Laboratory Quality Confab

Mayday Boss! CLIA Inspectors Are in Our Lab and They Are NOT Happy!

November 3, 2010

Introduction

- Chi Solutions, Inc. (Chi) is the country's largest laboratory consulting company.
- Chi's projects encompass many areas of laboratory operations. Regulatory compliance is one of our key service areas. We have been involved in helping to resolve some highly publicized regulatory cases in the past.
- During the past 9-12 months, we have seen a significant increase in the number of clients seeking help with CLIA-related issues.
- We have identified some common themes from these cases.

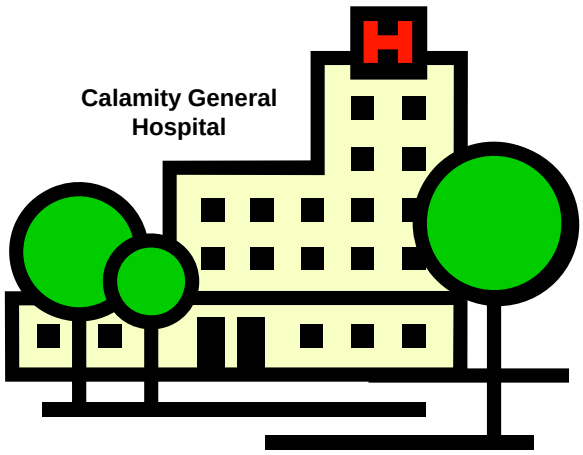
Case Study Overview

- Chi has been contacted by multiple laboratories in the past 12-15 months looking for assistance with addressing regulatory deficiencies identified during the laboratory's biannual inspection process.
- We have identified several common root causes of these deficiencies.
- By using case studies to present these findings, we hope to underscore how the current pressures facing laboratories can lead to regulatory problems.
- Regulatory standards are established to ensure quality patient care. Failure to address the underlying issues causing these failures will result in poor quality.

Background Information

- These case studies represent several different real-life situations. The cases have been combined so that neither case represents any particular institution, but all incidents are the result of recent inspection activity.
- In some instances, the laboratories were first inspected by organizations other than the local CLIA office. The results of those preliminary inspections, when communicated to CMS, triggered a follow-up CLIA inspection.

Case #1 Introduction



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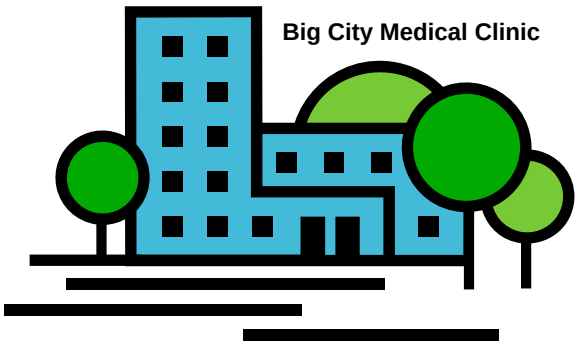
Case #2 Introduction



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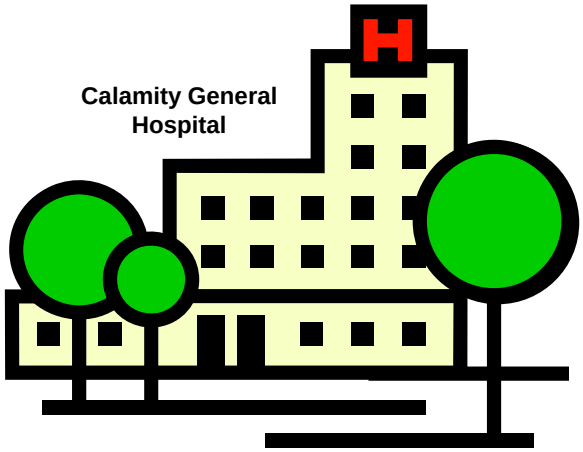
The Inspection Process

- In many cases, CMS authorizes state and local government agencies to perform CLIA inspections on its behalf.
- Several organizations have deemed status to inspect in lieu of a state agency. These groups have requirements that are more stringent than CLIA and must include all items found in the regulations.
- If one of these organizations discovers areas of CLIA noncompliance during the inspection, CMS will be notified and may or may not re-inspect the laboratory.
- CMS also authorizes validation inspections on a percentage of the laboratories inspected by other agencies.

Case #1 The Inspection

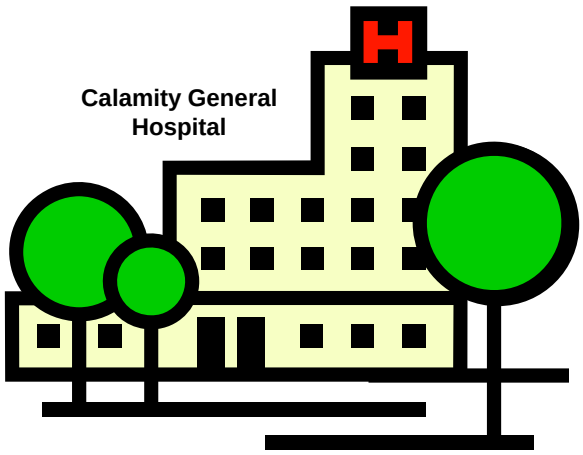


Case #2 The Inspection

Noncompliance and Sanctions

- After discovery of nonconformance, CMS may impose a number of different sanctions on the laboratory up to and including revocation of the CLIA certificate.
- The laboratory is given a time period to respond to the deficiencies as well as an explanation of the sanctions to be imposed if the situation is not corrected.
- The severity of the noncompliance and the potential for harm to patients are factors in determining the corrective actions required by the laboratory and the ultimate sanctions imposed.
- Often, follow-up inspections are planned to ensure that the corrective actions have been effective.

Case #1 Response



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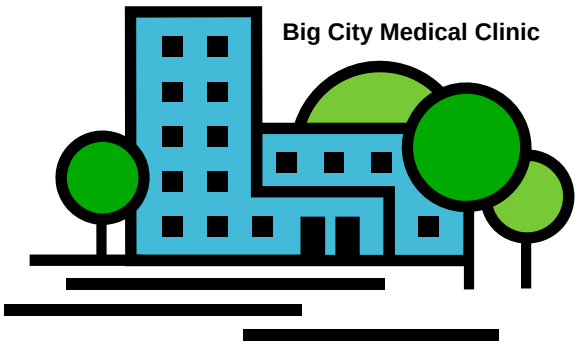
Case #2 Response



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Common Deficiencies

- CMS and each of the other laboratory regulatory agencies publish lists of the most common deficiencies cited.
- While these lists are helpful to laboratories as they assess inspection readiness, the root cause of the deficiencies in troubled laboratories goes much deeper.
- Virtually every laboratory is facing the challenges of:
  - The aging workforce.
  - Financial demands and constraints of the organization.
  - Cost of new technology.
- Some organizations deal with these issues better than others.

Common Issues in Troubled Laboratories

- Lack of involvement by the medical director.
- Administrative leadership unaware of the laboratory's regulatory status.
- All regulatory responsibility given to one individual in the laboratory.
- Excessive cost constraints resulting in critically decreased staffing.
- Incomplete/ineffective corrective action resulting in repeat deficiencies.
- No mechanism for incorporating new information or interpretation of regulatory standards into the operation.

What Can Be Done?

- Include specific regulatory responsibilities and tasks in the medical director's contract.
- Involve senior administrative leadership in the inspection process.
- Ensure that more than one individual in the laboratory is aware of and responsible for regulatory compliance.
- Consider regulatory requirements when discussing cost reductions.
- Set parameters for monitoring the results of corrective action.
- Develop a process to review new regulatory information and incorporate the changes into the laboratory operation.

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For a complete set of presentation PowerPoint slides visit: www.labqualityconfab.com

For more information about Chi Solutions, Inc. visit: www.chisolutionsinc.com

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