key statistics for the Hearing Instrument Fitter and Dispenser program and for all TDLR programs combined through October of Fiscal Year 2019.

<u>Statistic</u>	<u>HFD</u>	<u>TDLR</u>
• Number of cases opened:	3	1,831
• Number of cases resolved:	3	1,672
• Number of Agreed Orders:	1	202
• Total amount of penalties assessed:	\$0	\$519,980
• Total amount of penalties collected:	\$0	\$211,030

HEARING INSTRUMENT FITTERS AND DISPENSERS ADVISORY BOARD

JANUARY 3RD, 2019

STATISTICS AND TRENDS

PRACTICAL EXAMINATION STATISTICS

(AS OF OCTOBER 31ST, 2018)

FY 2019	SEP	OCT	NOV	Q1	DEC	JAN	FEB	Q2	MAR	APR	MAY	Q3	JUN	JUL	AUG	Q4	TOT
PASS	39	0	-	39	-	-	-	0	-	-	-	0	-	-	-	0	39
FAIL	9	0	-	9	-	-	-	0	-	-	-	0	-	-	-	0	9
TOTAL	48	0	-	48	-	-	-	0	-	-	-	0	-	-	-	0	48
RATE	81.3%	0.0%	0.0%	81.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	81.3%
Examinations are taken only in September (1 st Quarter) January (2 nd Quarter), and May (3 rd Quarter).																	
FY 2018	SEP	OCT	NOV	Q1	DEC	JAN	FEB	Q2	MAR	APR	MAY	Q3	JUN	JUL	AUG	Q4	TOT
PASS	27	0	0	27	0	34	0	34	0	0	35	35	0	0	0	0	96
FAIL	8	0	0	8	0	5	0	5	0	0	11	11	0	0	0	0	24
TOTAL	35	0	0	35	0	39	0	39	0	0	46	46	0	0	0	0	120
RATE	77.1%	0.0%	0.0%	77.1%	0.0%	87.2%	0.0%	87.2%	0.0%	0.0%	76.1%	76.1%	0.0%	0.0%	0.0%	0.0%	80.0%
Examinations are taken only in September (1 st Quarter) January (2 nd Quarter), and May (3 rd Quarter).																	
FY 2017	SEP	OCT	NOV	Q1	DEC	JAN	FEB	Q2	MAR	APR	MAY	Q3	JUN	JUL	AUG	Q4	TOT
PASS						39	0	39	10	0	38	48	0	0	0	0	87
FAIL						6	0	6	1	0	7	8	0	0	0	0	14
TOTAL						45	0	45	11	0	45	56	0	0	0	0	101
RATE						86.7%	0.0%	86.7%	90.9%	0.0%	84.4%	85.7%	0.0%	0.0%	0.0%	0.0%	86.1%

JURISPRUDENCE EXAMINATION STATISTICS

(AS OF OCTOBER 31ST, 2018)

FY 2019	SEP	OCT	NOV	Q1	DEC	JAN	FEB	Q2	MAR	APR	MAY	Q3	JUN	JUL	AUG	Q4	TOT
Jurisprudence Examinations Completed	2	8	-	10	-	-	-	0	-	-	-	0	-	-	-	0	10
FY 2018	SEP	OCT	NOV	Q1	DEC	JAN	FEB	Q2	MAR	APR	MAY	Q3	JUN	JUL	AUG	Q4	TOT
Jurisprudence Examinations Completed	1	7	1	9	1	4	7	12	3	3	5	11	6	3	6	15	47

PRACTICAL EXAMINATION PORTION STATISTICS

(AS OF OCTOBER 31ST, 2018)

FY 2019											
SEPTEMBER – OCTOBER – NOVEMBER				1 ST QUARTER		MARCH – APRIL – MAY				3 RD QUARTER	
EXAMINATION PORTION	PASS	FAIL	TOTAL	RATE		EXAMINATION PORTION	PASS	FAIL	TOTAL	RATE	
Practical – Audiometric Portion	19	7	26	73.08%		Practical – Audiometric Portion	-	-	-	0.0%	
Practical – Ear Impression Portion	20	2	22	90.91%		Practical – Ear Impression Portion	-	-	-	0.0%	
TOTAL	39	9	48	81.25%		TOTAL	-	-	-	0.0%	
DECEMBER – JANUARY – FEBRUARY				2 ND QUARTER		JUNE – JULY – AUGUST				4 TH QUARTER	
EXAMINATION PORTION	PASS	FAIL	TOTAL	RATE		EXAMINATION PORTION	PASS	FAIL	TOTAL	RATE	
Practical – Audiometric Portion	-	-	-	0.0%		Practical – Audiometric Portion	-	-	-	0.0%	
Practical – Ear Impression Portion	-	-	-	0.0%		Practical – Ear Impression Portion	-	-	-	0.0%	
TOTAL						TOTAL					

Examinations are taken only in September (1st Quarter) January (2nd Quarter), and May (3rd Quarter).

FY 2018											
SEPTEMBER – OCTOBER – NOVEMBER				1 ST QUARTER		MARCH – APRIL – MAY				3 RD QUARTER	
EXAMINATION PORTION	PASS	FAIL	TOTAL	RATE		EXAMINATION PORTION	PASS	FAIL	TOTAL	RATE	
Practical – Audiometric Portion	14	5	19	73.68%		Practical – Audiometric Portion	16	8	24	66.67%	
Practical – Ear Impression Portion	13	3	16	81.25%		Practical – Ear Impression Portion	19	3	22	86.36%	
TOTAL	27	8	35	77.14%		TOTAL	35	11	46	76.09%	
DECEMBER – JANUARY – FEBRUARY				2 ND QUARTER		JUNE – JULY – AUGUST				4 TH QUARTER	
EXAMINATION PORTION	PASS	FAIL	TOTAL	RATE		EXAMINATION PORTION	PASS	FAIL	TOTAL	RATE	
Practical – Audiometric Portion	14	5	19	73.68%		Practical – Audiometric Portion	0	0	0	0.0%	
Practical – Ear Impression Portion	20	0	20	100.00%		Practical – Ear Impression Portion	0	0	0	0.0%	
TOTAL	34	5	39	87.18%		TOTAL	0	0	0	0.0%	

Examinations are taken only in September (1st Quarter) January (2nd Quarter), and May (3rd Quarter).

CONTINUING EDUCATION STATISTICS

(AS OF OCTOBER 31ST, 2018)

FY 2019	SEP	OCT	NOV	Q1	DEC	JAN	FEB	Q2	MAR	APR	MAY	Q3	JUN	JUL	AUG	Q4	TOT
New Provider Licenses Issued	0	0	-	0	-	-	-	0	-	-	-	0	-	-	-	0	0
New Course Approvals	6	5	-	11	-	-	-	0	-	-	-	0	-	-	-	0	11
Provider License Renewed	2	0	-	2	-	-	-	0	-	-	-	0	-	-	-	0	2
Total Approved Providers	23	23	-	23	-	-	-	0	-	-	-	0	-	-	-	0	23
Total Approved Courses (Per Year)	364	369	-	369	-	-	-	0	-	-	-	0	-	-	-	0	369

FY 2018	SEP	OCT	NOV	Q1	DEC	JAN	FEB	Q2	MAR	APR	MAY	Q3	JUN	JUL	AUG	Q4	TOT
New Provider Licenses Issued	1	1	0	2	0	0	0	0	0	0	0	0	0	0	0	0	2
New Course Approvals	63	17	17	97	34	1	192	227	34	13	7	54	41	27	9	77	455
Provider License Renewed	1	0	1	2	0	1	1	2	2	4	0	6	2	2	0	4	14
Total Approved Providers	24	25	25	25	25	25	25	25	25	24	24	24	23	24	24	24	24
Total Approved Courses (Per Year)	441	458	475	475	34	35	227	227	261	274	281	281	322	349	358	358	358

Regulatory Program Management Staff Report
Texas Department of Licensing and Regulation
Hearing Instrument Fitters and Dispensers Advisory Board Meeting
January 3, 2019

Hearing Instrument Fitters and Dispensers Program Update

- Staff has conducted standard of care workgroup meetings. Topics covered by the workgroup included review and study of American National Standards Institute (ANSI) standards and rules under 16 Texas Administrative Code (TAC) Chapter 112 regarding audiometric testing and audiometric test rooms.
- Staff worked with the Office of Strategic Communication to review and update the program webpages, which went live on September 28, 2018.
- Staff has participated in other workgroup meetings for Licensing and Education and Examination.
- Staff has assisted Customer Service with Regulatory Program Management-related emails.

Public Outreach

- On June 14-16, 2018, staff attended the Texas Hearing Aid Association's 71st Annual Convention and Trade Show in Dallas, Texas.

Personnel Update

- Heather Muehr has replaced Stephen Mills as Section Manager of the Medical and Health Professions Section.
- Steven Uecker, Program Specialist, has been assigned to be the back-up staff member for this program.

Medical & Health Professions Section Update

- The Medical & Health Professions Section remains focused on maintaining the successful operation of the eleven programs assigned to the section.
- MHP has distributed two issues of *The Health Monitor* newsletter for the medical and health professions programs, since your last meeting. The fourth issue was emailed to subscribers on August 30 and the fifth issue was delivered in December 2018. The latest issue can be found on the program web pages. Links to previous issues can be found under Agency Newsletters on the main TDLR page.



To view online electronic magazine version:

Strategic Plan: [https://issuu.com/tdlr/docs/strat_plan_layout - 6-7-18 complete](https://issuu.com/tdlr/docs/strat_plan_layout_-_6-7-18_complete)

Supplemental Schedules: https://issuu.com/tdlr/docs/supplemental_schedules_complete_6-7



TEXAS DEPARTMENT OF LICENSING AND REGULATION

General Counsel's Office

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Fax: (512)475-3032 • www.tdlr.texas.gov

June 20, 2018

Mr. Ray Jones
2137 Hidden Creek Road
Fort Worth, Texas 76107

Sent Via U.S. Postal Service and
Via Email at [REDACTED]

RE: Response to Rulemaking Petition for 16 TAC §112.95, Information on Prospective Amplification Candidates.

Dear Mr. Jones:

The Texas Department of Licensing and Regulation (Department) received your rulemaking petition dated April 23, 2018, regarding 16 Texas Administrative Code (TAC) §112.95. For the reasons stated below, the Department is denying your rulemaking petition.

In your rulemaking petition, you requested to amend 16 TAC §112.95, Information on Prospective Amplification Candidates, by removing the existing title and text and adding a new title and text for §112.95. The text of your email rulemaking petition with the specific proposed language is attached to this letter for reference purposes.

Pursuant to Texas Government Code §2001.021 and 16 TAC §60.102, the Department is denying your rulemaking petition as explained below.

Removing Language Regarding Information on Prospective Amplification Candidates

The rulemaking petition alleges that §112.95 is preempted by federal law and suggests striking the title of the rule and the following text: "A license holder shall obtain information on each prospective candidate for amplification in accordance with Texas Occupations Code §402.352." The rulemaking petition, however, does not reflect the current text of §112.95.

Section 112.95 was recently amended as part of a larger proposed rulemaking that was published in the Texas Register on February 9, 2018 (43 TexReg 695). The Department did not receive any public comments on proposed §112.95 as amended. Except for three rules that were withdrawn, the proposed rules were recommended by the Hearing Instrument Fitters and Dispensers Advisory Board and adopted by the Texas Commission of Licensing and Regulation (Commission) at its meeting on March 27, 2018. The revised rules became effective May 1, 2018. The adoption notice was published in the Texas Register on April 27, 2018 (43 TexReg 2564).

Mike Arismendez, Chair – Shallowater, Texas

Tom Butler, Vice-Chair – Deer Park, Texas
Gerald R. Callas, M.D., F.A.S.A. – Beaumont, Texas
Helen Callier – Kingwood, Texas

Rick Figueroa – Brenham, Texas
Gary F. Wesson, D.D.S., M.S. – Bastrop, Texas
Deborah A. Yurco – Austin, Texas

As revised, §112.95 reads as follows: “A license holder shall try to obtain information on each prospective candidate for amplification in accordance with Texas Occupations Code §402.352.” As explained in the preamble of the proposed rules and the adoption notice, the revision to §112.95 was a clean-up change to make the rule match the statute, Texas Occupations Code §402.352, Information on Prospective Amplification Candidates.

Texas Occupations Code §402.352 reads as follows:

“A license holder shall try to obtain, personally or through a proper referral, at least the following information on each prospective candidate for amplification:

- (1) the candidate's pertinent case history;
- (2) otoscopic inspection of the outer ear, including canal and drumhead;
- (3) evaluation of hearing acuity using pure tone techniques through air and bone conduction pathways through a calibrated system;
- (4) an aided and unaided speech reception threshold and ability to differentiate between the phonemic elements of language through speech audiometry, using a calibrated system or other acceptable verification techniques; and
- (5) verification of satisfactory aided instrument performance by use of appropriate sound-field speech, noise, or tone testing, using a calibrated system.” (*emphasis added*)

The Department’s interpretation regarding Texas Occupations Code §402.352 was previously provided as part of its October 13, 2017, response to your rulemaking petition dated August 15, 2017, and the follow-up email dated August 23, 2017 (collectively the “August 2017 rulemaking petition”). The August 2017 rulemaking petition asserted that Texas Occupations Code §402.352 requires the licensee to do an evaluation of hearing acuity on all candidates. In fact, this section requires the licensee to try to obtain certain information, either personally or through a proper referral, on each prospective candidate for amplification. As explained in the Department’s response on October 13, 2017, requiring licensees to try to obtain information either personally or through referral is different from requiring licensees to do an evaluation of hearing acuity on all candidates.

The revised §112.95 repeats the statute. If you have concerns with the statutory provisions, those concerns would need to be addressed with the Texas Legislature. Only the Texas Legislature can change the statutory provisions. The Department does not have authority to change the statute.

Adding Language Regarding Scope of Practice

While the rulemaking petition explains why you believe the language under §112.95, regarding information on prospective amplification candidates, should be removed, there is no explanation regarding why the suggested scope of practice language must be added in its place.

The rulemaking petition states that under federal law States cannot establish or continue requirements that are different from or in addition to any federal requirements applicable to devices and that relate to the safety or effectiveness of devices (hearing aids). The rulemaking petition asserts, however, that “States are free to regulate licensees and their practices, including the services that they can provide.” It is *not clear* whether this is the rationale for the suggested scope of practice language under §112.95. If this is the

rationale, the Department would still be governed by the statutory authority established and granted by the Texas Legislature. The Department cannot adopt rules outside of its statutory authority.

The Department cannot add the suggested language regarding the scope of practice of a “hearing aid specialist” for the following reasons:

- 1) The suggested language introduces a new person and/or title -- “hearing aid specialist.” There is no such person or title under the Hearing Instrument Fitters and Dispensers statute, Texas Occupations Code Chapter 402. The statute currently provides for licensed hearing instrument fitters and dispensers, apprentice permit holders, and temporary training permit holders.
- 2) The suggested scope of practice rule language is beyond the scope of practice set out in the statute. The statute authorizes a license holder to engage in the fitting and dispensing of hearing instruments. The statutory definitions of “fitting and dispensing hearing instruments” and “hearing instruments” are as follows:

“Fitting and dispensing hearing instruments” means the measurement of human hearing by the use of an audiometer or other means to make selections, adaptations, or sales of hearing instruments. The term includes the making of impressions for earmolds to be used as a part of the hearing instruments and any necessary postfitting counseling for the purpose of fitting and dispensing hearing instruments. (Occ. Code §402.001(4))

“Hearing instrument” means any wearable instrument or device designed for, or represented as, aiding, improving, or correcting defective human hearing. The term includes the instrument's parts and any attachment, including an earmold, or accessory to the instrument. The term does not include a battery or cord. (Occ. Code §402.001(5))

The Department is charged with implementing those statutory provisions through rules, and those rules cannot change or conflict with the statute. The Department cannot create a new scope of practice or expand the existing scope of practice by rule.

- 3) The rulemaking petition does not provide any explanation, justification, or reasons regarding why a new rule is needed to address scope of practice and the statutory definition of “fitting and dispensing hearing instruments.” There is no explanation regarding how adding a scope of practice rule would eliminate your concerns about the existing rule §112.95, Information on Prospective Amplification Candidates. The rationale for the requested rule change is a necessary element under Texas Government Code §2001.021 and 16 TAC §60.102, regarding rulemaking petitions.
- 4) If you have concerns with the statutory provisions affecting the hearing instrument fitters and dispensers’ scope of practice, those concerns would need to be addressed with the Texas Legislature. Only the Texas Legislature can change the statutory provisions. The Department does not have authority to change the statute.

The Department will provide an update regarding your rulemaking petition and the Department’s response to the Hearing Instrument Fitters and Dispensers Advisory Board at the board’s next meeting.

Opportunities to Stay Informed and to Participate

The Department wants to make sure that you are aware of opportunities to stay informed about and to participate in the activities of the Hearing Instrument Fitters and Dispensers (HFD) Program:

- 1) The Department has a dedicated webpage for the HFD Program at: <https://www.tdlr.texas.gov/hearing/hearing.htm>. This page includes program information including the statute, rules, forms, examination information, HFD Advisory Board information, Frequently Asked Questions, proposed rules that are open for public comment, and adopted rules with the justification notice.
- 2) The meeting notices and information about upcoming HFD Advisory Board meetings are posted on the Department's website at: <https://www.tdlr.texas.gov/meetings.htm>. Each advisory board meeting has an agenda item for "Public Comment" that members of the public may make public comments about issues affecting the HFD program. You are welcome to make public comments at these meetings during this agenda item. The advisory board meetings are also broadcast on the Department's YouTube channel and archived on the HFD webpage.
- 3) You may sign up to receive email notices from the Department regarding the HFD Program at: https://public.govdelivery.com/accounts/TXDLR/subscriber/new?category_id=TXDLR_C37. These notices include information about upcoming HFD Advisory Board meetings, proposed rules that are open for public comment, and adopted rules.

If you have any questions, you may contact me by email at brad.bowman@tdlr.texas.gov or by phone at (512) 463-3306.

Sincerely,



Brad Bowman
General Counsel

Attachment –

- Text of the email Rulemaking Petition dated April 23, 2018 (without attachments)

Pauline Easley

From: Ray Jones [REDACTED]
Sent: Monday, April 23, 2018 12:10 PM
To: Brad Bowman <Brad.Bowman@tdlr.texas.gov>
Subject: April 23, 2018 Petition for Rule Change - from Ray Jones

April 23, 2018

Brad Bowman
General Counsel
Texas Department of Licensing and Regulation
P.O. Box 12157
Austin, Texas 78711

Dear Mr. Bowman,

Ray Jones is an “interested person” within the meaning of Section 2001.021 of the Administrative Procedures Act, hereby petitions the Hearing Instrument Fitters and Dispensers Advisory Board under Section 2001.021 of the Administrative Procedures Act to adopt the changes proposed herein to the rules currently published by the Texas Department of Licensing and Regulation in §112.95. Information on Prospective Amplification Candidates. A license holder *shall* obtain information on each prospective candidate for amplification in accordance with Texas Occupations Code §402.352. (See attached Ray Jones Profile)

The proposed rule changes contained herein are necessary to bring Hearing Instrument Fitters and Dispensers Administrative Rules 16 Texas Administrative Code, Chapter 112 into compliance with 21 U.S. Code § 360k - State and local requirements respecting devices.

Proposed Change

I kindly request the Board amended §112.95 by adding Hearing aid specialist; scope of practice. The scope of practice of a hearing aid specialist regulated pursuant to this Chapter shall include, but is not limited to, the following activities:

- (1) Fitting and selling hearing aids.
- (2) Eliciting patient histories.
- (3) Performing assessments for hearing aids
- (4) Administering and interpreting tests for medical referral if indicated and recommendations for amplification if indicated
- (5) Referring, as appropriate, for cochlear implant evaluation or other clinical, and rehabilitative services
- (6) Determining candidacy for hearing aids, tinnitus management devices, and other assistive listening device

- (7) Providing hearing aid, tinnitus management device, and assistive device recommendations and selection.
- (8) Performing hearing aid fittings, programming, and adjustments.
- (9) Assessing, apprising, interpreting hearing aid efficacy utilizing appropriate fitting verification methodology.
- (10) Cerumen management.

~~Information on Prospective Amplification Candidates. A license holder shall obtain information on each prospective candidate for amplification in accordance with Texas Occupations Code §402.352.~~

Justification

I call for the amendment to §112.95 because: 21 U.S. Code § 360k - State and local requirements respecting devices.

(a) General rule except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

- (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
- (2) which relates to the *safety or effectiveness of the device* or to any other matter included in a requirement applicable to the device under this chapter. (See attached 21 U.S. Code § 360k)

Texas rule §112.95 it is different from and in addition to the federal requirements and relates to the *safety and effectiveness of hearing aids*, the Texas Hearing Aid Statute's "*fitting and dispensing*" and licensure requirements are *expressly preempted*. (See Walmart Case and Texas AG Opinion)

Conclusion

Federal regulations preempt the state regulations where they conflict on the *sale of the device*. In the Texas and Missouri cases, the state statutes ran into trouble because they placed requirements on the sale of the device that were in addition to the federal requirements. Section 402.001 (4) was the reason the Texas AG Opinion as well as the Wal-Mart case stated that the fitting and dispensing of hearing aids required a measurement of human hearing and was hence preempted. In his 2007 opinion, the Attorney General Greg Abbott explained that the *hearing examination requirement* of "*fitting and dispensing*" services "*clearly pertain[s] to the safety and effectiveness of a hearing aid.*" Here, the Court similarly finds Texas' "*fitting and dispensing*" and corresponding licensure requirements relate to the *safety and effectiveness of hearing aids because they are intended to ensure the purchaser is fitted properly with a safe and effective hearing aid*. See, generally TEX. OCC. CODE §§ 402.451(a)(4), 402.201, 402.001(4), (6). (See attached TDLR 2017 Chapter 402)(See attached Texas AG Opinion)

States, however, are free to continue to regulate the licensed professions. The FDA promulgated regulations to help clarify the preemption provisions of the Medical Device Amendments Act. Please See 21 CFR 808 – “Exemptions from Federal Preemption of State and Local Medical Device Requirements.”

<https://www.law.cornell.edu/cfr/text/21/part-808/subpart-A>

They specifically address licensing:

(3) Section 521(a) does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of medicine, dentistry, optometry, pharmacy, nursing, podiatry, or any other of the healing arts or allied medical sciences or related professions or occupations that administer, dispense, or *sell devices*. However, regulations issued under section 520(e) or (g) of the act may impose restrictions on the sale, distribution, or use of a device beyond those prescribed in State or local requirements. If there is a conflict between such restrictions and State or local requirements, the *Federal regulations shall prevail*. That’s exactly what happened in the Texas AG Opinion the Wal-Mart and Missouri cases. (See attached Texas AG Opinion, Missouri Case and Walmart Case)

States are free to regulate licensees and their practices, including the services that they can provide. *States are not free, however, to place specific conditions on the sale of the device* that are different from the federal regulations.

Respectfully submitted this 23rd day of April 2017.

Sincerely,

Ray Jones
2137 Hidden Creek Road
Fort Worth, Texas 76107
(817) 832-2058
