State, Federal Regulators Target Specialty Labs

Specialty Laboratories' CLIA-88 license "yanked" by CMS laboratory enforcers

CEO SUMMARY: Specialty Laboratories, Inc. has earned the dubious honor of being the first-ever publicly-traded laboratory to have its CLIA-88 license revoked by federal regulators, terminating its right to payment for services covered by Medicare and Medicaid. The revocation is slated to take effect on April 26, but is subject to a court appeal that suspends the revocation until a decision is rendered.

NEWS THAT STATE AND FEDERAL laboratory regulators had **Specialty Laboratories, Inc.** targeted in their crosshairs captured the full attention of the nation's clinical laboratory industry.

On April 15, Specialty Labs publicly acknowledged that it faced a revocation of its CLIA-88 license due to "action taken by the federal **Centers for Medicare and Medicaid Services** (CMS) as the result of alleged noncompliance by Specialty with requirements of the federal Clinical Laboratory Improvements Act of 1988 (CLIA-88), including, subject to appeal, revocation of Specialty's CLIA-88 certificate and termination of its right to payment under the Medicare and Medicaid programs."

The sanctions issued by federal lab regulators were triggered by deficiencies noted during inspections of Specialty Laboratories conducted by the **California Department of Health Services** (CDHS). CDHS represented the State of California and acted as agent for CMS.

A CDHS agent identified deficiencies during a CLIA complaint survey of Specialty Labs that was conducted on June 25-26, 2001. These deficiencies were confirmed at a follow-up visit on October 9-10, 2001.

Based on its findings, the state generated written notifications to Specialty Laboratory "citing the fact that supervisors and testing personnel failed to possess current California clinical laboratory personnel licenses." It requested cor-

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rective action for these and other deficiencies that were noted during the surveys and inspections.

Sanctions And Revocation

On April 18, 2002, Specialty Labs filed a Form 8-K report with the **Securities and Exchange Commission**. Included in this filing is a copy of the April 12, 2002 letter sent to Specialty Labs by the CMS Regional Office in San Francisco. This letter imposed the sanctions noted above and detailed many of the deficiencies. Readers of THE DARK REPORT can access this public filing by going to Specialty's Web site at *www.specialtylabs.com*.

In response to the revocation of its CLIA-88 license, Specialty Labs is filing an appeal. By so doing, the implementation of CMS's license revocation and other sanctions is suspended until an administrative law judge issues a ruling. Effectively, this allows Specialty Labs to continue performing testing as a CLIA-88-licensed laboratory. However, the stakes are huge. If Specialty loses this appeal, it will have to stop performing lab tests.

Medicare Billing Affected

As part of this situation, Specialty Labs terminated billing for Medicare and Medicaid services as of February 22, 2001. The lab company believes it can be paid retroactively for such services if its appeal is upheld. It also believes that its hospital clients can legally bill Medicare and Medicaid, because Specialty's CLIA-88 license remains valid during the appeals period. The company is requesting a confirmatory opinion from CMS on this point.

"The State of California issued sanctions against Specialty Laboratories involving three separate points," stated Ken August, Public Affairs Officer for CDHS. "First, we gave them a directed plan of correction. Second, civil money penalties totalling $224,000 were assessed, based on a fine of $1,000 per day from a date last fall through March first.

"Third, once Specialty Laboratories corrects the identified deficiencies and is again in compliance, the State of California will maintain a program of random, on-site monitoring for a period of three years," noted August.

Feds Levy Four Sanctions

As detailed in the April 12 letter, following months of discussion, CMS (and CDHS) did not consider Specialty Lab's latest Plan of Correction (POC) to be acceptable. Its patience exhausted, CMS issued sanctions involving four elements. One, it revoked Specialty Lab's CLIA-88 certificate, subject to appeal. Two, it cancelled the lab company's approval to receive Medicare and Medicaid payments. Three, it imposed a civil money penalty of $3,000 for each day of non-compliance. Four, it imposed a directed plan of correction by which "CMS may notify Specialty's customers of its non-compliance and the nature and effective date of any sanctions imposed."

THE DARK REPORT discussed this situation with Paul Beyer, President of Specialty Laboratories. "We erroneously interpreted California regulations," he said. "How we built our staffing models was deemed to be out of compliance. In California, technical staff has a designation as CLS—clinical laboratory scientist. Regulations call for clear and constant supervision of testing. We are working to revise our Plan of Correction and will submit it to the authorities shortly."

Beyer was quick to point out one overlooked aspect of this matter. "There are no patient care issues," he stated. "That is why we continue to perform testing. Anytime there are

Specialty Labs' Management Now Must Deal With a Passel of Unique Problems

FACED WITH REVOCATION of its CLIA-88 license, executives at Specialty Laboratories must now deal with a host of consequences.

First and most importantly, Specialty Labs faces potential loss of its license to perform lab tests. If that happens, it can no longer perform lab testing. Development of a Plan of Correction (POC) to restore regulatory compliance is now high priority.

Second, the value of its stock has fallen dramatically. This may draw lawsuits from disgruntled shareholders who believe the company did not fully disclose the material facts of its troubles with CDHS and CMS in a timely fashion.

Third, Specialty Labs has a big damage control job ahead with its customers. Its problems with CMS undoubtedly make many hospitals nervous about continuing to refer testing to the lab. Because Specialty Labs' customers are themselves familiar with CLIA regulations, they have legitimate questions about the management integrity behind the testing performed at Specialty Labs, as well as the integrity of the lab test results. Allegations by state and federal regulators that unlicensed or improperly licensed personnel have been performing tests and supervising testing will certainly draw intense scrutiny by skeptical pathologists and lab administrators.

Taken collectively, these challenges place Specialty Laboratories at a crossroads. Its ability to successfully overcome all these problems will require adroit management skills. The irony of this situation is not lost on most lab executives and pathologists, because Specialty Laboratories has long prided itself on the quality of testing it performs, its innovations in esoteric testing, and the service it provides its customers.

concerns about patient safety, regulators will close a laboratory."

Beyer demurred when asked more detailed questions about this situation and the reasons why such an intense dispute developed between Specialty and government regulators since the "complaint survey" visits by CDHS on June 25-26, 2001 and October 9-10, 2001.

What Started This Mess?

Lab regulators identified a range of deficiencies during their visits to Specialty Laboratories. However, many deficiencies seem to center around unlicensed personnel performing lab tests and unlicensed personnel supervising lab testing.

California has regulations that define the educational requirements and experience required for the designation of "clinical laboratory scientist" (CLS). For that reason, the terms "medical technologist" and "medical technician" often used in other states, are not part of California's regulatory scheme.

THE DARK REPORT has learned that, in some cases, Specialty hired individuals who were board-certified in their area of laboratory medicine. But, for whatever reason, after arriving in California, neither Specialty nor the individuals had satisfied the full requirements for state licensure.

From a variety of sources, THE DARK REPORT has pieced together an early assessment of the situation. The April 12 letter from CMS to Specialty contains details about some of the most important non-compliance issues. On page 3 of the letter, paragraph four states "Persons unlicensed in California were observed in all sections performing clinical laboratory activities not permitted under BPC

§1269. While performing these clinical laboratory activities, the unlicensed personnel were not subject to the required direct and constant supervision under BPC §1206(a)(8)."

Similarly, on page 4 there is a statement that characterizes staffing practices this way "...Based on the large number of unlicensed personnel supervising and performing clinical laboratory testing in multiple specialty testing areas of the laboratory and [the] deficiencies previously cited in prior surveys..." Thus, concern about unlicensed staff performing and supervising testing represents a key element.

"Tech"/"Non-Tech" Ratios

In fact, the letter does identify some staffing ratios. On page five, it states that Specialty provided a "current list of personnel" showing 349 total staff, identified as "two directors and 142 other persons licensed under BPC Division 2, Chapter 3." There were "205 unlicensed persons, two listed as Technical Consultants, four Lead Technicians, nine Technicians III," and so forth. It also noted that "two unlicensed persons in the Cytogentics and Genotyping sections are listed as Technical Director on Attachment 58."

Of the 349 individuals, regulators identified only 144, or 41.2%, as licensed. Such statements indicate that regulators were specific in identifying what they considered to be deficiencies in the staffing model used at Specialty. Assuming, for the moment, this is true, there may be several factors that influenced how and why Specialty Laboratories organized its testing operations the way it did.

One contributing factor would be the shortage of trained medical technologists in the Santa Monica area of Los Angeles. It's no secret that Specialty Labs' unique test mix is labor-intensive; many of the assays are complicated, time-consuming and require more hands-on effort by the technical staff. Another factor is Specialty's rapid growth in specimen volume. Executives at the troubled lab have long acknowledged that hiring and retaining adequate technical staff has been a challenge.

Working Environment

The second factor probably involves management practices. It can be speculated that temporary surges in specimen volumes would bump up against the inadequate supply of technically-trained labor. It would not be surprising to find that, whenever there was a lack of sufficient licensed "clinical laboratory scientists" to handle large volumes of specimens, temporary "work-arounds" were implemented. Some of these, whether intentional or not, seemed to have become part of the daily routine.

In at least one area of the lab, the deficiencies identified by CDHS were serious enough to cause Specialty Labs to cease testing in that department. Sometime in February, Specialty ceased testing in its cytogenetics department and laid off most of the staff. Since that date, it refers cytogenetics specimens to other labs.

Unprecedented Sanctions

Because the action of CDHS and CMS to place serious sanctions and revoke the operating license of a publicly-traded lab company is unprecedented, it must be assumed that allegations of non-compliance involve more serious deficiencies than "sloppy recordkeeping" or "poorly-maintained procedure manuals."

It may well be that the reasons for this situation have to do with how pressures of a fast-growing laboratory business led to inappropriate decision-making. There is certainly much more to this story and the details will eventually become public knowledge. TDR

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