



MEMORANDUM

DATE	October 20, 2020
TO	Members, Board of Pharmacy
FROM	Eileen Smiley, Attorney III Legal Affairs Division
SUBJECT	Designating all or portions of the decision, <i>In the Matter of the Third Amended Accusation Against IV Solutions, Inc. Alireza Varastehpour, President and Renee Sadow</i> , (Case No. 3606, OAH No. 2011050988) as Precedential pursuant to Government Code section 11425.60 (Agenda Item IV)

The California State Board of Pharmacy (board) can designate and rely on decisions as precedential. In other words, once the board has publicly selected a decision or parts thereof as precedential, that decision or part of that decision, must be applied and followed. The statute that governs this process states,

- (a) A decision may not be expressly relied on as precedent unless it is designated as a precedent decision by the agency.
- (b) An agency may designate as a precedent decision a decision or part of a decision that contains a significant legal or policy determination of general application that is likely to recur. Designation of a decision or part of a decision as a precedent decision is not rulemaking and need not be done under Chapter 3.5 (commencing with Section 11340). An agency's designation of a decision or part of a decision, or failure to designate a decision or part of a decision, as a precedent decision is not subject to judicial review.
- (c) An agency shall maintain an index of significant legal and policy determinations made in precedent decisions. The index shall be updated not less frequently than annually, unless no precedent decision has been designated since the last preceding update. The index shall be made available to the public by subscription, and its availability shall be publicized annually in the California Regulatory Notice Register.
- (d) This section applies to decisions issued on or after July 1, 1997. Nothing in this section precludes an agency from designating and indexing as a precedent decision a decision issued before July 1, 1997. (Gov. Code, § 11425.60).

PROCEDURAL BACKGROUND

On April 17, 2015, the Board of Pharmacy adopted the proposed decision of the ALJ in the Third Amended Accusation filed by the staff with an effective date of April 30, 2015. The Board stayed the decision until May 21, 2015. On May 28, 2015, the Board granted IV Solutions, Inc. motion for reconsideration in part but the proposed decision became effective against Respondent Sadow who did not file a motion for reconsideration. On January 15, 2016, the Board issued a Decision after Reconsideration, effective February 15, 2016, revoking the pharmacy license issued to Respondents for misconduct. In its Decision after Reconsideration, the Board found that the causes of action were proven by clear and convincing evidence despite any factual or legal finding to the contrary (Legal Conclusions 4, subparagraph D, or 5, subparagraphs D and E). IV Solutions and Vara (Petitioners) filed a petition for a writ of mandamus against the board, which was denied by the Los Angeles Superior Court on January 31, 2017. The petitioners appealed the Superior Court's decision on numerous grounds, including that the administrative law judge applied incorrect standards of proof, and the board abused its discretion in imposing the most severe penalty. On September 1, 2020, the Court of Appeal issued an unpublished decision affirming the Superior Court's denial of the writ and upholding the decision of the board's discipline against the Petitioners.

FACTS/FINDINGS OF THE DECISION/RATIONALE

This case involved many instances of unprofessional conduct, including, among other things, a violation of Business and Professions Code (BPC) section 4301(f) by the pharmacy for intentionally concealing information about the costs of its services at the outset of the patient relationship as required by its policies and procedures and delays in its billings that were designed to conceal the charges being submitted to a patient's insurance company. Other charges proven against IV Solutions (and Vara), included violations for obtaining a pump from an unlicensed wholesaler, Vara performing duties of a pharmacist without a license and making decisions without the involvement of a licensed pharmacist, for using prescription labels on certain prescriptions that falsely represented the name of the pharmacy, making of false documents, failure to have consultation available, violations for ordering a dangerous drug from Canada and having it shipped to an unlicensed facility, and noncompliant security because Vara had a key to the pharmacy.

The staff believes that this decision, with limited exceptions described below, should be made precedential for many reasons, including the extensive findings of fact and application of the law to the facts proven.

Standard of Proof for Discipline Against a Pharmacy License

The Board, in its Decision after Reconsideration, made clear that the appropriate standard of proof in a disciplinary action against a pharmacy is a preponderance of the evidence. (Standard of Proof Paragraphs 1 and 2 of the Board's Decision after Reconsideration).

Designating IV Solutions as a *Precedential Decision*.

Clarification of Meaning of BPC Section 4301(f)

Section 4300(a) provides that “[e]very license issued may be suspended or revoked and requires the Board to take action against any holder of a license who is guilty of unprofessional conduct. BPC section 4301 provides examples of unprofessional conduct. Subparagraph (f) of section 4301 identifies as unprofessional conduct “[t]he commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.”

This decision should be designated as precedential because it clarifies the scope of BPC section 4301, subdivision (f). The ALJ found that the IV Solutions intentionally failed to disclose its pricing practices and the cost of services at the outset of the relationship as required by its policies and procedures that were required as a condition of accreditation by the Joint Commission on Accreditation of Health Care Organizations (now the Joint Commission). The decision clarifies that an act of moral turpitude, dishonesty or fraud need not violate a statute or rule to constitute unprofessional conduct under BPC Section 4301(f). Thus, the decision makes clear that the Board may consider a pharmacy’s adherence to its policies and procedures required by private accreditation standards and discipline a licensee for deceptive conduct related to its non-compliance with such policies.

This decision also makes clear that the Board, although disclaiming authority to regulate prices charged by pharmacies directly, may consider and discipline a pharmacy for deceptive pricing and billing practices under BPC section 4301(f). In this case, the Board found that the pharmacy intentionally concealed its pricing by not disclosing its prices at the outset of the patient relationship as required by its policies and procedures, and intentionally delayed billing in one case to conceal the prices charged and the amount the pharmacy was seeking from the patient’s insurance company. The harm from this fraud was potentially financial to the patient and/or the insurance company, and the decision makes clear that the Board may discipline a licensee for fraudulent or deceptive conduct resulting solely in financial harm under BPC section 4301(f).

There is increased public interest in the cost of healthcare given the COVID-19 pandemic. Designating this decision as precedential can provide pharmacies with valuable information about whether they should disclose their pricing and billing practices at the outset of a patient relationship and whether they should consider disclosing their status as in network or out of network and the impact on the pricing and billing for charges not covered by insurance depending on the facts and circumstances. This decision also may educate consumers about the limits on a pharmacy’s required regulatory disclosure obligations and potentially encourage consumers to ask more informed and pointed questions about the cost of services at the outset of a patient relationship and the pharmacy’s status as in or out of network that could trigger a duty of candor from the pharmacy.

PORTIONS OF THE DECISION TO BE DESIGNATED AS PRECEDENTIAL

Board staff, in consultation with the board's liaisons from the Office of the Attorney General and the Department of Consumer Affairs board counsel, is recommending that the entire decision be designated as precedential, excluding one factual finding and one related legal conclusion discussed below.

PORTIONS OF THE DECISION NOT TO BE DESIGNATED AS PRECEDENTIAL

Factual Finding 119/Legal Conclusion 5.D The ALJ found that, based on conflicting expert witness testimony, the Board did not establish by a preponderance of the evidence that any industry standard required a pharmacy to disclose its prices and status as an out of network provider of services to patients prior to rendering those services. The ALJ found that the Board's expert witness offered no research, literature or facts tending to show an industry standard for this type of disclosure.

The staff does not believe that this factual finding or the legal conclusion related to it, should be designated as precedential because industry standards, and/or regulatory changes could evolve that could create a standard disclosure obligation in the future. Also, in later cases, the Board may be able to meet its standard of proof in a particular case based on different facts.