Partners in Laboratory Oversight

9/06

Guidance for Coordination of CLIA Activities Among CMS Central Office, CMS Regional Offices, State Agencies (including States with Licensure Requirements), Accreditation Organizations and States with CMS Approved State Laboratory Programs

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BACKGROUND AND PURPOSE

The Partners in Laboratory Oversight are conducting meetings in response to a mutual commitment to enhance communication and coordination among all entities and have determined that a document outlining these improved communication mechanisms and information-sharing opportunities would be beneficial. The Partners' efforts are intended to facilitate ongoing communication, coordination and promote greater understanding of each entity's relevant activities and policies in order to establish higher level, more effective oversight programs that embrace our common goal of quality testing.

The ***purpose*** of this document is to provide the CLIA Partners with guidance for the communications necessary to consistently coordinate major activities, particularly in critical circumstances where an expeditious, effective response to a complaint, survey findings or a publicly volatile situation is necessary. This will ensure that each organization or government entity has timely, appropriate information to afford optimum effectuation of their individual oversight program and will concurrently, in collaboration with all affected parties, determine the best course of action and responsibilities required for a maximal response to the issue.

NOTE: This document is not intended to supersede or replace any government regulations; policies, organizational protocols utilized by individual government agencies or organizations to direct their specific program activities, but should be compatible with them. It is intended to be a dynamic, not static, representation of the Partners' agreements, efforts and accomplishments.

This document applies to the following entities.

- CMS central office (CO)
- CMS regional offices (RO)
- State agencies (SA), including States with licensure requirements
- Accreditation organizations (AO)
- AABB
- American Osteopathic Association (AOA)
- American Society for Histocompatibility and Immunogenetics (ASHI)
- COLA
- College of American Pathologists (CAP)
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
- States with CMS approved State Laboratory Programs
    - New York
    - Washington

One goal of the Partners' meetings was to identify certain critical elements that ensure an effective survey process and the above-listed parties have agreed to incorporate them into their individual survey protocols. Those elements are listed in *Attachment 1* of this document. *Attachment 2* includes a suggested list of information that should be shared among the Partners in a situation requiring the Rapid Response Protocol.

SECTION I: PARTNERS' ROLES IN ENHANCING COMMUNICATION AND COORDINATION

CMS CO is ultimately responsible for the effective administration of the CLIA program and, therefore, becomes actively involved in certain situations requiring a rapid response and coordinated actions to help ensure proper handling. A Rapid Response Protocol (RRP), one of the central features of this document, has been developed to assist Partners in quickly communicating and initiating coordinated activities when survey findings, actions or complaints have the probability of resulting in:

-Significant impact to the public health;
-Media coverage;
-Federal/State Congressional or political concerns;
-Legal/public interest or intervention;
-Involvement of CMS CO Staff;
-Involvement of other Federal and /or State agencies or entities; or
-Coordinated Partners' response in cases of immediate jeopardy.

The above list is not all-inclusive and Partners are encouraged to initiate the RRP in any instance where CMS CO coordination, special attention and handling may be necessary. An outline of the RRP is included as *Attachment 2*.

Once CO and the affected partners have decided the appropriate course of action and responsibilities for a situation, the CMS RO will continue the coordination process thereon from a CLIA perspective while keeping everyone informed.

CMS CO also oversees the validation survey protocols with their associated reports, the complaint process and related data system and other communication and coordination duties of the CLIA program.

SECTION II: COMMUNICATION

ACCREDITED LABORATORIES

RO, SA & AO Roles

The RO has the lead in coordinating and communicating many routine activities among all partners including validation surveys and complaint activities. The RO also is responsible for facilitating the implementation and ongoing follow up of the RRP.

Validation Surveys:

- In an immediate jeopardy (IJ) situation, the RO receives survey information and recommendations from the SA; notifies the SA, CO and AO via fax, overnight mail or e-mail of immediate actions initiated. If a situation reaches a significant level of concern, the affected entities will promptly further coordinate their efforts as outlined in the RRP.

- The AO must ensure that the laboratory responds to the survey findings and encourages the laboratory to remove the IJ expeditiously. If the laboratory does not remove the IJ within 23 days of notification by CMS, the RO alerts the AO that CMS will suspend the laboratory's certificate. The RO forwards copies of selected documents to CO for the validation per the SOM.

- For condition level deficiencies with no immediate jeopardy and deficiencies below the condition level, within 10 days, the RO routinely copies the SA and AO on all correspondence (including the statement o deficiencies). The AO will ensure the laboratory responds, at a minimum, to the condition level deficiencies.

Complaint surveys:

- If the complaint is received directly by the RO, the RO evaluates the complaint and determines whether the SA, the RO or the AO will investigate the complaint.

- If the SA receives the complaint directly, including those in states with a laboratory licensure program, the SA will forward it to the RO for disposition and the RO will notify the AO and coordinate their efforts.

- Communication requirements for complaint surveys performed by the SA or RO in accredited laboratories are the same as validation surveys.

- If the complaint survey identifies problems that are warranted, the RRP is initiated to engage appropriate entities to ensure a coordinated response.

SECTION II: COMMUNICATION

ACCREDITED LABORATORIES

***Complaint surveys:* (*continued*)**

- The SA conducts the complaint survey within 2 days of receipt from the RO, if the RO determines that the complaint involves a potential immediate jeopardy or if not, within 45 days. The SA reports their findings to the RO and AO at the conclusion of the survey.

- If the RO determines that a complaint investigation should be referred to the AO, the AO will notify the RO of the results of any investigative action taken. The AO will also notify and/or coordinate with any other involved AO of the investigation and actions taken.

- Complaints received directly by an AO will be addressed and investigated by the AO using its standards and procedures.

SECTION III: COMMUNICATION

CLIA EXEMPT LABORATORIES IN STATES WITH CMS APPROVED LABORATORY PROGRAMS

RO and Approved State Roles

Even though a State laboratory licensure program may be approved and its laboratories are exempt from the CLIA requirements, CMS CO retains ultimate authority over the applicable CLIA laboratory testing within the State program. The RO is responsible for the ongoing CLIA oversight of the approved State program; e.g. validation surveys, etc. In cases involving approved States that may qualify for the RRP, the entity that receives the information initially should promptly alert the involved parties, including CO and pertinent AOs. CO, in conjunction with the RO, will then coordinate their activities.

In the instance of New York which has an approved State program for a portion of the laboratories and a CMS-overseen component for the remainder, there needs to be ongoing communication and coordination of efforts between these entities and the RO.

Validation surveys:

- In an immediate jeopardy situation, within 2 working days of the survey, the RO sends a notification of determination (letter) that directs the State to take appropriate action under its approved licensure program and notifies CO and any relevant AOs. The State program and AO will coordinate with the RO and encourage expeditious removal of the immediate jeopardy. The State program notifies the RO and AO of the results and any actions taken. If a situation reaches a significant level of concern, the affected entities will promptly further coordinate their efforts as outlined in the RRP.

- For condition level deficiencies with no immediate jeopardy and for deficiencies below the condition level, the RO sends the State a notification of determination letter within 10 days of completing the survey and copies the AO on any correspondence (including the 2567). The State and AO follow up to obtain correction and respond to the RO with results and any actions taken.

Complaint surveys:

- If the RO receives a complaint against a CLIA exempt laboratory, the RO may investigate the complaint or transmit it to the approved State Laboratory Program and AO (if relevant) for their action.

- Communication requirements for complaint surveys performed by the RO in CLIA exempt laboratories are the same as validation surveys.

SECTION III: COMMUNICATION

CLIA EXEMPT LABORATORIES IN STATES WITH CMS APPROVED LABORATORY PROGRAMS

Complaint surveys: (continued)

- The State program will notify the RO and all involved AOs of CLIA associated complaints it receives directly and coordinate follow up actions with the RO and AO. If the laboratory is not accredited, the State should follow its standard operating procedures in investigating and initiating any necessary actions and provide copies of all relevant correspondence to the RO.

- If the complaint survey identifies problems that are warranted, the RRP is initiated to engage appropriate entities and to ensure a coordinated response.

- If the complaint survey in an exempt State identifies a situation with immediate jeopardy, the State, RO and any relevant AOs will encourage prompt removal of the jeopardy and coordinate their communication and correspondence as needed until the problem is resolved.

- If an AO receives a complaint directly against a State exempt lab under its jurisdiction or it is determined that the AO will investigate the complaint, the AO should notify the State, the appropriate RO and any other AOs, coordinate the investigation and copy them on all correspondence and actions taken.

SECTION IV: REGULATORY REPORTING REQUIREMENTS

AOs AND STATES WITH CMS APPROVED LABORATORY PROGRAMS

Regulatory responsibilities of each approved accrediting organization and State laboratory program include notifying CMS, through the appropriate RO, on an ongoing basis, when certain situations occur. This information must be communicated in writing or via the appropriate CMS data mechanism by the AO or State program within a specific time frame as required by the CLIA regulations and include the laboratory name, CLIA number, deficiencies identified, if applicable, and dates of identification or of any actions taken. The following describes those situations that should be communicated by the AO or State program to the RO.

- Immediate jeopardy situations (within 10 days)

- Newly accredited or licensed laboratories, including specialty, subspecialty and test volume information (within 30 days)

- Data related to unsuccessful PT performance and actions taken (within 30 days)

- Any adverse actions taken by the AO or the State, e.g., denial, withdrawal or revocation of accreditation or State licensure, limitation of specialty/subspecialty, etc (within 30 days)

- Revisions in specialty/subspecialty testing (additions or deletions) in existing accredited or CLIA exempt laboratories (within 30 days of receipt from the laboratory)

SECTION V: DEFINITIONS

For clarity purposes, the following definitions are provided:

- A ***complaint investigation*** includes any activity or follow up conducted by the SA, RO, approved State program, State licensure program or AO concerning a complaint received from any source. The investigation may or may not result in an on-site survey. A ***complaint*** is any information received by any of the above that causes doubt or concern regarding CLIA compliance of a regulated entity.
- A ***focused survey*** is an on-site survey that addresses the deficient condition and requirements alleged by the complaint.
- An ***expanded survey*** is a ***focused*** survey that has been enlarged to include all condition and standard level requirements applicable to the laboratory operations because the focused survey findings resulted in a condition level deficiency or other findings or information warrant it.
- ***Immediate Jeopardy*** means a situation in which prompt corrective action is necessary because the laboratory's noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury, or harm, or death, to individuals served by the laboratory, or to the health and safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard to the public health.
- ***State Operations Manual (SOM)*** contains policies, procedures and instructions on day-to-day CLIA activities based on regulatory requirements.
- ***Unsatisfactory PT performance*** means a failure to attain a minimum satisfactory score for an analyte, test, specialty or subspecialty for a testing event.
- ***Unsuccessful participation in PT*** means one of the following:
    - Unsatisfactory performance for the same analyte for 2 consecutive or 2 out of 3 testing events;
    - Repeated unsatisfactory overall testing event scores for 2 consecutive or 2 out of 3 testing events for the same specialty or subspecialty;

SECTION V: DEFINITIONS (continued)

- An unsatisfactory testing event score for those subspecialties not graded by analyte, that is, bacteriology, mycobacteriology, virology, parasitology, mycology, blood compatibility, immunohematology, or syphilis serology for the same subspecialty for 2 consecutive or 2 out of 3 testing events; or
- Failure of the laboratory performing gynecologic cytology to meet the requirements at 42 CFR 493.855.

- ***Unsuccessful PT Performance*** means a failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for 2 consecutive or 2 of 3 testing events with a rolling time frame.
- ***Validation Survey*** is an on-site inspection of an accredited or state exempt laboratory by CMS or its agent, up to 90 days after the accrediting organization's (AO) or State Laboratory program's inspection, to assess compliance with CLIA requirements and ultimately, the results of these validation surveys reflect the performance of the AO or State program.

Attachment 1

THE SURVEY PROCESS: CRITICAL ELEMENTS
Partners in Laboratory Oversight

Representatives of CMS CO, ROs, SAs (including those with State licensure requirements), AOs, and CMS approved State laboratory programs met February 14-15, 2005, and determined the critical elements of a survey process. Each of the parties agreed the following critical elements would be incorporated into their survey protocol.

Pre-Survey Preparation

1. Initiate initial contact, as applicable (clarifying application information, scheduling survey if announced)
2. Request proficiency testing history
3. Review general laboratory history (changes since last survey, complaints, previous survey findings and corrective actions, laboratory staffing)

Entrance Conference

1. State the overall survey goals and objectives (who, what, why?)
2. Provide an overview of survey process (what will happen during this survey?)
3. Tour the laboratory (may include the specimen workflow path)

Sample Selection Criteria

1. Include new personnel, tests, equipment, laboratory information system, location
2. Select proficiency testing data
3. Identify number of testing sites, services offered, patient population served
4. Observe critical activities (e.g., blood banking)
5. Request critical values, laboratory's policy for such and actions taken
6. Review prior compliance and complaint history

Information Gathering/Interviews/Record Review/Investigational Techniques

1. Become interactive—show me
2. Evaluate laboratory practice against written policy and procedures
3. Observe and evaluate laboratory output (all testing steps, proficiency testing data, comparative data, QC and maintenance,)
4. Examine quality Assessment program
5. Balance records review and staff interaction (achieving the right balance is a surveyor skill learned through training and experience)

THE SURVEY PROCESS: CRITICAL ELEMENTS (continued)

Exit Conference

1. Provide a summary of findings: for deficiencies, include the standard, severity, and examples or data
2. Afford an opportunity for laboratory to provide additional information
3. Outline process for submitting plan of correction
4. Indicate authority to remove copies of documents
5. Solicit a Root Cause Analysis
    a. State this is a laboratory responsibility
    b. Look for and offer patterns and indicators
    c. Include corrective and preventive actions
    d. Offer guidance to the laboratory; however, laboratory must perform analysis

Plan of Correction

1. Must demonstrate sustained compliance
2. Ensure communication and collaboration among affected parties on serious issues

Surveyor Selection/Training/Oversight

1. Qualifications: Medical technology training, laboratory experience, communication skills, auditing skills
2. Training: teamwork skills, standards, mentoring and evaluation, documenting meaningful findings from observations, knowing and understanding the survey process, auditing techniques, flexibility, confidentiality, conflict of interest, professional conduct, sensitivity, continuing education in technical and soft skills, ongoing monitoring for effectiveness

Attachment 2

RAPID RESPONSE PROTOCOL

The Rapid Response Protocol (RRP) is the vehicle Partners will use for quickly communicating and initiating coordinated activities when survey findings, actions or complaints have the probability of resulting in:

- Significant impact to the public health;
- Media coverage;
- Federal/State Congressional or political concerns;
- Legal/public interest or intervention;
- Involvement of CMS CO staff;
- Involvement of other Federal and/or State agencies or entities; or
- Coordinated Partners' response in cases of immediate jeopardy.

The above list is not all-inclusive and Partners are encouraged to initiate the RRP in any instance where CMS CO coordination, special attention and handling may be necessary.

Attached is a suggested format which may be used for the RRP, however use of the format is optional and Partners may invoke the RRP via email, telephone, fax or other means. Whatever method is used for communicating the RRP, the following information should be provided:

- The reason for invoking the RRP;
- The facility/laboratory name, the laboratory director/owner(s), CLIA number, addresses and telephone number(s);
- The issue(s) and relevant dates;
- Pending or planned action in response to the issue;
- All potentially impacted parties (and whether other parties have been contacted); and
- If applicable, requested action.

NOTE: For situations with national or regional issues, a broadcast notification or red-flag email should be made to all parties. Otherwise, for local issues only, notification can be limited to the known involved parties.

An RRP should be generated as soon as relevant facts are known, and communicated to the appropriate CMS RO, as well as CMS CO. The CMS RO and CMS CO will promptly review each RRP and determine the need for any further actions or activities. Although CMS will be responsible for helping to plan a coordinated response if circumstances warrant, accreditation organizations and approved State programs will retain their full responsibilities for taking necessary actions under their programs.

Rapid Response Protocol -- Information to be Shared with Partners

From: _____ _____
(Name of CO/RO person/AO/State) (Date)
_____
(Telephone Number/Email Address)

Facility Information:

_____ ----------
(Name of Facility) (CLIA#/AO #/State #)

_____ ----------
(Address) (Laboratory Director/Owner Name)

---------- ----------
(City/State/Zip) (Facility Telephone Number)

Additional facility-related information:

Need for Rapid Response (*potential or actual*): [Check all applicable.]

___ Significant impact to the public health (Describe)

___ Media coverage (Describe)

___ Federal/State Congressional or political concerns (Describe)

___ Legal/public interest or intervention (Describe)

___ Involvement of CMS CO staff (Describe)

___ Involvement of other Federal and/or State agencies or entities (Describe)

___ Coordinated Partner response in cases of immediate jeopardy (Describe)

___ Other (Describe)

Is immediate jeopardy involved? (Describe) _____ (Yes) _____ (No)

Briefly describe the issues and supply relevant dates:

Identify all potentially impacted parties: (Have other parties been contacted?)

Requested action(s):