

Associate Director Government Compliance and Pricing and Contracts, Cheyenne Cook,
Director of State Government Affairs.

Both documentary and testamentary evidence was received. The matter was submitted for decision and the record was closed on Thursday, October 8, 2020, at 1:53 p.m. PDT.

PROCEDURAL HISTORY

The following findings of procedural facts were made by the Hearing Officer and are adopted by the Director.

1. On May 22, 2020, OSHPD assessed a penalty against Appellant in the amount of \$28,000 for its two delinquent quarterly Wholesale Acquisition Cost (“WAC”) Increase Reports.
2. Appellant appealed the penalty by submitting a Request for Administrative Hearing form dated June 18, 2020, and received by the OSHPD Hearing Office on July 1, 2020.
3. Appellant submitted its appeals within the required thirty days from the date of the penalty notice.¹
4. The hearing was not scheduled within 60 days of receipt of the appeal due to the Hearing Officer being on military leave. No party objected to the scheduling of the hearing.
5. The hearing was held electronically at the election of the Hearing Office. No party requested an in-person hearing or objected to an electronic hearing.
6. OSHPD representatives submitted written exhibits to the Hearing Office and Appellant in advance of the hearing in a timely manner. Exhibits 1 through 8 were found to be authentic and relevant and admitted to the record.
7. Appellant submitted written exhibits to the Hearing Office and OSHPD representatives in advance of the hearing. Exhibits A through F were found to be authentic and relevant and admitted to the record.

FACTUAL FINDINGS

The following findings of fact were made by the Hearing Officer and are adopted by the Director:

¹ Health & Saf. Code, § 127681(f).

1. On April 2, 2020, OSHPD sent via regular mail a courtesy reminder letter to Appellant indicating 67 National Drug Codes (“NDCs”) which may owe a WAC Increase Quarterly Report by April 30, 2020.
2. On April 24, 2020, Appellant submitted 69 WAC Increase Quarterly Reports but did not file the reports for the drug OFEV.
3. Appellant was required under Health and Safety Code section 127679 to file two WAC Increase Quarterly Reports for the drug OFEV in two dosages by April 30, 2020.² Penalties accrued from May 1, 2020, until May 14, 2020, when the reports were filed.
4. In accordance with Health and Safety Code section 127679, subsection (e), OSHPD assessed penalties in the amount of \$1,000 per day for 14 days for each report, resulting in a total penalty amount of \$28,000.³ These facts were substantiated both by oral statements made under oath by Mr. Christensen at the hearing and written exhibits.
5. 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.
6. Appellant testified that it made a mistake in calculating the price increases for the drug OFEV. When calculating the price increases over the previous two-year period, Appellant mistakenly calculated beginning on January 3, 2018, rather than January 1, 2018. This mistake caused the price increases for OFEV to appear to be under the reporting threshold and the two reports were not filed by mistake. During the time that Appellant was preparing these quarterly reports the personnel preparing the reports were required to switch to telework due to the COVID-19 pandemic. Connecticut issued stay-at-home orders on or about March 20, 2020. Appellant also testified that the impacts of the COVID-19 pandemic impacted them, particularly from March to June of 2020 as network and IT systems connecting employees to the company servers required adaptation and expansion.
7. The parties offered no rebuttals following the initial statements.

² See also Cal. Code Regs., tit. 22, § 96071.

³ Cal. Health & Saf. Code, § 127679. See also Cal. Code Regs., tit. 22, § 96080.

8. OSHPD's representative stated that despite the delay, the data was able to be included in OSHPD's scheduled quarterly data public release.

9. OSHPD's representative confirmed that Appellant's previous report filings were timely.

The Director makes the following additional findings of fact:

1. The quarterly WAC reports for 69 drug products submitted by the Appellant with OSHPD on April 24, 2020, were timely filed.

2. On May 13, 2020, Appellant discovered that it had failed to file two WAC Increase Quarterly Reports for the drug OFEV in two dosages and submitted the reports to OSHPD the next day.

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 two quarterly WAC Increase Reports for the drug OFEV by April 30, 2020, or other good cause for reduction of the penalty, such that 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."⁴ Good cause must be directly related to the specific legal requirement which the party failed to perform and should be outside the reasonable control of the party.⁵ 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

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

⁵ *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].

bodies have often found that hospitalization, incapacitation, accident involvement, or loss or unavailability of records may constitute good cause.⁶ However, good cause is not limited to the listed reasons. The determination of good cause in a particular context should utilize common sense based upon the totality of the circumstances, including the purpose of the underlying statutory scheme.⁷

3. As its grounds for good cause for its late reports, the Appellant cites an inadvertent oversight, and extenuating circumstances and disruptions from the COVID-19 pandemic that resulted in a delay of OSHPD's April 2, 2020, courtesy reminder letter, and hence a delay in the Appellant discovering its error. There is nothing in the statutes codifying the CTRx program, or the accompanying regulations, that requires a courtesy notice or any affirmative action by OSHPD to a drug manufacturer before it is responsible for filing a WAC Increase Quarterly Report.⁸ Any delay in a courtesy notice from OSHPD, receipt of an incomplete notice, or failure to receive such a notice at all, whatever the cause, cannot be relied upon to excuse a manufacturer's failure to file a timely report.

4. However, the larger extenuating circumstances created by the COVID-19 pandemic and outside of the Appellant's reasonable control can still be considered in assessing good cause for a waiver of the penalty. At the time these reports were due, the Appellant's Connecticut office preparing the reports, like much of the United States, was under stay-at-home orders and heavily impacted by the early stages of the COVID-19 pandemic. Appellant testified that administrative operations suffered severe disruptions, especially from late March through June of 2020, right as Appellant was preparing these reports. Specifically, the staff preparing the reports were required to switch to telework and encountered disruptions in connecting to company servers.

5. In response to the disruptions caused by the COVID-19 pandemic, many state and federal agencies issued extensions and penalty waivers for everything from reports to tax filings,

⁶ 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 December 4, 2019]. See also *Waters, supra*, 58 Cal.2d 885, 893.

⁷ *Laraway v. Sutro & Co.* (2002) 96 Cal.App.4th 266, 274.

⁸ Chapter 9, Part 2, Division 107 of the Cal. Health & Safety Code, §127675 et seq.; Chapter 9.5, Division 7, Title 22, Cal. Code Regs., § 96060 et seq.

typically ranging from 30 to 90 days.⁹ While an extension was not available to Appellant, Appellant's testimony indicates that operations were certainly impacted by COVID-19 and the Connecticut stay-at-home orders, factors which were clearly outside the control of Appellant.

6. A party's diligence is a factor in determining good cause for an extension or a delay.¹⁰ Here the Appellant timely submitted 69 of the 71 reports that were in fact due by April 30, 2020.¹¹ The two reports that were missed during the unfolding COVID-19 pandemic disruptions were overlooked following a calculation error of just two days, which made them appear to be under the reporting threshold, and which was small enough that it was not immediately obvious to Appellant that the calculations contained a mistake. Once the mistake was realized, the two reports were filed within a single business day, enabling OSHPD to include these reports in the quarterly data release and fulfill the statutory intent of providing public transparency of these drug price increases with no delay. While the lack of harm does not directly show good cause for the late filing of the reports, it does demonstrate that Appellant is taking its statutory responsibilities seriously and acted with reasonable haste after realizing its mistake. Also, the Appellant, participating in the CTRx reporting program since early 2019, had never previously submitted a late report.

7. These facts taken together demonstrate that circumstances outside of the Appellant's control related to the COVID-19 pandemic contributed to the late filings, and that Appellant acted with due diligence under the circumstances and with reasonable haste to provide the late reports. Therefore, the substantiated facts show good cause for waiver of the penalty.

CONCLUSION

For the reasons set forth above, the Appellant has established good cause for waiver of the assessed penalty of \$28,000.

⁹ See example IRS Notice 2020-18, IRS Notice 2020-20, IRS Notice 2020-23; see also Executive Order N-55-20 (April 22, 2020). OSHPD issued 90-day extensions for its Health Data and Advisory Council Consolidation Act reports, but extensions were not offered for the CTRx program reports which are mandated only if and when a manufacturer sufficiently increases a WAC price or releases a new product at a sufficient WAC price.

¹⁰ *People v. Financial Casualty & Surety, Inc.* (2016) 2 Cal.5th 35, 47. See also *Wang v. Unemployment Ins. Appeals Bd.* (1990) 225 Cal.App.3d 412, 420.

¹¹ Cal. Code Regs., tit. 22, § 96071.

ORDER

The assessed penalty is waived for good cause.

Dated: July 15, 2021

//original signed//

ELIZABETH A. LANDSBERG
Director
Office of Statewide Health Planning and
Development