BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

IN THE MATTER OF:	) CASE NO: 2018-123) DIA NOS. 20PHB0001
Nonresident Pharmacy License of	)
EMPOWER PHARMACY License No. 4263 Respondent	))) FINDINGS OF FACT,) CONCLUSIONS OF LAW,) DECISION AND ORDER

On July 9, 2019, the Iowa Board of Pharmacy Examiners (Board) found probable cause to file Statements of Charges against licensed Empower Pharmacy (Empower). The Statements of Charges allege that Empower:

> COUNT I: Violated 657 IAC 20.12 by compounding essentially copies of approved drugs and failing to comply with Board rules for pharmacy compounding.

The hearing was initially scheduled for September 10, 2019 but was later continued six times. The hearing was ultimately held via video conference on March 9, 2021 at 9:00 a.m. The following members of the Board served as presiding officers for the hearing: Janson Hansel, Chairperson, Edward McKenna, Joan Skogstrom, Gayle Mayer, Brett Barker, Kathryn Stone, and Sherill Whisenand. Empower was represented by attorneys, David Brown and Alexander Wonio. Assistant Attorney General Laura Steffensmeier represented the State. The hearing was closed to the public at Empower's election, in accordance with Iowa Code §272C.6(1). Administrative Law Judge Rachel Morgan assisted the Board in conducting the hearing and was later instructed to prepare the Board's written Decision and Order for its review, in conformance with its deliberations.

THE RECORD

The record includes the Notice of Hearing and Statement of Charges. The record also includes hearing testimony of investigator Sue Mears. The State introduced Exhibits 1 through 12, which were admitted as evidence without objection. Respondent entered into evidence an Affidavit from Susan Van Bergen, Empower Employee. Both parties submitted post hearing briefs.

FINDINGS OF FACT

On January 1, 2014, the Board issued nonresident pharmacy license number 4263 to Empower Pharmacy, 5980 W. Sam Houston Pkwy N. Ste 300, Houston, TX 77041. The pharmacy license is current and active. On January 1, 2018, the Board issued an outsourcing facility license to

Empower Pharmacy, license no. 9022. This license is also current and active. At all times material to the Statements of Charges, Jordan Cuccia has been the pharmacist-in-charge at Empower Pharmacy.

On September 6, 2017, the Board enacted rule, 657 Iowa Administrative Code (IAC) 20.12, prohibiting the compounding of drugs which are essentially copies of a Federal Drug Administration (FDA) approved drug. The FDA reviews drugs for safety, effectiveness, and quality. Therefore, drugs that are not approved by the FDA, including compounded drugs, pose a higher risk to patients than FDA-approved drugs. (Ex. 3 at 69).

Empower is charged with dispensing compounded human chorionic gonadotropin (HCG) in a form that is essentially a copy of an FDA approved drug. HCG is dispensed in a powder which is dissolved in bacteriostatic water and injected into a patient. HCG is commercially available and approved by the FDA in the following preparations: 5,000 IU and 10,000 IU. Because HCG requires reconstitution, the commercially available HCG can be prescribed with specific directions for reconstitution to meet different doses as required by specific patients. For example, a 10,000 IU vial can be reconstituted with 1 mL of bacteriostatic water and administered to a patient who needs 10,000 IU of HCG. The same vial can be reconstituted with 10 mL of bacteriostatic water and used for multiple doses for a patient who requires a lower dosage of HCG. Therefore, the commercially available preparations of HCG, 5,000 IU and 10,000 IU, may be used for a variety of patients and doses. (Mears Testimony; St. Ex. at 12, 97-114).

On June 13, 2018, Empower entered into a non-disciplinary agreement with the Board of Pharmacy for the State of Oklahoma following an allegation that it was compounding HCG preparations in 11,000 IU and 5,000 IU that were essentially copies of commercially available products. (St. Ex. at 21-28). After entering into the agreement with the Oklahoma Pharmacy Board, Empower voluntarily reported the agreement to the Board. In response, the Board assigned an investigator to review Empower's practices in Iowa. (Mears Testimony; St. Ex. at 12).

The Board investigator learned that beginning in September 13, 2017 through December 21, 2017, Empower dispensed compounded HCG preparations in 5,000 IU and 11,000 IU preparations to twenty-two Iowa patients. In 2018, sixteen of the twenty-two patients continued to receive compounded HCG preparations. However, the HCG preparations in 2018 were slightly modified. Patients who were receiving HCG 5,000 IU preparations in 2017 instead received HCG 6,000 IU preparation in 2018. Likewise, patients who previously received HCG 11,000 IU preparations in 2017 instead received HCG 12,000 IU preparations in 2018. (Mears Testimony; St. Ex. 2).

The Board's investigator requested prescription records for eight of the sixteen patients who received HCG preparations from Empower in 2018. Specifically, records were requested for two patients who received HCG 11,000 IU in 2017 and 12,000 IU in 2018; and six patients who received HCG 5,000 IU in 2017 to 6,000 IU in 2018.

All the patients who formally received 5,000 IU in 2017 and then received 6,000 IU in 2018, except for one, were prescribed the same dosage of HCG in 2017 and 2018. Despite the fact that the patients' dosages had not changed, Empower dispensed different preparations to the patients for 2017 and 2018. For example, Patient SC was prescribed Prescription #494654 for HCG 5,000 IU in 2017. The drug was to be reconstituted with 5 mL of bacteriostatic water for a dose of 250 IU twice weekly. In 2018, Empower provided the same patient, Patient SC, with Prescription #660152 for HCG 6,000 IU. The patient's dose had not changed; therefore, Empower instructed the patient to reconstitute the drug with 6 mL of bacteriostatic water to dilute it to the dose of 250 IU. (Mears Testimony; St. Ex. 2).

Although Empower provided different preparations to the patients, none of the prescriptions for the six patients had any patient specific documentation as to why the FDA-approved HCG 5,000 IU preparation could not be used by the patient. Rather, some of the prescriptions merely contained a general statement as follows: "The compounded medications above are made at the request of the prescribing practitioner signed below due to a patient specific medical need and the preparation producing a clinically significant therapeutic response compared to a commercial product." (Mears Testimony; St. Ex. 2).

Similarly, the records from the two patients who initially received 11,000 IU and later received 12,000 IU preparations indicate that neither patient had changes to their prescribed dosages of HCG from 2017 to 2018. Rather, both patients were instructed to inject 400 IU twice weekly in both 2017 and 2018. There is no explanation as to why Empower dispensed 11,000 IU preparations in 2017 and 12,000 IU in 2018 to the patients. In addition, neither prescription has any patient specific documentation as to why the FDA-approved HCG 10,000 IU could not be used by the patients. (Mears Testimony; St. Ex. 2).

In light of the fact that it appeared that Empower was compounding and dispensing essentially copies of FDA approved drugs with no patient-specific documentation of a clinically significant change, the Board found probable cause to issue a Notice of Hearing and Statement of Charges on July 9, 2019. Empower was charged with compounding essentially copies of approved drugs in violation of 657 IAC 20.12. (Statement of Charges).

Empower raised several arguments at the hearing and in its post-hearing brief. Initially Empower argues that it did not have proper notice of the charges in violation of its due process rights. In addition, Empower argues that Board rule 657 IAC 20.12 is unconstitutionally vague. Finally, Empower contends that its HCG preparations are not essentially copies of approved drugs because it alters the strength of the product and such alteration is recognized by the FDA as "significant" and "not easily substitutable."

CONCLUSIONS OF LAW

A. DUE PROCESS

1. Board Authority to Rule on Constitutional Challenges

Empower argues that it was not provided with due process because it did not have sufficient notice of the allegations and that the law at issue is vague. The general rule in Iowa is that agencies and their boards can decide as applied constitutional challenges, but not facial challenges. *Shell Oil Co. v. Bair*, 417 N.W.2d 425, 429 (Iowa 1987) ("A fundamental distinction must be recognized between constitutional applicability of legislation to particular facts and constitutionality of the legislation. When a tribunal passes upon constitutional applicability, it is carrying out the legislative intent, either express or implied or presumed. When a tribunal passes upon constitutionality of the legislation, the question is whether it shall take action which runs counter to the legislative intent. We commit to administrative agencies the power to determine constitutional applicability, but we do not commit to administrative agencies the power to determine constitutionality of legislation. Only the courts have authority to take action which runs counter to the expressed will of the legislative body.").

In regards to Empower's vagueness argument, this Board finds that the argument is a facial challenge to the constitutionality of Rule 657 IAC 20.12 and, as such, the argument cannot be decided by this Board. Rather, this Board may only preserve this issue. *See, e.g., McCracken v. Iowa Dept. of Human Services*, 595 N.W.2d 779, 785 (Iowa 1999) ("To preserve constitutional issues for . . . review, a party must raise such issues at the agency level. The party must raise such issues, even though the agency lacks authority to decide constitutional issues."). However, Empower's notice argument constitutes an as applied constitutional challenge and such argument may be addressed by the Board.

2 Proper Notice

The fundamental requirement of due process is the opportunity to be heard "at a meaningful time and in a meaningful manner." *Mathews v. Eldridge*, 424 U.S. 319, 333, 96 S.Ct. 893, 902, 47 L.Ed.2d 18, 32 (1976) (citing *Armstrong v. Manzo*, 380 U.S. 545, 552, 85 S.Ct. 1187, 1191, 14 L.Ed.2d 62, 66 (1965)); *Carr v. Iowa Employment Security Commission*, 256 N.W.2d 211, 214 (Iowa 1977); *Hearth Corporation v. C–B–R Development Co., Inc.*, 210 N.W.2d 632, 637 (Iowa 1973). While these principles are immutable to our jurisprudence, "the full panoply of procedural due process rights is not necessary for an administrative hearing to pass constitutional muster...." *Carr*, 256 N.W.2d at 214.

Under Iowa Code section 17A.12(2)(d), notice to the parties must include:

> [a] short and plain statement of the matters asserted. If an agency of other party is unable to state the matters in detail at the time the notice is served, the initial notice may be limited to a statement of the issues involved. Thereafter upon application a more definite and detailed statement shall be furnished.

However, "[o]rdinarily, all that need to be shown to validate administrative proceedings against persons who participate in a contested case hearing is that they had a reasonable opportunity to know of the claims which affect them and to meet those claims." *Fischer v. Iowa State Commerce Comm'n*, 368 N.W.2d 88, 94 (Iowa 1985).

In this case, Empower received appropriate notice and its due process rights were not violated. Empower argues that it did not have notice of the specific conduct that the State contends violates Board Rule 657 IAC 20.12. However, in the Notice of Hearing and Statement of Charges, the Board states that it is charging Empower with "compounding essentially copies of approved drugs in violation of the requirements of 657 IAC 20.12." The Notice then alleges that Empower shipped HCG in 5,000 IU, 6,000 IU, 11,000 IU, and 12,000 IU preparations to Iowa patients. Per the Statement of Charges, Empower had notice that the Board had concerns that it was compounding essentially copies of HCG to Iowa patients when it dispensed HCG in 5,000 IU, 6,000 IU, 11,000 IU, and 12,000 IU preparations. (Statement of Charges).

Empower also argues that it should have been provided with copies of the specific prescriptions that the Board was concerned about. However, Empower shipped HCG to only 22 Iowa patients in 2017 and sixteen patients in Iowa patients in 2018. The Statement of Charges is clear that the Board is concerned about <u>all</u> the prescriptions dispensed for HCG to Iowa patients during this time period in following preparations: 5,000 IU, 6,000 IU, 11,000 IU, and 12,000 IU. Further, Empower has copies of the prescriptions in its own records. This is not a case where there are thousands of prescriptions at issue and/or Empower did not have access to the documents at issue. Accordingly, contrary to Empower's arguments, it had sufficient notice of the factual basis for the Board's charge that it violated Rule 657 IAC 20.12.

Finally, Empower alleges that it was not certain what law it was being charged with because the Board's investigator referenced a FDA guidance article. This argument is also without merit. The Statement of Charges specifically states that Empower was being charged with violation of Board Rule 657 IAC 20.12. Accordingly, the Board finds that the Statement of Charges provides Empower had sufficient notice and Empower's due process rights were not violated.

B. Violation of 657 IAC 20.2

Iowa Code §155A.13A provides, in relevant part, that the Board may deny, suspend, or revoke a nonresident pharmacy license for any violation of this section or any rules of the Board adopted under this chapter.

657 IAC 20.2 provides the following relevant definitions:

> *"Compounding"* means preparing, mixing, assembling, packaging, and labeling a drug or device for an identified individual patient as a result of a practitioner's prescription drug order or initiative based on the prescriber/patient/pharmacist relationship in the course of professional practice...All compounding, regardless of type of product, is to be done pursuant to a prescription...

Board rule 657 IAC 20.12 provides that a pharmacy or outsourcing facility may only compound preparations that are essentially copies of approved drugs if the compounded preparation is changed to "produce for an individual patient a clinically significant difference to meet a medical need as determined and authorized by the prescriber." Board rule 657 IAC 20.12(1) provides that the Board may consider the following factors as an indication that a compounded preparation is essentially a copy of an approved drug:

a. The compounded preparation has the same active pharmaceutical ingredient(s) as the commercially available drug product;
b. The active pharmaceutical ingredient(s) has the same, similar, or an easily substitutable dosage strength; and
c. The commercially available drug product can be used by the same route of administration prescribed for the compounded preparation.

In addition, Board rule 657 IAC 20.12(2) provides guidance as to when a prescription demonstrates a clinically significant difference. The rule states that a prescription for a compounded preparation that is essentially a copy of an approved drug shall "clearly indicate the relevant change and the significant clinical difference produced for the patient." Further, "a prescription that identifies only a patient name and compounded preparation formulation is insufficient documentation" for a pharmacy to rely upon to conclude that the prescriber made a determination regarding a clinically significant difference. 657 IAC 20.12(2).

The preponderance of the evidence establishes that Empower's compounded HCG is an essential copy of a FDA-approved formulation. As discussed above, Board rule 20.12(1) sets forth three factors that the Board may consider as indications that a compounded preparation is essentially a copy of an approved drug. The first and third factors are undisputed. Empower's compounded HCG formulations and the commercially available products both have the same API-HCG active pharmaceutical ingredient and both are injectable.

In regards to the second factor, whether Empower's HCG and the commercially available HCG have the same, similar, or easily substitutable dosage strength, this factor is also satisfied. Empower argued at the hearing that its HCG preparation is 20% stronger than the commercially available drug products and cites to a FDA guidance article: Compounded Drug Products that are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug and Cosmetic Act dated January 2018 as support for its argument that its HCG compound is not similar to a commercially available product. The 503A Guidance Document provides that the "FDA generally intends to consider two drugs to have a similar dosage strength if the dosage strength of the compounded drug is within 10% of the dosage strength of the commercially available drug product." (St. Ex. 3). However, Empower's argument ignores the fact that HCG powder, unlike other drugs, requires dilution and reconstitution by the end patient. Therefore, although Empower may have provided stronger preparations of HCG to patients than what is commercially available, the patients did not need to receive such a high preparation. In every case, a patient who received Empower's compounded HCG formulation could have had their dosages and needs met by the commercially available HCG product by simply mixing different amounts of the bacteriostatic water with the HCG drug. (State Post-Hearing Brief, Table 2; Exs. C-G). The fact that patients could have their medical

needs met by a commercially available product but instead received unregulated, compounded formulations by Empower is preciously the type of conduct prohibited by Board Rule 657 IAC 20.12. Accordingly, the Board finds that Empower's compounded HCG preparations were essentially copies of commercially available drug products.

Having found that Empower's HCG preparations were essentially copies of commercially available drug products, the Board must determine whether one of the exceptions under Rule 657 IAC 20.12 applies. Rule 657 IAC 20.12 allows essentially copies of commercially available products to be dispensed if the compounded preparation was changed to produce a clinically significant difference to meet a medical need. In this case, Empower has failed to prove that the change in its HCG preparations from 11,000 IU to 12,000 IU and 5,000 IU to 6,000 IU constituted a clinically significant difference to meet a medical need. Indeed, this is not a case where a patient cannot swallow a pill and therefore the medication must be changed to a liquid form. Empower merely provided slightly more HCG and bacteriostatic water than the commercially available products and then instructed the patient to change how he/she dilutes the medication. This is a packaging change; it is not a medically significant difference.

In addition, Empower has failed to provide adequate documentation from a prescriber indicating that the affected patients needed a greater concentration of HCG. Board rule 657 IAC 20.12 requires that a prescription for a compounded preparation that is essentially a copy of an approved drug "clearly indicate" that a change is needed from the commercially available product and identify the "significant clinical difference produced for the patient." None of the prescriptions received have documentation explaining why a change was needed from the commercially available product and how the compounded HCG created a significant clinical difference for the patient. Rather, some of the prescriptions contain a general statement without specific information and some of the prescriptions contain no statement at all. This is not sufficient.

Based on this record, the Board finds that Empower violated Rule 657 IAC 20.12 by compounding essentially copies of approved drugs.

Order

IT IS THEREFORE ORDERED that Respondent Empower Pharmacy, License No. 4263, is hereby CITED for violating Board Rule 657 IAC 20.12 and WARNED that future violations of the laws governing pharmacies will result in further disciplinary action.

IT IS FURTHER ORDERED that Empower shall permanently cease shipping compounded HCG preparations into Iowa.

IT IS FURTHER ORDERED that Empower's nonresident pharmacy license is placed on PROBATION for a period of three years, subject to the following terms:

1. Within thirty days of this Order, Empower shall pay a CIVIL PENALTY in the amount of twenty-five thousand dollars ($25,000). The check shall be made payable to the "Treasurer of Iowa" and shall be deposited in the general fund. The civil

penalty should be mailed to the Iowa Board of Pharmacy, Attn: Amanda Waltz, 400 SW 8th St., Ste E, Des Moines, IA 50309.

2. On a quarterly basis, Empower shall submit a report listing all compounded preparations dispensed to Iowa patients for that quarter, including the prescription number, date, compounded preparation, and patient name. For any preparations that are essentially copies of approved drugs, the report shall include a notation of the clinically significant difference that was necessary to meet the medical need as determined and authorized by the prescriber. Empower shall provide copies of any prescriptions within 72 hours upon request. Empower shall be subject to further disciplinary action for shipping compounded preparations in violation of 657 IAC 20.12.

3. Empower shall ensure the required quarterly reports are submitted to the Board in a timely manner. The quarterly reports are due by March 5th (reporting on December – February), June 5th (reporting on March-May), September 5 (reporting on June – August), and December 5th (reporting on September –November).

4. Empire shall undergo at least one on-site inspection by one or more Board compliance officers while on probation. Empire shall reimburse the Board for the costs associated with any inspection, up to the maximum of five thousand dollars ($5,000) per inspection. Empower shall remedy any deficiencies identified during an inspection within the timeframe provided by the compliance officer.

5. During the probationary period, Empower shall maintain its accreditation through the Pharmacy Compounding Accreditation Board (PCAB), or an equivalent organization as approved by the Board.

6. Empower shall appear before the Board upon request for purposes of evaluating performance of the terms set forth herein during the probationary period. Empower shall be given reasonable notice of the date, time, and place for such appearances.

7. Empower shall abide by all state and federal laws and regulations governing the practice of pharmacy. Empower shall operate in accordance with its policies and procedures.

8. Any documentation required to be submitted to the Board should be emailed to Amanda.Woltz@iowa.gov by the specified deadline unless otherwise directed.

IT IS FURTHER ORDERED, pursuant to 657 IAC 36.10(2), Empire shall pay $75.00 for fees associated with conducting the disciplinary hearing, including the recording fees for the certified shorthand reporter and the cost of the transcript. The check shall be made payable to the "Iowa Board of Pharmacy" and shall be considered repayment receipts. The check should be mailed to the Iowa Board of Pharmacy, Attn: Amanda Woltz, 400 SW 8th St. Ste E, Des Moines, IA 50309.

Dated this 12th day of May, 2021.

Brett Barker
Chairperson, Iowa Board of Pharmacy

cc: Laura Steffensmeier, Assistant Attorney General

A default decision or decision rendered on the merits after a party has failed to appear or participate in a contested case hearing shall become final board action unless within 15 days after the date of notification or mailing of the decision a motion to vacate is filed and served on all parties or unless an appeal of a decision is timely initiated within the time provided by rule 35.26. A motion to vacate must state all facts relied upon by the moving party which establish good cause existed for that party's failure to appear or participate at the contested case proceeding. Each fact so stated shall be substantiated by at least one sworn affidavit of a person with personal knowledge of each such fact, which affidavit(s) shall be attached to the motion. 657 IAC 35.21. The time for further appeal of a decision for which a timely motion to vacate has been filed is stayed pending a decision on the motion to vacate. 657 IAC 35.21(4).

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

RE: Nonresident Pharmacy License of **EMPOWER PHARMACY** License No. 4263 Respondent	CASE NO. 2018-123 **NOTICE OF HEARING AND STATEMENT OF CHARGES**

COMES NOW the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Empower Pharmacy ("Respondent"), 5980 W Sam Houston Pkwy N, Ste 300, Houston TX 77041, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)"e", and 657 IAC 35.6 and 35.7. Respondent's Iowa nonresident pharmacy license number 4263 is currently active through December 31, 2019.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on September 10, 2019, before the Board. The hearing shall begin at 9:00 a.m. and shall be located in the Board conference room located at the Iowa Board of Pharmacy Office, 400 SW 8th St, Ste E, Des Moines IA 50309.

Answer. Within twenty (20) days of the date you are served this Notice of Hearing and Statement of Charges, you may file an Answer pursuant to 657 IAC 35.16. The Answer should specifically admit, deny, or otherwise answer all allegations contained in sections C and D of this Notice of Hearing and Statement of Charges.

Filing of Pleadings. Pleadings shall be filed with the Board either by e-mail, if done in compliance with 657 IAC 35.17(2), to Amanda.Woltz@iowa.gov, or by mail/delivery to the following address: Iowa Board of Pharmacy, 400 SW 8th St, Ste E, Des Moines IA 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.

Hearing Procedures. The procedural rules governing the conduct of the contested case hearing, including prehearing matters, 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 charges against you, 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. The hearing may be open to the public or closed to the public at your discretion, pursuant to Iowa Code section 272C.6(1) and 657 IAC 35.25(10).

Prosecution. The Office of Attorney General of Iowa is responsible for representing the public interest (the State) in this proceeding. Counsel for the State in this matter is Assistant Attorney General Laura Steffensmeier. Ms. Steffensmeier can be reached by phone at (515) 281-6690. Copies of pleadings should be provided to counsel for the State either by email to Laura.Steffensmeier@ag.iowa.gov, or by mail/delivery to the following address:

Laura Steffensmeier
Assistant Attorney General
Hoover State Office Building—2nd Floor
1305 E Walnut St
Des Moines IA 50319

Communications. You may not contact individual Board members in any manner, including by phone, letter, or e-mail, regarding this Notice of Hearing and Statement of Charges. 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 and serve upon all parties in the case.

B. LEGAL AUTHORITY AND JURISDICTION

Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 155A, and 272C (2018).

Legal Authority. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you under Iowa Code chapters 155A, and 272C, and 657 IAC chapter 36.

Default. If you fail to appear at the hearing, the Board may enter a default decision or proceed with the hearing and render a decision in your absence, in accordance with Iowa Code section 17A.12(3) and 657 IAC 35.27.

C. STATEMENT OF CHARGES

COUNT I
COMPOUNDING ESSENTIALLY COPIES OF APPROVED DRUGS

Respondent is charged with compounding essentially copies of approved drugs in violation of the requirements of 657 IAC 20.12, and may be disciplined pursuant to Iowa Code section 155A.13A(5)(d) and 657 IAC 19.11(5) and 36.6(21).

D. FACTUAL CIRCUMSTANCES

1. Respondent's nonresident pharmacy license number 4263 is currently active through December 31, 2019.

2. On June 13, 2018, the Oklahoma State Board of Pharmacy approved an Agreed Order in which Respondent agreed to pay a fine to resolve allegations of compounding commercially available or essentially copies of commercially available FDA-approved drug products.

3. In 2017 and 2018, Respondent shipped human chorionic gonadotropin (HCG) in the following formulations to Iowa patients: 5,000 IU; 6,000 IU; 11,000 IU; and 12,000 IU.

4. FDA-approved HCG is commercially available in 5,000 IU and 10,000 IU formulations.

5. Based on the factors described in 657 IAC 20.12(1), Respondent's HCG preparations are essentially copies of the commercially available products.

6. Respondent's prescription documentation did not clearly indicate the relevant change and the significant clinical difference produced for the patient as required by 657 IAC 20.12(2).

E. SETTLEMENT

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 IAC 35.24. To cancel a scheduled hearing, an executed settlement agreement must be received by the Board at least three (3) business days prior to the scheduled hearing. If you are interested in pursuing settlement in this matter, please contact the Assistant Attorney General identified above.

F. FINDING OF PROBABLE CAUSE

On July 9, 2019, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.

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Chairperson
Iowa Board of Pharmacy

Copies to:

Michael M. Sellers
400 Locust St, Ste 170
Des Moines, IA 50309
ATTORNEY FOR RESPONDENT

Laura Steffensmeier
Assistant Attorney General
Hoover State Office Building—2nd Floor
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).