Attachment 2

Survey Protocol for First Cycle (FY2004-FY2005) (Includes Initial and Recertification Surveys)

Outlined below are four survey finding scenarios listing the required forms that need to be completed and entered into the ODIE/CLIA systems and in ASPEN Survey Explorer.

Scenario 1 **Laboratory has no deficiencies.**

Forms: CMS-1539, Certification & Transmittal form: mark 'in compliance with program requirements.'
CMS-1557, Laboratory Survey Report Form: update with personnel and specialty/test volume information.
CMS-670, Survey Team Composition and Workload form: complete according to standard instructions.
CMS-2567, Statement of Deficiencies and Plan of Correction form: update ASPEN Survey Explorer by annotating D0000 with 'no deficiencies.'
CMS-116, Laboratory Application form: ask laboratory to provide any updates to information on record.

Scenario 2 **Laboratory's only deficiency(ies) include analytic systems provisions that are new to that laboratory.**

Forms: CMS-1539: mark 'in compliance with program requirements, based on receipt of an acceptable plan of correction'; annotate State Agency Remarks to state that Model Letter 1 was sent to laboratory.
CMS-1557: update with personnel and specialty/test volume information; also update the 'Letter Sent' field in ODIE.
CMS-2567: update ASPEN Survey Explorer by annotating D0000 with 'see attached letter.'
Model Letter 1: prepare and present to laboratory.
CMS-670: complete according to standard instructions, count time taken to prepare Model Letter 1 in Off-Site Report Preparation category.
CMS-116: ask laboratory to provide any updates to information on record.

Scenario 3 **Laboratory's only deficiency(ies) include provisions that were required under the former CLIA rules.**

Forms: CMS-1539: mark 'in compliance with program requirements, based on receipt of an acceptable plan of correction.'
CMS-1557: update with personnel and specialty/test volume information.
CMS-2567, CMS-2567B: update ODIE and ASPEN Survey Explorer with required deficiency data.

CMS-670: complete according to standard instructions.
CMS-116: ask laboratory to provide any updates to information on record.

Scenario 4 **Laboratory has deficiencies in items that were required under the former rule as well as deficiencies in the analytic systems provisions of CMS-2226-F that are new to the laboratory.**

Forms: CMS-1539: mark 'in compliance with program requirements, based on receipt of an acceptable plan of correction;' annotate State Agency Remarks to state that Model Letter 2 was sent to laboratory, along with CMS-2567.
CMS-1557: update with personnel and specialty/test volume information; also update the 'Letter Sent' field.
CMS-2567, CMS-2567B: update ODIE and ASPEN Explorer with required deficiency data, as appropriate. Also, annotate D0000 with 'see attached letter.'
Model Letter 2: prepare and present with CMS-2567.
CMS-670: complete according to standard instructions, include time taken to prepare Model Letter 2 in report preparation category.
CMS-116: ask laboratory to provide any updates to information on record.

Other Survey Protocols for First Cycle (FY2004-FY2005)

Follow-up/Revisit Surveys

Any deficiencies cited at the time of the survey on the CMS-2567 will require corrective action by the laboratory. Use the standard operating procedures already in place. For deficiencies listed in either letter, encourage the laboratory to correct by the next recertification survey. In lieu of a follow-up survey, contact laboratories to provide education and assistance. Any time immediate jeopardy is found, consult with the CMS RO.

- Deficiencies cited that apply to former CLIA rules must be collected on the Post-Certification Revisit Report form, CMS-2567B, and reported in both OSCAR/ODIE and in ASPEN Survey Explorer.
- Deficiencies cited that apply to provisions solely contained in the newly effective revised rules, as listed in Model Letters 1 and 2, are not reported in OSCAR/ODIE or in ASPEN Survey Explorer.

Complaint Surveys

Investigate complaint allegations according to existing survey policies and procedures. If problems are noted in provisions contained in the newly effective revised rules, base deficiency citations/letter issuances and enforcement action(s) on whether or not the issue concerns analytic systems provisions that are new to the laboratory and have an impact on patient care (see Attachment 1). Consult the

CMS RO when in doubt. Follow standard operating procedures for problems identified that are contained in the final regulations, but not new to the laboratory.

Validation surveys

As always, validation surveys are to be conducted like compliance surveys and copies of all validation packages (including Letter 1 or 2, if used) forwarded to the CMS RO as soon as the survey is closed out. For the validation review, no action will be necessary regarding deficiencies related to analytic systems provisions new to the laboratory surveyed that are communicated in Letters 1 or 2. The rationale is two-fold:

- In the validation review, determinations about similarity of accreditation organization inspection findings/CLIA survey findings and the calculation of disparity rate are focused only on condition-level deficiencies cited on the CMS-2567.

- For the first cycle, CMS will have an educational approach for those laboratories having deficiencies related to the analytic provisions newly applicable to them (except for harm or potential risk of harm).

Please note: Even though deficiencies listed a Letter 1 and 2 will not be included in the validation review comparisons and disparity rate calculations, include the letter, if issued, with the validation package when forwarded to Central Office. It will help provide a fuller picture of the case, which is helpful for the overall review.

Enforcement Actions

The enforcement procedures remain the same for the CLIA regulations that **have not** changed in the final regulation.

In order to help laboratories understand the new requirements, the first cycle survey conducted under the final regulation will take an educational approach. For first cycle surveys, no enforcement actions will be taken when a laboratory is not in compliance with analytic systems provisions that are new to the laboratory. However, enforcement action may be taken during the first cycle of the final regulation requirements when there is immediate jeopardy. If there is any question regarding enforcement during this first survey cycle, consult with the CMS RO or Central Office.

After the first cycle survey, enforcement for all final regulation requirements will be handled as for the former regulation requirements, i.e., all deficiencies will be cited on the CMS-2567 and enforcement actions will be taken if deficiencies are not corrected.