



**ENFORCEMENT COMMITTEE  
 DRAFT MEETING MINUTES**

DATE: July 9, 2020

LOCATION: Teleconference

COMMITTEE MEMBERS PRESENT: Maria Serpa, Licensee Member Chair  
 Albert Wong, Licensee Member Vice-Chair  
 Greg Lippe, Public Member  
 Ricardo Sanchez, Public Member  
 Debbie Veale, Licensee Member

STAFF MEMBERS PRESENT: Anne Sodergren, Executive Officer  
 Norine Marks, DCA Staff Counsel  
  
 Michelle Angus, DCA Assistant Chief Counsel  
 MaryJo Tobola, Senior Enforcement Manager  
 Debbie Damoth, Administration Manager

**1. Call to Order and Establishment of Quorum**

Chairperson Maria Serpa called the meeting to order at 9.05 a.m. Roll call was taken. A quorum was established. Due to technical difficulties chairperson Serpa stated Board Member Lippe would be joining the meeting at a later time.

**2. Public Comment on Items Not on the Agenda, Matters for Future Meetings**

Chairperson Serpa invited public comment.

Members of the public requested two items be placed on the agenda for future meetings: Discussion of the Alternative Disciplinary Model and discussion of the decline of mandates of attendance to an ethics course as a condition of settlement. Members discussed adding both issues to future agendas.

Board Member Lippe joined the meeting at 9:18 a.m.

Chairperson Serpa confirmed that the Alternative Disciplinary Model has already been scheduled for discussion at a future meeting.

**3. Presentation and Discussion on the Administrative Case Process**

Chairperson Serpa introduced Kristina Jarvis, Deputy Attorney General and Michelle Angus, Assistant Chief Counsel with the Department of Consumer Affairs. Chairperson Serpa added that to supplement the presentation, the meeting materials provided included historical statistical information on disciplinary matters and Attachment 1 included a flowchart of the general process.

DAG Jarvis with ACC Angus provided the committee with a presentation of Office of the Attorney General and Their Role in the Disciplinary Process for the California State Board of Pharmacy. DAG Jarvis introduced herself and stated that she introduced Assistant Chief Counsel Michelle Angus with DCA. DAG Jarvis informed the committee she has been with the Licensing section for just over seven years now and has handled more than 80 pharmacy cases and close to 600 licensing cases. She informed the committee ACC Angus was also formally with the Office of the Attorney General (OAG) before joining the DCA.

To start, DAG Jarvis informed the committee that the OAG represents state agencies and employees in judicial and other proceedings pursuant to GC 11040, as well as the OAG Licensing Section's Mission to protect the integrity in business and professions by pursuing the enforcement of licensing laws.

DAG Jarvis focused her presentation on accusations, since they make up the majority of cases. She reviewed the steps a case takes once it arrived at the OAG's office. Initially a thorough review of the case itself is conducted, which in part involves a review of the evidence as well as which parts of the law and regulations may have been violated. Next, the actual drafting of the accusation is completed. DAG Jarvis informed the committee the accusation is a public document, it sets forth the jurisdictional information, license history, relevant statutes and regulations that have been violated which are generally BPC section 4301 and charging paragraphs. DAG Jarvis explained the accusation is served on the respondent's address of record and sometimes on another address that is identified by the agency, although the only address required by law in order is the Address of Record. DAG Jarvis explained the accusation and the service of the accusation to the Address of Record ensures due process.

DAG Jarvis continued that along with the service of the accusation, a Notice of Defense (NOD) is provided. The NOD is provided to the respondent pursuant to Government Code section 11506. This form allows the respondent to notify the AGO of respondent's desire to contest the allegations and go to hearing if they are interested in a settlement, or if they are opting to surrender their license. This also allows respondent the option to update their contact information and provide the OAG with their attorney's contact information. DAG Jarvis clarified that the Notice of Defense is a request for hearing noting that failure of the respondent to respond to the NOD would lead to a Default Decision. She added the if the licensee explains that they never received the NOD and they did not realize that the accusation existed, if they reach out within 7 days of the service of the Default Decision, they can file for a Relief for Good Cause to set aside the Default Decision.

DAG Jarvis reviewed the process for requesting a hearing with the Office of Administrative Hearings (OAH). She explained the challenging factors involved in scheduling including identification of dates that are available on the OAH Calendar, the respondent and DAG calendars and the witness availability. As a result of conflicting schedules, DAG Jarvis informed the committee that it typically takes four to eight months to schedule a hearing.

DAG Jarvis explained that Discovery is usually a DAG sending an investigative file to the respondent or to their counsel pursuant to Government Code section 11507.6. This provides them the opportunity to review the evidence. She explained that a settlement offer is almost always offered by the Agency even if that settlement is only a surrender of licensure, rather than proceeding to a hearing. DAG Jarvis provided the committee some reasons for settlement like risk avoidance, saving time and saving expense. In general DAG Jarvis encouraged stipulations; she explained settlement agreements can contain any agreement that is not contrary to any policy or law. Both parties can tailor those terms to the violations through negotiation. DAG Jarvis provided clarification that in the case of a settlement a respondent is agreeing to compliance to the terms of a stipulation versus going to a hearing then resulting in terms the respondent may completely not agree to the terms and conditions determined by the administrative law judge.

DAG Jarvis introduced the Disciplinary Guidelines (DG) California Code of Regulation, Title 16, section 1760 which provides direction to board staff, AGO, respondents, ALJ and Superior Court. She explained the DG contains the factors to be considered in determining whether the penalty in any particular case should be a minimum penalty, a maximum penalty or intermediate penalty. She reviewed the four categories of violations, in ascending seriousness with Category IV being the most serious. DAG Jarvis provided a review of each category. She also reviewed the model language provide in the DG for Probation Terms and Conditions. She stressed the importance of the use of model language to maintain consistency, while still deciding cases based on their own merits.

DAG Jarvis explained that the entire process has two fundamental guiding principles: due process of the respondent and the protection of the public. She stated these two principles can often be at odds. DAG Jarvis stated the State has the right and the responsibility to ensure the licensee is competent and trustworthy. DAG Jarvis ensured the committee that the purpose of a hearing is not to punish a respondent. Rather, the purpose is to ensure the appropriate professional and legal standards are upheld and that the respondents are compliant with laws and regulations governing pharmacy.

DAG Jarvis reviewed components of an administrative hearing including the testimonies provided, the challenges of reviewing evidence at the hearing, the fact that the DAG has the Burden of Proof as the complainant to prove the case to the Clear and Convincing standard. She defined Clear and Convincing as highly and substantially more probable to be true than not and the trier of fact (the ALJ) must have a firm belief or conviction in its factuality.

DAG Jarvis continued that post hearing a proposed decision is due to the agency from the ALJ within 30

days after the submission of the case. The board members subsequently review the ALJ's decision. Board members vote to either adopt or reject resulting in a non-adoption. If, after a hearing and the board's decision and order the respondent, does not agree they can request a reconsideration that may delay the final order as the board reconsiders their final decision. Respondent may also file a Writ of Mandate in Superior Court; the Superior court judge will exercise their independent judgement on the evidence and make a determination to whether or not the violation occurred.

DAG Jarvis answered committee questions regarding Vicarious Liability in which a PIC is held responsible for ensuring the pharmacy complies with rules and regulations. She also addressed questions regarding the severity of punishment of first time DUI offenders. DAG Jarvis explained that the issue with a DUI offense is that is evidence of a problem of a substance with a person who we are trusting to control, possess and dispense controlled substances that are ripe for abuse and we now have evidence that we have someone who has abused a substance to the point where they have received a DUI; that is evidence that we may not be able to allow them to practice for the protection of the public.

A member of the public opined that the Administrative Case Process Presentation showed an assumption of guilt which further justified the need for an Alternative Disciplinary Model. Chairperson responded, there is actually an assumption of innocence because in most cases, the licensee maintains their license for many months while the investigation is taking place and process is taking place. A member of the public asked whether the 15-day response to a NOD could be changed. In response, DAG Jarvis stated that the 15-day response is in Government Code and is for all licensees, extensions are made for special circumstances and situations.

11:00 Break

11:12 Resume

Roll Call was taken.

#### **4. Presentation and Discussion on the Board's Citation and Fine Program**

Chairperson Serpa stated consistent with prior policy direction members have provided to staff as well as the Board's strategic plan, a presentation would be provided on the Citation and Fine program.

She informed the committee, reviewing the data reveals a, the significant increase in the number of Orders of Abatement issued in the last two years. This would be consistent with the direction we provided to staff during our May 2018 Board meeting.

Executive Officer Anne Sodergren provided the committee with the Citation Presentation. EO Sodergren provided that the majority of the citation issued by the board are issued pursuant to Business and Professions Code section 4314. She explained that the board uses its authority to issue citations to address important violations that are serious in nature but do not rise to the level of removal or restriction of a license through the administrative case process. She explained that staff use policy direction provided by the Board when we are making decisions on outcomes, including the levels of fines, noting that the board has indicated that the highest fines are really reserved for the most serious

violations. In most cases the board is limited to a maximum of \$5000 per investigation although there are some exceptions.

EO Sodergren explained to the committee the factors considered assessing administrative fines pursuant to CCR section 1775.2; these factors serve as guiding principles.

The citation process was reviewed. Once an investigation is completed and violation(s) had been substantiated the inspector submits the investigation report to a supervising inspector for review. Upon review by the Supervising Inspector (SI), a recommended outcome is determined. Based on the recommendation, it is forwarded for second level review by the Chief of Enforcement. Then as a collective group the chiefs of enforcement and executive officer meet to review the investigation and recommendation to ensure consistency whenever possible. Cases with recommendations for the issuance of a citation are reviewed using this process. Citation can be issued with or without a fine or with or without an abatement. Once the citation is issued to the licensee they then have the opportunity to comply and pay the fine, comply with an abatement order, or appeal the matter. If they opt to appeal they can have an office conference with the board or go through the OAG in a hearing with an ALJ.

EO Sodergren provided historical data which showed that 38% of citations are issued without a fine. Further, the average fine issued is about \$1570. She noted the number of fines issued is trending down as well as the fines assessed is a significant trend down which has resulted in fines collected trending down as well.

EO Sodergren shared the boards processing times. It showed a significant increase over the past five fiscal years. She expects this number will go down as overall investigations decrease.

She reviewed orders of abatement and explained to the committee that compliance with an order of abatement typically results in either a reduction or forgiveness of the fine. EO Sodergren explained the different abatement types and how each type might be recommended.

EO Sodergren stated licensees are always provided the opportunity to appeal. The informal office conference allows the opportunity to present additional or mitigating information to the board's executive officer or designee and a supervising inspector. In addition a licensee may submit a formal appeal to the board within 30 days of issuance of a citation for referral to the Office of the Attorney General.

EO Sodergren provided data on citation appeal outcomes for FY 19/20, noting that data suggests participation in the office conference appeal provides the licensees an opportunity to provide additional information, present mitigation, etc., which can lead to modifications of the citation, reduction to the letter of admonishment or even dismissal.

EO Sodergren provided data on top ten violations resulting in the issuance of a citation for pharmacies,

pharmacists, interns and technicians for FY 19/20. Data was provided on citations issued on violations of Duty to Consult CCR section 1707.2.

Chairperson Serpa requested a comparison of the time it takes a respondent to go through the AG appeal process for citation appeals to that of the AG process for disciplinary matters.

**5. Presentation and Discussion on Board's Inspection Program**

Chairperson Serpa informed that committee Members, that inspections can be triggered for a variety of reasons, including consumer complaints, to perform statutorily mandated inspections as a condition of licensure or renewal, to perform probation monitoring activities, or on a routine basis, to name a few. The inspection process provides staff with the opportunity to observe the practice, evaluate for compliance with pharmacy law, as well as provide education.

Executive Officer Anne Sodergren provided the committee with the Inspection Presentation. She stated inspections provide significant opportunity for education as part of the consumer protection process. The board established a policy goal to inspect all pharmacies every four years. While the inspection provides staff with the opportunity to observe and evaluate for compliance, it also provides an opportunity to educate licensees.

EO Sodergren reviewed the inspection process with the committee which includes in large part the observation of the practice and activity in that location. Ms. Sodergren continued by sharing a list of items reviewed once an inspector informs the pharmacy of their inspection. In addition, the inspector will also ask to see information and confirm compliance with various aspect of Pharmacy Law. As the inspection progresses the inspector will proceed to inspect general operation issues such as: the condition of the physical plant, review of security measures, overall cleanliness and orderliness and conduct an audit of expiration dates.

EO Sodergren explained that during the inspection there are opportunities for the licensee to ask questions and we use this and an opportunity to provide education especially on current laws. Current topics inspectors are covering with licensees are: Subscriber Alert email notifications; Staffing in Community Pharmacies; Pharmacy Relocation in a Declared Disaster; Compounding of Drug Preparations; HIV PrEP and Pep; Warning Labels; Inventory Reconciliation and Self-Assessments.

EO Sodergren reviewed inspection data which showed a significant decrease in the number inspections conducted in FY 19/20 in large part a bi-product of COVID-19. She stated, similar to many other regulators, the Board suspended inspections in mid-March and only recently resumed inspections. Board staff have performed desk audits between mid-March through mid-June.

A breakdown of the different of inspections was provided. The routine number represented those inspections that were not triggered by some other factor. EO Sodergren emphasized that it was important to note that in most cases, an inspection, irrespective of the triggering event, will encompass a routine assessment.

The following lists were provided to the committee: A list of the Top Ten Corrections On a Routine Pharmacy Inspections FY 19/20 and Top Ten Violation Notices on Routine Pharmacy Inspections FY 19/20.

EO Sodergren reviewed data relevant to findings during routine visits regarding violations of Duty to Consult. Data from our true routine data set indicates about 8% of all identified a problem with consultation. Further in 20% of such instances, consultation was not being provided.

As part of public comment, a member of the public stated, there are problems with pharmacies that are not pre-inspected before they are given a license in order to obtain an NPI number. In response, EO Sodergren stated we are not resourced to do inspections prior to issuing licenses.

## **6. Review and Discussion of Board's Enforcement Statistics**

Chairperson Serpa informed the committee based on her review of the fiscal year end statistics, the Board received 2,647 complaints and closed 2,910 investigation. It also appeared that the average days for investigation was overall trending down. Chairperson Serpa provided additional summary information noting that Board issued 327 Letters of Admonishment, issued 1,428 Citations and referred 230 investigations to the Office of the Attorney General to pursue administrative cases.

Additionally, the Board filed 248 accusations during the time period and disciplinary action was taken in a range of outcomes from revocation of a license to public reproof of a license.

The Board also secured 16 immediate protection orders including 8 interim suspension orders, 2 automatic suspension orders, 5 Penal Code 23 restrictions and 1 cease and desist for unlicensed activity.

Chairperson Serpa noted improvement in investigation times including decreases in timeframes reported at the January Meeting, from 186 average days to currently 170 days. Dr. Serpa also noted the most significant improvement with supervisor review where the decrease in time went from an average of 107 days as reported at our January meeting to an average of 41 days.

Chairperson Serpa noted that it appeared second level review time has doubled from an average of 20 days to currently an average of 42 days and indicated expected improvement in this area.

## **7. Future Committee Meeting Dates**

Chairperson Serpa stated that the next committee meeting date is scheduled for October 27, 2020.