IN THE COURT OF APPEALS OF IOWA

No. 22-0052
Filed February 8, 2023

EMPOWER PHARMACY,
Petitioner-Appellant,

vs.

IOWA BOARD OF PHARMACY,
Respondent-Appellee.

Appeal from the Iowa District Court for Polk County, Celene Gogerty, Judge.

A pharmacy appeals the denial of its petition for judicial review challenging administrative action of the Iowa Board of Pharmacy. **AFFIRMED.**

David L. Brown and Alexander E. Wonio of Hansen, McClintock & Riley, Des Moines, for appellant.

Brenna Bird, Attorney General, and Laura Steffensmeier, Assistant Attorney General, for appellee.

Heard by Bower, C.J., and Badding and Buller, JJ.

BADDING, Judge.

Empower Pharmacy appeals the denial of its petition for judicial review that challenged adverse administrative action by the Iowa Board of Pharmacy for a violation of Iowa Administrative Code rule 657-20.12, governing compound preparations that are essentially copies of approved drugs. Empower argues the district court erred in determining: (1) the rule is not unconstitutionally vague, (2) it was afforded due process in the administrative proceeding, (3) the Board's decision was supported by substantial evidence, and (4) the sanction levied was appropriate. We affirm.

I. Background Facts and Proceedings

To understand the relatively uncomplicated issues in this disciplinary licensing proceeding, we must first wade into the more complicated world of drug compounding. In pharmacist-speak, "[d]rug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61 (2002); *accord* Iowa Admin. Code r. 657-20.2 ("'Compounding' means the combining, mixing, diluting, pooling, flavoring, or otherwise altering of a drug or bulk drug substance to create a drug."). According to guidance from the Food and Drug Administration (FDA) contained in this agency record,

> Compounded drug products serve an important role for patients whose clinical needs cannot be met by an FDA-approved drug product, such as a patient who has an allergy and needs a medication to be made without a certain dye, an elderly patient who cannot swallow a pill and needs a medicine in a liquid form that is not otherwise available, or a child who needs a drug in a strength that is lower than that of the commercially available product.

That said, the same guidance recognizes compounded drugs "can also pose a higher risk to patients" because those drugs "have not undergone FDA premarket review for safety, effectiveness, and quality."

State and federal regulation of drug compounding has waxed and waned over the years until an incident in 2012, "in which a drug compounding center 'produced contaminated injections that caused a meningitis outbreak, killing more than 60 people and infecting hundreds more.'" *Hope Med. Enters. Inc. v. Fagron Compounding Servs., LLC*, No. 2:19-cv-07748-CAS(PLAx), 2021 WL 4963516, at *4 (C.D. Cal. Oct. 26, 2021) (citation omitted). To improve the "overall quality and safety of compounded drugs following" that incident, Congress passed new legislation in 2013 creating federal regulatory power over compounding firms, consisting of amendments to section 503A (applying to pharmacies) and creating section 503B (applying to a new category of drug makers called outsourcing facilities) of the Food, Drug, and Cosmetic Act. *Id.* at *4–6. Iowa has since enacted its own regulations on compounding, modeled after federal regulations and guidance, which Empower Pharmacy (Empower) is alleged to have violated.

The regulation at issue—Iowa Administrative Code rule 657-20.12—became effective on September 6, 2017.[1] It limits "compound preparations that are essentially copies of approved drugs" unless "the compounded preparation is changed to produce for an individual patient a clinically significant difference to

[1] A shorter version of the rule took effect in November 2015. The addition of subparts (1) and (2) of the rule took effect on September 6, 2017.

meet a medical need as determined and authorized by the prescriber."[2] Iowa Admin. Code r. 657-20.12. Rule 657-20.12(1) sets forth factors the Iowa Board of Pharmacy (Board) may consider "as an indication that a compounded preparation is essentially a copy of an approved drug." If the Board determines the compounded preparation is essentially a copy, the prescription for the preparation "shall clearly indicate the relevant change and the significant clinical difference produced for the patient." *Id.* r. 657-20.12(2).

Empower, whose headquarters are in Texas, is licensed as a non-resident pharmacy in Iowa and several other states, including Oklahoma.[3] In June 2018, Empower consented to the imposition of a $37,200 civil penalty, plus two years of probation, by the Oklahoma Board of Pharmacy for its compounding of human chorionic gonadotropin (HCG).[4] The agreed findings of fact in the order imposing that penalty stated Empower "compounded . . . products that the [Oklahoma] Board alleges are commercially available or essentially copies of commercially available FDA approved drug products under Oklahoma law," namely prescriptions of HCG in 11,000 units per vial and 5,000 units per vial. According to the order, "HCG injection in 5,000 units per vial is commercially available" and "HCG injection in 11,000 units per vial is essentially a copy of the HCG 10,000 units/vial." The order,

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[2] The rule also allows compound preparations that are essentially copies of approved drugs "if the approved drug is identified as currently in shortage on the FDA drug shortages database." This part of the rule is not at issue.

[3] Empower is also licensed in Iowa as an outsourcing facility. *See* Iowa Code § 155A.13C (2018); Iowa Admin. Code r. 657-41.3. This proceeding only involves Empower's pharmacy license.

[4] HCG is an FDA-approved, commercially available, and prescription-only drug used to treat fertility issues in women and hormonal issues in men. It is also used for weight loss, though that use has not been approved by the FDA.

which deferred disciplinary action against Empower pending completion of probation, noted Empower "neither admitted nor denied violating" applicable Oklahoma law.

Empower immediately notified the Board of the agreed order in Oklahoma although, in doing so, it asserted that its conduct complied with FDA guidance and inspections. Even so, Empower told the Board that once it was "made aware that Oklahoma considered the products essential copies, Empower immediately ceased compounding them." Upon receiving this notification from Empower, an investigation was opened by Board compliance officer and licensed pharmacist, Sue Mears.

During her investigation, Mears reviewed dispensing records from September 6, 2017, the date rule 657-20.12 became effective, through the end of calendar year 2017. She learned that during that timeframe, Empower dispensed the same formulations of HCG that were the subject of the Oklahoma order—5000 and 11,000 units per vial—to twenty-two Iowa patients. While Empower supposedly ceased compounding these formulations after the Oklahoma non-disciplinary action, it continued to dispense "slightly modified" formulations of HCG to sixteen of those twenty-two patients in Iowa throughout 2018. Specifically, "[p]atients previously receiving an HCG 5,000 IU formulation instead received an HCG 6,000 IU formulation in 2018. Likewise, patients previously receiving an HCG 11,000 IU formulation instead began receiving an HCG 12,000 IU formulation in 2018."

In late 2018 and early 2019, the Board requested prescription records from Empower. In reviewing the first batch of information, Mears concluded there were

"nine prescriptions which could potentially be considered essentially copies of approved products." Not one of those prescriptions, according to Mears, "contained patient-specific documentation for why the compounded medication was being prescribed when an FDA-approved product would have been available," which "indicate[s] the pharmacy does not routinely ensure such patient-specific documentation is provided on such prescriptions as required by board rules." Exhibit E of the investigative report shows that four of these prescriptions were for HCG. The bottom of the first prescription provides the following language:

> The compounded medications listed are made at the request of the prescribing practitioner whose signature appears above due to the medical need of a specific patient and the preparation is prescribed because the practitioner has determined that the preparation will produce a clinically significant therapeutic response compared to a commercially[5]

The third prescription provides a similar notice; the second and fourth do not.

The Board requested a second batch of prescription records to assess Empower's "dispensing of HCG formulation following the Oklahoma order." This included records for eight of the sixteen patients who continued to receive HCG from Empower in 2018 in slightly different formulations. A review of the records disclosed that "none of the prescriptions provided patient-specific documentation for the need for the compounded formulation instead of an FDA-approved formulation." Exhibits F and G of the investigative report show this batch of records included sixteen prescriptions for HCG, eight of which included a boilerplate

[5] If there was any other language, it was cut off at the bottom of the page. The third prescription, discussed next, has "available product" at the end of its notice.

notification on a clinically significant difference, and eight of which included no such notification.

In February 2019, Mears advised Empower of what her investigation had disclosed and requested the pharmacy

> to provide a response to [its] lack of patient-specific documentation on each prescription for a compounded preparation which is essentially a copy of an approved drug as well as the pharmacy's reason or justification in asserting that it has discontinued production of a formulation when, in reality, it has continued production of essentially the same formulation . . . just in a different volume.

In its response, Empower stated it had not been disciplined for its compounding by any other states and the compounds complied with FDA guidance and inspections. It then asserted that it

> does not believe that its compounded formulations are in fact "essentially copies" or "copies" of approved or otherwise commercially available drugs. Specifically, the active pharmaceutical ingredients in the products that Empower compounds do not have the same, similar or easily substitutable dosage strength as the approved drug product that is commercially available.

Yet Empower's own "account setup form" for prescribers listed its formulations of HCG on its "essential copy list" of FDA-approved products.

In July 2019, the Board issued a statement of charges and notice of hearing against Empower for one count of "compounding essentially copies of approved drugs," in violation of Iowa Administrative Code rule 657-20.12. The statement of charges included these facts:

> 3. In 2017 and 2018, [Empower] shipped [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), [Empower's] HCG preparations are essentially copies of the commercially available products.
>
> 6. [Empower'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).

After several continuances, a hearing before the Board was held in March 2021. Mears was the sole witness at the hearing, and several exhibits were admitted. Through this evidence, the Board learned that FDA-approved formulations of HCG come in multi-dose vials of 5000 and 10,000 volume units in a powder form. Mears explained that patients who use HCG mix the powder "with a diluent . . . to create a solution that then they can withdraw the amount for the dose and inject it." Mixing the HCG powder with the diluent to reach the desired dosage for injection is called reconstitution.

On whether Empower's preparations of HCG in 5000, 6000, 11,000, and 12,000 units are essentially copies of the commercially available product, rule 657-20.12(1) provides:

> The board may consider the existence of 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 as prescribed for the compounded preparation.

As to the first and third factors, Mears testified Empower's compounded formulation has the same active pharmaceutical ingredient as the commercially available HCG and both are administrated through injection. For the second factor,

Mears explained how the dosage of Empower's compound, when properly reconstituted and regardless of the units per vial, also has the same dosage strength as the commercially available drug.[6] She added that Empower's assertion that its dosage was different was incorrect because they changed both the amount of powder and diluent provided, which would not result in a change of the dosage strength.

Following the hearing, the parties submitted written closing arguments. The State argued Empower compounded essential copies of an approved drug and did not meet either exemption provided in rule 657-20.12. As a result of the violation, the State recommended formal citation, warning, a civil penalty, and probation. In its brief, Empower argued for the first time that "the State failed to provide due process with lack of proper notice" because it was unaware of what conduct the Board considered a violation of the rule. Second, Empower argued rule 657-20.12 "is unconstitutionally vague" because it only provides that the Board "may" consider certain factors in determining whether a compound is an essential copy. Lastly, Empower argued "the State failed to prove a violation by a clear preponderance of the evidence."

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[6] Using Empower's compound preparation of HCG in 6000 units as an example, Mears testified that if it was reconstituted with six milliliters of bacteriostatic water, as one of the prescriptions directed, the resulting concentration "would have been 6,000 units of drug within the six milliliters of liquid solution, so 1,000 units per milliliter." That particular patient was to inject "[p]oint five milliliters," or "500 units," which, as Mears explained, could be achieved using the commercially available 5000-unit vial: "They would have reconstituted it with five milliliters of their diluent and then still injected a half a milliliter of the resulting solution to get their 500-unit dose."

In its ruling, the Board rejected Empower's as-applied due process claim, finding it had sufficient notice about what conduct was alleged to be in violation of the administrative rule. The Board preserved Empower's facial constitutional vagueness claim for judicial review. As to the rule violation itself, the Board found "Empower's compounded HCG is an essential copy of a[n] FDA-approved formulation." After finding the first and third factors in rule 657-20.12(2) were undisputed, the Board rejected Empower's argument under the second factor "that its HCG preparation is 20% stronger than the commercially available drug products." The Board explained that

> 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. . . . The fact that patients could have their medical needs met by a commercially available product but instead received unregulated, compounded formulations by Empower is preci[sely] the type of conduct prohibited by [rule 657-20.12].

The Board also found Empower did not meet the exception that authorizes compounding of essential copies to produce a clinically significant difference to meet a medical need and did not meet the documentation requirements of rule 657-20.12(2). For the violation, Empower received a citation and warning, was ordered to "cease shipping compounded HCG preparations into Iowa," placed on three years of probation, and assessed a civil penalty of $25,000.

Empower petitioned for judicial review. In its ruling denying the petition, the district court rejected Empower's claims that the administrative rule is

unconstitutionally vague, its due process rights were violated, the Board's determination was not supported by substantial evidence, and the sanctions were unreasonable. Empower appeals, raising these same claims.

II. Standard of Review

"Judicial review of agency decisions is governed by Iowa Code section 17A.19" (2021). *Brakke v. Iowa Dep't of Nat. Res.*, 897 N.W.2d 522, 530 (Iowa 2017) (citation omitted). The district court acts in an appellate capacity in judicial-review proceedings. *Iowa Med. Soc'y v. Iowa Bd. of Nursing*, 831 N.W.2d 826, 838 (Iowa 2013). On appeal, this court "appl[ies] the standards of section 17A.19(10) to determine if we reach the same results as the district court." *Brakke*, 897 N.W.2d at 530 (citation omitted). If so, "we affirm; otherwise, we reverse." *Des Moines Area Reg'l Transit Auth. v. Young*, 867 N.W.2d 839, 842 (Iowa 2015) (citation omitted). Relief in a judicial-review proceeding is appropriate only "if the agency action prejudiced the substantial rights of the petitioner and if the agency action falls within one of the criteria listed in section 17A.19(10)(a) though (n)." *Brakke*, 897 N.W.2d at 530.

III. Analysis

A. Vagueness

For its first claim on appeal, Empower argues "the district court erred in determining Iowa Administrative rule 20.12 is not unconstitutionally vague." *See* Iowa Code § 17A.19(10)(a) (allowing for relief when agency action is "based upon a provision of law that is unconstitutional on its face or as applied"). The vagueness doctrine is a concept of due process and is rooted in the "rough idea of fairness." *Sloman v. Bd. of Pharmacy Exam'rs*, 440 N.W.2d 609, 611 (Iowa 1989).

> A statute[7] offends the Due Process Clause if it does not give a person of ordinary intelligence a reasonable opportunity to know what is prohibited so that he may act accordingly. It meets the constitutional test if the meaning of the words used can be fairly ascertained by reference to similar statutes, other judicial determinations, reference to the common law, to the dictionary, or if the words themselves have a common and generally-accepted meaning.

Id. (quoting *Miller v. Iowa Real Est. Comm'n*, 274 N.W.2d 288, 291 (Iowa 1979)). However, "[a] presumption of constitutionality exists that must be overcome by negating every reasonable basis on which the statute can be sustained." *Devault v. City of Council Bluffs*, 671 N.W.2d 448, 451 (Iowa 2003).

Notably, the administrative rule at issue is civil—rather than criminal—in nature. "Although the presumption of validity is operable in both criminal and civil statutes, the relevant test of vagueness differs." *Miller*, 274 N.W.2d at 291. When considering civil statutes, "the test for vagueness is less stringent: 'Even if more specific language could be devised, it is apparent the absence of criminal sanctions requires less literal exactitude to comport with due process; unless the statute clearly, palpably and without doubt infringes the constitution it will be upheld.'" *Sloman*, 440 N.W.2d at 611 (quoting *Miller*, 274 N.W.2d at 292). "[I]n the field of regulatory statutes governing business activities, where the acts limited are in a narrow category, greater leeway is allowed." *Id.* (quoting *Papachristou v. City of Jacksonville*, 405 U.S. 156, 165 (1972)).

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[7] While most analyses on vagueness reference statutes, the same analysis has been applied to administrative regulations. *See, e.g.*, *Fisher v. Iowa Bd. of Optometry Exam'rs*, 510 N.W.2d 873, 873 (Iowa 1994) (applying same analysis to "statutory and administrative rule language"); *Eaves v. Bd. of Med. Exam'rs*, 467 N.W.2d 234, 236 (Iowa 1991) (same); *Butt v. Iowa Bd. of Med.*, No. 12-1118, 2013 WL 2637283, at *15 (Iowa Ct. App. June 12, 2013) (applying statutory vagueness framework to administrative rule).

With this tough row to hoe, Empower begins its vagueness challenge by quoting the factors in rule 675-20.12(1) that the Board "may" consider in determining whether a compounded preparation is essentially a copy of an approved drug and then arguing, "there remains considerable vagueness about not only what is prohibited by [the] [r]ule, but equally under what conditions the exemptions are satisfied." But Empower does not expound on *how* the rule is vague in relation to these claims. And the pharmacy's own documentation classified its compounded preparations of HCG as essentially copies of the approved drug showing, as the Board argues, that Empower "was perfectly capable of determining whether its compounded products were essentially copies"—an issue that is not meaningfully disputed on appeal.

Empower next argues the rule is vague because the first part of rule 675-20.12(2), governing "clinically significant difference," "could be read to require a detailed explanation, of unlimited length, expressly contained in the prescription itself." That subrule is not so complicated, requiring only that the "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." Iowa Admin. Code r. 675-20.12(2). Though Empower argues these requirements are ambiguous, the examples given in the FDA guidance for compliance with the comparable federal requirements show they can easily be met with simple notations on the prescription like, "'No Dye X, patient allergy' (if the comparable drug contains the dye)" or "[l]iquid form, patient can't swallow tablet' (if the comparable drug is a tablet)." And the subrule goes on to detail what is *not* sufficient documentation: "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." *Id.*

Empower has not explained how these requirements are so inexact that they "clearly, palpably and without doubt" infringe the constitution. *Sloman*, 440 N.W.2d at 612 (citation omitted). Instead, the pharmacy suggests it was in "substantial compliance" with rule 675-20.12(2) because it secured more than just a patient name and compounded preparation formulation from its prescribing providers, pointing to the blanket certification on some of the prescriptions "that the preparation will produce a clinically significant therapeutic response" "due to the medical need of a specific patient." But Empower's claimed "substantial compliance" with the rule has no bearing on whether the statute is vague. *Cf. Dix v. Casey's Gen. Stores, Inc.*, 961 N.W.2d 671, 682 (Iowa 2021) (discussing substantial compliance in determining whether a statute has been violated). Even if it did, only a few of the prescriptions for Empower's compounded preparations of HCG contained that general certification. The rest had nothing beyond the patient's name and compounded preparation formulation, which Empower acknowledges is insufficient documentation under the rule.

As a result, rule 675-20.12 cannot be considered vague as applied to Empower, meaning that Empower lacks standing to lodge a facial challenge since the rule is constitutional as applied to it.[8] *See Garren*, 620 N.W.2d at 285. For these reasons, we reject Empower's vagueness challenge.

[8] There are exceptions to this standing rule, but like the appellant in *In re Detention of Garren*, Empower does not address how it falls within one of those exceptions.

B. Due Process

Next, Empower claims "the district court erred in finding due process mandates were met in the [administrative] proceeding." *See Aluminum Co. of Am. v. Musal*, 622 N.W.2d 476, 479 (Iowa 2001) ("[P]arties to administrative agency proceedings are entitled to due process of law."). The pharmacy argues the charging document did not provide it with sufficient notice of the pending charge or an opportunity to prepare a defense because the document "cited one lone alleged violation of the [rule], yet [the Board's] submitted evidence included scores of prescriptions." Empower contends it is still unaware which of the prescription documents violated the rule. Setting aside the error-preservation concerns raised by the Board, *see State v. Taylor*, 596 N.W.2d 55, 56 (Iowa 1999), we conclude Empower's due-process challenge fails on its merits.

A contested case is initiated by a notice that includes (1) the time, place, and nature of the hearing; (2) a statement of legal authority and jurisdiction; (3) a reference to rules involved; and (4) "[a] short and plain statement of the matters asserted." Iowa Code § 17A.12(2). "[T]he initial notice may be limited to a statement of the issues involved"; a statement of matters in detail is not required, and the adverse party is only entitled to a more definite and detailed statement *upon application*. *Id.* § 17A.12(2)(d). As to the detail required, Iowa Administrative Code rule 657-35.7 only mandates that the statement of charges "be in sufficient detail to enable the preparation of the respondent's defense."

See 620 N.W.2d 275, 285 (Iowa 2000). So we apply the general rule and hold Empower lacks standing to make a facial attack. *See id.*

The charging document—which came after the conclusion of Mears's investigation and her notification to Empower of her findings—met these requirements by setting out the specific drug, compounded preparations, applicable rule, and timeframe of the alleged violations, which were entirely based on documents provided to the Board by Empower. We accordingly agree with the district court that Empower was provided with notice and an opportunity to defend, which is all that is constitutionally required. *See Musal*, 622 N.W.2d at 479 ("The two fundamental principles of due process are (1) notice and (2) the opportunity to defend."). To the extent Empower implies it was on notice of just one potential prescription being in play because only one count was charged, the charging document was clear that multiple formulations of HCG prescriptions in two different calendar years were at issue. We accordingly affirm the court's conclusion that Empower was afforded due process.

C. Sufficiency of Evidence

This brings us to Empower's claim that the district court erred in concluding the Board's decision is supported by substantial evidence. *See* Iowa Code § 17A.19(10)(f) (allowing relief on judicial review when agency action is "[b]ased upon a determination of fact clearly vested by a provision of law in the discretion of the agency that is not supported by substantial evidence in the record before the court when that record is viewed as a whole"). But while the issue heading is captioned as a substantial-evidence challenge, Empower mainly complains that the Board provided insufficient reasons for its conclusions. *See id.* § 17A.16(1) ("Each conclusion of law shall be supported by cited authority or by a reasoned opinion."). Specifically, the pharmacy argues the Board, and district court by

extension, did not identify "what compounded prescription (patient, prescription, and prescribing provider) violated the [r]ule."

"The requirement that the [Board] explain [its] decision is not intended to be onerous . . . ." *Schutjer v. Algona Manor Care Ctr.*, 780 N.W.2d 549, 560 (Iowa 2010). There need only be enough detail to show the path the agency has taken through the evidence, and "the law does not require the [Board] to discuss each and every fact in the record and explain why or why not [it] has rejected it. Such a requirement would be unnecessary and burdensome." *Id.* (citation omitted). An agency's "duty to furnish a reasoned opinion [is] satisfied if it is possible to work backward . . . and to deduce what must have been the agency's legal conclusions." *Bridgestone/Firestone v. Accordino*, 561 N.W.2d 60, 62 (Iowa 1997) (cleaned up).

Factually, the Board found that Empower dispensed essential copies to twenty-two Iowa patients between the effective date of rule 675-20.12 and the end of 2017, and Empower continued to dispense slightly modified essential copies to sixteen of those patients in 2018. As to its conclusions of law, the Board determined (1) the compounded HCG preparations Empower sent to Iowa patients were essential copies; (2) Empower did not meet the exemption for a clinically significant difference; and (3) even if it had, it did not meet the documentation requirements of the rule. Based on these conclusions, the Board found Empower violated the rule.

In making these findings of fact and conclusions of law, the Board had before it exhibits C through G of Mears's investigative report, which the district court relied on in concluding the Board's decision is supported by substantial evidence. All of those exhibits, along with other evidence, were relevant to and

supportive of the Board's first conclusion, that Empower's HCG preparations were essential copies. Exhibits E through G show Empower dispensed twenty prescriptions among twelve Iowa patients in late 2017 and throughout 2018, half of which included a clinically significant difference notification the Board found to be insufficient to meet the rule, and the other half of which included no notification at all. These exhibits were key to the Board's second and third conclusions on whether the exemption applied and whether Empower met the documentation requirements.

Working backward and applying our powers of deduction, it is not hard to surmise that the Board found Empower violated the rule in relation to the twenty prescription documents for HCG that the Board had before it. That is because the Board could not have reached its conclusions on clinically significant difference and documentation deficiencies without those exhibits. While Empower complains the Board did not pinpoint what specific prescriptions were violations, it points to nothing requiring the Board to do so. The State charged only one count of a violation, and the Board found the State met its burden to prove one count. In our view, the overall conclusion that Empower violated the rule was sufficient and supported by substantial evidence.

D. Sanction

Finally, Empower claims "the district court erred [in] approving the sanction levied." Focusing on the civil penalty of $25,000, the pharmacy identifies lesser sanctions in other cases decided by the Board "despite much more egregious conduct" and submits the "severe sanction imposed by the Board in this case is

unreasonable, unfair, and not in line with prior precedent established by the Board."[9]

On judicial review, the district court did not find the sanctions imposed in other cases to be instructive and chose to defer to, rather than second guess, the Board's sanction. We agree with this approach. As our supreme court stated in another pharmacy case:

> We have previously noted the limited scope of judicial review of sanctions imposed by administrative agencies. When a licensing board is made up of members of the profession they are licensing, the court should not second guess the board's decision as to the appropriate sanction. The pharmacy board is primarily constituted of pharmacists, and we see no basis in the record to depart from this sound rule.

Houck v. Iowa Bd. of Pharmacy Exam'rs, 752 N.W.2d 14, 21 (Iowa 2008) (cleaned up).

Given the broad authority afforded to a professional licensing board to impose sanctions against those it licenses, the deference afforded to that decision, and the evidence before the Board, we cannot say the sanction imposed was

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[9] We note these other Board cases Empower relies on in making this argument are not part of the record before us, though they are described by the parties in their briefs. While we could hunt for the cases on our own, it would be a better practice for the litigants to provide the district court with copies so that they are included in the appellate record. *See* Iowa R. App. P. 6.801 ("Only the original documents and exhibits filed in the district court case from which the appeal is taken, the transcript of proceedings, if any, and a certified copy of the related docket and court calendar entries prepared by the clerk of the district court constitute the record on appeal.").

Furthermore, at oral argument, the State explained the only thing that would be available to us on the matters Empower cites would be the final orders embodying settlement agreements that are posted on the Board's website, which we have confirmed. *See State v. Washington*, 832 N.W.2d 650, 656 (Iowa 2013) (denying a request on appeal to take judicial notice of sentencing orders in misdemeanor cases where the filings did "'not tell the full story' behind each sentence imposed").

unreasonable as "against the manifest weight of the evidence" or "shockingly unfair." *See Burns v. Bd. of Nursing*, 528 N.W.2d 602, 605 (Iowa 1995) (citations omitted) (discussing cases from other jurisdictions). We accordingly affirm the decision of the district court.

IV. Conclusion

We affirm the district court's denial of Empower's petition for judicial review, finding the rule is not unconstitutionally vague, Empower was afforded due process, substantial evidence supports the Board's decision, and the sanction imposed was not an unreasonable abuse of discretion.

AFFIRMED.