

BEFORE THE IOWA BOARD OF PHARMACY

RE:
Application for Wholesale Drug License of

DIA NO. 18PHB0008

PREMIER DISTRIBUTION INC.,

Applicant

FINDINGS OF FACT,
CONCLUSIONS OF LAW,
DECISION AND ORDER

On August 30, 2017, the Iowa Board of Pharmacy (Board) issued a Notice of Intent to Deny License to Premier Distribution, Inc. An appeal was filed, and a Notice of Hearing was issued scheduling the appeal hearing for October 31, 2017 at 10:00 a.m. A telephone prehearing conference was held on October 25, 2017 to clarify procedures for the hearing. The hearing was held on October 31, 2017 before the following members of the Board: Sharon Meyer, Chairperson; Edward McKenna; Jason Hansel; Gayle Mayer; Brett Barker; LaDonna Gratias; and Joan Skogstrom. Assistant Attorney General Laura Steffensmeier represented the state. Premier Distribution Inc. was represented by Mercedes Batista, who was identified as the designated facility manager. The hearing was open to the public and was recorded by a certified court reporter. Administrative Law Judge Margaret LaMarche assisted the Board in conducting the hearing and was instructed to prepare the Board's Findings of Fact, Conclusions of Law, Decision and Order, in conformance with its deliberations.

THE RECORD

The record includes the testimony of Jean Rhodes, Mercedes Batista, and Noel Castillo; State Exhibits 1-12 (See Exhibit List for description) and Applicant Exhibit A. By agreement of the parties, the Board provided a certified interpreter for Noel Castillo's testimony.

FINDINGS OF FACT

New Wholesale Drug Application. On March 6, 2017, the Board received a new Iowa Wholesale Drug License Application that identified "Noel Castillo, 801 Ashworth Road, 2 Floor, West Des Moines, Iowa 50265" as the Legal Name and Licensed Location Address for the applicant. "Corporation" was checked under type of ownership. Noel Castillo was identified as the "President-Owner, but no corporation name or State of incorporation was listed. Question 10 asked the applicant to attach a "complete typewritten description of the licensed facility operations" including: "a. YOUR type

and hours of operation...; b. ALL types of prescription drugs, devices, or medical gases that you distribute or market...; and c. ALL types of customers that you sell or distribute to.” The typewritten attachment submitted in response to Question 10 had the heading “Description of Operation” and stated the following:

- a) Hours of operation: as Monday to Friday, 9AM-3PM
Wholesale distribution only
- b) Noncontrolled prescription drugs
- c) wholesalers.

Noel Castillo reported no convictions, no other trade or business names, and no other states where he is licensed for wholesale drug or device distribution. (Exhibit 1; Rhodes testimony)

Onsite Visits. When a wholesale license application is received for a new location, the Board sends a Compliance Officer to conduct an onsite visit of the proposed facility. Compliance Officers Jean Rhodes and Mark Mather conducted the site visit for this application on April 3, 2017. Jean Rhodes is a licensed pharmacist and has been employed by the Board as a compliance officer for 13 years. Noel Castillo was present for the site visit along with his secretary, Myra Rubio. Noel Castillo, who speaks Spanish, had Myra Rubio translate for him when he spoke with the Compliance Officers. Mr. Castillo reported that Ms. Rubio was his only employee. (Rhodes, Castillo testimony; Exhibit 2)

The proposed facility was the second story of a converted house that had outside access by a steep exterior wooden stairway. There was also an interior stairway to the second floor, but the first floor entrance was locked at the time of the visit. A cleaning business was located on the first floor. The doors were key locked, and a security system was being installed when the Compliance Officers arrived. Mr. Castillo told the Compliance Officers that he had been in Iowa for 4 months. He also told them that he had lived in Florida for 4 years before coming to Iowa and that he had lived in Cuba before that. Although the application had been filed in Mr. Castillo’s name, documents at the business location were in the name of Premier Distribution, Inc. Mr. Castillo was advised that he would need to update the application and provide the name of the corporation and the State of incorporation. Mr. Castillo denied having any previous convictions or felonies, and this was confirmed through an FBI background check (Rhodes testimony; Exhibit 2)

Compliance Officer Mark Mather recorded part of the conversations. Compliance Officer Jean Rhodes prepared a written Inspection Report following the site visit, which

included the following additional information that was provided to the compliance officers by Noel Castillo:

- Although the initial application stated that the business would sell only to other wholesalers, Mr. Castillo told the compliance officers that the business would be selling to wholesalers and to pharmacies;
- Mr. Castillo stated that he intended to sell to “any business America,” but was unaware that there would be additional licensing requirements for other states;
- Mr. Castillo admitted that he had no background in wholesale drug distribution. He reported that his previous employer was a cleaning business and before that he had been a vice-president for an importer-exporter in Cuba for 16 years. He claimed that he learned the drug wholesaling business from his ex-wife, who had worked for an unnamed wholesaler in Florida more than six years ago. Mr. Castillo agreed to submit information about his wife’s previous employment. He further reported that he had plans to hire a surgeon, who was from Cuba but who may be in Miami, and who had experience working with drugs because he did a pharmacy rotation in medical school;
- Mr. Castillo was not familiar with the federal Drug Supply Chain Security Act (DSCSA);¹
- Mr. Castillo had no written policies and procedures to address the receipt, security, storage, inventory, and distribution of prescription drugs or to address identifying, recording and reporting losses and thefts; stock rotation; recalls and market withdrawals; emergency and disaster plans; and outdated drug segregation and distribution;
- Mr. Castillo had a sample customer application that included a request for a copy of the customer’s license, but he had no policy for verification and continued monitoring of a customer’s licensing status;
- The business’s air system was regulated by the thermostat on the main floor. The humidity was at 40% and Mr. Castillo was unfamiliar with proper humidity and temperature requirements for storing drugs;
- Mr. Castillo planned to store drugs in one of the smaller rooms with a locked door and to use a plastic locked cabinet for quarantine; and
- Mr. Castillo had not yet developed a record keeping system for transaction records.

¹ 21 U.S.C. §§360eee-1 to 360eee-4. The DSCSA sets national standards for prescription drug wholesale distributors (and for manufacturers, repackagers, and dispensers of prescription drugs) pertaining, in part, to the storage of handling of prescription drugs including facility standards, the establishment and maintenance of records of the distributions of such drugs, and for tracing products through the distribution system.

(Rhodes testimony; Exhibits 1, 2)

Noel Castillo submitted an updated application in the name of Premier Distribution Inc. and attached the Articles of Incorporation for Premier Distribution, Inc., which had been filed with the Iowa Secretary of State on February 24, 2017. Mr. Castillo also submitted a local business tax (LBT) form for Miami Cleaning Performance Corp in Dade County, Florida, which had expired on September 30, 2016. He submitted Electronic Articles of Incorporation for Miami Cleaning Performance Corp, which identifies the incorporator as Marta Hernandez. Mr. Castillo's name does not appear on these documents. (Rhodes testimony; Exhibits 3-5)

Mr. Castillo also submitted a five page "Policies and Procedures for the Management of Pharmaceutical Products" document, which he reported had been prepared by "Steve" at Community CPA in Des Moines. The Policies and Procedures were dated April 7, 2017, which was four days after the initial site visit. (Exhibit 6; Rhodes testimony)

The compliance officers returned for a follow-up site visit on April 19, 2017. The notes for this visit were incorporated into the initial Inspection Report and appear in lighter type. The updated report notes that Mr. Castillo had submitted the updated application, the articles of incorporation, and the policies and procedures. At the time of this visit, a portable dehumidifier had been installed and the humidity level was 38%. Mr. Castillo had recorded the last four days of temperature and humidity, and he had a pest control contract. (Exhibit 3; Rhodes testimony) Photographs taken by Mr. Mather show the portable dehumidifier that was vented out a window. The photos show a few folding tables and folding chairs, a desk and chair, a computer monitor, the plastic cabinet that was to be used to quarantine drugs, and some packaging and mailing supplies. (Exhibit 7)

At this visit, Mr. Castillo provided his previous address in Miami, and he identified his ex-wife as Niurca Lorenzo Perez. He told the compliance officers that his ex-wife would not provide the name of the wholesale drug company that she had worked for because she was under a non-disclosure with her employer. Mr. Castillo refused to provide any other information about his ex-wife. He stated that he had printed off information about the DSCSA but had not yet read it. (Exhibit 2; Rhodes testimony)

Notice of Intent to Deny and Appeal. On August 30, 2017, the Board issued a Notice of Intent to Deny License to Premier Distribution Inc. The Notice of Intent to Deny cites the legal grounds and the factual circumstances that supported the decision, including the fact that Mr. Castillo did not have any experience in the wholesale distribution of drugs or any knowledge of the Drug Supply Chain Security Act. (Exhibit 8) Noel

Castillo appealed the Board's Notice of Intent to Deny on September 26, 2017. His appeal stated that he was contesting the decision based on the fact that he was employing persons who are experienced in wholesale distribution and who have knowledge of the Drug Supply Chain Security Act. (Exhibit 9)

On or about October 12, 2017, the Board received the resume of Mercedes Batista. The resume states, in part, that Ms. Batista received an Associate of Science degree from Miami Dade Community College in 2007 and that she has "advanced understanding of local, state and federal laws pertaining to Healthcare and the Pharmaceutical Industry." Ms. Batista's resume covers a period of ten years and lists her involvement with five different pharmacy related businesses in Florida during that time. According to her resume, Ms. Batista was Co-Owner or Owner of three different pharmacies from 2008 to 2015. Her association with each pharmacy lasted approximately two years. From 2015 to the current time, Ms. Batista's resume states that she was a Health Care Consultant for two different companies. She was with the first company for eight months and has been with the second company for less than two years. (Exhibit 11)

Mercedes Batista represented Premier Distribution Inc. at the appeal hearing and testified that she will be the "designated responsible person" for Premier Distribution Inc. if a license is issued. The day prior to hearing, Ms. Batista traveled to Iowa and saw the proposed facility for the first time. Ms. Batista currently resides in Florida but reports that she will be a full-time employee of Premier Distribution and will move to Iowa when the wholesale drug license is issued. She anticipates that she will be with Premier Distribution Inc. for "about a year." (Batista testimony)

On cross examination, Mercedes Batista testified that her resume was accurate and that it included all of her relevant employment and all of the businesses with which she had been involved. She was then shown a list of corporations from the Florida Secretary of State website that listed Mercedes Batista and was asked if these were her corporations or if she was involved with them. Ms. Batista acknowledged that she had been involved in the past with 11 of the corporations on the list but that she chose not to include them on her resume, either because they were "very old" or because they were not relevant. The eleven corporations included a real estate business, an import/export company, and several healthcare or pharmacy related businesses. (Batista testimony)

The only specific drug wholesale experience claimed by Mercedes Batista was her co-ownership and management of United Care Pharmacy in Miami, Florida from January 2013 to January 2015. Ms. Batista testified that she co-owned this business with Jose Batista (who is not a relative) and further testified that United Care was licensed as a

wholesale distributor in about 2014. She testified that United Care Pharmacy was now closed and had been sold. (Batista testimony; Exhibit 11)

On cross-examination, Ms. Batista was shown documentation from the Florida Secretary of State indicating that Jose Batista was listed on the Articles of Incorporation for United Care Pharmacy in August 2011 and that in 2012, Marlena Fernandez was also listed on the United Care Pharmacy Articles of Incorporation as an owner. Ms. Batista testified that she had no idea who Ms. Fernandez is and that she had never heard of her. Ms. Batista also denied any knowledge of Ms. Fernandez' reported federal drug conviction, which had been related to her work at United Care Pharmacy from August 2013 through June 2014. Mercedes Batista's resume indicates that she was a manager and co-owner of United Care Pharmacy throughout this period of time. (Batista testimony; Exhibit 11)

Ms. Batista testified that she finished her last position as a Health Care Consultant/Project Manager, which was with Serenity Behavioral Health in Hollywood, Florida, in the last week of September 2017. She reports being hired as a consultant for Premier Distribution "about a month ago." She further testified that Noel Castillo found her "by word of mouth" through one of her clients. She first met with Mr. Castillo a couple of weeks earlier when he came to Florida, and she realized that he needed more than a consultant. She testified that Noel Castillo is basically "just the owner" of Premier Distribution and that he would not have any of the operational roles in the business. (Batista testimony)

Mercedes Batista submitted an updated and more detailed (148 pages) version of the Policies and Procedures for Premium Distribution Inc., which she stated that she had created two weeks earlier. When she was questioned about the contents of the document, however, she was unable to explain the meaning of several of its provisions and several acronyms (e.g., GPO, ARC, PSL eligible). (Exhibit A; Batista testimony)

Noel Castillo testified that he moved to Iowa about a year ago and that he had previously lived in Florida for three years.² He did not know anyone in Iowa when he moved here. He admitted that he moved here to open a drug wholesaling business and that he had no personal experience in the drug wholesaling business. He stated that he was interested in the wholesale business because his wife had worked in drug wholesaling for a long time and he "liked the business." Mr. Castillo was unable to recall the name of the wholesale business that his wife had worked for and further

² At the time of the on-site inspection, Mr. Castillo told the compliance officers that he had lived in Florida for four years.

stated that his wife did not want to give him any more information because she did not want to help him out. Mr. Castillo stated that he wanted to open the business in Iowa because there is a lot of competition in Florida. (Castillo testimony)

Noel Castillo is renting his business location from the cleaning business that is located on the first floor of the building. He believed that his lease started in around February and the rent is \$1300 per month. Myra Rubio is his secretary and interpreter and has been his only employee. He testified that Ms. Rubio has been working Monday through Friday from 9AM to 3PM and that he has been paying her for the last eight months. When asked how he was financing the business so far, he testified that he has rental homes and two rental cars in Cuba that are profitable. He acknowledged that he paid his license fee with a money order because he did not have a bank account at the time, but stated he now has a business bank account. He further testified that he had to return to Cuba about two and a half months ago because his son had been in an accident and that he has had to travel back and forth to Cuba about six times. (Castillo testimony)

At the time of his testimony, Mr. Castillo could not recall the name of the company that prepared the initial policies and procedures that he submitted. He does not understand the policies and procedures in English and has to have someone translate them for him. (Castillo testimony)

Noel Castillo admitted that he did not hire anyone with experience in the pharmacy business until about a month ago. When asked how he found Mercedes Batista, he initially responded that he thought it was through a friend. When asked to identify the friend, he then stated that he "just kept asking" and got a response after he "put up an inquiry." He denied that he had been put in touch with Ms. Batista by one of her former clients. Mr. Castillo testified that he originally intended to hire Ms. Batista as a consultant to teach him the "procedures and all that." He further testified that Ms. Batista did not originally intend to move to Iowa but she changed her mind based on the salary that he offered. When asked what salary he offered her, Mr. Castillo was vague and stated that he offered to pay her moving expenses and her rent. He denied that she would have an ownership interest in the business. (Castillo testimony)

As of the date of the hearing, Mr. Castillo's only business plan was to sell "all types of noncontrolled prescription drugs" to "whoever he can sell to." He would like to sell all over the United States. He had not developed any marketing materials or a website. He was unable to identify where he would purchase the drugs and had not contacted any potential suppliers. He did not know how much it would cost to purchase the drugs or how he would obtain customers. (Castillo testimony)

CONCLUSIONS OF LAW

A “wholesaler” means a person or business operating or maintaining, either within or outside of Iowa, a manufacturing plant, wholesale distribution center, wholesale business, or any other business in which prescription drugs, medicinal chemicals, medicines, or poisons are sold, manufactured, compounded, dispensed, stocked, exposed, or offered for sale at wholesale in Iowa.³ A person shall not establish, conduct or maintain a wholesale drug business without a license.⁴ The Board may deny a drug wholesale license for failure to meet the applicable standards.⁵ The legislature has authorized the Board to establish standards for drug wholesale licensure and to adopt rules, pursuant to Iowa Code chapter 17A, on matters pertaining to the issuance of the wholesale drug license.⁶ Pursuant to this authority, the Board has adopted rules governing wholesale drug licenses at 657 Iowa Administrative Code (IAC) chapter 17.

Wholesale drug businesses are highly regulated. The Board’s rules governing licensed wholesalers include requirements pertaining to personnel, responsibility for conduct, distribution to authorized licensees, written policies and procedures, facilities, security, storage, drugs in possession of representatives, returned, damaged and outdated drugs, and record keeping. Wholesalers are required to operate in compliance with applicable federal, state, and local laws, rules and regulations.⁷

657 IAC 17.4 addresses the minimum qualifications for licensing a person or business to engage in the wholesale distribution of prescription drugs and provides, in part, that the board will consider the following factors in determining eligibility for licensure:

3. The applicant’s past experience in the manufacture or distribution of prescription drugs, including controlled substances;
- ...
8. Any other factors or qualifications the Board considers relevant to and consistent with public health and safety.

The Board’s rules also require a wholesaler to employ personnel with education or experience appropriate to the responsibilities of the position to be held by the

³ Iowa Code section 155A.3(46)(2017); 657 IAC 17.1.

⁴ Iowa Code section 155A.17(2017); 657 IAC 17.3.

⁵ Iowa Code section 155A.17(2)(2017).

⁶ Iowa Code section 155A.17(2),(3)(2017).

⁷ 567 IAC Chapter 17.

individual.⁸ Wholesalers are required to establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories.⁹

Based on this record, the Board is not persuaded that Premier Distribution Inc. and its employees will have the knowledge, expertise, or necessary policies and procedures to operate a legitimate wholesale drug distribution business in Iowa. Noel Castillo, who filed the application initially in his own name and then in the name of Premier Distribution, Inc., has no relevant experience in the pharmaceutical business or prescription drug wholesale business. At the time of the site inspection, Mr. Castillo appeared to be entirely unfamiliar with the federal Drug Supply Chain Security Act or with any of the other requirements for operating as a licensed drug wholesaler, including facility and drug storage requirements.

After the application was denied by the Board, Mr. Castillo hired Mercedes Batista as a consultant. The plan is now for Ms. Batista to become a full-time employee and the designated facility manager and responsible person if a license is issued to Premier Distribution Inc. The Board was not persuaded that Ms. Batista has the necessary education or experience to operate a drug wholesale business consistent with all of the state and federal requirements. Although Ms. Batista testified that she personally prepared the updated Policies and Procedures that were submitted for Premier Distribution, she was unfamiliar with a number of key terms and acronyms that appeared in this document.

Ms. Batista's resume indicates that she has been a co-owner of three pharmacies and has worked as a Healthcare Consultant over the last ten years, but she concedes that her only involvement with wholesale drug distribution was from 2014 to 2015 when she was a co-owner of United Care Pharmacy. Ms. Batista's responses on cross-examination concerning that company raised serious concerns about whether she has been forthright in describing her professional background.

The Board finds it highly unusual and inexplicable that Noel Castillo would move to Iowa to operate a very complex prescription drug wholesale business without having any prior relevant experience, without associating with persons who do have relevant experience, and without any business plan. Although he has been in Iowa for nearly a year and has been paying rent and a full time employee for over six months, he has not

⁸ 657 IAC 17.5.

⁹ 657 IAC 17.8.

yet developed any coherent or concrete plan for the scope or operation of his proposed business. Moreover, many of the responses that Mr. Castillo and Ms. Batista provided were simplistic and vague. Based on this record, the Board is unable to conclude that Premier Distribution Inc. is qualified or prepared to operate a prescription drug wholesale business in Iowa in conformance with the Board's statute and administrative rules, in conformance with federal law, and consistent with public health and safety.

DECISION AND ORDER

IT IS THEREFORE ORDERED that the application for a wholesale drug license filed by Premier Distribution Inc. is hereby DENIED.

Dated this 16th day of January, 2018.



Sharon Meyer, Chairperson
Iowa Board of Pharmacy

cc: Laura Steffensmeier, Assistant Attorney General

Any aggrieved or adversely affected party may seek judicial review of this decision and order of the board, pursuant to Iowa Code section 17A.19.

BEFORE THE IOWA BOARD OF PHARMACY

<p>RE: Application for Wholesale Drug License of</p> <p>PREMIER DISTRIBUTION INC., Applicant</p>	<p>NOTICE OF HEARING</p>
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A. TIME, PLACE, AND NATURE OF HEARING

A contested case hearing shall be held on October 31, 2017. The hearing shall begin at 10:00 a.m. and shall be located in the Board conference room located at the Iowa Board of Pharmacy Office, 400 SW 8th Street, Suite E, Des Moines, Iowa, 50309. The contested case hearing will concern whether the Iowa Board of Pharmacy (“Board”) will deny the wholesale drug license application submitted by Premier Distribution Inc. (“Applicant”).

B. LEGAL AUTHORITY AND JURISDICTION

1. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A and 155A (2017).
2. An applicant may appeal a notice of intent to deny a license application within 30 days by filing a written notice of appeal and request for a hearing with the Board, pursuant to 657 IAC 36.16.
3. A hearing regarding a license application denial is a contested case hearing conducted according to the procedures in Iowa Code chapter 17A and 657 IAC chapter 35.

C. FACTUAL CIRCUMSTANCES

1. On August 30, 2017, the Board voted to deny the wholesale drug license application submitted by Applicant and issued a Notice of Intent to Deny License (“Notice”).
2. On August 31, 2017, the Notice was personally served on Applicant. The Notice describes the factual circumstances and legal grounds supporting the Board’s decision to deny the wholesale drug license application submitted by Applicant.
3. On September 26, 2017, the Board received a timely appeal of the Notice from Applicant.

D. HEARING INFORMATION

Filing of Pleadings. Pleadings shall be filed with the Board at the following address: Iowa Board of Pharmacy, 400 SW 8th Street, Suite E, Des Moines, Iowa, 50309.

Presiding Officer. The Board shall serve as presiding officer, but the Board may request an Administrative Law Judge from the Department of Inspections and Appeals make initial rulings on prehearing matters, and be present to assist and advise the Board at hearing. Pursuant to 657 IAC 35.6, any party who wishes to request that an Administrative Law Judge from the Department of Inspections and Appeals serve as the presiding officer assigned to render a proposed decision must file a written request within 20 days after service of this Notice of Hearing.

Prehearing Conference. Any party may request a prehearing conference in accordance with 657 IAC 35.15 to discuss issues related to the hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC chapter 35. At the hearing, you may appear personally or be represented by counsel at your own expense. You will be allowed the opportunity to respond to the factual circumstances and legal grounds cited in the Notice, to produce evidence on your behalf on issues of material fact, cross-examine witnesses present at the hearing, and examine and respond to any documents introduced at the hearing. If you need to request an alternative time or date for the hearing, you must comply with the requirements in 657 IAC 35.16. The hearing will be open to the public.

Prosecution. The Office of Attorney General is responsible for representing the public interest (the State) in this proceeding. Copies of pleadings should be provided to counsel for the State at the following address:

Laura Steffensmeier
Assistant Attorney General
Iowa Attorney General's Office
2nd Floor, Hoover State Office Building
Des Moines, Iowa 50319

Ms. Steffensmeier can also be reached by phone at (515) 281-6690 or by e-mail at laura.steffensmeier@iowa.gov.

Communications. You may not contact individual Board members in any manner, including by phone, letter, or e-mail, regarding this Notice of Hearing. Board members may only receive information about the case when all parties have notice and the opportunity to participate, such as at the hearing or in pleadings you file with the Board office and serve upon all parties in the case.

Issued on September 27, 2017.



Andrew Funk
Board Executive
Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier
Assistant Attorney General
Office of the Attorney General of Iowa
1305 E. Walnut St.
Des Moines, IA 50319
ATTORNEY FOR THE STATE

PLEASE NOTE: If you require the assistance of auxiliary aids or services to participate in this matter because of a disability, immediately call 515-281-5944. (If you are hearing impaired, call Relay Iowa TTY at 1-800-735-2942).

BEFORE THE IOWA BOARD OF PHARMACY

RE:
Application for Wholesale Drug License of

PREMIER DISTRIBUTION INC.,
Applicant

NOTICE OF INTENT TO DENY LICENSE

COMES NOW the Iowa Board of Pharmacy ("Board") and issues this Notice of Intent to Deny License to Premier Distribution ("Respondent"), 801 Ashworth Rd, 2nd Floor, West Des Moines IA 50265, pursuant to Iowa Code sections 17A.17 and 155A.17. This Notice of Intent to Deny License is based on the following:

A. LEGAL GROUNDS

1. Applicants for an Iowa wholesale drug license must apply for a license in accordance with Iowa Code section 155A.17 and 657 IAC chapter 17.

2. The Board has the authority to deny a wholesale drug license for failure to meet the applicable standards. See Iowa Code § 155A.17(2).

3. The board considers the applicant's past experience in the manufacture or distribution of prescription drugs in determining eligibility for licensure. See 657 IAC 17.4(3).

4. A wholesaler shall employ personnel with the education or experience appropriate to the responsibilities of the position held by the individual. See 657 IAC 17.5.

5. A wholesaler shall establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. See 657 IAC 17.8. A wholesaler shall have policies and procedures covering all areas listed in 657 IAC 17.8(1)-(6).

B. FACTUAL CIRCUMSTANCES

1. On March 6, 2017, the Board received a wholesale drug license application from Noel Castillo.

2. In April 2017, Board compliance officers visited the location for an inspection. At that time, the Board learned the name of the wholesaler was Premier Distribution Inc.

3. At the time of the inspection:

a. Mr. Castillo employed only one person as a secretary/interpreter.

- b. Mr. Castillo did not have any experience in the wholesale distribution of drugs or any knowledge of the Drug Supply Chain Security Act.
- c. Applicant lacked the policies and procedures required by 657 IAC 17.8.
- d. The compliance officers learned the name of the wholesaler was Premier Distribution Inc.

4. On April 19, 2017, Mr. Castillo submitted a revised wholesale drug license application in the name of Premier Distribution Inc. Mr. Castillo was listed as the President-Owner.

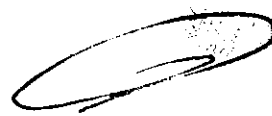
5. Applicant supplied the required policies and procedures, which had been prepared by a third party, at a subsequent visit.

C. APPEAL RIGHTS

1. Pursuant to the provisions of 657 IAC 36.16, you may appeal this Notice of Intent to Deny of license by serving a written notice of appeal and request for hearing upon the Board not more than thirty (30) days following the date of service of this notice. Applicant's written notice of appeal and request for a hearing should be directed to Andrew Funk, Executive Director, Iowa Board of Pharmacy, 400 SW 8th St, Ste E, Des Moines IA 50309. The written notice of appeal and request for hearing shall specifically describe the facts to be contested and determined at the hearing. The hearing shall be a contested case conducted pursuant to the procedures outlined at 657 IAC chapter 35.

2. IF A WRITTEN NOTICE OF APPEAL AND REQUEST FOR HEARING IS NOT TIMELY FILED, THIS NOTICE OF INTENT TO DENY LICENSE WILL BECOME FINAL, AND THE IOWA WHOLESALE DRUG LICENSE APPLICATION SUBMITTED BY PREMIER DISTRIBUTION INC. WILL BE DENIED.

Date issued: August 30, 2017



Andrew Funk
Executive Director
Iowa Board of Pharmacy

Copy to:
Laura Steffensmeier
Assistant Attorney General
Office of the Attorney General of Iowa
1305 E. Walnut St.
Des Moines, IA 50319
ATTORNEY FOR THE STATE