



## PROCEDURAL FINDINGS

1. On April 10, 2020, OSHPD assessed a penalty against Appellant in the amount of \$96,000 for its delinquent Wholesale Acquisition Cost (“WAC”) Increase Quarterly Reports.
2. Appellant appealed the penalty by submitting a Request for Administrative Hearing form dated April 29, 2020 and received by the OSHPD Hearing Office on May 4, 2020.
3. Appellant submitted its appeals within the required thirty days from the date of the penalty notice.<sup>1</sup>
4. The hearing was scheduled more than 60 days from receipt of the appeal due to the hearing officer being on military leave for COVID-19 response. No party objected to the scheduling of the hearing.
5. The hearing was held electronically at the election of the Hearing Office. No party objected to an electronic hearing.
6. OSHPD submitted written exhibits to the Hearing Office and Appellant in advance of the hearing in a timely manner. Exhibits 1 through 9 were found to be authentic and relevant and admitted to the record.
7. Appellant did not submit written exhibits to the Hearing Office and OSHPD in advance of the hearing.

## FACTUAL FINDINGS

1. Appellant was required under Health and Safety Code section 127679 to file two WAC Increase Quarterly Report for the drug prochlorperazine by Friday, January 31, 2020.<sup>2</sup> Penalties accrued from February 1, 2020 until March 19, 2020 when the reports were filed.
2. In accordance with Health and Safety Code section 127679, subsection (e), OSHPD staff assessed penalties in the amount of \$1,000 per day for 48 days for each report, resulting in a total

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<sup>1</sup> Health & Saf. Code, § 127681(f).

<sup>2</sup> See also Cal. Code Regs., tit. 22, § 96071.

penalty amount of \$96,000.<sup>3</sup> These facts were substantiated both by oral statements made under oath by Mr. Christensen at the hearing and written exhibits.

3. Under Health and Safety Code section 127679, subsection (f), a penalty may “be reviewed on appeal, and the penalty may be reduced or waived for good cause.”

4. Appellant submitted a written statement with its appeal and made oral statements of facts it believes show good cause why its reports were not submitted in a timely manner. Appellant stated that they initially believed they did not need to report the WAC Increase for prochlorperazine because it was below the statutory cost threshold. Appellant stated that it has always tried to comply with reporting requirements as demonstrated by its registering with the CTRx Program on or around May 2, 2019 in anticipation of future reporting requirements. Appellant repackages this drug for hospital use and received notice from the original manufacturer that their WAC price was increasing and thus Appellant was forced to raise its WAC price due to the manufacturer raising its WAC price. Appellant initially considered not purchasing and repackaging the drug due to the WAC increase of the manufacturer. In or about January 2020, shortly before the report was due, Appellant made the decision to keep the drug due to the need for repackaging for hospital use.

5. In or about February 2020, after the WAC Increase Quarterly Report was already past due, Appellant purchased more of the drug in the two dosages for repackaging. Because Appellant repackages the drug for supervised courses of therapy, they are not selling to consumers. This repackaged drug is typically dispensed in hospitals in small and short courses of therapy, for example, one or three tablets. Appellant typically tracks the price as a unit price, not 30-day course of therapy price, and Appellant testified that this made them unsure about whether they had to report the WAC increase at all because that cost is below the statutory threshold when calculated for a short term course of therapy. In or about early March 2020, a newly hired contractor for Appellant, Prescription Analytics, Inc., reviewed all recent drug releases and cost increases to determine if Appellant was in compliance with various state laws, including California. Prescription Analytics, Inc. recommended that Appellant report the WAC

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<sup>3</sup> Health & Saf. Code, § 127679. *See also* Cal. Code Regs., tit. 22, § 96080.

increase as the 30-day course of therapy cost is over the CTRx reporting threshold, even though the typical hospital course of therapy does not exceed the threshold. Appellant's responsible party immediately began working on the report and submitted the report on or about March 19, 2020. These facts were substantiated by oral statements made under oath by Ms. Hoffman and Mr. LaJoice at the hearing.

6. As OSHPD's Exhibit 6 shows, the cost for a bottle containing 50 of the 5 mg tablets after the WAC Increase is a mere \$67.14, putting the cost of single dose at \$1.34. A course of therapy which is only three tablets would cost \$4.02, well under the cost reporting threshold of \$40. However, a 30-day course of therapy would cost over \$40. Due to the fact that the drug can be prescribed both under and over the reporting thresholds, Appellant described this drug report as a "grey area."

7. No facts were disputed, and the statements of both parties were not rebutted.

8. OSHPD's representative confirmed that Appellant has filed its subsequent New Drug report timely.

## DISCUSSION AND LEGAL CONCLUSIONS

1. The issue here is whether Appellant had good cause, as required by Health and Safety Code section 127679, for failing to file the AvKARE, Inc. WAC Increase Quarterly Reports for prochlorperazine by February 1, 2020 and whether the penalty should be waived in whole or in part.

2. In *Waters v. Superior Court*, the California Supreme Court stated that, "good cause may be equated to a good reason for a party's failure to perform that specific requirement from which he seeks to be excused."<sup>4</sup> Good cause must be directly related to the specific legal requirement

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<sup>4</sup> *Waters v. Super. Ct. of Los Angeles County* (1962) 58 Cal2d 885, 893 (hereafter *Waters*).

which the party failed to perform and should be outside the reasonable control of the party.<sup>5</sup> Good cause is sometimes defined as circumstances beyond the party's control, and not related to the party's own negligent act or failure to act. On an individual basis, courts and administrative bodies have often found that hospitalization, incapacitation, accident involvement, or loss or unavailability of records may constitute good cause.<sup>6</sup> However, good cause is not limited to the listed reasons. In civil actions, a mistake can constitute good cause under some circumstances. This excusable neglect must be honest and reasonable.<sup>7</sup>

3. The substantiated facts demonstrate that Appellant made a good faith effort to comply with the law by registering with OSHPD on or about May 2, 2019 even though they had no upcoming reports to file. The substantiated facts also demonstrate that Appellant made a mistake interpreting law about whether the WAC increase was over the statutory cost threshold of \$40 for a "course of therapy" requiring a WAC Increase Notice and subsequent quarterly report.<sup>8</sup> This mistake is supported by credible testimony under oath and no conflicting facts or testimony were presented. Therefore, the mistake was honest. The question then becomes whether the mistake was reasonable.

4. The substantiated facts showed Appellant's confusion related to the term "course of therapy" in the statute which is defined as either of the following:

- (1) The recommended daily dosage units of a prescription drug pursuant to its prescribing label as approved by the federal Food and Drug Administration for 30 days.

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<sup>5</sup> *Waters, supra*, 58 Cal.2d 885,893 and Secretary of State, "Good Cause" Reasons for Waiving Late Campaign & Lobbying Filing Fees <https://www.sos.ca.gov/campaign-lobbying/good-cause-reasons-waiving-late-campaign-lobbying-filing-fees/> [as of December 4, 2019].

<sup>6</sup> Fair Political Practices Commission, Guidelines for Waiving Late Fines (Nov. 2017) <http://www.fppc.ca.gov/content/dam/fppc/NS-Documents/TAD/FilingOfficer/700FO-Folder/Late%20Fine%20Guidelines.pdf> [as of November 2, 2020]. See also *Waters, supra*, 58 Cal.2d 885, 893.

<sup>7</sup> Black's Law Dict. (8<sup>th</sup> ed. 2004), p. 1601. See also Code Civ. Pro., §473.

<sup>8</sup> Health & Saf. Code, §§ 127677, 127678.

(2) The recommended daily dosage units of a prescription drug pursuant to its prescribing label as approved by the federal Food and Drug Administration for a normal course of treatment that is less than 30 days.<sup>9</sup>

The substantiated facts show that patients often receive one to three tablets in a supervised course of therapy which falls under subsection (a)(2) above. However, outside of a hospital setting, a patient could be prescribed a longer course of therapy which falls under subsection (a)(1). The substantiated facts also show that the cost as calculated for subsection (a)(1) does exceed the reporting threshold. Due to the nature of the course of therapy which repackaging is designed for, it appears reasonable that confusion could have resulted over the definition of course of therapy and which definition applied and thus caused confusion over whether the cost threshold was met. OSHPD staff did not object to Appellant's characterization of the course of therapy as a grey area or present facts or testimony which demonstrated that Appellant's claim of confusion is unreasonable. Finally, Appellant acted in good faith and chose to err on the side of reporting and filed the reports in good faith, even knowing that it may incur a penalty for doing so. The substantiated facts show that the mistake was also reasonable.

5. The substantiated facts meet the typical showing of good cause. Therefore, Appellant met the burden of showing good cause for waiver of the penalty assessed.

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<sup>9</sup> Health & Saf. Code, § 127677(a).

PROPOSED ORDER

The assessed penalty is waived for good cause.

Dated: December 9, 2020

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MICHELLE CHURCH-REEVES  
Attorney, Hearing Officer  
Office of Statewide Health Planning and  
Development

**DECISION**

Pursuant to California Code of Regulations, Title 22, Section 96087, after due consideration of the record, the Proposed Decision is:

Accepted

Rejected

Dated: 1/15/2021

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ELIZABETH LANDSBERG  
Director  
Office of Statewide Health Planning and  
Development