MEDICAL BOARD OF CALIFORNIA
Executive Office

ENFORCEMENT COMMITTEE
Medical Board of California
Sheraton Gateway
6101 West Century Blvd.
Los Angeles, CA 94010
May 6, 2011

MINUTES

Agenda Item 1 Call to Order/Roll Call
The Enforcement Committee of the Medical Board of California was called to order by Reginald Low, M.D. With due notice having been mailed to all interested parties, the meeting was called to order.

Members Present:
Reginald Low, M.D., Chair
Sharon Levine, M.D.
Mary Lynn Moran, M.D.
Gerrie Schipske, R.N.P., J.D.
Frank Zerunyan, J.D.

Members Absent:
John Chin, M.D.

Staff Present:
Catherine Hayes, Probation Manager
Kurt Heppler, Legal Counsel
Teri Hunley, Business Services Manager
Rachel LaSota, Supervising Inspector
Ross Locke, Business Services Office
Regina Rao, Business Services Office
Anita Scuri, Department of Consumer Affairs, Supervising Legal Counsel
Jennifer Simoes, Chief of Legislation
Cheryl Thompson, Executive Assistant
Renee Threadgill, Chief of Enforcement
Linda Whitney, Executive Director
Curt Worden, Chief of Licensing

Members of the Audience:
Stan Furmanski, Member of the Public
Tara Kittle, Member of the Public
Rehan Sheikh, Member of the Public
(This list only identifies those who signed in at the meeting; staff was not able to record the names of all persons in attendance.)

DRAFT

Agenda Item 2 Public Comment on Items not on the Agenda

Stan Furmanski, Member of the Public, stated that at the last Enforcement Committee meeting it was divulged that the University of California San Diego was performing human research on doctors participating in the PACE (Physician Assessment and Clinical Education) program. Mr. Furmanski referenced documentation received from DHSS stating that their project in human research had been activated, was active now, and that they planned to use 400 human beings for their research; subjects being obtained from the Medical Board of California when physicians are required PACE. Mr. Furmanski referenced documentation which stated all UC San Diego PACE participants are potential subjects for this human research study. Mr. Furmanski also stated he has received documentation indicating the study would like to obtain 1,000 human subject participants, and questioned where those 1,000 subjects would come from, doubting voluntary participation. Mr. Furmanski's second comment was related to the Enforcement Committee's discussion of Practice Monitors. Mr. Furmanski suggested that the probation monitoring costs should be abolished and referenced the contingency fund data that was provided as meeting material, suggesting that the excess funds could be used in-lieu of the probation monitoring costs, allowing the program to operate without costs to the probationer.

Mr. Heppler read into the record, for public comment, a facsimile transmission received from Jeannette Dreisbach, Women's Advocate, regarding Practice Monitors. Ms. Dreisbach's letter stated that the existing order in which the Board assigns Practice Monitors is insufficient and needs to be revamped; and secondly, that the identity of the Practice Monitor should be public information and available for disclosure.

Agenda Item 3 Approval of Minutes

Dr. Levine moved to approve the minutes from the January 27, 2011 meeting; seconded; motion carried.

Agenda Item 4 Update on Probation Practice Monitors

A. Follow-up on Immunity/Waiver

Mr. Heppler stated that at the last meeting it was suggested that perhaps one of the bars to participating as a Practice Monitor was that there was a fear the Practice Monitor may be the subject of civil litigation resulting in a chilling of participation. Mr. Heppler referenced data provided by the Board's Probation Unit, indicating there are approximately 200 physicians currently required to have a Practice Monitor, as a condition of probation. After analysis of the data provided, Mr. Heppler opined that the data does not readily support the contention that fear of legal exposure is a significant reason for non-participation. Reasons given for difficulty obtaining a Practice Monitor included costs, possible Health Insurance Portability and Accountability Act (HIPPA) violations, problems finding a physician in the proper specialty, and problems finding a Practice Monitor without a prior relationship between the disciplined physician and presumed Practice Monitor. Mr. Heppler stated that based on this information the fear of litigation did not appear to be a significant contributor to non-participation, and in his capacity as the Board's Legal Counsel suggested the consideration of extending a shield of civil immunity to a potential Practice Monitor was not warranted.

Dr. Low asked whether the Probation Unit would be revising the probation monitoring forms to recommend that the Practice Monitor seek and execute a hold harmless agreement. Mr. Heppler responded that this was in the process of being implemented.

There were no public comments.

B. Practice Monitor Improvements

Ms. Hayes and Ms. LaSota provided a presentation on the Practice Monitor improvements, including a Power Point presentation. At the January Enforcement Committee meeting the current processes used by the Probation Unit for the Practice Monitor condition was presented. Options to strengthen the performance of the Practice

Monitors were identified, including exclusively using the Physician Enhancement Program provided by UC San Diego; developing a pool of Practice Monitors who have been trained and approved by the Board; using the current system, but develop and require the Practice Monitors complete a training course; or, retain the existing system, but enhance the overall education provided to the Practice Monitors and develop a more structured program identifying the requirements.

After review of the options and assessment of the Board's current resources it was determined that the best option would be to enhance the existing system. Staff envisions the new process will strengthen the role of the Practice Monitors, and will provide them with more structure and guidance. The process will include an orientation given by a Probation Unit Inspector; a detailed monitoring plan; a checklist for the site visit, as well as the quarterly reports; and, a sample to be used for the standardized reports. The enhanced process will provide the Practice Monitors with a better understanding of the expectations of the Probation Unit.

The Inspectors will have a more active role in educating the Practice Monitors on what their function is and what information the Board needs in order to ensure compliance with this condition. Additional forms have been created to enhance this condition:

Practice Monitor Nomination – Pending Legal approval, a form will be provided to probationer at the time the initial contact letter is sent. If the probationer has already identified a physician or several physicians, he/she can complete this form and provide to the Inspector at the time of the intake interview. If the probationer has not identified someone, he/she can complete the form and provide it within the specified timeframe to the Inspector. Language has been incorporated into this form to require that the probationer "hold harmless the Practice Monitor, the State of California, Medical Board of California, its officers, agents, and employees from any liability associated with the practice monitor requirement."

Pre-Visit Information – Pending Legal approval, a form will be completed by the probationer and provided to the "approved" Practice Monitor; this will provide the Practice Monitor with a general overview of the type of practice setting and patient volume handled by the probationer; and, it will assist in the preparation of the Monitoring Plans as well as the Site Visit Evaluation that will be performed by the approved Practice Monitor.

Roles and Responsibilities of the Practice Monitor – Pending Legal approval, a document will be provided to the nominated Practice Monitor(s), or after a Practice Monitor has been approved by the Supervising Inspector, which will provide the Practice Monitor a perspective of what the Probation Unit is seeking to fulfill with this condition.

Monitoring Plan – Pending Legal approval, a multi-page document with new and revised procedures will be provided to the Practice Monitor. Changes include:

- A requirement for an "initial site audit" which will be performed by the Practice Monitor on an annual basis, providing the Practice Monitor and Inspector with more insight into the probationers practice;

- Revisions to the Chart Review requirement from requiring 10% review of the patient charts per month and a quarterly report that represents 30% of the patients, to requiring review of 50% of the charts within the quarter. With this new model the Practice Monitor will review 50% of the charts in a quarter when the physician has 20 or less patients, 40% if they have 21-40 patients, and 30% for 40 or more (which is the current level provided regardless of the number of patients).

Information provided in the plan includes:

- Description of the selection process of the patient charts;
- Explanation of the HIPAA mandates;
- Timeline reflecting when the reports are due to the assigned Inspector;
- Information related to medical marijuana practices.

A copy of this agreement will be provided to the approved Practice Monitor and reviewed during the orientation, and will be used by the Practice Monitor during the annual site audit.

Individual Chart Audit – Pending Legal approval, a form will be used to document findings during chart review.

A side by side comparison was then presented of the current process versus the proposed process. Key differences included: the requirement that the probationer complete a pre-site information form; the Practice Monitor perform an initial site audit of the practice; the monitoring plan be more detailed; the orientation provided with the agreement be more extensive; forms developed and provided to the Practice Monitor for the chart audits; and, a sample report be provided.

At the last meeting it was suggested that a survey of past and current Monitors be completed to obtain information on concerns with the existing system. After review of materials, it was determined that a new survey was unnecessary because a survey previously performed identified the following: the amount charged by the Practice Monitor varies; the average amount of time spent conducting the service is 2-3 hours per month; Monitors wanted a standardized chart audit tool; and, Monitors wanted a training course. After reviewing the results of the survey, Staff is confident that they have addressed many of the concerns of the Practice Monitors. Upon Legal approval the new procedures will be implemented, and re-evaluated 3-6 months post implementation.

For instances where the Practice Monitor condition has been ordered in cases resulting from physician substance abuse, a new concept, utilizing a Worksite Monitor whose role and responsibilities would differ from performing chart reviews and worksite inspections, is being developed and will be presented at future committee meetings.

Dr. Low thanked Ms. Hayes and Ms. LaSota for their thorough overview.

Dr. Levine asked how a probationer might attain a Practice Monitor. Ms. LaSota responded that this process varies, and problems do arise when probationers find it difficult to ask for a Practice Monitor due to embarrassment or has difficulty finding a Practice Monitor because of a lack of resources in the area.

Dr. Levine suggested that it may be possible to have county medical societies act as a reference point to publicize information on the responsibilities of being a Practice Monitor as well as act as a referral source of willing Practice Monitors. Dr. Low concurred with this suggestion and recommended Board Staff appeal to the medical societies for assistance with this.

Ms. Schipske thanked staff for their presentation and made two suggestions: on page two of the practice monitor pre-visit sheet, nurse practitioner and midwife should be added as options; secondly, on the assessment, if the practitioner utilizes others to perform procedures, evidence of their written standardized procedures should be required. Ms. LaSota responded that when the initial intake interview occurs, one of the items asked is if there are written protocols for staff utilized in the office, however, they will look into adding this to the assessment requirements as well.

Mr. Zerunyan thanked Staff for their presentation and recommended a matrix be provided in the future, to document the effectiveness of the new forms and procedures.

Terra Kittle, Member of the Public, commented that the Committee is taking positive steps in developing a consistent program for physicians on probation, and encouraged developing a concrete system of expectations of all physicians practicing medicine.

Mr. Heppler referenced Ms. Dreisbach's comment that was read into the record during Agenda Item 2, stating that it was appropriate for this Agenda Item as well.

Agenda Item 5 Expert Reviewer Utilization

A. Central Complaint Unit

Ms. Threadgill provided a presentation on Expert Reviewer Utilization including a Power Point presentation. The Central Complaint Unit is responsible for performing the intake review, or triage, on new complaints filed with the Medical Board to identify those which warrant formal investigation. Business and Professions Code Section 2220.08 requires that before a quality of care complaint can be referred for formal investigation, the complaint must be reviewed by a medical expert practicing in the same specialty area as the physician named in the complaint. This statute went into effect in 2003 and, since that time, the Complaint Unit has increased the size and composition of their expert pool from about 15 general practice physicians to approximately 184 physicians in a variety of practice specialties.

The experts are hired as independent contractors similar to the expert reviewers used by the Board's District Offices and are compensated at a rate of $75 per hour for their reviews. The selection criteria used by the Complaint Unit for experts is very similar to that required for the expert reviewers. Staff looks for a physician with an active license with no complaint or disciplinary history and an American Board of Medical Specialties (ABMS) certification. The Complaint Unit can be less stringent with requirements related to active practice and can accept physicians who have retired within the last three years.

Upon receipt of an application for an expert reviewer, staff performs a background review and if no detrimental information is identified, the physician is appointed to the Complaint Unit expert reviewer pool and provided with a training manual. Staff will typically send several cases for review shortly after the training material has been provided and will then contact the reviewer by phone to walk them through the review process.

Cases are prepared for expert review by staff in the Complaint Unit. Staff will collect all relevant medical records and contact the physician named in the complaint to request a written summary of the care and treatment provided to the patient. Physicians are not required by law to provide a written summary; however, the board is required to give the physician the opportunity to respond. Once all relevant information has been gathered, the entire complaint file is referred for an expert review.

The complaint must be reviewed by a medical expert practicing in the same specialty area as the physician named in the complaint. Staff in the Complaint Unit will review the Complaint Unit expert reviewer list to identify an expert available to review the complaint. A chart provided in the meeting material was referenced, which reflected the composition of the current expert pool. There are approximately 184 physicians in a variety of practice specialties; however, some practice specialties are underrepresented and cases may be delayed waiting for experts to review them.

After reviewing the complaint file and the medical records, the expert prepares a written report of the findings, indicating that the complaint represents: no departure from the standard of care; simple departure; or will recommend the case be referred for further investigation to one of the Board's District Offices.

If the expert finds no departure from the standard of care, the complaint is closed by the Complaint Unit and retained for one year. If the expert finds an error or omission in the physician's care that represents a simple departure from standard, the complaint is also closed in the Complaint Unit but retained for five years. Finally, care that potentially represents an extreme departure from the standard is referred for a formal investigation to one of the Board's District Offices.

B. District Offices

Ms. Threadgill then presented on how the Field utilized Expert Reviewers. Qualifications for experts in the Field are similar to the Complaint Unit experts, with the exception that the experts must have an active practice where they work at least 80 hours per month, 40 of which must involve direct patient care. Each expert is provided with a guideline book for reference. The expert review is typically the last part of the investigation as the Investigators job is to gather enough information that the expert has enough information to make an educated opinion.

The Expert Review Database, utilized by Investigators, lists experts by specialty and sub-specialty. Once the Investigators select a potential expert from the database, they can review comments made by other Investigators, Medical Consultants, or Attorneys who have used the expert. Experts who receive poor ratings may receive remedial training, or may be removed from the program entirely.

Investigators or Medical Consultants interview the prospective experts. A checklist is utilized which includes confirmation that the experts understands their role, that there is no conflict of interest, that they understand the correct terminology, and that they have the expertise to render an opinion about the issue at hand. Because there is potential to bias an expert, resulting in an unusable opinion, the package is reviewed by the District Office Supervisor, and the Deputy Attorney General to insure it is complete, prior to the expert receiving it. Investigators are required to follow up with experts three weeks after delivery of the package. Ideally, the Board would like the opinion within 30 days of the expert package being delivered for review. Since July 2010 out of 299 records, the average number of days from delivery of package to receipt of the opinion is 47 days.

Experts from the database are also utilized for oral, mental, and physical exams. Once the opinion is received, it is reviewed by many, including the Medical Consultant, Expert, and the Attorney General assigned to the case.

Common problems that are encountered with the process: experts use incorrect terminology, arrive at a conclusion without analysis, fail to review all documents, and fail to listen to recordings. Staff is hopeful that the expert reviewer training that is currently being developed will resolve most, if not all of these issues.

After review of the case, the Expert will determine if a case represents: no violation, simple departure, or extreme departure. The expert's findings will decide the outcome of a case being closed or moving forward to filing. Upon receipt of the opinion, the Investigator, Medical Consultant, and Deputy Attorney General are key in rating the Experts for future use. The evaluation is not based on the outcome of the case.

Dr. Low thanked Staff for the thorough presentation and commented that the program was very comprehensive, structured, included checks and balances, as well as a system for the ongoing review of the Experts utilized.

Rehan Sheikh, Member of the Public, inquired how the Board is complying with the requirements of the Expert Reviewers and what the checks and balances consisted of. Dr. Low responded that the Enforcement Program has the interaction of the Medical Experts, Investigators, and the Attorney General's office, which act as the checks and balances.

Agenda Item 6 Enforcement Data Process and Data Markers/Timeline

Ms. Threadgill presented information on the Enforcement processes and timeframes associated with them, referencing the flow charts and data spreadsheet provided in the meeting materials. At the last Enforcement Committee meeting, Staff was requested to examine all processes used by the Board to investigate complaints, with the goal of identifying opportunities for process improvement and reducing investigative timeframes. Staff identified four major complaint categories from the Annual Report and prepared flow charts identifying each major step or activity, from the initial intake review through the investigation, to either closure or referral for administrative action.

Data was generated from the Enforcement tracking system on the Consumer Affairs System (CAS) to identify the average number of days to complete each step in the process, for each complaint type. The average number of days was posted to the flow charts by the appropriate step in the process. The data produced, reflects those cases where the activity was completed January 01, 2011 through March 31, 2011. The average timeframes presented in the initial report contained a relatively small data set and the number of records used to calculate the average time was displayed on the chart.

At the next meeting a larger data set will be provided which will allow a truer reflection of the average processing times. Data from past years will also be provided for comparison purposes.

Dr. Low was pleased with the work that went into making the flow charts and the data associated with them, and looked forward to the further analysis with the larger data set.

Mr. Zerunyan questioned what the expectations of the committee members were in relation to the data provided in the flow charts; whether any concerns noted should be reported back to Dr. Low as committee chair. Dr. Low responded that at the next meeting when a larger data set is provided, representing a truer reflection of the averages, discussion and possible action could be addressed at that time.

Ms. Threadgill indicated that because of the relatively small data set the numbers may be skewed due to cases with anomalies. Once the data is provided in a larger data set, it will be a truer reflection and can be included as regular meeting material.

Dr. Low requested that future data be provided with and without outliers to better represent the actual averages of the processes. Dr. Low indicated the data could be included in the Enforcement Report in the case the Enforcement Committee does not convene.

Ms. Schipske stated that it would be helpful to provide data with the outliers, including detail of those cases that are anomalies, to provide a better understanding of the actual timeframes.

Agenda Item 7 Agenda Items for July 28-29, 2011 Meeting in Sacramento, CA

Dr. Low requested that the following be included on the next Enforcement Committee agenda in October as there will be no July committee meeting:

- Update of Enforcement Process Data Markers/Timelines

Agenda Item 8 Adjournment
There being no further business, the meeting was adjourned.

DRAFT