

PROCEDURAL FINDINGS

1. On July 10, 2020, HCAI assessed a penalty against Appellant in the amount of \$1,638,000 for its 39 delinquent quarterly Wholesale Acquisition Cost (“WAC”) Increase Reports.
2. Appellant appealed the penalty by submitting a Request for Administrative Hearing form dated August 7, 2020 and received by the Hearing Office on September 29, 2020.
3. Appellant submitted its appeals within the required thirty days from the date of the penalty notice.²
4. The hearing was held electronically using videoconferencing at the election of the Hearing Office. No party requested an in-person hearing or objected to an electronic hearing.
5. HCAI representatives submitted written exhibits to the Hearing Office and Appellant in advance of the hearing in a timely manner. Exhibits 1 through 7 were found to be authentic and relevant and admitted to the record.
6. Appellant submitted written exhibits to the Hearing Office and HCAI representatives in advance of the hearing. Exhibits A through AH were found to be authentic and relevant and admitted to the record.

FACTUAL FINDINGS

1. On or about April 2, 2020, HCAI mailed a quarterly courtesy reminder via USPS regular mail. The courtesy notice was not emailed because it was sent to other potential filers who had not yet registered with the CTRx program.
2. On or about June 11, 2020, Appellant submitted 39 WAC Increase Reports.

² Health & Saf. Code, § 127681(f).

3. Appellant was required under Health and Safety Code section 127679 to file its WAC Increase Quarterly Report for 39 drugs by April 30, 2020.³ Penalties accrued from May 1, 2020 until June 11, 2020 when the reports were filed.

4. In accordance with Health and Safety Code section 127679, subsection (e), HCAI assessed penalties in the amount of \$1,000 per day for 42 days for each of the 39 reports, resulting in a total penalty amount of \$1,638,000.⁴

5. These facts were substantiated both by oral statements made under oath by Mr. Christensen at the hearing and written exhibits.

6. 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.”

7. 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.

8. Appellant testified that it was aware of, registered with, and participating in the CTRx program from the beginning, publishing its first 60-day advance notice for a WAC increase in November of 2019. Appellant had timely filed numerous WAC Increase Quarterly Reports and New Drug Reports beginning in 2019. At the time of the deadline for the reports at issue, Appellant had experienced staff transitions which were complicated by the COVID-19 emergency orders which began on or about March 9, 2020 in New Jersey. The Governor of New Jersey issued stay-at-home orders a few days after Appellant made the decision to close its facilities and move to remote work on or about March 16, 2020. Appellant adopted Microsoft Teams to address communication while working remotely, but as it was not previously using this software employees required training and practice to become proficient in this new way of conducting business. This caused disruptions to some of Appellant’s administrative operations from March through June of 2020.

9. Beginning in January of 2020, the division responsible for preparing and filing the reports experienced numerous staff transitions which were further stressed and complicated by the

³ See also Cal. Code Regs., tit. 22, § 96071.

⁴ Health & Saf. Code, § 127679. See also Cal. Code Regs., tit. 22, § 96080.

COVID-19 pandemic. On or about January 20, 2020 the primary responsible party for Appellant left her position but transitioned with her replacement. Additionally, in February and April two of the staff in its compliance department who were responsible for preparing and filing the reports left employment without filing the reports at issue. These staff were the contacts for HCAI, and other staff did not receive notices that reports had been filed, or not, until the contacts were updated, an otherwise routine process which was disrupted by the COVID-19 pandemic and the New Jersey emergency orders. Appellant believed the reports had been filed timely and was unaware they were delinquent due to the combination of staff turnover and COVID-19 pandemic impacts. However, once the mistake was realized, the reports were filed the same day. Despite the difficulties of doing so remotely due to COVID-19 restrictions, new hires were made, and new staff were trained to prepare and file the reports. One replacement started working on transparency reporting on May 1, 2020, and the subsequent reports were filed timely despite ongoing impacts of COVID-19.

10. 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. Appellant noted that HCAI issued 90-day emergency extensions for its Health Data and Advisory Council Consolidation Act reports and the IRS issued automatic tax extensions. Had a 60 or 90-day extension been granted to Appellant, the reports would have been filed timely. Appellant argued that a 60-day extension should be retroactively granted due to the circumstances, which would waive its penalty as the reports were filed only 42 days late.

11. These facts were substantiated by oral statements made under oath by Ms. Fitzsimmons and Mr. Goldfarb at the hearing and written exhibits.

12. The initial statements of both parties were not rebutted.

13. HCAI's representative testified that Appellant has a history of timely report filing and that Appellant has filed its subsequent reports timely. Additionally, the delay in the filing of the reports was so short that the data was able to be included in HCAI's quarterly data release so public access to the data was not delayed or impacted.

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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 Novartis's 39 quarterly WAC Increase Reports by April 30, 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."⁵ 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.⁶ 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.⁷ 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.⁸
3. The larger extenuating circumstances created by the COVID-19 pandemic and outside of the Appellant's reasonable control can be considered in assessing good cause for a waiver of the penalty. The substantiated facts show that at the time these reports were due, the Appellant's New Jersey office filing 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

⁵ *Waters v. Super. Ct. of Los Angeles County* (1962), 58 Cal.2d 885, 893 (hereafter *Waters*).

⁶ *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].

⁷ 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.

⁸ *Laraway v. Sutro & Co.* (2002) 96 Cal.App.4th 266, 274.

that administrative operations suffered severe disruptions, especially from late March through June of 2020, right as these reports became due. Specifically, the staff filing the reports were required to switch to telework and transition to new software platforms such as Microsoft Teams. In addition, three of the staff who were primarily responsible for filing the reports on behalf of Appellant left employment between January and April of 2020, causing further disruption to operations and communications, and causing Appellant to have to interview and hire new staff while navigating the restrictions in place due to COVID-19. While a staff transition and communication issues absent the COVID-19 pandemic impacts would be clearly within the control of Appellant and not constitute good cause for a reduction or waiver of the penalties, the communication and operational disruptions caused by COVID-19 were clearly outside the control of Appellant and interfered with the business practices which Appellant had established to enable timely filing of its previous reports.

4. 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, typically ranging from 30 to 90 days.⁹ While an extension was not available to Appellant, Appellant's testimony indicates that operations were heavily impacted by COVID-19 and the New Jersey stay-at-home orders, factors which were clearly outside the control of Appellant. Furthermore, despite these factors, Appellant submitted its reports only 42 days late.

5. A party's diligence is a factor in determining good cause for an extension or a delay.¹⁰ The substantiated facts show that Appellant prepared the reports for a timely filing and believed it had filed the reports. Absent the impacts of the COVID-19 pandemic, a simple staff transition resulting in such a mistake would not be reasonable. However, the disruptions experienced by Appellant in those first weeks of the emergency orders stressed Appellant's staff and procedures until adaptations could be made. Furthermore, the reports were filed the same day the mistake was

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). HCAI 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 increase 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, 45. See also *Wang v. Unemployment Ins. Appeals Bd.* (1990) 225 Cal.App.3d 412, 420.

PROPOSED ORDER

The assessed penalty is waived for good cause.

Dated: November 1, 2021

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MICHELLE L. CHURCH-REEVES
Hearing Officer
Department of Health Care Access and Information

DECISION

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

Accepted

Rejected

Dated: November 2, 2021

//original signed//
ELIZABETH A. LANDSBERG
Director
Department of Health Care Access and Information