

**MEDICAL BOARD STAFF REPORT**

DATE REPORT ISSUED: July 2, 2013  
 ATTENTION: Board Members  
 SUBJECT: Outpatient Surgery Setting Task Force Update and Requested Action  
 STAFF CONTACT: Curt Worden/Kimberly Kirchmeyer

**REQUESTED ACTION:**

Approve the Task Force's recommendation for a legislative proposal to require accredited outpatient surgery settings to submit adverse event reports to the Medical Board of California (Board) and authorize the Board the authority to issue a penalty to the outpatient surgery setting that does not submit the required report.

**BACKGROUND AND ANALYSIS:**

On June 25, 2013 the Outpatient Surgery Setting (OSS) Task Force met in Sacramento to: review and discuss the Board's Web site, specifically the OSS section; to discuss the core standards and additional standards required by the accreditation agencies and determine if additional standards are needed; and to discuss the adverse event reporting as required in law. The Board's OSS Task Force consists of Board Members Janet Salomonson, M.D. and Dev Gnanadev, M.D.

The OSS Task Force provided several suggested edits to the Board's Web site, including making edits and clarifications to the initial page for the OSS Program, requesting the ability to search for an OSS by city, and other minor changes that will enhance the Web site and make it more understandable. The Board staff will be working on these changes and those that do not require programmatic changes will be completed prior to the next OSS Task Force meeting and programmatic changes should be done before the Board Meeting in October.

The OSS Task Force also reviewed the list of core standards required by the accreditation agencies. Overall, the Members felt the core standards, as required in the Board's laws and regulations, provide the necessary consumer protection. However, the Members did feel that a few changes need to be made to existing statutes. The Members had some clarifying questions that they requested be provided by the accreditation agencies. Staff will be working to obtain that additional information prior to the next Task Force meeting. Once this information is received, the Members will be able to meet and make a recommendation to the Board on changes to the current laws and regulations.

Lastly, the Task Force discussed the adverse event reporting as required by Health and Safety (H&S) Code section 1248.15(h). This section subjects each OSS to the reporting requirements of H&S Code section 1279.1 and to penalties for failure to report specified in H&S Code section 1280.4. These sections, which are under the authority of the California Department of Public Health (CDPH), require the adverse event reports be submitted to the CDPH and authorize the CDPH to issue a citation for failing to report. OSSs that are only accredited by the Board have no relationship with the CDPH, and these sections of law do not authorize the Board to receive these reports.

Although the Board has been in discussion with the CDPH to try and obtain the information that has been submitted to it, the Board has been unsuccessful in procuring any information that could be used to initiate an investigation. The CDPH, in conjunction with the Center for Medicare and Medicaid Services (CMS), has stated that the information cannot be submitted to the Board. Although there is a process whereby the Board could petition CMS for the necessary information, such as patient name,

physician name, etc., the Board would have to submit a request for each report, would not receive the information until after the CDPH investigation is completed (which could take a significant amount of time), and the request may be denied by CMS.

Reports that are submitted to CDPH for facilities that are not licensed by CDPH or certified by CMS currently are not being investigated, as the CDPH has no authority over these facilities. Therefore, the Board believes it is necessary to change the law to require adverse event reports on accredited OSSs be submitted to the Board, and not CDPH. Additionally, due to H&S Code section 1280.4 only authorizing the CDPH to issue a civil penalty, the Board would need to have authority to issue penalties to entities that do not report to the Board.

The Task Force Members have reviewed this issue and support the proposal to seek legislation to require accredited OSSs to submit adverse event reports to the Board and to authorize the Board to issue a penalty to the OSS for failing to report.