

Lend Me Your Ears:

Legal and Compliance
Issues Impacting
Audiology Practice-
Manufacturer Loan
Agreements

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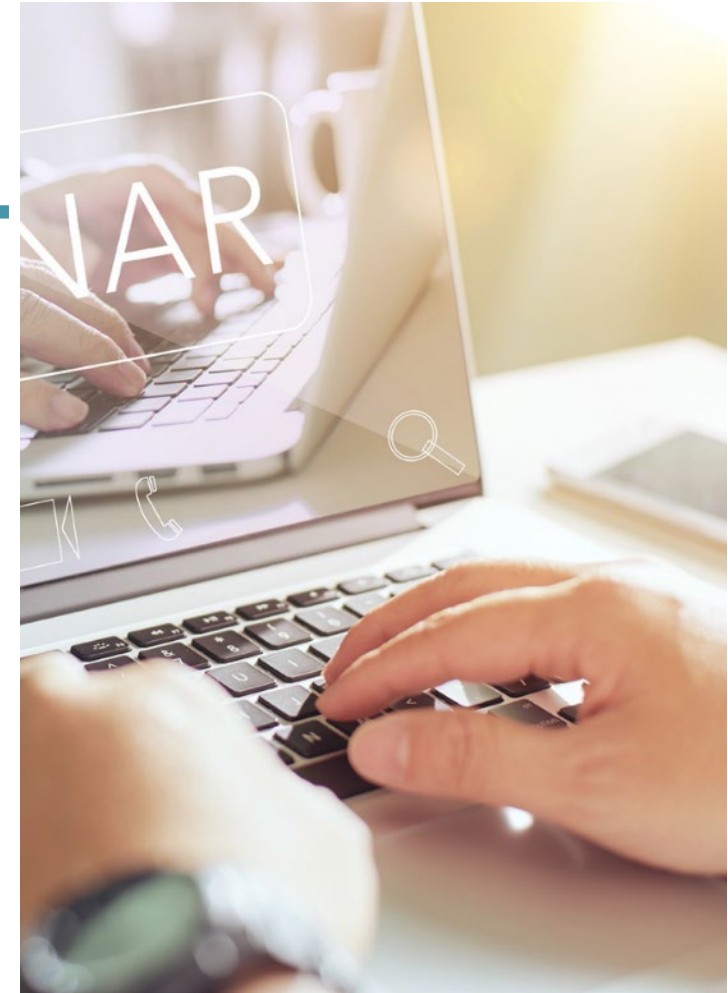
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AGENDA

- Introduction
- Practical Legal Business Issues
- Fraud, Waste, and Abuse: Compliance and Ethical Considerations
- Recommendations for Audiologists
- The Decision to Obtain Legal Analysis
- Questions



Introduction

- Meet the panelists



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OVERVIEW

- Manufacturer loan agreements pose a unique set of legal issues and considerations for audiology practice owners.
- Today, we will:
 1. Provide an overview of common terms found in audiology practice loan agreements obtained from hearing aid manufacturers and/or buying groups
 2. Offer candid recommendations to help practice owners protect their business interests and mitigate civil and criminal legal liability

Practical Legal Business Issues

The Basics: Audiology Financing Agreements

ADA members will benefit from understanding a few key points:

- **Standard loan terms can be negotiated**
 - Provisions such as events of default, termination fee, notice provisions and opportunity to cure can be negotiated
 - Goal: Reform existing boilerplate language that is one sided in favor of manufacturer
- **Understand buying group implications**
 - For example: Cross default provisions
- **Right of First Refusal (ROFR) terms can be negotiated**
 - Expand the terms applicable to the ROFR. For example, financial matching isn't enough. Ask for same reps and warranties as well
 - Clearly define process and procedure for exercising ROFR to provide certainty for potential buyers

Lending Relationship Terms

- **Cost/Expense recovery in the Event of Default**
- **Personal Guaranty(ies) from practice owners/key individuals**
- **Events of Default tied to:**
 - Material breach of loan agreement
 - False/Misleading reps/warranties by borrower
 - Bankruptcy/Assignment of Collateral
 - Failure to comply with applicable laws
- **Remedies including, but not limited to:**
 - Accelerating loan
 - Recover and take possession of collateral/practice
 - Enforce guaranty
- **Jurisdiction/Venue at lender's home state/city**
- **Security Agreement for Collateral including business assets**

Manufacturer Loan Agreement Terms

- **Right of First Refusal**
 - Some ROFR provisions are only bound to the financial terms of the competing offer. Even if a willing buyer agrees to favorable terms, the manufacturer is *not* bound!
- **Minimum Purchase Requirements**
 - **Percentage sales obligation**
 - 70-90% unit obligations
 - **Unit Requirement**
 - Minimum sales of manufacturer devices

Why are these Agreement Provisions So Risky?

Right of First Refusal Limited to Financial Terms

- Can provide additional obligations in the event a practice seeks to sell its practice
- Problematic: Any favorable terms aside from financial terms are not binding if manufacturer exercises ROFR!

Minimum Purchase Commitments

- Problematic: Not carving out state/fed reimbursed services. If at end of quarter, presumably the purchase percentage/unit requirement could influence clinical decisions!

Minimum Sales of Manufacturer Devices

- Clinical impact on patients if practice needing to push manufacturer's product to meet minimum unit and percentage threshold
- If practice fails this threshold, penalty for every non-compliant unit sold
- Some agreements expressly exclude sales related to federal/state health programs. Not a silver compliance bullet!

Fraud, Waste, and Abuse: Compliance and Ethical Considerations

MLA Regulatory and Compliance

The following sections and corresponding language create concern from a regulatory and compliance perspective:

- **Minimum Purchase Requirements:** From the Effective Date to [term date] or until all obligations of this Agreement have been met, Customer agrees that no less than the greater of 80% of its total quarterly hearing aid purchases, net of returns (measured for each calendar quarter) made by, or on behalf of, Customer will consist of [Products] ordered on accounts affiliated with [Company].
- **Purchase Requirements:** Business agrees to purchase from [Company] ninety (90%) percent of Business's total purchase requirements for hearing instruments, and the Business agrees to purchase from [Company] a total of 1,638 Qualified Hearing Instruments at the average rate of nineteen (19) units per month.
- **Waiver of Interest:** In the event Customer on average purchases and delivers payment for not less than 80% of their quarterly Net Purchases from [Company] during the Term up to the repayment of the loan and repays the entire principal of the loan, [Company] shall waive all interest accrued as of the repayment date or the last day of the Term.
- **Use of Loan Principal:** The Loan Principal will be used to acquire [Business] and to provide working capital for the Customer's business and for any other purpose(s) set forth in a prior written consent of [Company].

Federal Fraud and Abuse Laws

- Federal fraud and abuse laws will apply to any provider of Medicare, Medicaid, or other federal healthcare reimbursable services.
 - There may be some audiology practices that will not be serving any Medicare/Medicaid patients, so these laws may not apply to those entities.
- Most state laws mirror the federal fraud and abuse laws.
 - Some state laws go beyond Medicaid and also address commercial payors.
- The key federal fraud and abuse laws include the Anti-Kickback Statute, the Civil Monetary Penalties Law, and the Stark Law.

Anti-Kickback Statute

(42 U.S.C. § 1320a-7b)

- Prohibits *knowingly and willfully* offering, paying, soliciting, or receiving remuneration to induce or reward referrals for items or services covered by a federal health care program.
- Remuneration includes anything of value: cash, loans, free or reduced rent, product discounts.
- The statute applies to both the giver of the remuneration and the giver of the referral if the referral is for services reimbursable by a federal health care program including Medicare or Medicaid.
- If even *one purpose* of an arrangement is to induce or reward referrals, then the AKS has been violated. The bar for violations is low and easy for the government to meet in an enforcement context.

AKS Safe Harbors

- There are no safe harbors directly applicable to manufacturer loan agreements, so they are not protected from AKS liability.
- Concern: manufacturer waives the interest or penalties for any reason!
 - If a manufacturer makes a loan to an audiologist and then waives their interest for whatever reason, they are giving the audiologist a gift (not having to repay the loan) in return for the satisfactory referral of hearing aid customers.
- Concern: the inclusion of terms that exclude federal healthcare beneficiaries from minimum purchasing requirements!
 - An audiologist who excludes federal healthcare beneficiaries from the terms of a manufacturer loan agreement risks creating a dual fee schedule and discriminating against Medicare/Medicaid beneficiaries.

Civil Monetary Penalties Law

(42 U.S.C. § 1320a-7a(a)(7))

- Authorizes the Secretary of Health and Human Services to impose civil money penalties, up to \$100,000 per violation, and program exclusion for various forms of fraud and abuse involving the Medicare and Medicaid programs.
- The part of the CMPL that applies to the manufacturer loan agreement is 42 U.S.C. § 1320a-7a(a)(7), which subjects any person (including an organization, agency, or other entity) that commits an act that violates the AKS to civil monetary penalties.
- There is no intent requirement for CMPL violations, so if an AKS violation can be proved, then adding a CMPL violation on top of that is not difficult.
 - The manufacturer loan agreements, because they could be shown to violate the AKS, create a large amount of liability under the CMPL for audiologist participants.

Stark Law (42 C.F.R. § 411.350(a))

- Prohibits referrals by a physician of a Medicare/Medicaid patient to an entity (hospital, physician practice, or other provider organization) for certain designated health services (“DHS”) if the physician has a financial relationship with that entity.
 - The Stark Law could be implicated for audiology services because certain audiology services may be considered designated health services. However, although audiologists are doctors of audiology, they are not considered physicians under Federal law.
- Stark should not be implicated in the manufacturer loan agreements unless the audiology practice is owned by a physician type that is covered by Stark.

Enforcement Examples

- 2014: Ear Nose and Throat Associates of Corpus Christi, LLC entered into a settlement agreement with the OIG for \$200,630 to resolve allegations that for nearly three years the practice improperly submitted claims to Medicare and Texas Medicaid for hearing assessment services performed by unqualified technicians.
- 2018: In connection with the resolution of False Claims Act liability, John Balko & Associates, Inc. d/b/a Senior Healthcare Associates (SHA), agreed to be excluded from participation in all Federal health care programs for a period of ten years for knowingly and intentionally submitting or caused to be submitted claims for payment to Medicare for cerumen removal procedures, etc., which were not medically necessary, were not authorized or requested by patients, were not supported by patient medical records, lacked required medical documentation, and/or were provided in reliance upon improper standing orders.
- 2022: Eargo Inc. agreed to a \$34.37 Million settlement with the United States Department of Justice (DOJ) over allegations that it submitted – or caused the submission of – claims for hearing aid devices for reimbursement to the Federal Employees Health Benefits Program (FEHBP) with unsupported hearing loss diagnosis codes.

Ohio Fraud and Abuse Law

- Ohio Administrative Code gives the Ohio Speech and Hearing Professionals Board the power to reprimand, place on probation, deny, suspend, revoke, or refuse to issue or renew the license of an applicant or a licensee that “[obtains] a fee through fraud, deception, or misrepresentation or accepting commissions or rebates or other forms of remuneration for referring persons to others.” OAC 4753-3-08(E)(3).
 - Ohio law applies to audiologists generally. An audiologist could potentially lose their license for agreeing to accept a loan or other form of remuneration in return for referrals.
- Audiologists who have signed or are considering signing a manufacturer loan agreement should closely evaluate their state licensure and Medicaid laws to understand if they would be subject to any sort of enforcement actions as a result of the agreement.

A Sampling of Other States' Laws

- Each manufacturer loan agreement should be evaluated based on the licensing state of the audiologist who is subject to the agreement. Many states have laws that mirror the federal AKS.
- **Pennsylvania**
 - Unlike the federal AKS, this statute only has two small exceptions for the bona fide lease of office space and properly disclosed discount exception. A manufacturer loan agreement that requires minimum purchasing standards for an audiologist licensed in Pennsylvania would be a violation of Pennsylvania's Medicaid law if any of the hearing aids sold as part of the purchasing agreement were sold to Medicaid beneficiaries.
- **New Jersey**
 - This statute is broader than Pennsylvania's law because it applies to audiologists generally, not just those serving Medicaid beneficiaries.

National Ethical Standards

- The Academy of Doctors of Audiology (ADA), the American Academy of Audiology (AAA), and the American Speech-Language-Hearing Association (ASHA) have all published Codes of Ethics.
 - Quid pro quo arrangements are present in the relationship between audiologists and manufacturers, including gifts, trips, business support programs, advertising efforts, and other remuneration tied to purchases of hearing products.
 - Quid pro quo arrangements are unethical and prohibited by the Federal Anti-Kickback Statute.

State Ethical Standards

- Some states also incorporate the national ethical standards and guidelines into their state-specific codes of conduct.
 - For example, the Illinois Professional Conduct Standards for audiologists references the Code of Ethics of the American Speech-Language-Hearing Association (2016).
- Audiologists should consult their state's code of ethics and conduct to understand their state's view on conflicts of interest, both real and perceived.
- The controversy and concern that the manufacturer loan agreements have caused indicates that a perceived conflict of interest already exists, so audiologists entering into these agreements should evaluate their terms carefully in the context of their own state's law.

Recommendations for Audiologists

The Main Takeaways

- Audiologists entering into or bound by manufacturer loan agreements should review them for any potential conflicts of interest as well as the perception of prohibited referrals.
- Minimum purchase agreement terms are risky because they create an expectation that audiologists will refer based on the purchase requirement rather than using their own professional judgment.
- Each audiologist will need to evaluate a manufacturer loan agreement on a case-by-case basis to understand whether the audiologist will be able to comply with the terms of the agreement without violating fraud and abuse and ethics laws.
- It is best practice to treat all patients similarly by ensuring that any discounts or deals are offered to all patients on the same terms.

Remember, Consider, Revise

- Remember, terms included in the loan agreements could constitute violations of federal and state anti-kickback laws as well as state ethical codes that could open the audiologist who took the loan up to a significant amount of liability.
- Consider the loan agreements from the regulatory and compliance perspective. Look out for specific terms, including minimum sales and purchase requirements, rights of first refusal, and waivers of interest.
- Revise your participation in the MLA if it appears too risky or one-sided. Consult legal counsel to assist you in reviewing MLA terms.

The Decision to Obtain Legal Analysis

Why, How, and When to Seek Legal Advice

- Why: Manufacturer loan agreements can be (and often times are) one-sided, illegal, or confusingly worded.
- How: Reach out to an experienced attorney with your questions and concerns.
- When: As soon as possible!



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Questions?

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