BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

On or about March 30, 2006, respondent GabeCare Direct Rx (GabeCare), filed an application for a non-resident Iowa pharmacy license. GabeCare filed a packet of information with its application, including a statement for relief. The statement for relief stated that GabeCare had once been licensed in Iowa, but had inadvertently allowed its license to lapse. GabeCare asked the Iowa Board of Pharmacy Examiners (the Board) to grant its application for licensure retroactively to cover the years its license had lapsed. GabeCare asked the Board to consider its application at the Board’s meeting scheduled for April 25-26, 2006.

On April 26, 2006, the Board conducted a contested case hearing to consider GabeCare’s application. The following board members were present for the hearing: Katherine Linder, Barbara O’Roarke, Michael Seifert, Leman Olson, Paul Abromowitz, and Kathleen Halloran.1 Jeffrey Farrell, an administrative law judge from the Iowa Department of Inspections and Appeals, assisted the board. Scott Galenbeck, an assistant attorney general, represented the public interest. Attorney Monica Navarro represented respondent.

THE RECORD

GabeCare’s exhibits A-D and 101-102 were admitted. GabeCare presented Santa Zawaideh and Jalal Zawaideh as witnesses.

1 Ms. Linder’s term ended on April 30, 2006, so she was not on the Board at the time this written decision was entered. However, the Board had a quorum without Ms. Linder, and the Board’s decision was unanimous, so the end of Ms. Linder’s term has no impact on the decision.
The state's exhibits 1-3 were admitted, including all attachments to exhibit 1. The State presented Terry Witkowski and Roger Zobel as witnesses.

**FINDINGS OF FACT**

**Introduction:** GabeCare is operated from its home office in Troy, Michigan. GabeCare arose from a small family-owned pharmacy known as Gabe Drugs. The company was started and operated by members of the Zawaideh family. Santa Zawaideh is president of GabeCare. Her husband and four children are or have been pharmacists with the company. (S. Zawaideh testimony; exhibit D).

GabeCare was created after Ms. Zawaideh became interested in other areas of patient care, most particularly, durable medical equipment (DME). At one point, the company focused on DME and effectively got out of the pharmacy business. This changed in 1996, when the company returned to pharmacy based on patient demand. Ms. Zawaideh testified that patients with conditions such as diabetes require drugs and DME to provide treatment. GabeCare returned to pharmacy to provide both types of goods to its customers. (S. Zawaideh, J. Zawaideh testimony).

In 1998, GabeCare merged with Health US, a company owned and managed by Ms. Zawaideh's brother, Joseph Poggi. Mr. Poggi owned 40 percent of GabeCare after the merger. Mr. Poggi also managed aspects of the business, including personnel and accounting. Ms. Zawaideh remained in charge of the pharmacy operations; Mr. Poggi was not a pharmacist. (S. Zawaideh testimony; exhibit D).

There were several business disputes between Ms. Zawaideh and Mr. Poggi, including mismanagement and questionable marketing practices. In July of 2003, the disputes came to a head and Ms. Zawaideh literally locked Mr. Poggi out of the company building. There is pending litigation between the two. (S. Zawaideh testimony).

GabeCare's business grew rapidly after its creation. The company is licensed in nine states: Michigan, Florida, Idaho, Illinois, Indiana, Kentucky, Minnesota, Ohio, and Washington. It is unclear how the company obtained patients from states that do not border Michigan. GabeCare attributes its success to outstanding patient care, which includes making pharmacists more available to customers by telephone. The company believes many of its out-of-state patients were former Michigan patients who
have moved, or others who have heard about the business from good word of mouth (S. Zawaideh, J. Zawaideh testimony; exhibit D).

**Iowa licensure:** It is unclear when GabeCare received a nonresident license in Iowa, but it is clear that GabeCare was licensed in Iowa during the 2001 calendar year. The license lapsed on December 31, 2001. GabeCare continued to sell drugs to patients in Iowa after its license lapsed. GabeCare did not learn about the problem until March 17, 2006, when it received a letter from the Iowa Department of Human Services (DHS). DHS demanded a repayment of approximately $1,349,843.40 of Iowa Medicaid funds paid to GabeCare since January 1, 2002. DHS claimed the funds were incorrectly paid because GabeCare was not licensed as a pharmacy in Iowa during that time period. (S. Zawaideh, J. Zawaideh testimony; exhibit 1-J).

Terry Witkowski oversees licensing and renewals for the Board. Ms. Witkowski testified that the Board, as a matter of practice, mails a renewal application to all licensees. The Board does not follow-up to ensure that licensees received the renewal application. Ms. Witkowski did not specifically recall whether the Board mailed the GabeCare renewal application. (Witkowski testimony).

Ms. Zawaideh testified that, in 2001, she was ultimately responsible to ensure that the pharmacy was properly licensed in each state. However, she relied on Mr. Poggi to keep track of the each license and tell her when they were due. The system clearly did not work. In September of 2001, the State of Illinois disciplined GabeCare for dispensing prescriptions in Illinois without a license. Illinois reprimanded the company and imposed a $5,000 fine. (S. Zawaideh; exhibit 1-H).

After Mr. Poggi was removed from the company, Ms. Zawaideh assigned her son, Jalal, to maintain licensing compliance. However, Mr. Zawaideh did not update GabeCare’s compliance methods. The Zawaidehs testified that their system of maintaining current licensure was to post the various licenses on a wall of the business, and review the licenses each month to determine which were expired. The company’s safeguard was to expect each state to send a reminder when the license was due. Mr. Zawaideh testified that he did not know the Iowa license was expired because the company did not have an Iowa license on the wall. He did not personally receive any reminder (he was not in charge of licensing when Iowa sent its renewal application in late 2001). Also, Ms. Zawaideh did not tell her son about the
prior problem in Illinois, so Mr. Zawaideh had no personal knowledge of prior licensing deficiencies. (S. Zawaideh, J. Zawaideh).

Mr. Zawaideh has changed GabeCare’s licensing renewal practices after learning about the company’s lapsed Iowa license. He now keeps a spreadsheet listing each state in which GabeCare is licensed, and when the license is due. He checks the spreadsheet each month to ensure that the company submits timely license renewals. (J. Zawaideh testimony; exhibit D-1).

There is no evidence to indicate that the company has been disciplined in any other state, other than the aforementioned discipline in Illinois. There is no evidence to show that GabeCare’s license has lapsed in any other state. GabeCare remains licensed in good standing in nine other states, including Illinois. (J. Zawaideh).

**Other licensing issues:** The State put on evidence regarding other licensing issues for the Board to consider when deciding whether to grant GabeCare’s license application. This evidence will be discussed as necessary in the conclusions of law section of this ruling.

**CONCLUSIONS OF LAW**

**Regulatory framework:** The board was created for the express purpose to promote, preserve and protect the public health, safety, and welfare through the effective regulation of the practice of pharmacy. The board regulates the practice, in part, through the licensing of pharmacies, pharmacists, and others engaged in the sale, delivery, or distribution of prescription drugs and devices.

The board has the authority to grant licenses to pharmacists, adopt regulations creating standards for licensure, and to enforce compliance with those standards. The board may impose discipline against the license holder, including revoking or suspending a license, putting a licensee on probation, imposing a civil penalty up to $25,000, issuing a citation and warning, and requiring professional education.

---

2 Iowa Code section 155A.2.
3 Iowa Code section 272C.1(6)(q), 272C.3.
4 Iowa Code sections 155A.12, 155A.18, 272C.3(2).
The board may grant licenses for pharmacy's located outside the state. The board may impose disciplinary action against a nonresident pharmacy in the same manner as it would against Iowa pharmacies.

Sale of drugs without a license: A nonresident pharmacy shall apply for and obtain a license prior to providing prescription drugs, devices, or pharmacy services to an ultimate user in Iowa. GabeCare admittedly sold drugs, devices, pharmacy services to clients in Iowa from January 1, 2002, through at least March 17, 2006. The exact number of sales is unknown, but they were substantial; DHS has demanded repayment for more than $1.3 million in drugs and services paid for by Medicaid funds. Moreover, DHS' demand letter solely concerned Medicaid patients. GabeCare also sold drugs and products to private-coverage customers, so the actual sales to Iowa patients are higher than the $1.3 million figure provided by DHS.

GabeCare has no excuse for failing to renewing its license. Each licensee is ultimately responsible to ensure it is licensed. Additionally, the Board, as a matter of practice, sends a renewal application to each licensee to remind them to renew their license. There is no evidence that the Board's practice was not followed here. Rather, it is more likely that GabeCare bungled the reapplication process by failing to properly monitor its licensure in Iowa.

GabeCare witnesses testified that it did not notice the problem earlier because Iowa Medicaid paid claims throughout the period its license lapsed. The company acknowledged, as it must, that this does not excuse its violation. Rather, the company pointed out this fact to explain why it did not discover the mistake sooner.

However, it is troubling that GabeCare did not discover the problem sooner in light of the amount of business it did in Iowa. GabeCare sold to Iowa customers without a license for more than four years, but never cross-referenced its sales list to its licensing list to ensure it was legally selling in Iowa. GabeCare's failure to better monitor its licensing is further disturbing when considering the sanction it received from Illinois in 2001. Even after being disciplined by a state for

---

5 Iowa Code section 155A.13A.
6 Id.; 657 IAC 19.10.
7 657 IAC 19.2.
Case No. 2006-21
Page 6

selling without a license in 2001, GabeCare committed the same violation in Iowa beginning on January 1, 2002.

Promotions: A pharmacy shall not participate in any prohibited agreement with any person in exchange for accepting or promising to accept pharmaceutical services. "Prohibited agreement" is defined to include providing a premium or kickback as compensation for soliciting business with a pharmacy.

The company acknowledged that it has given free gifts to new customers. The company has given away cheap five-inch black and white television sets, flashlights, heating pads, and AM/FM headphones to customers. The company ceased its promotion program after Mr. Poggi was removed from the company in 2003. Mr. Poggi developed the promotions concept and implemented the program. The promotion program was one of the areas of conflict between Mr. Poggi and Ms. Zawaideh.

The Board does not expressly find a violation of its rules, based on the circumstances of this case. GabeCare's activity likely violated the regulation. However, there is no evidence that GabeCare has given away free gifts in the past three years. There is strong evidence to show that GabeCare will not use promotions again, based on Ms. Zawaideh's opposition to the practice and Mr. Poggi's exodus from the company. The board cautions GabeCare to comply with the regulation in the future. Any future violations may lead to disciplinary action.

Compounding practices: A pharmacy may compound, for an individual patient, drug products that are commercially available in the marketplace, if the compounded product is changed to produce a significant difference between the compounded drug and the comparably commercially available drug product, or if the compounded drug is in the best interest of the patient.

GabeCare provided a compound of albuterol sulfate and ipratriopium bromide, when another product (DuoNeb) was commercially available. Mr. Zawaideh testified that GabeCare provided the compound order because it was five times cheaper and there was no clinical difference between the two. Mr. Zawaideh testified that the company would provide DuoNeb if the physician prescribed that specific drug, but it otherwise sought to reduce patient cost by providing the compounded drug.

8 657 IAC 8.11(5).
9 657 IAC 20.3(1).
The Board does not expressly find a violation of the regulation. The Board finds that there was no therapeutic difference between the compounded drug and DuoNeb, but use of the compounded drug was arguably in the patient's best interest based on the cost. However, the Board stresses that GabeCare must abide by the rule in future practice. The Board has expressly applied the compounding regulation to nonresident pharmacies, thus emphasizing the importance of the rule. In the event GabeCare commits a violation of the rule in the future, the Board will take disciplinary action.

Other allegations: The Board does not find sufficient evidence to support violations with regard to other allegations discussed at hearing or elsewhere in the record.

DECISION and SANCTION

Decision on GabeCare's license application: In consideration of the evidence as a whole, the Board determined that GabeCare's license application should be granted. GabeCare sold drugs in Iowa for more than four years without a license, which is a clear violation of Iowa law. However, GabeCare was licensed in good standing in nine other states at the time its license lapsed in Iowa, and there is no showing or basis for belief that the company intentionally or knowingly allowed its license to lapse. The State raised some questions as to past GabeCare practices, but the Board does not find sufficient bases to deny licensure. The Board believes that GabeCare's violations for selling without a license can be more fairly addressed by a less severe penalty.

The Board notes that it is treating GabeCare's application as a new license application, as opposed to a renewal. The Board prescribes penalties for licensees who are tardy when submitting a renewal application. The initial penalty is $150; it rises to $250 if more than a month late; it rises to $350 if more than two months late; and rises to $450 if more than three months late. The maximum late renewal penalty is $600.

GabeCare's application was not just tardy; it was submitted more than four years after its license lapsed. This case does not fit within the penalty scheme set forth in the regulations. It must be deemed a new application.

10 657 IAC 8.35(4)(a).
Retroactivity: GabeCare asked the Board to grant its application retroactively back to January 1, 2002. GabeCare based its claim on 657 IAC 8.35(4)(a), which sets the scheduled fines for late renewals. GabeCare argued that the schedule fines are the sole penalty for a late renewal, and that any license is effective retroactive once the late fee is paid.

GabeCare did not take into account section 8.35(4)(b), which immediately follows the section upon which it relied. Section 8.35(4)(b) states:

If a license is not renewed before its expiration date, the license is delinquent and the licensee may not operate or provide pharmacy services to patients in the state of Iowa until the licensee renews the delinquent license. A pharmacy that continues to operate in Iowa without a current license may be subject to disciplinary sanctions.

The Board cannot grant retroactive licensure. The company sold drugs in Iowa while its license had lapsed, which is directly in violation of Iowa law. It is responsible for its conduct. The Board cannot fix the company’s transgressions at this point in time.11

Sanction: The Board has decided to grant GabeCare’s license application, but the Board must sanction GabeCare for selling pharmacy goods and services after its license had lapsed. This is not a minor violation. GabeCare sold drugs in Iowa for more than four years after its license had lapsed. It did more than $1.3 million in business during that period. Notwithstanding the amount of money it received from Iowa customers, its licensing compliance system consisted of looking at the licenses on the wall once a month. GabeCare used this primitive compliance method even after it was disciplined by another state for the same problem. GabeCare did not take the State of Iowa’s pharmacy licensing requirements as seriously as it should have.

GabeCare’s misconduct is mitigated by other factors. It was clearly a licensable pharmacy; it was licensed in good standing in nine other states. There is no evidence it engaged in

11 This decision should not be read to offer an opinion whether GabeCare must repay the Department of Human Services for Medicaid payments made while GabeCare was not licensed. The Board’s authority is limited to deciding issues relating to GabeCare’s pharmacy licensing and discipline.
misconduct that would prevent its licensure during the period after its license lapsed. There is no evidence to suggest that it intended or knowingly failed to renew its license in Iowa. The company has adopted better controls to ensure there are no similar occurrences in the future.

GabeCare shall pay a civil penalty of $25,000.00 for selling pharmacy goods and services in Iowa without an Iowa license. The Board finds that this sanction best serves the public welfare and interests of fairness, based on the circumstances set forth in this case.

ORDER

The Iowa Board of Pharmacy Examiners grants the license application submitted by GabeCare Direct Rx. The license shall be granted prospectively after GabeCare submits its license application fee and the civil penalty discussed below.¹²

GabeCare shall pay a civil penalty of $25,000.00. GabeCare shall remit the civil penalty and the application fee to the Board at the following address: Iowa Board of Pharmacy Examiners, 400 SW 8th St., Suite E, Des Moines, Iowa 50309-4688. The Board shall issue GabeCare’s license after the fee and penalty are paid.

GabeCare shall comply with the other practice provisions discussed in this decision. GabeCare shall otherwise comply all provisions of Iowa law relating to nonresident pharmacies. Failure to abide by any Iowa statute or regulation shall result in disciplinary action.

Dated this 7th day of June, 2006.

Michael J. Seifert, Chairperson
Iowa Board of Pharmacy Examiners

¹² The Board is returning the checks previously sent by GabeCare. Those checks were intended to represent renewal fees and penalties. As discussed above, the Board is treating this case as a new license application.
Notice

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.