March 5, 1997

Judy Yost, MA, MT
Director, CLIA Program
Health Care Financing Administration
7500 Security Boulevard, 2-09-28
Baltimore, MD 21244

Dear Ms. Yost:

Enclosed you will find the American Society of Internal Medicine (ASIM) summary and results of our CLIA inspection process survey. Based on the survey results, many CLIA inspectors appear to have taken the outcome based inspection protocol seriously and have attempted to make the inspection process a more educational one. ASIM encourages HCFA to consider the following recommendations as they continue to find innovative ways to lessen the hassle of physician office lab (POL) inspections:

- Continue to solicit and seriously consider feedback from physicians, POL staff, ASIM and other physician organizations. Only by keeping an open discussion going between inspectors and POLs can the inspection process become as streamlined, efficient and *education-oriented* as possible.

- Continue to devote resources to educating state surveyors about the new and evolving outcome-oriented inspection process. While ASIM's survey results suggest that the inspector education process has been a successful one thus far, it is important to continue making progress in the right direction and to keep all surveyors informed about new policies and procedures as they are implemented.

- Address remaining weaknesses in the inspection process. While those filling out inspection surveys after the outcome-oriented process was implemented strongly agreed or agreed with the majority of the survey's positive statements, the median response for the statement: "The deficiencies cited have an impact on patient outcomes" was "No opinion", indicating a lower level of agreement.

The slight improvement in POL staffs' impressions of the CLIA inspection process is consistent with the stated goals of the program and ASIM encourages the Health Care Financing Administration to continue to work with state surveyors to make patient outcomes the number one priority, while at the same time, making it easier for physicians to continue to offer valuable laboratory tests in their own offices by easing the burden that CLIA inspections place on physician office labs. If you have any further questions about our survey results, please contact me at (202) 466-0299.

Sincerely,

John P. DuMoulin, Director
Managed Care and Regulatory Affairs

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CLIA OUTCOMES ORIENTED INSPECTION
SURVEY SUMMARY AND RESULTS
"A Survey: Rating your CLIA Inspector"
February 1997

Introduction

In May 1996, the Health Care Financing Administration (HCFA) announced a move toward an outcome-oriented physician office laboratory (POL) inspection process aimed at increasing its emphasis on evaluating those laboratory practices potentially having a direct impact on the quality of patient care and favorable patient outcomes. These changes were instituted in response to comments received by HCFA over the past several years from the American Society of Internal Medicine (ASIM) and other physician organizations who were concerned that the survey process mandated by the Clinical Laboratory Improvement Amendments of 1988 (CLIA)--which had been established in 1992-- was based on overly rigid and ambiguous standards that did little to educate laboratory staff on those practices and procedures having the greatest impact on patient outcomes. As a result of the punitive and overly critical nature of the survey process, many internists and other physicians discontinued all or most of the moderate and high complexity laboratory tests that they previously offered in their offices, thus forcing patients to obtain necessary tests at different sites.

At a May 1996 meeting during which the new outcome-oriented survey process was outlined, HCFA emphasized that surveyors would start paying more attention to what providers wanted, focusing on what labs are doing *right*, and placing more emphasis on the quality component of CLIA regulation. Concerned with the impact of burdensome on-sight CLIA laboratory inspections on patient access and quality of care, ASIM supported the move by HCFA to make inspections more "POL-friendly" and educational. In an October 1996 letter to ASIM, HCFA emphasized that surveyors would use their "experience and professional judgement . . . to determine whether the nature and severity of a situation lends itself to the citing of condition-level deficiencies and at this time [HCFA] has not constructed finite limits on the use of condition-level deficiencies in describing noncompliance." The agency had also previously noted that less emphasis would be placed on quality control, personnel verification, patient test management and proficiency testing. These issues would continue to be addressed but not reported unless deficiencies in these areas clearly have a potentially damaging impact on patient outcomes.

While HCFA's altered inspection policy appeared to be a favorable one for POLs, ASIM realized that many inspectors were accustomed to the old process and would likely require a period of adjustment to the new one. It was therefore difficult to predict whether or not there would be perceivable benefits to internists and other physicians with in-office labs in the short term. In order to evaluate the progress made so far in implementing these changes, in January 1997, ASIM asked POLs enrolled in its Medical Laboratory Evaluation (MLE) proficiency testing program to fill out surveys rating the impact of the new outcomes based focus in order to determine whether or not HCFA was achieving its stated objective of "partner[ing] with regulated laboratories to help improve patient care and not to promote an antagonistic atmosphere by citing deficiencies that have no direct impact on the laboratory's overall performance."

The Survey Methodology

The survey was sent to 2331 POLs in January 1997. It queried respondents on twelve items ranging from the helpfulness and courteousness of the inspectors to their belief about whether or not cited deficiencies pointed to problems having a direct impact on patient outcomes. Respondents were asked to answer each question using the following scale: (1) Strongly Agree; (2) Agree; (3) No Opinion; (4) Disagree; and (5) Strongly Disagree. ASIM received 170 completed[1] responses from labs throughout the country; 86 filled out for inspections occurring before HCFA's May 1996 implementation of the outcomes oriented process, and 71 for those occurring after May 1996.

[1]ASIM received a total of 195 responses, 25 of which were not properly completed; therefore the data could not be used.

Respondents were also given an opportunity to explain why they strongly agreed or disagreed with any or all of the statements. Selected comments will appear at the conclusion of this summary report.

Principal Findings

The "Rating Your CLIA Inspector" survey sought to determine whether or not the implementation of the outcome-oriented inspection process in May 1996 has, in practice, altered the perception that POL staff have of CLIA inspections in general, and more specifically, the effectiveness of the CLIA inspectors themselves under the new process. Additionally, several questions were aimed at determining whether or not the inspections have become a *more educational* and constructive experience.

Based on the survey results, several conclusions can be drawn about the impact of the newly focused inspection process:

- In general, those POLs undergoing CLIA inspections after May 1996, had a slightly **more favorable and more educational experience** than those inspected before the institution of the new process.

- The CLIA inspections ratings **slightly increased** on all twelve of the survey measures in the post May 1996 survey period.

- While surveys filled out for both time periods indicated that the majority of POL staff strongly agreed that the inspector was courteous and helpful, respondents for inspections occurring post-May 1996 also **strongly agreed** that "The inspector's overall focus was on the quality of laboratory testing," and that "The inspector clearly explained reasons for each deficiency." Those undergoing pre-May inspections agreed, but did not strongly agree with both statements. This improvement demonstrates a **consistency with the stated goals of the new process**.

- Respondents offered fewer comments regarding any of the statements for inspections completed after May 1996. Many of those comments that were included, however, tended to reflect a rather negative impression of the inspection process. This indicates that while POL staff may now be having more positive experiences with CLIA inspectors, many do believe that there are **still problems to be addressed**. The majority of such comments expressed the respondents' belief that many of the deficiencies cited were still minor in nature having little impact on patient outcomes. (It should be noted that more post-May 1996 respondents noted that they had *no deficiencies.*) CLIA inspectors are still citing POLs for standard deficiencies that do not have a readily discernable impact on patient outcomes.

Recommendations

Based on ASIM's survey results, many CLIA inspectors appear to have taken the outcome based inspection protocol seriously and have attempted to make the inspection process a more educational one. ASIM encourages HCFA to consider the following recommendations as they continue to find innovative ways to lessen the hassle of POL inspections:

- Continue to solicit and seriously consider feedback from physicians, POL staff, ASIM and other physician organizations. Only by keeping an open discussion going between inspectors and POLs can the inspection process become as streamlined, efficient and *education-oriented* as possible.

- Continue to devote resources to educating state surveyors about the new and evolving outcome-oriented inspection process. While ASIM's survey results suggest that the inspector education process has been a successful one thus far, it is important to continue making progress in the

right direction and to keep all surveyors informed about new policies and procedures as they are implemented.

- Address remaining problems and weaknesses in the inspection process. While those filling out inspection surveys after the outcome-oriented process was implemented strongly agreed or agreed with the majority of the survey's positive statements, the median response for the statement: " The deficiencies cited have an impact on patient outcomes" was "No opinion", indicating a lower level of agreement.

While ASIM will continue to encourage HCFA to ease the burden that CLIA inspections place on physician office labs, the preliminary impression gleaned from the survey results indicates that the institution of a more outcome oriented process has begun to produce the results that HCFA--and ASIM--hoped it would. The slight improvement in POL staffs' impressions of the CLIA inspection process is consistent with the stated goals of the program and ASIM encourages HCFA to continue to work with state surveyors to make patient outcomes the number one priority, while at the same time, making it easier for physicians to continue to offer valuable laboratory tests in their own offices.

ASIM Survey: "Rating Your CLIA Inspector" Results

Total Responses: 170

(5) Strongly Agree (4)Agree (3)No Opinion (2)Disagree (1)Strongly Disagree

		Mean[2](post 5/96)	Median(post 5/96)	Mean(pre 5/96)	Median(pre 5/96)
1.	**The inspector was courteous and helpful.**	**4.65**	**5**	**4.47**	**5**
2.	**The inspector's overall focus was on the quality of laboratory testing.**	**4.56**	**5**	**4.24**	**4**
3.	**The inspection was an educational process.**	**4.28**	**4**	**4.02**	**4**
4.	**Inspector provided suggestions for improving laboratory practices.**	**4.52**	**4**	**4.04**	**4**
5.	**I have a better understanding of my responsibilities regarding the laboratory.**	**4.17**	**4**	**3.81**	**4**
6.	**I am able to correct any problems in my laboratory with the information provided by the inspector.**	**4.23**	**4**	**3.86**	**4**
7.	**I learned something that I did not know regarding good laboratory practices.**	**3.76**	**4**	**3.56**	**4**

[2]The mean was rounded up to the second decimal place.

8.	**The inspector gave useful and understandable feedback.**	**4.40**	**4**	**4.03**	**4**
9.	**The inspector clearly explained reasons for each deficiency.**	**4.37**	**5**	**4.08**	**4**
10.	**The inspector provided helpful suggestions for correcting any deficiencies.**	**4.34**	**4**	**4.00**	**4**
11.	**The deficiencies were valid.**	**3.96**	**4**	**3.64**	**4**
[3]12.	**The deficiencies cited have an impact on patient outcomes.**	**3**	**3**	**2.52**	**3**

Selected Comments: (post May 1996 inspections)

"Inspector was excellent. Can't say enough good things about him."

"The problems were with [quality assurance] records regarding PT specimen collection and tracking. I feel that even though we did not have the documentation, we carefully monitor all labs."

"All deficiencies were very minor and unrelated to patient outcomes."

"We were doing everything right so we didn't learn anything - they are more concerned with written policies than how the lab runs. The one deficiency was running controls for physician performed microscopy which is useless for quality."

"We changed to COLA because of the condescending, authoritative manner expressed by the CLIA representative."

"All deficiencies were very minor and unrelated to patient outcomes."

"The deficiencies were minor and had no effect on patient care or lab results."

"Not sure what deficiencies were found - he offered good suggestions."

"Deficiencies cited for not having 'written' job descriptions for lab director to general supervisor - this lab has one technician with the doctor acting as lab director. This has been the status quo for the last 7 ½ years, with the same personnel. Jobs are 'understood' and completed as required."

"Our laboratory deficiencies comprised of documentation - not laboratory practices . . . I strongly feel the deficiencies had no impact on patient outcomes . . . I am already aware of my responsibilities regarding the lab - the correction of problems and good laboratory practices."

[3]25 of the respondents indicated that they had no deficiencies. Whether or not the others had no deficiencies or truly had no opinion is unknown.