Introduction

The Senate Budget Subcommittee #3 (Health & Human Services) requested that the California Department of Public Health (CDPH) provide a six-month update on the efforts of the Licensing and Certification Program (L&C) to improve its enforcement of state and federal law regarding health care facility oversight.

CDPH Licensing & Certification Program

CDPH is organized into five Centers dedicated to different aspects of public health. L&C is part of the Center for Health Care Quality (CHCQ) and is the largest program within CDPH, consisting of about 1,200 management and staff located in 14 District Offices and Los Angeles County. L&C has responsibility for enforcement of regulatory standards related to the quality of care provided in California’s approximately 8,000 health care agencies and facilities through its dual functions of state licensure and federal certification. L&C licenses approximately 30 different types of health care facilities conducting approximately 27,000 complaint investigations annually.

L&C is also the “state survey agency” for the Centers for Medicare and Medicaid (CMS) and is responsible for certifying to the federal government that the health care facilities are eligible for payments under CMS programs. L&C makes a certification recommendation after surveying the health care facilities and establishing that they are in compliance with all federal Conditions of Participation.

During confirmation hearings during the spring of 2012 for CDPH Director Ron Chapman and Chief Deputy Directors Kathleen Billingsley and Daniel Kim, the Senate expressed concern regarding CDPH’s health care facility oversight in several areas. Specifically, CDPH was asked to address:

- A 2010 Consumers Union report that stated CDPH had not held hospitals accountable related to medical error reporting.
- The impact of staffing reductions in the early 2000s.

The timeline for the development of several regulations packages, including Administrative Penalty fines

Degree to which surveyors use discretion in determining the severity of violations rather than employing standardized criteria.

Opportunities to merge the federal and state survey standards into a single survey tool.

All of these issues were addressed in-depth in writing and in hearings. This update discusses the way CDPH and L&C have built upon their responses to these issues to continue to improve enforcement for the remainder of 2012, and looks toward to plans for improving enforcement in the future.

Improving Enforcement

CHCQ, L&C is dedicated to strengthening its enforcement of state and federal law in order to ensure that patient safety oversight is as rigorous as possible. CHCQ, L&C recognizes that the health and safety of California’s most vulnerable populations is to be protected.

CHCQ, L&C has organized its oversight activities with a three-fold focus:

1. Building L&C organizational capacity to enforce state and federal law;
2. Improving L&C accountability for its fulfillment of responsibilities in the enforcement of state and federal law; and,
3. Sustaining L&C focus on enforcement of quality of care issues.

Throughout 2012, L&C has strived in enhancing its performance with this approach. There were a significant number of successes and lessons learned from implementing this three-fold focus. L&C’s willingness to do the collaborative hard work and adapt the necessary changes to the organization and business processes fostered the incremental successes of the program. In this report, we have highlighted L&C’s accomplishments.

1. Building Organizational Capacity

In addressing its responsibilities for ensuring regulatory compliance in California, L&C has focused first on building its organizational capacity to fulfill the mandated requirements. Its accomplishments this year in this area include:
• Increasing the personnel available for enforcement through active and effective recruitment for long-vacant surveyor positions.

In January 2012, the L&C surveyor vacancy rate was 11 percent. As of October 2012, the Health Facility Evaluator Nurse (HFEN) vacancy rate was 4 percent. In support of its ongoing recruitment to fill the remaining vacancies, L&C continues to work with CDPH Human Resources to streamline the hiring process to meet recruitment and retention goals. During the last quarter of 2012, L&C will send hiring postcards to all 300,000 registered nurses in California to fill the remaining vacant surveyor positions.

To recruit and retain surveyors with specific skills, clinical expertise, and training, L&C worked with California Department of Human Resources (Cal-HR) to modify the pay structure of surveyors, supervisors, and managers to recruit competitive candidates to fill the current vacancies.

• Providing surveyors with the necessary training to provide consistent enforcement statewide, including leadership development.

During 2012, L&C:
  o Filled 100 percent of the training slots provided by the federal government for federal surveys.
  o Ensured that all new surveyors complete appropriate training. This is including the state survey academy and the CMS long-term care training within one year of hire. In addition, new supervisors attended appropriate training as soon as possible, but in no case no later than six months after hire.
  o Provided the following training to surveyors:
    ▪ The federal enforcement protocols for End State Renal Disease Centers, Hospitals, Home Health Agencies, Ambulatory Surgical Centers, and Intermediate Care Facilities; and
    ▪ The Emergency Medical Treatment and Labor Act (EMTALA).
  o In collaboration with DHCS, provided mandated training on the new surveyor tool related to evaluating antipsychotic medication use. This tool is required for use on all SNF surveys as of August 1st, 2012.
  o Provided mandatory training to all surveyors conducting complaint investigations, including assessing scope and severity to ensure consistent application of federal regulations throughout the District Offices. This training was completed on September 27th, 2012.

Additionally, four members of California’s surveying training team received Long Term Care (LTC) Instructor training. This is an efficient means to provide LTC training locally and more frequently.

Finally, L&C is committed to providing leadership training at headquarters as well as the District Offices. L&C has implemented a formal mentoring program that allows District Office Managers and Administrators to transmit their institutional
knowledge to the supervisors and new surveying staff. L&C is also offering a companion mentoring program for new supervisors to foster and promote consistent application of processes and application of enforcement activities among district offices.

- **Patient Safety Regulations Ensuring Consistent Licensing Standards**
  L&C made significant progress moving forward with several important regulations packages that will provide updated or new guidance to surveyors on the consistent application of state licensing standards. Among the regulations packages in development are the following:
  
  (a) **Administrative Penalties** (released for public comment October 27th, 2012). This package will provide clear and consistent guidance to surveyors throughout California on the application of administrative penalties for Immediate Jeopardy, and non-Immediate Jeopardy state licensing violations.
  
  (b) **Cardiac Catheterization Laboratory (Emergency Regulations)** (anticipated release by February 2013). This package addresses legislation chaptered in 2012 (AB 491, Ma, Chapter 772) that allows hospitals with cardiac catheterization laboratory services to locate the services in a building adjacent but connected to a hospital.
  
  (c) **Tuberculosis Testing** (anticipated release by June 2013). This package will update the allowable choices for TB screening tests.
  
  (d) **General Acute Care Infection Control (including Surgical Site Infection Reporting)** (anticipated release by June 2014). This package will clarify and specify what hospitals must report regarding surgical site infections and revise existing regulations to reflect changes in statute.

### 2. Enhancing Accountability

To support fulfillment of its responsibilities, L&C has focused on how to measure its accountability for the enforcement of state and federal laws related to health care facilities. L&C’s accomplishments during 2012 in improving accountability include:

- **Implementation of new tracking logs and workload management processes.**
  L&C’s monitors new tracking logs at both the District Office and state Headquarters levels to ensure that survey and complaint investigation activities are completed in a timely manner. As a result, L&C has identified several opportunities to improve the consistency and timeliness of enforcement activities. Going forward, L&C will be using the logs to quantify L&C’s current performance against performance goals, statutory requirements, and historical performance.

- **Increase in the number of required federal surveys completed at every type of health care facility.**
  CMS establishes annual workload standards that define the number of surveys for each type of certified health care facility that state survey agencies must
complete. During the 2012 federal fiscal year, ending September 30th, L&C fulfilled all but one of the standards. In fulfilling the federal workload standards, L&C conducted 3,429 federal surveys (of a required 3,397) reviewing California’s health care facilities during 2012. However, L&C had 8 surveys that were not completed in the appropriate federal timeframe. Below is a table reflecting recent federal workload completion rates.

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<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
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<tr>
<td>Percentage of Standards Met</td>
<td>30%</td>
<td>50%</td>
<td>50%</td>
<td>94%</td>
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<tr>
<td>Number of Surveys Not Completed within the Specified Interval</td>
<td>67</td>
<td>61</td>
<td>66</td>
<td>8</td>
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- **Timely resolution of Long Term Care (LTC) complaints.**
  Since 2007, CDPH has initiated over 99 percent of long term care complaints within the statutory timeframe of ten (10) days. Effective March 2012, L&C is now regularly achieving closure of skilled nursing complaints and entity reported incidents investigations within 60 days of the exit date of the investigation. Since March, L&C has closed 90 percent of long term care complaints and entity reported incidents within 60 days.

3. **Sustaining L&C Focus on Enforcement of Quality of Care Issues**

L&C retains its focus on rigorously holding health care facilities accountable and improving health care facility performance through enforcement of appropriate state and federal regulations that impact quality of care. Following are several examples of this focus:

- **Administrative Penalties and Adverse Events:**
  From 2007 through August 2012, L&C had issued 242 Administrative Penalties (APs), 197 as a result of investigating Adverse Events (Health and Safety Code Section 1279.1 requires hospitals to report approximately 28 specific events to Licensing and Certification that may have an adverse impact on patients). To date, $9,650,000 has been assessed ($7,337,208.35 collected). Of those APs resulting from Adverse Events, over 66 percent of them have been attributed to the retention of foreign objects in a patient following a surgical or other procedure, medication errors, and patient care issues.

  Administrative penalty fines are deposited into the Internal Departmental Quality Improvement Account (established by Section 1280.15 of the Health and Safety Code). L&C has used IDQIA funds appropriated by the Legislature to contract for
patient safety improvement work for retained foreign objects, medication safety and under reporting of adverse events.

• **Skilled Nursing Facility (SNF) Staffing Audits:**
SNFs in California are required to provide 3.2 Nursing Hours per Patient per Day (NHPPD) as a basic and minimal standard of what is required to provide care. Compliance with this requirement enables SNFs to qualify for consideration for incentive payments. During State Fiscal Year 2011-2012, L&C completed 1,095 staffing audits (100 percent of California’s SNFs) and found 86 percent were fully compliant with the NHPPD for every audited day. Of the 14 percent (153) that were not in compliance: 57 were subject to a $15,000 administrative penalty (for non-compliance during 5 to 49 percent of audited days) and 10 were subject to a $30,000 administrative penalty (for non-compliance for more than 49 percent of audited days); 88 were non-compliant for only one of the audited days and not subject to an administrative penalty.

• **Medication Error Reduction Plan (MERP):**
All licensed hospitals are surveyed every three years for compliance with applicable laws and regulations related to reducing medication-related errors. In 2012, 100 percent of hospitals subject to MERP surveys have been found to have deficient practices, whereas 94 percent of hospitals received deficiencies in the 2009-2011 cycle of MERP surveys.

• **Antipsychotic Medication Collaborative:**
In partnership with the Department of Health Care Services (DHCS), CMS, and numerous stakeholders, L&C responded to a U.S. Health and Human Services Report regarding a high percentage of skilled nursing facility (SNF) residents receiving antipsychotic medications inappropriately, by developing and implementing a new survey tool to identify and cite inappropriate use. All L&C surveyors have received training in this issue and in the use of the new survey tool, which is being evaluated for use in every SNF survey, including all complaint investigations.

**Looking Forward**

L&C will continue to build on its accomplishments in 2012 and welcome the opportunity to demonstrate its dedication to serving the people of California in 2013. Among the projects and/or programs currently anticipated are:

• **L&C organizational performance assessment**
L&C is currently contracting for an outside organizational assessment of effectiveness and performance. The assessment, targeted to initiate before the end of the calendar year, will evaluate L&C’s resources, workload mandates and performance, workload management processes, organizational culture, and
propose opportunities for L&C to implement operational efficiencies and best practices.

- **Tools to improve performance.**
  Related to our focus on consistent application of state and federal enforcement requirements, beginning in 2013, surveyors will utilize an electronic tablet during health care facility inspections from which they will be able to access the L&C Policy and Procedures Manual (which provides specific instruction to surveyors on a variety of enforcement activities and procedures), as well as federal regulations and interpretive guidance, online at any time.

- **Evaluation of coordinating state licensing and federal certification surveys.**
  L&C will use the recommendations of the organizational and performance assessment to begin an evaluation process of both state and federal survey processes to identify efficiencies and areas for process improvement.

- **Improving Medication Error Reduction Plan (MERP) Performance.**
  L&C is committed to developing ways to reduce medication errors for all licensed hospitals. L&C has recently revised the MERP survey tools and survey activity guidelines to better embrace evidenced based best practices, including ongoing medication safety concerns so as to promote quality care. With the passage of recent legislation regarding centralized packaging, compounding pharmacies (AB 377 (Statutes of 2012, Chapter 687)), L&C has begun development of a "Sterile Compounding Products" survey tool to address regulatory compliance and safety concerns in this unique practice environment. The new survey tools will be implemented in early 2013.

- **Complete Antipsychotic Survey implementation.**
  The Antipsychotic Collaborative has developed an action plan for the coming year to continue to promote appropriate non-pharmacological interventions in lieu of inappropriate antipsychotic medication use for dementia residents of California nursing homes. The Partnership's primary goal is ending misuse of antipsychotic medication in California's nursing homes, and specifically reducing use of antipsychotics by 30 percent by June 30, 2013. (A "Summary Report" outlining this group's activities and "next steps" is to be available late December 2012.)

- **Increase the number of revisits.**
  With L&C’s commitment to the federal complaint process and surveyor training it is our goal to increase the number of revisits when a deficiency is cited at the level of immediate jeopardy, actual harm to a resident(s) or when there is substandard quality of care.

- **Increase compliance with applicable laws through state issued citations.**
  State law authorizes CDPH to issue citations as enforcement remedies which includes monetary penalties for violations that constitute harm or the potential for
harm to residents of skilled nursing facilities. L&C will continue to exercise this authority to ensure patient safety through investigating complaints and issuing citations where appropriate.

CDPH is committed to its role of protecting the health and safety of California’s most vulnerable populations. CDPH continues to examine process and procedures to improve oversight enforcement of the laws and regulations governing health facilities.