Place: Spring Room, Silver Spring Holiday Inn, 8777 Georgia Avenue, Silver Spring, Maryland 20910.

The meeting is open to the public with the exception of the period from approximately 8:30 a.m. until 9:30 a.m. on April 18, when grant applications will be reviewed.

Agenda: Updates on and discussion of Agency, Bureau and Division activities, and the legislative and budget status of programs; overview of the national nursing workforce; review of nurse practitioner workforce trends, implications and options for the future; review of nursing informatics workgroup recommendations for a national agenda.

Anyone wishing to obtain a roster of members, minutes of meeting or other relevant information should write or contact Ms. Elaine G. Cohen, Acting Executive Secretary, National Advisory Council on Nurse Education and Practice, Health Resources and Services Administration, Parklawn Building, Room 9–36, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–5786.

Agenda Items are subject to change as priorities dictate.

Dated: February 25, 1997.

J. Henry Montes,

Director, Office of Policy and Information Coordination, HRSA.

[FR Doc. 97–5071 Filed 2–28–97; 8:45 am]

BILLING CODE 4160–15–P

Office of Inspector General

Publication of the OIG Model Compliance Plan for Clinical Laboratories

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This Federal Register notice sets forth the recently issued model compliance plan for clinical laboratories developed by the Office of Inspector General in cooperation with, and input from, several provider groups and industry representatives. Many providers and provider organizations have expressed an interest in better protecting their operations from fraud through the adoption of compliance plans. We believe the development of this initial model compliance plan for clinical laboratories will serve as a positive step towards promoting a higher level of ethical and lawful conduct throughout the health care industry.

FOR FURTHER INFORMATION CONTACT: Joel J. Schaer, Office of Counsel to the Inspector General, (202) 619–0089.

SUPPLEMENTARY INFORMATION: The creation of model compliance plans has become a major initiative of the Office of Inspector General (OIG) in its effort to engage the private health care community in the fight to combat fraud and abuse. In developing these compliance plans, the OIG continues to work closely with the Health Care Financing Administration and various sectors of the health care industry.

The clinical laboratory model compliance plan represents the OIG's initial effort to develop such a plan for use by the industry. The plan considers elements of the Federal Sentencing Guidelines and policy guidance given to major independent laboratories through corporate integrity agreements. Specifically, this model plan recommends that clinical laboratories implement a number of substantive changes, such as developing better requisition forms and policies that promote the physician's right to order only medically necessary tests.

Adoption of the clinical laboratory model compliance plan set forth below, and future model compliance plans for other health care providers, will be voluntary. All future models will be similarly structured, that is, substantive policy recommendations resulting from our investigations and civil settlements combined with the elements of the Federal Sentencing Guidelines.

A reprint of the OIG model compliance plan follows.

MODEL COMPLIANCE PLAN FOR CLINICAL LABORATORIES

Introduction

The Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) and other Federal agencies charged with responsibility for enforcement of Federal law have emphasized the importance of voluntarily developed and implemented compliance plans. In recent years, the OIG has been asked to supply guidance as to the elements of a model compliance plan. The purpose of this issuance, therefore, is to respond to those requests by providing some guidance to health care providers that supply clinical laboratory testing services for Medicare and Medicaid beneficiaries. Like other compliance plan models that will be issued for other areas of the health care community, this guidance is based upon the OIG's experience in fraud investigations of clinical laboratories, the Health Care Financing Administration's (HCFA) regulations and guidelines, requirements imposed on clinical laboratories in corporate integrity agreements negotiated by the OIG, and input from the clinical laboratory industry.

The government, especially the OIG, has a zero tolerance policy towards fraud and abuse and will use its extensive statutory authorities to reduce fraud in Medicare and other federally funded health care programs. Compliance plans offer the health care provider an opportunity to participate in a nationwide effort to reduce fraud and abuse in our national health care programs. The OIG believes that through a partnership with the private sector, significant reductions in fraud and abuse can be accomplished. Compliance plans offer a vehicle to achieve that goal.

This information is being supplied to assist laboratory providers in crafting and refining their own compliance plans. Elements of these guidelines can be used by all laboratories, regardless of size, to establish a compliance program. We are not suggesting that all laboratories must implement all of the compliance elements discussed in this document, nor do we suggest that a laboratory that does not incorporate all of these elements will be at a disadvantage when under the scrutiny of the OIG or other governmental agency. Rather, these guidelines represent the government's suggestions on how to correct and prevent fraudulent activity, and they can be tailored to fit the individual needs and financial realities of any clinical laboratory, be it an independent national laboratory, a hospital laboratory, or a small, regional laboratory. We expect variations reflecting the specific factual context in which each individual laboratory operates.

This model compliance plan focuses on topic areas recently addressed in corporate integrity agreements with several players in the laboratory industry. Consequently, this model laboratory compliance plan is not all inclusive as to subject matter. We recognize that laboratories are accountable for complying with far more laws, regulations and guidelines than we have tried to cover in this model, and we believe that laboratories implementing compliance plans should address any and all areas where abuse may be prevalent in the industry. For example, the OIG suggests that laboratory compliance programs should include training on topics such as, the anti-kickback act, Stark self-referral issues and CLIA requirements. Depending on the nature of its business, a laboratory also may need to add specific measures covering areas such as ESRD testing and billing, which is governed by rules and regulations and which has been subject to abuse by many companies. Ultimately, each company bears the responsibility for

determining the appropriate topic areas and measures to be included in its compliance program.

We see this model compliance plan as a dynamic document, and therefore, one that may be modified or expanded as we gather more information and knowledge about best practices and successful compliance plans. Through this document, we are attempting to provide guidance and structure to assist providers as they attempt to comply with our civil, criminal and health care laws. All providers should be aware that the development and implementation of compliance programs can raise a host of sensitive and complex legal issues. Nothing stated herein should substitute for or be used in lieu of legal advice from competent, experienced counsel. In addition, it should be noted that implementing a compliance program will not provide a laboratory with immunity from criminal, civil or administrative prosecution, but it may be a relevant factor in negotiations with the Office of Inspector General.

Compliance Plan Elements

Every laboratory adopting a compliance plan should develop a program and policies that ensure that the plan is implemented and enforced. Compliance plans that are merely cosmetic are not effective and, in the long run, may harm the laboratory. The OIG suggests that the comprehensive compliance program should include, at a minimum, the following elements: (1) Written standards of conduct for employees; (2) the development and distribution of written policies that promote the laboratory's commitment to compliance and that address specific areas of potential fraud, such as billing, marketing and claims processing; (3) the designation of a chief compliance officer or other appropriate high-level corporate structure or official who is charged with the responsibility of operating the compliance program; (4) the development and offering of education and training programs to all employees; (5) the use of audits and/or other evaluation techniques to monitor compliance and ensure a reduction in identified problem areas; (6) the development of a code of improper/illegal activities and the use of disciplinary action against employees who have violated internal compliance policies or applicable laws or who have engaged in wrongdoing; (7) the investigation and remediation of identified systemic and personnel problems; (8) the promotion of and adherence to compliance as an element in evaluating supervisors and managers; (9) the development of policies addressing the non-employment or retention of sanctioned individuals; (10) the maintenance of a hotline to receive complaints and the adoption of procedures to protect the anonymity of complainants; and (11) the adoption of requirements applicable to record creation and retention. These compliance program elements are spelled out in greater detail below.

A. Written Procedures and Policies

Laboratory compliance plans should require the development and distribution of written compliance policies. These policies should be developed under the supervision and direction of the chief compliance officer or the equivalent and should, at a minimum, be provided to all individuals who are affected by the specific policy at issue. One convenient method of achieving this goal and maintaining policies is to create a three-ring compliance policy notebook. This format permits the filing of new and amended or revised compliance policies and ensures that affected individuals have easy access to the laboratory's written policies.

1. Standards of Conduct

Laboratories should develop standards of conduct for all employees which clearly delineate the policies of the laboratory with regard to fraud, waste and abuse and adherence to all guidelines and regulations governing federally funded health care programs. These standards should be made available to and understandable by all employees (e.g., translated into other languages, if necessary) and regularly updated as the policies and regulations of these programs are modified.

2. Medical Necessity

Laboratory compliance plans should ensure that claims are only submitted to federally funded health care programs for services that the laboratory has reason to believe are medically necessary. Upon request, a laboratory should be able to provide documentation, such as requisition forms containing diagnosis codes, supporting the medical necessity of a service the laboratory has provided and billed to a Federal program. We recognize that laboratories do not and cannot treat patients or make medical necessity determinations. However, there are steps that such facilities can and should take to help maximize the likelihood that they only bill federally funded health care programs for tests that meet the reimbursement rules for those programs.

As a preliminary matter, the OIG recognizes that physicians must be able to order any tests, including screening tests, that they believe are appropriate for the treatment of their patients. However, we believe that physicians must be made aware that Medicare will only pay for tests that meet the Medicare definition of ''medical necessity'' and that Medicare may deny payment for a test that the physician believes is appropriate, such as a screening test, but which does not meet the Medicare definition of medical necessity. The laboratories themselves are in a unique position to deliver this information to their physician clients.

In our opinion, laboratories can and should advise physicians that when they instruct the laboratory to seek Medicare reimbursement for tests ordered, they should only order those tests that they believe are medically necessary for the diagnosis and treatment of their patients. We recommend that laboratories implement the following steps through their compliance plans or some other appropriate mechanism to help ensure, as best they can, that the claims they submit to federally funded health care programs meet the appropriate program requirements:

a. *Requisition Design:* Each laboratory (or laboratory company) should standardize its noncustomized test offerings and use common, uniform requisition forms that emphasize physician choice and encourage doctors to order, to the extent possible, only those tests that they believe are appropriate for each patient. In addition, the requisition forms should require physicians to document the need for each test ordered by inserting a diagnosis code for each such test. With respect to chemistry tests, requisition forms should be designed to require physicians to order such tests individually (i.e., separately) unless: (1) the test is specifically part of a CPT or HCPCS defined automated multichannel test series (e.g., 80002–80019, G0058–G0060 which will be amended to G0095–G0098); (2) the test is part of a CPT-defined ''clinically relevant test grouping'' such as an organ or disease panel or profile (e.g., 80050–80099); or (3) the test is part of a profile that has been customized at the request of the physician. In addition, a printed statement should appear on every requisition form reiterating that when ordering tests for which Medicare reimbursement will be sought, physicians (or other individuals authorized by law to order tests) should only order tests that are medically necessary for the diagnosis or treatment

of a patient, rather than for screening purposes.

b. *Notices to Physicians:* All laboratories should provide all of their clients with annual written notices that set forth: (1) The Medicare medical necessity policy; (2) the individual components of every laboratory profile that includes a multichannel chemistry test or other automated multiple test result (e.g., 80002–80019, G0058–G0060); (3) the CPT or HCPCS codes that the laboratory uses to bill the Medicare program for each such profile; (4) the Medicare National Limitation Amount for each CPT or HCPCS code used to bill Medicare for each profile and its components; and (5) a description of how the laboratory will bill Medicare for each profile. If the laboratory engages a physician clinical consultant, the notice also should provide the phone number of the physician clinical consultant and advise of his or her availability to discuss appropriate testing and test ordering.

In addition to the general notices above, laboratories offering clients the opportunity to create customized profiles should provide all clients who request customized profiles with annual notices that: (1) Explain the Medicare reimbursement paid for each component of each such profile; (2) encourage physicians who are ordering tests for which Medicare reimbursement will be sought to order only tests that are medically necessary for each patient; (3) inform physicians that using a customized profile may result in the ordering of tests for which Medicare may deny payment; and (4) inform physicians that the OIG takes the position that a physician who orders medically unnecessary tests for which Medicare reimbursement is claimed may be subject to civil penalties. Once again, if the laboratory engages a physician clinical consultant, the notice also should provide the phone number of the physician clinical consultant and advise of his or her availability to discuss appropriate testing and test ordering.

c. *Physician Acknowledgments:* Laboratories that agree to customize profiles in response to physician requests should require such requesting physicians to sign a Physician Acknowledgment. By signing the Physician Acknowledgment, the physician would affirm that: (1) The physician has requested the creation of a custom profile that includes the tests listed on the acknowledgment; (2) the physician has been informed of the reimbursement amount that Medicare (and where appropriate, Medicaid) will pay for each test included in each customized profile; (3) the physician understands that when ordering tests for which Medicare reimbursement will be sought, the physician should only order those tests which the physician believes are medically necessary for each patient; (4) the physician knows that using a customized profile may result in the ordering of tests for which Medicare or other federally funded health care programs may deny payment; (5) the physician will order individual tests or a less inclusive profile when not all of the tests included in the customized profile are medically necessary for an individual patient; (6) the physician has been informed that the OIG takes the position that a physician who orders medically unnecessary tests may be subject to civil penalties; and (7) if appropriate, the physician is aware that the laboratory makes available the services of a clinical consultant to assist the physician in ensuring that appropriate tests are ordered.

d. *Test Utilization Monitoring:* The OIG believes that laboratories can and should take the steps described above to help ensure that physicians will make a determination and document the medical necessity of tests billed to the Medicare program. We also believe that there are steps laboratories can take to determine whether physicians are being encouraged to order medically unnecessary tests. The OIG believes that a laboratory which has reason to believe that its clients are ordering medically unnecessary tests has a duty to determine why that behavior has occurred. More importantly, if the laboratory discovers that it has in some way caused that behavior, we believe the laboratory has the duty to correct the cause.

Recognizing that there may be other ways to do so, the OIG suggests the following methodology for monitoring test utilization and detecting ordering abuses. We suggest that laboratories retain and analyze test utilization data from year to year, by CPT or HCPCS code, for the top 30 tests they perform for Medicare beneficiaries. Laboratories could do this by keeping track of the number of tests performed by CPT or HCPCS code or of the number of claims submitted to Medicare for each test. The laboratories would then compute the percentage growth in claims submitted for each of the top 30 tests from one year to the next. We believe that if a test's utilization grew more than 10 percent, the laboratory should undertake a reasonable inquiry to ascertain the cause of such growth. If the laboratory determines that the increase in test utilization occurred for a benign reason, such as the acquisition of a new laboratory facility, then the laboratory need not take any action. However, if the laboratory determines that the increase in utilization was caused by the use of basic chemistry profiles or some other action on the part of the facility, the laboratory should take any steps that it deems reasonably necessary to address the issue and to insure that fraud is not being committed.

3. Billing

Laboratory compliance policies should ensure that all claims for testing services submitted to Medicare or other federally funded health care programs are accurate and correctly identify the services ordered by the physician (or other individual authorized by law to order tests) and performed by the laboratory.

a. *Selection of CPT or HCPCS Codes:* Laboratory compliance policies should ensure that the CPT or HCPCS code that is used to bill Medicare or Medicaid accurately describes the service that was ordered and performed. Laboratories should choose only the code that most accurately describes the ordered and performed test. To ensure code accuracy, laboratories may wish to include a requirement that the codes be reviewed by individuals with technical expertise in laboratory testing before such codes are approved for claims submissions. The OIG views intentional up coding (i.e., the selection of a code to maximize reimbursement when such code is not the most appropriate descriptor of the service) as raising false claims issues. If a laboratory continues to have questions about code selection, even after review by technical experts, the facility should direct its questions to its Medicare carrier or intermediary.

b. *Selection of ICD–9CM Codes:* At the direction of the Health Care Financing Administration (HCFA), Medicare carriers and intermediaries have established lists of tests that must be accompanied by diagnostic information to establish medical necessity before Medicare coverage will be assumed (''limited coverage policy''). Such diagnostic information may be submitted either through the use of ICD–9CM codes or a narrative description. Laboratory compliance policies should direct that laboratories will only submit diagnostic information obtained from the test ordering physician. Laboratories should not: (1) Use diagnostic information provided by the physician from earlier dates of service (other than standing orders, as discussed below at paragraph (4)); (2) use ''cheat sheets'' that provide diagnostic information that has triggered reimbursement in the past; (3) use

computer programs that automatically insert diagnosis codes without receipt of diagnostic information from the physician; or (4) make up diagnostic information for claims submission purposes. Laboratories should: (1) Contact the ordering physician to obtain diagnostic information in the event that the physician has failed to provide such information; (2) provide services and diagnostic information supplied pursuant to a standing order executed in connection with an extended course of treatment; and (3) accurately translate narrative diagnoses obtained from the physician to ICD–9CM codes. Where diagnostic information is obtained from a physician or the physician's staff after receipt of the specimen and the requisition form, documentation of the receipt of such information should be created and maintained.

c. *Tests Covered by Claims for Reimbursement:* Laboratory compliance policies should ensure that the laboratory only submits claims for tests that were both ordered and performed. If a laboratory receives a specimen without a test order or with an ambiguous test order that is subject to multiple interpretations, the facility should check with the doctor to determine what tests he or she wanted performed before submitting a claim for reimbursement to Medicare. Thus, if the laboratory performed a test that the doctor did not order, the laboratory will not erroneously bill for that test. Similarly, if a laboratory cannot perform an ordered test due to, for example, a laboratory accident or insufficient quantities of specimen, the laboratory should not submit a claim to Medicare. The OIG considers the submission of a claim for tests that were either not ordered or were not performed to be a potential false claim.

d. *Billing of Automated Multichannel Chemistry Tests:* Laboratory compliance policies should ensure that the laboratory bills Medicare appropriately for automated multichannel chemistry tests. All tests appearing on HCFA's most recent list of automated multichannel chemistry tests should be billed using the appropriate CPT (80002–80019) or HCPCS (G0058–G0060) codes. Tests appearing on this list should not be billed individually unless only one such analyte test is ordered and performed.

e. *Billing of Calculations:* Since the OIG views compliance programs as a check and balance system to reduce error and improve quality, laboratory compliance policies should ensure that the laboratory does not bill for both calculations (e.g., calculated LDLs, T7s, indices, to name only a few) and the tests that are performed to derive such calculations. In many situations, physicians are not offered a choice about whether to receive such calculations, nor are they aware of the practice of some laboratories to bill Medicare for such calculations in addition to the underlying tests, as the physicians themselves are only billed for the underlying tests. At the current time, the OIG views billing for both the calculations and the underlying tests to be double billing which may subject a laboratory to criminal or civil penalties.

4. Reliance on Standing Orders

Although standing orders are not prohibited in connection with an extended course of treatment, too often in the past they have led to fraudulent and abusive practices. Laboratories must be vigilant about this and take appropriate steps to prevent abuse. Thus, while laboratory compliance plans can permit the use of standing orders executed in connection with an extended course of treatment, the compliance plan should require the laboratory to monitor existing standing orders to ensure their continuing validity. We suggest that, consistent with State law requirements, a laboratory should contact all nursing homes from which the laboratory has received such standing orders and request that they confirm in writing the validity of all current standing orders. In addition, in accordance with State law, laboratories should verify standing orders relied upon at draw stations with the physician, physician's office staff, or such other persons authorized by law to order tests who have provided the standing orders to the laboratory. With respect to End Stage Renal Disease (ESRD) patients, at least once annually, laboratories should contact each ESRD facility or unit to request confirmation in writing of the continued validity of all existing standing orders.

5. Compliance with Applicable HHS OIG Fraud Alerts

The HHS OIG periodically issues fraud alerts setting forth activities believed to raise legal and enforcement issues. Laboratory compliance plans should require that any and all fraud alerts issued by the OIG are carefully considered by the legal staff, chief compliance officer, or other appropriate personnel. Moreover, the compliance plans should require that a laboratory cease and correct any conduct criticized in such a fraud alert, if applicable to laboratories, and take reasonable action to prevent such conduct from recurring in the future. If appropriate, a laboratory should take the steps described in Section G regarding investigations, reporting and correction of identified problems.

6. Marketing

Laboratory compliance plans should require honest, straightforward, fully informative and non-deceptive marketing. It is in the best interests of patients, physicians, laboratories and Medicare alike that physicians fully understand the services offered by the laboratory, the services that will be provided when tests are ordered, and the financial consequences for Medicare, as well as other payers, for the tests ordered. Accordingly, laboratories that market their services should ensure that their marketing information is clear, correct, non-deceptive and fully informative.

7. Prices Charged Physicians for Profiles

Laboratories are paid for their services by a variety of payers in addition to Medicare and other federally funded health care programs. Such payers often include health insurers, other health care providers, and physicians. The prices that laboratories charge, particularly to physicians and especially for profiles, raise compliance issues that should be addressed in a laboratory's written compliance policies. Such compliance policies should ensure that as tests are included in or added to profiles, the price for the enhanced profile increases and the overall price for the profile is never below cost. Laboratories that do not increase the price to a doctor for an enhanced profile or that charge below cost for an enhanced profile and then bill Medicare or another federally funded health care program the full third-party price for the profile components will be risking false claims and kickback enforcement actions.

8. Retention of Records

Compliance programs should ensure that all records required either by Federal or State law or by the compliance plan are created and maintained. One of the best ways to confirm that a compliance plan is effective is through reports that reflect results. The creation of such documents will reach this goal, but it may also raise a variety of legal issues, such as patient privacy and confidentiality. These issues are best discussed with legal counsel.

9. Compliance As An Element of a Performance Plan

To ensure that corporate integrity rises to the level of importance required of laboratories participating in Medicare

or other federally funded health care programs, compliance programs should require that the promotion of and adherence to compliance be an element in evaluating the performance of managers and supervisors. They, along with other employees, should be periodically trained in new compliance policies and procedures. In addition, all managers and supervisors involved in the sale, marketing, or billing of laboratory services, and those who oversee phlebotomists should: (1) Discuss with all supervised employees the compliance policies and legal requirements applicable to their function; (2) inform all supervised personnel that strict compliance with these policies and requirements is a condition of employment; and (3) disclose to all supervised personnel that the laboratory will take disciplinary action up to and including termination for violation of these policies or requirements. In addition to making performance of these duties an element in evaluations, the compliance officer or laboratory management may also choose to include in the laboratory's compliance plan a policy that managers and supervisors may be sanctioned for failure to adequately instruct their subordinates or for failing to detect non-compliance with applicable policies and legal requirements, where reasonable diligence on the part of the manager or supervisor would have led to the discovery of any problems or violations and given the laboratory the opportunity to correct them earlier.

B. Designation of a Compliance Officer (or Equivalent)

Every laboratory compliance plan should require the designation of a chief compliance officer or an equivalent (e.g., committee). This individual should be responsible for developing compliance policies and standards, overseeing and monitoring the company's compliance activities, and achieving and maintaining compliance. The individual should be delegated sufficient authority by the Board of Directors (or other governing body) to undertake and comply with these responsibilities and should have open access to senior management and the governing body. Further, the chief compliance officer should develop and distribute to appropriate individuals all written compliance policies and procedures. These policies and procedures should be readily understandable by all employees (e.g., translated into other languages, if necessary) and at a minimum, should address the issues discussed herein.

C. Education and Training

Laboratory compliance programs should require compliance and ethics training for all employees, especially personnel involved in billing, sales, marketing and specimen collection and/or test ordering. Such training should emphasize the company's commitment to compliance with all laws, regulations and guidelines of Federal and State programs. Training should be conducted at least annually and repeated at regularly scheduled times, using a variety of teaching methods and where appropriate, languages to ensure that all employees fully comprehend the implications of failing to comply with the laboratory's compliance plan and all applicable health care program requirements. The training and education program should cover the laboratory's compliance policies and should reinforce the fact that strict compliance with the law and laboratory policies is a condition of employment. Employees should be informed that failure to comply may result in disciplinary action, including termination. Training of sales and marketing personnel should highlight the prohibition against offering remuneration in return for referrals, and the fact that the laboratory will take appropriate disciplinary action up to and including termination for violations of the laws or failure to report a potential violation by another employee, supervisor or outside contractor or provider.

In addition to compliance and ethics training, we believe that laboratory compliance plans also should address the need for periodic continuing education, which may be required by law or regulation for certain laboratory personnel, such as phlebotomists and laboratory technicians. Continuing education programs of this type will help ensure a knowledgeable and more productive staff.

Laboratory compliance programs should leave no doubt in the minds of employees and others who are associated with the provider about the company's commitment to compliance with all laws, regulations and guidelines governing federally funded health care programs. Compliance should be one of the company's most important priorities. In addition to the compliance and ethics training and continuing education programs, a simple way to re-emphasize this message is to post in common work areas and other prominent places accessible to all employees a notice clearly reminding employees of the laboratory's commitment to compliance with all laws and regulations.

D. Communication

1. Access to the Compliance Officer

An open line of communication between the compliance officer and his or her staff is critical to the successful implementation and operation of a compliance program. If fraud and abuse is going to be reduced, there should be an open door, complete anonymity, non-retribution policy available to all employees to encourage communication. Working with or through the legal department can clarify the gray areas of interpretation of Medicare and Medicaid guidelines and regulations, but in all cases, the laboratory should encourage employees not to guess, but to ask if there is confusion or a question. Where appropriate, awards for reporting violations should be available.

2. Hotline

There are many vehicles for developing a line of communication between the employee and the compliance office. Hotlines, e-mails, and written memoranda are examples of just a few. We suggest that laboratories make available to all employees a hotline telephone number which can be used to anonymously report suspected misconduct. Laboratories using a hotline should post in common work areas notices describing the hotline and providing the telephone number. Matters reported through the hotline that suggest violations of compliance policies or legal requirements should be investigated immediately to determine their veracity.

E. Auditing and Monitoring

The OIG will be critical of compliance plans and programs that exist on paper but are not earnestly implemented or enforced. In addition to education and training programs, policies, and notices, a successful compliance program should require the thorough monitoring of its implementation and regular reporting to senior executives and members of the Board of Directors. Although many monitoring techniques are available, an effective tool to ensure enforcement is the performance of regular, periodic audits of the laboratory's operations, with particular attention paid to billing, sales, marketing, notices and disclosures to physicians, requisition forms, pricing, and activities of phlebotomists and others involved in the ordering of laboratory services. Such audits should be designed and implemented to ensure compliance with the laboratory's

compliance policies, the laboratory's compliance plan, and all applicable Federal and State laws. In addition, auditing should address issues related to contracts, competitive practices, marketing materials, CPT/HCPCS coding and billing, test information, reporting and record keeping.

Quality assurance and zero tolerance of fraud and abuse should be the goal of the compliance division, and we believe that auditing is a good tool to use to reach that goal. Compliance audits should be conducted in accordance with pre-established comprehensive audit procedures and should include, at a minimum: (1) On-site visits; (2) interviews with personnel involved in management, operations, billing, sales, marketing, and other related activities; (3) reviews of written materials and documentation used by the laboratory; and (4) trend analysis studies. Formal audit reports should be prepared and submitted to the chief compliance officer and the Board of Directors or other governing body to ensure that laboratory management is aware of the results and can take whatever steps necessary to correct past problems and deter them from recurring. We suggest that the audit or other analytical reports specifically identify areas where corrective actions are needed. In certain cases, subsequent audits or studies would be advisable to ensure that the recommended corrective actions have been implemented and are successful.

F. Disciplinary Actions

A viable compliance program must include the initiation of corrective and/or disciplinary action against individuals who have failed to comply with the laboratory's compliance policies and/or Federal or State laws or who have otherwise engaged in wrongdoing that has the potential of impairing the laboratory's status as a reliable, honest, trustworthy provider. The compliance program should include a written policy statement setting forth the degrees of disciplinary actions that can be imposed upon employees for failing to comply with the company's code of conduct, company policies, and the law. Employees must be advised and convinced that disciplinary action will be taken, and punishments enforced, for a discipline policy to have the required deterrent effect.

G. Corrective Action

1. Investigating, Reporting and Correcting Identified Problems

a. *Investigation:* Violations of a laboratory's compliance program, failures to comply with Federal and/or State law, and other types of misconduct threaten a laboratory's status as a reliable, honest and trustworthy provider capable of participating in federally funded health care programs. Consequently, laboratory compliance programs should require that when the chief compliance officer or others involved in management of a laboratory learn of potential violations or misconduct, they promptly investigate the matter to determine whether a material violation has in fact occurred, so that if a violation has occurred, management can take steps to rectify it, report it to the government if necessary, and make any appropriate payments to the government. Depending on the nature of the allegations, the investigation into allegations of wrongdoing or misconduct will probably include interviews and review of relevant documents, such as submitted claims, test requisition forms, and laboratory test reports. Some laboratories may wish to engage outside auditors or counsel to assist them with the investigation.

If an investigation of an alleged violation is undertaken and the compliance officer believes the integrity of the investigation may be at stake because of the presence of employees under investigation, the employee(s) allegedly involved in the misconduct probably should be removed from his/her current work activity until the investigation is completed. In addition, the laboratory should take steps to prevent the destruction of documents or other evidence relevant to the investigation. Once an investigation is completed, if disciplinary action is warranted, it should be immediate and imposed in accordance with the company's written standards of disciplinary action.

b. *Reporting:* If management receives credible evidence of misconduct from any source and, after appropriate investigative inquiry, has reasonable grounds to believe that the misconduct either: (a) Violates criminal law, or (b) constitutes a material violation of the civil law, rules and regulations governing federally funded health care programs, then the laboratory should report the existence of the misconduct to the OIG as soon as possible. The OIG recommends that the laboratory give notice to the OIG of this type of misconduct within sixty (60) days after receipt of the credible evidence of misconduct. Such prompt reporting will demonstrate the laboratory's good faith and willingness to work with the government to correct and remedy the problem.

When reporting misconduct to the government, a laboratory should give the OIG any evidence relating to the misconduct that the laboratory has, including evidence disclosed to the laboratory from another source. The laboratory then should continue to investigate the reported violation, and once finished, should notify DOJ and the OIG of the outcome of the investigation, including a description of the effect of the misconduct on the operation of federally funded health care programs or their beneficiaries. If the investigation ultimately reveals that criminal activity may have occurred, the appropriate State or Federal authorities should be notified immediately. As discussed below, the laboratory should also take appropriate corrective action, including prompt restitution of any damages to the government and the imposition of appropriate disciplinary action.

c. *Corrective Action:* If the investigation reveals that misconduct did occur, corrective actions should be immediately initiated. For instance, if the investigation reveals that the laboratory has received overpayments, the laboratory should make prompt restitution of such sums to the appropriate federally funded health care program. Failure to repay the overpayment immediately could be interpreted as an intentional attempt to hide the overpayment from the government. For that reason, laboratory compliance programs and written policies and procedures should emphasize that monies to which the laboratory had no legal entitlement in the first place may not be legally retained and must be returned immediately. In addition to making prompt restitution and taking corrective action, the laboratory should take whatever disciplinary action is necessary to cure the problems identified by the investigation and prevent it from happening again.

2. Non-Employment or Retention of Sanctioned Individuals

Compliance programs should prohibit the employment of individuals who have been convicted of a criminal offense related to health care or who are listed by a Federal agency as debarred, excluded or otherwise ineligible for participation in federally funded health care programs. In addition, until resolution of such criminal charges or proposed debarment or exclusion, individuals who are charged with criminal offenses related to health care or proposed for exclusion or debarment should be removed from direct responsibility for or involvement in any

federally funded health care program. If resolution results in conviction, debarment or exclusion of the individual, the laboratory should terminate its employment of that individual or company.

Conclusion

These basic recommended elements coupled with other published regulations and guidelines are the foundation for a comprehensive compliance plan for clinical laboratories. On advice from in-house counsel and senior management, clinical laboratories should add to or modify these elements to better reflect the corporate structure of the laboratory, its mission, and its employee composition. The OIG believes that by implementing an effective compliance plan, a laboratory will achieve better quality control of claims submission and reduce the risk of future criminal and civil liabilities.

Dated: February 24, 1997.

June Gibbs Brown,

Inspector General.

[FR Doc. 97–5192 Filed 2–28–97; 8:45 am]

BILLING CODE 4150–04–P

National Institutes of Health

Notice of Meeting of the Advisory Committee on Blood Safety and Availability

Pursuant to Pub. L 92–463, notice is hereby given of the meeting of the Advisory Committee on Blood Safety and Availability, Department of Health and Human Services, March 20–21, 1997. This meeting will be held at the National Institutes of Health, Warren G. Magnuson Clinical Center, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, Maryland 20892.

The entire meeting will be open to the public from 8:30 a.m. on March 20 to adjournment on March 21. On March 20, the Committee will discuss hepatitis C virus (HCV) infection, its occurrence following blood transfusion, other epidemiology of HCV infection and appropriate ways of approaching the public health aspects of this infection. On March 21, the Committee will address multiple aspects of the theoretical possibility that Creutzfeldt-Jakob disease (CJD) can be transmitted by blood transfusion. For each topic, a time will be set aside for the public to comment. Prospective speakers should notify the Executive Secretary for this meeting of their wish to present and should plan for no more than 5 minutes of comments.

Contact: Paul R. McCurdy, M.D. Acting Executive Secretary, Advisory Committee on Blood Safety and Availability, Director, Blood Resources Program, DBDR–MSC–7950, NHLBI, NIH, Bethesda, Maryland 20892–7950. Phone: 301/435–0065; Fax 301/480–1060; E–Mail: paul—mccurdy@nih.gov.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the Executive Secretary in advance of the meeting.

Dated: February 25, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–5164 Filed 2–28–97; 8:45 am]

BILLING CODE 4140–01–M

National Cancer Institute; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting of the National Cancer Institute Initial Review Group:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: Subcommittee H—Clinical Trials Subcommittee.

Date: April 8–9, 1997.

Time: 8 a.m.

Place: Buffalo Marriott, 1340 Millersport Highway, Amherst, New York 14221.

Contact Person: John L. Meyer, Ph.D., Scientific Review Administrator, National Cancer Institute, NIH, 6130 Executive Blvd. Room 611C, Bethesda, Md 20892, Telephone: 301–496–7721.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. Applications and/or proposals and the discussion could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower, 93.399, Cancer Control)

Dated: February 25, 1997.

LaVerne Y. Springfield,

Committee Management Officer, NIH.

[FR Doc. 97–5166 Filed 2–28–97; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel (SEP) meetings:

Name of SEP: NIAMS Supplemental (Teleconference).

Date: March 18, 1997.

Time: 11:00 a.m.–12:30 p.m.

Place: Natcher Building, 45 Center Drive, Rm 5AS–25U.

Contact Person: Aftab A. Ansari, Ph.D., Natcher Building, 45 Center Drive, Rm 5AS–25U, Bethesda, Maryland 20892–6500, Telephone: 301–594–4952.

Name of SEP: NIAMS Program Project.

Date: April 1, 1997.

Time: 8:30 a.m.–adjournment.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, Maryland 20814.

Contact Person: Aftab A. Ansari, Ph.D., Natcher Building, 45 Center Drive, Rm 5AS–25U, Bethesda, Maryland 20892–6500, Telephone: 301–594–4952.

Purpose/Agenda: To evaluate and review research grant applications.

These meetings will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. The discussion of these applications could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. [93.846, Project Grants in Arthritis, Musculoskeletal and Skin Diseases Research], National Institutes of Health, HHS)

Dated: February 25, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–5163 Filed 2–28–97; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings of the National Institute of Mental Health Special Emphasis Panel:

Agenda Purpose: To review and evaluate grant applications.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: March 17, 1997.

Time: 11 a.m.

Place: Parklawn, Room 9–101, 5600 Fishers Lane, Rockville, MD 20857.