THE VISION COUNCIL

GUIDE TO U.S. REGULATIONS & MANUFACTURING STANDARDS

Covering Eyeglass Frames, Prescription Lenses and Finished Eyewear Sold in the United States

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AUTHORS:

Rick Van Arnam, Esq.
Barnes, Richardson & Colburn, LLP
rvanarnam@barnesrichardson.com

Michael C. Vitale, ABOM
The Vision Council
mvitale@thevisioncouncil.org

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LEGAL DISCLAIMER

The organizations that compiled this guidance document intend its use to be helpful in educating manufacturers, importers, retailers, and eye care professionals about the U.S. regulations and national manufacturing standards that affect the manufacture and sale of eyeglasses, eyeglass frames and prescription lenses in the United States. The document is not a complete listing of all federal and state laws or manufacturing standards that could possibly affect the manufacture, sale or other disposition of such a product.

This guide reflects the laws, regulations and standards as of the date of its publication, September, 2020. Because laws and regulations may change and standards may be revised, readers should make sure that they are consulting the most recent iteration of those laws, regulations or standards, and seek advice from legal counsel when appropriate.

This has been prepared by The Vision Council for its members for informational purposes only and does not constitute legal advice. This information is not intended to create, and receipt of it does not constitute, a lawyer-client relationship, and you must not rely on this as an alternative to legal advice from your attorney or other professional legal services provider. Consult with your attorney if you have specific questions about any legal matter.

RESOURCES

1. The Vision Council, **www.thevisioncouncil.org**
2. American National Standards Institute (ANSI), **www.ansi.org**
3. International Organization for Standardization (ISO), **www.iso.org**

INTRODUCTION

The prescription eyewear industry in the United States is a 25.7 billion dollar business. Historically, the process of getting corrective eyewear has been fairly clear cut. Those in need of eyeglasses saw either an ophthalmologist or an optometrist to get a prescription, and then armed with that prescription had it filled either at their eye doctor's office or at an optician's office. The internet, however, now provides an alternative means through which prescriptions may be filled.

Whether dispensed through the traditional "3Os" (optician, optometrist and ophthamalogist) or filled on-line with a prescription provided by an eye doctor, eyeglasses and their key components — frames and lenses — are products regulated as "medical devices" by the U.S. Food and Drug Administration (FDA). If the products are imported, either as components or as finished eyeglasses, then other U.S. federal agencies will be implicated, most obviously U.S. Customs and Border Protection. Because of this, those entities distributing or dispensing eyeglasses, frames or lenses will be well served if they understand the regulatory fabric that cloaks the introduction of these medical devices into the commerce of the United States.

These laws, regulations and standards apply to eyeglasses and their components regardless of how they are sold. Whether sold through a traditional brick and mortar store or via an on-line source, the laws are intended to apply evenhandedly. This guide will highlight those situations where distinctions can be made.

Additional information about the various domestic and international manufacturing standards covering these and other ophthalmic products can be accessed through of the American National Standards Institute (ANSI) and the International Organization for Standardization (ISO). Standards, however, have no legal authority of enforcement unless they have been incorporated into U.S. law or regulation. They are voluntary.

I. THE REGULATION OF EYEGLASS FRAMES AND PRESCRIPTION LENSES

A. U.S. FOOD AND DRUG ADMINISTRATION

The United States FDA has jurisdiction over the federal regulation of medical devices made or sold in the United States. Two such medical devices are eyeglass frames and prescription lenses. Because the constituent parts of prescription eyeglasses (frames and prescription lenses) are regulated by the FDA as devices, so too is finished prescription eyewear.

These devices are regulated as Class I medical devices. The FDA has exempted most Class I devices from filing a pre-market notification application. Nor is FDA clearance required before marketing a Class I device in the United States. Manufacturers and initial importers/distributors, however, must register their establishments with the FDA annually.

The means by which the devices are sold will not impact their status as medical devices.

Thus, prescription eyeglasses sold via the internet are still an FDA regulated product.

1. Establishment Registration

Companies that are involved with medical devices may have to register themselves with the FDA, depending on their respective activities. This would include online optical retailers domiciled outside of the United States that ship finished eyewear into the United States.

a) Who must register?

While the regulations are written to include a broad class of establishments (companies involved in the "manufacture, preparation, propagation, compounding, assembly, or processing" of a medical device for commercial distribution), this can be simplified into two groups:

a. Foreign or U.S. companies that manufacture eyeglass frames or prescription lenses. This would include exporters, direct manufacturers, contract manufacturers, repackagers/relabelers, and re-manufacturers. This would also include companies that manufacturer prescription eyeglasses sold over the internet.

b. Initial distributors and importers of medical devices. These businesses receive devices imported into the U.S. and further distribute them.

Entities that "dispense devices to the ultimate consumer or whose major responsibility is to render a service necessary to provide the consumer with a device or the benefits to be derived from the use of a device" need not register with the FDA. The logic here is that the dispensing entity is merely dispensing or providing a service through the use of a previously manufactured device. Likewise, retail establishments that make final delivery or sale of a medical device do not have to register.Nor do U.S.-based optical laboratories, so long as the lab is doing typical optical laboratory processing and operations.

However, if "Big Box Store A" also imports the frames or lenses that it, in turn, uses in its dispensary to provide finished eyewear to U.S. customers, it would still have to register as an initial importer. A complete list of the different classes of establishments that must register can be found at **http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm**.

b) FURLS

Establishment registration is done "on line" through the FDA's Unified Registration and Listing System, which is a web portal known as "FURLS." FURLS can be accessed at **https://www.access.fda.gov/oaa/**. Any establishment, whether located in the United States or abroad, involved in the production, importation or

distribution of eyeglass frames or prescription lenses to be marketed in the U.S. is required to register with the FDA, and to renew that registration annually.

c) Must I pay?
Establishments should also check this list to determine whether or not they will owe the FDA the annual filing fee. As a general rule, if the establishment, either foreign or U.S., has to register then the fee will apply. Companies characterized as initial distributors or importers are no longer exempt from the fee.

d) Annual renewal
The fee is paid annually, during the annual renewal process. Every year between October 1st and December 31st, all registered establishments wishing to maintain an active status with the FDA must enter FURLS and renew their registration. This is true whether or not a fee is owed; if a fee is owed, it is paid at this time. If a company fails to renew, or chooses not to renew, then the establishment will be delisted from FURLS and that enterprise cannot legally manufacture, distribute or sell medical devices in the U.S. Reviving a delisted establishment is a time consuming process, so electing not to renew, or failing to renew during the renewal period, can complicate business transactions that might come up during a period when you have been delisted.

e) Official correspondent
Each company registering with the FDA will need to designate an individual as the company's "official correspondent." Any communications from the company to the FDA must be initiated by the official correspondent, so companies should select as their official correspond someone with authority to discuss issues with the FDA. Please note that the official correspondent differs from the official U.S. Agent, which is discussed later.

2. Device Listings

a) What must be listed?
Manufacturers of medical devices are required to file a medical device listing for each medical device they produce. Therefore, companies must file a separate device listing for eyeglass frames and for prescription lenses if they manufacture those devices. New device listings are done on-line through FURLS, and device listers are required to update their existing devices as part of the annual registration process.

b) Who must list?
Manufacturers of medical devices are required to file a medical device listing. Companies that characterize themselves as initial importers or distributors do not need to list the devices they import or distribute. This is true even though initial importers or distributors must register their establishments with the FDA.

3. U.S. Agent

a) Definition of a U.S. Agent
All foreign establishments required to register with the FDA must designate a U.S. Agent. The U.S. Agent is responsible only for 1) assisting the FDA in communicating with the foreign establishment; 2) responding to FDA questions concerning the foreign establishment's products that are imported and offered for sale in the U.S.; and, 3) assisting the FDA in scheduling an inspection of the foreign establishment.

b) What's the difference between U.S. Agent and official correspondent?
If the foreign establishment needs to inquire of the FDA, then this communication must originate from the company's "official correspondent," not its U.S. Agent. As discussed above, the official correspondent is the individual designated by the company in its FDA registration as the spokesperson for the company. The FDA will not address

any inquiry put to it by anyone who is not the official correspondent of the registrant.

c) **The Visions Council's U.S. Agent Program**
The Vision Council administers a fee-based U.S. Agent program. Participants in this program benefit from The Vision Council's additional resources and optical world expertise. Foreign companies interested in learning more about this program should contact The Vision Council.

4. Impact Resistant Lenses and the Impact Resistant Statement

a) **Requirement for impact resistant lenses**
Prescription lenses must be impact resistant. This would include prescription lenses in frames that are sold as finished eyewear over the internet. The test for impact resistance is known as the "drop ball" test. Every glass lens, and a statistically significantly sample of a batch of plastic lenses, must be tested for impact resistance. The requirements and test methodology for impact resistance are set out at **21 CFR 801.410**.

b) **Certification of "drop ball" test**
Tested lenses are certified as compliant. This is particularly important if you import lenses or finished eyeglasses into the U.S. Each shipment of a device with lenses into the U.S. must be accompanied by certification that the lenses, whether loose or mounted, comply with the FDA's impact resistance regulations. The "drop ball" test certification must state that the imported eyewear/lens was tested for, and passed, impact resistance. If a "drop ball" certificate does not accompany a shipment, then the FDA is authorized to hold and then detain the shipment. At this point, the impacted parties will have to petition to have the merchandise released, with no guarantee that the shipment will be released into the commerce of the United States.

c) **Actual test data**
Manufacturers of lenses or finished prescription eyeglasses, whether domestic or imported, must retain the data supporting the finding that the lenses are impact resistant. Importers of prescription lenses should note that even when a drop ball certificate accompanies a shipment the FDA has the right to request the actual test data underlying that certificate. In a situation where the FDA requests the actual test data, the importer and/or the manufacturer will be given the opportunity to provide the supporting data, and if found to be sufficient, the agency will close its books on the matter or, if imported merchandise is being held, release the merchandise. Of course, if the FDA is unconvinced about the validity of the data it can then refuse to release the shipment into the commerce of the United States.

5. Biocompatibility of Materials

Eyeglass frames, prescription lenses and finished eyeglasses should be made of materials that are not flammable. In addition, these devices should also be made of materials that are non toxic, and which do not produce an allergic reaction under normal use. The **ANSI/ISO 7998 / 8624 / 12870 - Optics Set** standard sets out voluntary standards for measuring the flammability of materials used in eyeglass frames, while criteria for measuring the biocompatibility of materials is found at **International Organization for Standardization's ISO 10993**.

6. FDA Labeling Requirements

a) **Language and common name of device**
Because eyeglasses, frames, and prescription lenses are medical devices, they are subject to FDA labeling requirements. These labeling requirements apply to all medical devices, both U.S. origin and foreign origin. All medical devices must state the common name of the device in BOLD FACE type in a reasonable size font. The label must be in English,

except in Puerto Rico or other U.S. Territories where English is not the primary language. In those situations, the label must be in the predominate language, such as Spanish for Puerto Rico.

b) Information that must be included

The label must also identify other information. It must identify the name and place of manufacture or distribution. This must be done in a conspicuous way, and must list the street, city and zip code of the principal place of business or site of production – an email address will not satisfy this requirement. If the device is made by a company other than the one identified on the label, then the label must say "Manufactured for ____" or "Distributed by ____" to denote that the company on the label did not actually manufacture the device. The label must also explain how the device is used. Eyeglass frames and prescription lenses are exempt from providing use information but clip-ons are not.

c) Misbranding

False or misleading labels can result in the FDA determining a product to be misbranded or adulterated. For example, labels are misbranded when they contain statements that are false or misleading in any regard, are ambiguous or create a false impression. In certain circumstances silence as to a material fact can result in an allegation that a device is misbranded.

d) Unsubstantiated claims of therapeutic or preventative value

Eyeglass, frames and prescription lens companies should be particularly concerned about making unsubstantiated claims of therapeutic or preventative value, as these would be considered false or misleading statements. As mentioned above, eyeglasses, frames and prescription lenses are considered by the FDA to be Class I medical devices, requiring no FDA pre-market approval. This exemption, however, extends only to claims of use and performance previously authorized by the FDA. For example, frames have been approved to hold spectacle lenses to be worn by a patient to correct refractive errors and prescription lenses have been approved to be worn by a patient in a spectacle frame to provide refractive corrections in accordance with a prescription. Any claim touting a therapeutic or preventative benefit not previously authorized by the FDA would need to be submitted to the FDA via the 510K procedure for pre-market approval.

e) Public service information

While the Class I exemption limits statements as to how the eyeglasses, frames or prescription lens is to be used or will perform, labels can contain information on safety or of a public service type. Therefore, labels can contain statements such as "lenses not shatterproof or unbreakable," "not intended to function as impact protective eyewear for use in high risk impact sports or for industrial safety," or "tinted eyewear not recommended for night driving."

7. Good Manufacturing Practices

Companies that manufacture eyeglasses, frames and prescription lenses must meet current good manufacturing practices (cGMP). The FDA describes these as "quality system regulations" impacting the design, manufacture, labeling, purchasing, storing and servicing of medical devices. Periodically the FDA audits facilities to ensure compliance with cGMPs. If you are audited, and found to be non-compliant, then the FDA will issue a detention order covering that facility.

8. 510(k) Pre-market Notification

a) Exemption for medical devices

As mentioned above, eyeglasses, frames and prescription lenses are designated Class I medical devices by the FDA. Therefore, they are exempt from 510(k) pre-market notification as long as they are marketed in a manner consistent with the exemption.

b) Misbranding violates exemption
Any claim or advertisement that an eyeglass, frame or prescription lens provides a therapeutic or preventative benefit that was not pre-cleared by the FDA as part of the agency's granting eyeglass frames and prescription lenses Class I status, would be considered misbranding unless first made subject to the 510(k) process.

9. Demo Lenses

Often, eyeglass frames are imported with demonstration lenses. These lenses are not intended to be sold to consumers and, as such, typically these lenses have not been rendered impact resistant. While not actually set out in the applicable law or regulations, the FDA suggests that steps be taken to ensure that non-impact resistant demo lenses are not offered for sale or distribution to consumers. The agency suggests in its **guidance document** on impact resistance that the lenses be marred in such a way as to render them commercially impractical. Note, however, that variation to the suggestions on the list might suffice, depending on what is said:

a) "You may have the word 'demonstration' etched in the lower quadrant of at least one lens in each pair of eyeglasses. The letters should be large enough to be seen easily with normal vision."

b) "You may draw a visible line through the center of the lens."

c) "You may remove a notch from the lower quadrant of at least one lens in each pair of eyeglasses."

d) "You may drill a hole in each lens in the wearer's line of sight."

10. Unique Device Identifier

a. The Unique Device Identification system, known as the UDI, will be used to identify and trace medical devices through distribution and use. Labels of medical devices will include a UDI in human and machine-readable forms, and UDI labelers must submit information into the FDA's Global Unique Identifier Database ("GUDID").

b. UDI applies to all medical devices, including Class I medical devices such as eyeglass frames, sunglasses, reading glasses and many low vision devices. Class I medical devices will be required to comply with the UDI regulations as of September 24, 2022. For most of The Vision Council's members, the UPC code will suffice as the UDI per FDA guidance.

c. The Vision Council was successful in carving out prescription lenses from all UDI requirements. As a result, manufacturers of prescription lenses and optical laboratories that process them are exempt from all UDI compliance requirements.

d. For more UDI info, see **https://www.thevisioncouncil.org/sites/default/files/assets/media/TVC_UDI_SystemFinalRule_2020.pdf**

B. U.S. CUSTOMS AND BORDER PROTECTION

1. Customs Regulations for Eyeglass, Frames, and Prescription Lenses

a) Imported merchandise
U.S. Customs and Border Protection ("Customs") is the federal agency with jurisdiction over the movement of merchandise into the United States. Many eyeglass frames and prescription lenses are imported, and now complete prescription eyeglasses are a growing import, so understanding the role Customs plays is important to those companies importing these products. Please note, however, that this document is simply

an overview of the Customs laws, and that importers should consult with their Customs attorneys or other trade consultants to ensure compliance with these complex laws.

b) Tariff classification

All merchandise imported into the United States must be classified under the Harmonized Tariff Schedule of the United States ("HTSUS"). This process results in the assignment of a ten digit tariff number to the imported product, and will identify what, if any, Customs duty is owed on the product. The tariff number and duty are presented to Customs by the importer (typically through its Customs broker) when the required paperwork is submitted to the agency at the time the merchandise is entered into the commerce of the United States.

c) Rates of duty

As of 2020, the tariff classification assigned to eyeglass frames is 9003.11.0000 if plastic, and the rate of duty is 2.5 percent ad valorem; or 9003.19.0000 if made of any other material, free of duty. Likewise, the tarif classification for prescription lenses is 9001.40.0000 if of glass, dutiable at 2.0 percent ad valorem or 9001.50.00 if made of any other material, dutiable at 2.0 percent ad valorem. Finished prescription eyewear, if imported, would be classified under 9004.90.0000, dutiable at 2.5 percent ad valorem.

d) Special trade programs

Certain countries or regions have entered into free trade agreements with the United States, with one of the benefits being the reduction or elimination of duty on most products imported into the United States that originate in those other signatory countries. The United States-Mexico-Canada ("USMCA") Free Trade Agreement, the successor to the North American Free Trade Agreement ("NAFTA") is the best known of these free trade agreements. The following is a list of countries and regions that currently (as of 2020) have signed free trade or similar agreements with the United States where the U.S. is allowing duty-free treatment to eyeglass frames and prescription lenses that qualify under the various agreements: Australia, Bahrain, Canada, Chile, Colombia, the Dominican Republic, Israel, Japan, Jordan, Mexico, Morocco, Nepal, Oman, Panama, Peru, Singapore, South Korea, various Caribbean basin countries, various Andean region countries and various Central American countries, and various developing countries under the generalized system of preference ("GSP"). Each of these free trade agreements incorporates complicated rules of origin for determining whether or not a product is, in fact, a product of a qualifying country. Therefore, consult with your trade attorney or other customs professional to confirm that your product does qualify. Simply shipping a product from a qualifying country will not qualify it as originating in that country.

2. Customs Valuation and Appraisement

a) Taxes imposed on value of merchandise

Because most duty rates are ad valorem (a tax imposed on the value of the merchandise), the Customs laws require that importers report an appraisable value for the merchandise. Several methods of valuing merchandise exist; however, "transaction value" is the preferred method. In a nutshell, transaction value seeks to arrive at a "free on board" ("FOB") value for the imported merchandise. As a result and depending on whether the invoice price for the imported merchandise includes things like international freight, insurance, or even duty, the appraised value that is declared to Customs might differ from the invoice price.

b) Complicated and intricate laws

The Customs valuation laws are much more complicated than can be described in this pamphlet. Things such as raw materials, components, packing materials, tools, dies, molds, patterns, machinery and certain engineering, blueprints or other technical data,

when provided free or at a reduced cost, to the seller by or on behalf of the buyer, and when not recaptured in the invoice price, must be declared to Customs. Royalty and licensing fees, likewise, could have a Customs consequence. If present, these types of costs increase the appraisable value of the imported merchandise, resulting in more Customs duty being owed. Failure to declare these costs to Customs is a violation of the Customs laws. This can result in the imposition of civil penalties against an importer and a demand to pay back duties.

c) Focus of Customs officials

Customs is also more likely to scrutinize the appraisable value of transactions between related parties, such as sales between a foreign parent and its U.S. subsidiary or a U.S. parent and its foreign subsidiary. Typically it is these types of transactions where elements of appraisable value go unreported, making them of greater interest to Customs.

3. Country of Origin Marking

a) What must be marked?

All merchandise imported into the United States must physically be marked with its country of origin. This marking must be conspicuous, legible, indelible and permanent so that the country of origin is conveyed to the ultimate purchaser of the product. The marking must be in English.

b) Defining country of origin

The country of origin is the country where the merchandise originates. It could be made in a certain country. It could be mined, raised, or grown in a particular country. It is not simply the country of export (though the country of origin and of export could be the same). In situations where the imported product is the result of manufacturing raw materials or components from multiple countries, then the country of origin of the imported product will be the country where the components or raw materials were "substantially transformed" into the imported product. A substantial transformation occurs when the components or materials undergo a change in name, character and use when manufactured into the finished product.

c) Implications of Customs marking and FDA labeling

Importers and manufacturers of eyeglass frames and prescription lenses must take special care to ensure that their country of origin marking and their FDA labeling coincide with each other. As discussed above, the FDA requires that the labels on medical devices have the name and address of the manufacturer or distributor. That name and address could likely be a U.S. address if a distributor is identified. If that is the case, and if the eyeglass frame or lens is imported, then the Customs country of origin law requires that the country of origin marking (i.e. "Made in China" etc.,) be in close proximity to the U.S. address so that the ultimate purchaser of the product can be informed as to where the product was made.

d) Exception from marking

Many exceptions exist to the country of origin marking rule. Where an exception exists, the outermost packaging rather than the actual item need only be marked with the product's country of origin. Importers or foreign manufacturers who believe that a marking exception applies to their product should consult with their Customs professional or with Customs directly before unilaterally electing to not physically mark their product but rather to mark the outer most packaging.

e) Consequences of improper marking

Improper country of origin marking can result in civil penalties assessed against the importer. Customs can also demand that mis-marked merchandise be redelivered to the port for marking, export or destruction. Failure to redeliver can result in the assessment of other

types of damages based on a violation of the Customs bond that the importer has posted.

C. OTHER FEDERAL AGENCIES

1. Federal Trade Commission

a) What is covered by the Federal Trade Commission (FTC)?
Companies should be mindful of using the "Made in the USA" marking. This marking designation is overseen by the U.S. FTC and applies to products made and sold in the United States. It is different than the Customs country of origin marking requirement, which applies to imported goods.

b) "Made in the USA" marking
Simply stated, merchandise cannot be sold in the United States as "Made in the USA" (or similar marking) unless the product is all or virtually all U.S. origin and is in fact made here. There is no bright line test published by the agency for what constitutes "virtually all," but any product with more than a de minimis amount of non-U.S. origin material would likely disqualify the use of this marking. So, companies manufacturing eyeglass frames, prescription lenses or finished eyewear in the United States using imported components or materials must be careful not to violate this marking law.

c) Conditional markings
Conditional markings may be available for qualifying products. Depending on the facts, it may be possible to mark a product sold in the United States "made in the USA of U.S. and imported goods" or "80% made in the USA." Companies that believe they can comply with the FTC marking law should ensure that, in fact, the product satisfies these requirements before proceeding to mark accordingly.

2. Consumer Products Safety Commission (CPSC)

a) What is covered by the CPSC
As its name suggests, the Consumer Products Safety Commission ("CPSC") regulates certain consumer products. The various laws administered by the CPSC exclude products regulated by the FDA as medical devices, so eyeglass frames and prescription lenses companies typically need not concern themselves with the CPSC. However, its laws touch a number of different areas, most notably the presence of lead in paint or surface coatings, or in paint or surface coatings found on toys or other children's products, and total lead and phthalates in toys and other children's products intended for children 12 and under. In the ophthalmic industries, items such as eyeglass cases or neck chains could fall within the jurisdiction of the CPSC if they are intended for children 12 and under.

b) Compliance issues
The lead and phthalate laws apply to children's product, so even if eyeglass frames, prescription lenses or prescription glasses were not exempt because of their status as medical devices anything intended for people older than 12 would not be covered either. Accessories, such as cases or chains, when marketed and sold (or given away with the eyeglasses) to children 12 and under would implicate the CPSC laws.

D. THE DEPARTMENT OF AGRICULTURE

1. What is covered by the Lacey Amendment?

A recent amendment to a long standing Department of Agriculture law, known as the Lacey Act, could create compliance issues for eyeglass frame companies that incorporate any wood or other plant material in their products.

2. Compliance Issues

The amendment made it unlawful to import plant or "plant products" without an import declaration containing the scientific name of the plant, its value, quantity and country of origin. As amended, the revised law could be broadly applied to capture any number of products. In light of this, Customs and the Animal and Plant Health Inspection Service ("APHIS"), the section within Agriculture responsible for overseeing this law, have moved to limit the products actually covered by the law. Companies knowing that their products incorporate any type of plant matter should review the Lacey Act to determine whether or not the amendment applies to them.

E. STATE LAW RESTRICTIONS OF NOTE

Dispensary laws and on-line distribution of eyeglasses with the advent of direct-to-consumer sales of prescription eyeglasses via the internet means the traditional ways of dispensing eyeglasses are changing. However, those companies selling finished eyeglasses via the internet or catalogs must be mindful of various U.S. state dispensary laws. If you are involved in this method of sales you should know that the following 22 states regulate the dispensing of prescription eyeglasses to some degree: Alaska, Arizona, Arkansas, California, Connecticut, Florida, Georgia, Hawaii, Kentucky, Massachusetts, Nevada, New Jersey, New York, North Carolina, Ohio, Rhode Island, South Carolina, Tennessee, Vermont, Virginia, Washington, Colorado. Puerto Rico also regulates eyewear dispensing.

Consequently this means the remaining states at the time of publication of this guide do not have any state licensing laws (voluntary or otherwise).

Those entities involved in direct-to-customer internet sales are encouraged to review the relevant laws with counsel so to ensure that all required authorizations are secured before placing sales into a particular state.

To view a state's licensing and examination requirements, go to **https://www.abo-ncle.org/ABO/Education/Licensing_Boards/ABO/Boards/Licensing_Boards.aspx?hkey=c38ffeae-0ffb-472c-87ab-4bed32837354** and select the state name from the drop-down menu.

1. California Proposition 65

a) What is California Proposition 65?

Proposition 65 is a California state initiative that became law in 1986 as the Safe Drinking Water and Toxic Enforcement Act of 1986. Proposition 65 enacted environmental regulations regarding toxic chemicals that importers are subject to when they sell merchandise in that State, but may be unaware of. While some of the Proposition 65 controls are intended to protect California's drinking water sources from contamination by these chemicals, others are more widely applicable and intended to allow California consumers, residents and workers to make informed choices and take precautions about the products they purchase and are exposed to which contain potentially hazardous chemicals.

b) Who is affected?

Any company with ten or more employees that operates within California or sells products in California must comply with the requirements of Proposition 65. Proposition 65 also applies to retail, mail order or internet sales of products in California. If you operate in California, or simply sell your products in California, then you are subject to this law.

c) What are the implications?

Companies selling merchandise in California need to certify their product as compliant with the State of California's Proposition 65. The law requires the Governor to publish a list of chemicals that are known to the State of California to cause cancer, birth defects or other reproductive harm. The list is updated quarterly, (see **http://www.oehha.ca.gov/prop65/prop65_list/Newlist.html**), and so companies should review it often to ensure that they are compliant.

d) **Restrictions, warnings and labeling**
If a business has products containing chemicals which are on the list, those businesses are: (1) prohibited from knowingly discharging listed chemicals into sources of drinking water; and (2) required to provide a "clear and reasonable" warning before knowingly and intentionally exposing anyone to a listed chemical. This warning can be given by a variety of means, such as labeling a consumer product, by posting signs at the workplace, or by publishing notices in a newspaper (§ 25249.11(f)), but such applications will depend on the circumstances and placement. For the most part, the obligation to label is placed on the producer or packager rather than on the retail seller (except where the retail seller itself is responsible for introducing a chemical known to the state to cause cancer or reproductive toxicity into the consumer product in question).

e) **Exceptions**
This warning is required unless you are able to demonstrate that the exposure caused by the banned substance poses no significant risk (for carcinogens, no significant risk assuming lifetime exposure, and for chemicals causing birth defects or other reproductive harm, no observable effect assuming exposure at 1000 times the level in question). This exception may be difficult to demonstrate so companies should not use it unless they have compelling proof that the levels in their products pose no risk. For additional information on Prop 65, see The Vision Council website at **https://www.thevisioncouncil.org/members/california-prop-65**

2. States Requiring Device Manufacturer Registration

a) California requires that medical device manufacturers physically located within the state file for a license from the state..

b) The state charges a fee both for new licenses and for a bi-annual license renewal.

c) The licensing process requires the state to inspect the facility unless an exemption can be applied.

II. STANDARDS

A. WHAT IS A STANDARD?

A standard is an established minimum norm or guideline for the performance or design of a product. They help insure that products and systems perform as intended and are safe to use. They may set out how things are supposed to look or function. They may define certain terms of art found in standards. Most standards are voluntary and arise from consensus developed by technical committees of standards developing organizations. These committees can be comprised of both private and public sector members, who function as equal participants. Standards, being voluntary and promulgated by non-government associations, do not carry the status of law and you need not follow a standard. However, sometimes governments adopt or reference standards as part of their regulations, thus elevating all or part of a standard to the status of law. The impact resistance standard (the "drop ball" test) is a good example of a voluntary standard that has been incorporated into the U.S. federal regulations.

The following section on standards has been included in this guidance document because standards have been published covering prescription lenses and eyeglass frames. These standards, though voluntary, set out the essential performance characteristics of those products. Therefore, conformance to these standards is encouraged.

B. WHY SET STANDARDS ?

Standards are set to establish minimum levels of safety and performance of products providing a consensus for what elements demonstrate "quality" and "safety" for that product. The international harmonization of standards has as its goal to facilitate trade between nations.

C. U.S. STANDARDS ORGANIZATIONS

1. American National Standards Institute (ANSI)

a) What is ANSI?

ANSI is the national standards organization that coordinates the voluntary consensus standards and conformity assessment systems in the U.S. Eyeglass frames and prescription lenses have ANSI standards in place.

b) What are the Standards for Eyeglass Frames

The relevant standard for eyeglass frames is the **ANSI/ISO 7998 / 8624 / 12870 - Optics Set** standard which ANSI has approved as an American National Standard.

c) What are the Standards for Prescription Lenses?

The relevant stand for prescription lenses is the Z80.1 standard, which ANSI has approved as an American National Standard.

d) Regulations and Procedures

Standards are actively reviewed to reflect changes in technology and marketplaces. All Z80 standards must be reviewed every five years. The revised standard is circulated to the entire committee as a ballot. ANSI requires 100 percent voting yes. Any "no" votes must be resolved before the standard can be passed or re-approved, and an explanation must be stated for a "no" vote. In the event of a "no" vote, the proposal is returned to the drafting subcommittee, where the subcommittee reviews the reason stated for the "no" vote. Thereafter the subcommittee will report out the proposed standard again, and the entire committee will vote on it again. So, at ANSI, one vote can block the process.

D. INTERNATIONAL ORGANIZATIONS THAT REGULATE STANDARDS

1. The International Organization for Standardization (ISO)

a) What is the ISO?

The ISO is a non-governmental organization, consisting of national standards institutes representing 165 countries. The purpose of the ISO is to achieve industry-wide standardization for products.

b) Regulation and procedures

Standardization within the ISO takes place through the formation of Technical Committees and subcommittees for each specific product. Then each member organization determines its national proposed standard for the product and argues its position in the committee and subcommittee. When the subcommittee has negotiated a draft proposal and the committee has agreed upon it, the proposal goes before the entire ISO membership for a vote. If accepted by at least 75 percent of the membership, that standard then becomes the official ISO international standard for the product.

c) Are there international eyeglass frame and lens standards?

In the U.S. many companies and individual experts contribute to the global eyewear standard group known as ISO. Like ANSI standards in the U.S., ISO standards are routinely updated on a planned three-to-five year schedule, and new standards intended to cover developing products and market segments are continually under development.

The primary ISO standard that is analog to the ANSI Z80.1 prescription is currently known as **ISO 21987**. There are also related ISO standards that work in conjunction with ISO 21987 and address the standards process in the various stages of manufacture prior to the device becoming complete.

Those standards cover different steps in the manufacturing process including unmounted frames (frames prior to the insertion of

lenses), semi finished and finished lenses criteria, standards for aspheric lens designs, as well as a host of detail standards related to abrasion, visible transmittance, ultraviolet (UV) transmittance, and others.

d) Interactions between the ISO and the World Trade Organization (WTO)

While the standards promulgated in the ISO may technically be voluntary, as is discussed, below, membership in the WTO may require members, including the United States, to accept new ISO standards or risk defending their regulations in the WTO dispute settlement system.

2. The World Trade Organization (WTO)

a) What is the WTO?

The WTO is an international organization dealing with the rules of trade between nations. At its heart are the WTO agreements, negotiated and signed by the bulk of the world's trading nations and ratified in their parliaments. The goal is to help producers of goods and services, exporters, and importers conduct their business.

b) Harmonizing national and international standards

As part of the negotiations for the WTO, the parties, including the U.S., agreed to the Agreement on Technical Barriers to Trade ("TBT"). Pursuant to the TBT, WTO Members agree to ensure that domestic technical regulations, voluntary standards, and conformity assessment procedures do not amount to unnecessary obstacles to trade. Annex 3 of the TBT provides the Code of Good Practice. By accepting the TBT, WTO Members agree that (1) central governmental standardizing bodies will comply with the Code of Good Practice and (2) measures will be taken to ensure that local governmental bodies and non-governmental bodies also comply. In situations where international standards exist or are in the process of implementation, the Code of Good Practice requires the standardizing bodies at the national level to adhere to such standards, or at a minimum use them as the basis for their own national standards.