Laboratory Sanctions for Proficiency Testing Sample Referral and Result Communication

A Review of Actions From 1993–2006

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Context.—The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations for proficiency testing (PT) include prohibitions against intentional PT sample referral or result communication, and specify sanctions against laboratories that violate these regulations. There has been little published analysis of sanctions against clinical laboratories because of PT violations.

Objective.—To examine the application of principal sanctions as reported by the Centers for Medicare and Medicaid Services annually in the Laboratory Registry and to examine relevant aspects of judicial hearings and appeals in these cases.

Design.—The Laboratory Registry was examined for all available years (1993–2006) to determine the incidence of application of principal sanctions for PT violations. In addition, the decisions from the US Department of Health and Human Services hearings and appeals were reviewed to better understand the judicial disposition of these cases.

Results.—During the 14-year period examined, 78 laboratories received a principal sanction for a PT violation involving sample referral or result communication. During the same period, the number of laboratories in nonexempt states that would be expected to have participated in PT averaged 45,983. The interpretive meaning of the key terms intentional and referral, and the implications for sanctioned laboratories and their owners and operators are discussed.

Conclusions.—Applications of a principal sanction for a PT violation were rare during the period of this study. However, the consequences of the imposition of such a sanction are severe. Suggestions are offered on policies and practices to minimize the risk of a PT sample referral or result communication.

(Arch Pathol Lab Med. 2009;133:979–982)
operator of the laboratory are effectively prohibited from owning or operating a clinical laboratory for a 2-year period (§493.1840[a][8]). Laboratories may ask for a hearing to contest certain CMS-imposed sanctions before an administrative law judge and may appeal a judge’s decision to the Department of Health and Human Services (DHHS) Departmental Appeals Board (§493.1844). Further appeals may be made to the US Court of Appeals for the district in which a laboratory has its principal place of business.

Little information is available in the literature on the frequency or types of sanctions for PT sample referral or result communication that are imposed under the CLIA regulations. A review of all sanctions applied between 1993 and 2001 found that most sanctions were applied because of regulatory noncompliance, with fraud being a relatively infrequent reason, but PT violations were not specifically discussed.2 A US Government Accountability Office report that called for strengthening of clinical laboratory oversight noted that only 1 of a total of 4 accredited laboratories that had been found by their accrediting organization to have engaged in improper PT referral had been sanctioned.3

The purpose of this study was to survey the frequency of actions by CMS and the accrediting organizations for this type of violation and to examine the judicial review of cases in Departmental hearings and appeals.

METHODS

Data on sanctions imposed on clinical laboratories by CMS or by the accrediting organizations are published in the annual Laboratory Registry (LR).4 As required by the CLIA regulations, CMS includes in the LR a listing of laboratories that were sanctioned by CMS or by an accrediting organization in the preceding year and the reasons for imposing these sanctions. The decisions of all appeals and hearings are also published in the LR. The LR was reviewed for the 14 years from its inception in 1993 to the most recently available report, which covers 2006. For each year, data on the application of a principal sanction or denial of accreditation because of PT sample referral or interlaboratory communication were obtained from the LR. For the purpose of this analysis, these sanctions were considered to have been applied during the year in which they were first recorded in the LR even if an appeal decision was delivered in a later year. During the period of this study, CMS or its predecessor, the Health Care Financing Administration (HCFA), prevailed in all appeals. Laboratories that lost their CLIA certification because they were under common ownership or operation with a laboratory that had had its CLIA certificate revoked for a PT violation were not included in the data set. Additional information was obtained by review of cases decided by administrative law judges in the Civil Remedies Division of DHHS and by the Departmental Appeals Board.

Data on the annual numbers and types of CLIA certificate from 1993 to 2006 were obtained from the CMS CLIA database.5

RESULTS

From 1993 to 2006 the annual LR reports list 78 laboratories that received a principal sanction by CMS or were denied accreditation by an accrediting organization because of PT sample referral or result communication. Of the 78 cases, 8 were denials of accreditation by an accrediting organization; the remainder of cases involved CMS (or HCFA) actions. The distribution by year is shown in the Figure. Data on the number of CLIA certified laboratories (other than those holding a certificate of waiver or provider-performed microscopy) are shown in Table 1. During this period, the number of laboratories in nonexempt states with a certificate of compliance or accreditation averaged 45,983 and the number of additional laboratories of all types in exempt states averaged 6,175.5

There were more than 30 hearings and appeals before administrative law judges or the Departmental Appeals Board related to PT referral or result communication. The Centers for Medicare and Medicaid Services (or HCFA) prevailed in all cases. Relevant findings from these cases are discussed below.

COMMENT

During the first 14 years in which sanctions were documented in the LR, 78 laboratories are recorded as having
received a principal sanction or denial of accreditation because of PT sample referral or communication. Given the much larger number of certified laboratories that were performing PT during this time, it is apparent that application of principal sanctions or denials of accreditation for PT violations was rare. There was an increase in the number of sanctions imposed from 1999 through 2000 arising in part from a related cluster of cases in one state. With the exception of the increase during those years, the number of applications of principal sanctions has been relatively stable during the 14-year period.

It is instructive to review the hearings and appeals decisions in these cases. The CLIA regulations prohibit intentional PT sample referral and result communication. In this context, it has been repeatedly held that the meaning of the word intentional does not require that there be a finding of an intention to cheat on proficiency testing.6 Any referral, other than one made inadvertently, of a PT sample to another laboratory is a violation of the regulation. Although §493.801(b)(4) (prohibiting referral) specifies revocation of a CLIA certificate as a sanction, whereas §493.801(b)(3) (prohibiting communication) does not, the 2 types of violations are considered by CMS as effectively the same and either can result in revocation of a CLIA certificate. Importantly, judicial decisions have determined that it is not necessary to find that physical transfer of a PT sample occurred to conclude that there was referral.7–9

The consequences for the laboratory owner and operator in cases of PT sample referral or result communication are considerable. By regulation, a CLIA certificate can be revoked for a laboratory owned or operated by a person who owned or operated another laboratory that had its CLIA certificate revoked for any reason during the preceding 2 years. (This regulation effectively amounts to a 2-year ban on the owner and operator). In an organization that owns multiple laboratories, there may therefore be a

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### Table 1. Number of Laboratories Holding Certificates of Compliance and Accreditation (Nonexempt States) and Number Receiving Principal Sanctions or Denials of Accreditation by Year

<table>
<thead>
<tr>
<th>Year</th>
<th>Compliance</th>
<th>Accreditation</th>
<th>Total</th>
<th>Sanction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1993</td>
<td>44,762</td>
<td>23,751</td>
<td>68,513</td>
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</tr>
<tr>
<td>1994</td>
<td>40,384</td>
<td>19,359</td>
<td>59,743</td>
<td>1</td>
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<td>1995</td>
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<td>57,004</td>
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<tr>
<td>1996</td>
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<td>55,601</td>
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<td>15,803</td>
<td>46,843</td>
<td>1</td>
</tr>
<tr>
<td>1998</td>
<td>30,546</td>
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<td>48,041</td>
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<td>1999</td>
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<table>
<thead>
<tr>
<th>Year</th>
<th>Compliance</th>
<th>Accreditation</th>
<th>Total</th>
<th>Sanction</th>
</tr>
</thead>
<tbody>
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<td>2000</td>
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<td>16,992</td>
<td>42,060</td>
<td>17</td>
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<td>21,809</td>
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<td>20,832</td>
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<tr>
<td>2006</td>
<td>20,026</td>
<td>15,957</td>
<td>35,983</td>
<td>2</td>
</tr>
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</table>

### Table 2. Suggested Dos and Don’ts to Comply with CLIA Requirements for Proficiency Testing (PT) Samples

**Dos**

1. Handle PT samples like patient samples (but never send a PT sample outside the laboratory, even if patient samples are normally referred for additional, confirmatory, or reflex testing).
2. Keep records of PT testing (including any corrective actions following unsuccessful PT performance) for at least 2 years.
3. Be aware of all CLIA certifies and their respective laboratories within an institution. There must be no referral of PT samples or communication of results between laboratories that operate under different certificates, even if owned by the same institution. Results from multiple laboratories should be returned to the PT organization by different members of personnel.
4. Be aware of patient sample referral practices to other laboratories. Ensure that personnel who are responsible for referring patient samples know that PT samples must never be referred to another laboratory.
5. Notify the accrediting organization or CMS if the laboratory receives what appears to be a PT sample from another CLIA-certified laboratory. Do not test the sample.
6. Ensure that laboratory staff members regularly review and understand the rules for handling PT samples.

**Don’ts**

1. Send a PT sample outside the laboratory for any reason. If a sample requires review or interpretation by an outside pathologist, the pathologist should perform that task in the laboratory that received the PT sample.
2. Discuss PT results with staff from another laboratory before they are returned to the PT organization by different members of personnel.

Abbreviations: CLIA, Clinical Laboratory Improvement Amendments of 1988; CMS, Centers for Medicare and Medicaid Services.

Arch Pathol Lab Med—Vol 133, June 2009

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significant impact following revocation of a CLIA certificate, well beyond the impact on the laboratory that was directly implicated in a PT violation. As an illustration of this point, the CLIA certificates of at least 27 laboratories that had not participated in any PT impropriety were revoked because they were under common ownership with laboratories that had been found to have engaged in such activities. It should also be emphasized that under the CLIA regulations, the laboratory director is an operator (§493.2), and therefore may be subject to the 2-year ban on directing a clinical laboratory after revocation of a certificate. Laboratories are held responsible for the actions of employees that engage in prohibited PT sample referral or result communication even if management was unaware of or had not authorized such actions.

Proficiency testing sample referral and sample communication undermine the principle that PT, despite its limitations, remains an important measure of the ability of a laboratory to produce reliable test results. It is, of course, not possible to use PT to gauge the reliability of a laboratory if its reported PT results are generated wholly or in part in a different laboratory operating under different management and using different testing personnel, instruments, and methods and following a different quality assurance program. For this reason, PT sample referral and result communication are treated as serious matters, which can incur severe sanctions.

In addition to negating the primary purpose of PT, it has also been argued that collaboration among PT participants that leads to submission of similar or identical results by a group of laboratories may affect the validity of the PT program for all participants. For example, such an effect might be expected for those PT challenges in which the mean and standard deviation of participants’ results form the basis for determining the allowable range of results to achieve a passing score for all participants. The magnitude of the effect of such collaboration would be expected to depend on the survey, its grading scheme, the number of collaborating participants, and the total number of participants. However, there appear to be no available published data on this topic from known cases of PT collaboration.

Laboratory owners, directors, and employees should be aware of the serious consequences that can result from intentional PT sample referral or result communication. A suggested list of dos and don'ts for handling PT samples is given in Table 2 and in a recent CMS communication to laboratory directors.

References
14. Melvin C. Murphy, MD v HCFA, CR 590 (1999).