TABLE 1.—FRAMEWORK FOR EQUIVALENT PROTECTIONS—Continued

Specific protection	Example procedures	45 CFR part 46 subpart A authority
		46.111(a)(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by § 46.116. 46.116(a)(1–8) Necessary elements of disclosure. 46.116(b)(1–6) Necessary elements of disclosure. 46.116(c)(1–2) Waiver of informed consent. 46.116(d)(1–4) Approval of alternate consent procedures or waiver. 46.117(a) Written informed consent.

Bernard A. Schwetz,

Director, Office for Human Research Protections.

[FR Doc. 05–5947 Filed 3–24–05; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

The National Center for Chronic Disease Prevention and Health Promotion

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention announces the following meeting.

Name: Interagency Committee on Smoking and Health.

Time and Date: 9 a.m.–4:30 p.m., April 13, 2005.

Place: Omni Shoreham Hotel, Hampton Ballroom, 2500 Calvert Street, NW., Washington, DC 20008. Telephone: 202–234–0700.

Status: Open to the public, limited only by the space available. Those who wish to attend are encouraged to register with the contact person listed below. If you will require a sign language interpreter, or have other special needs, please notify the contact person by 4:30 e.s.t. on April 4, 2005.

Purpose: The Interagency Committee on Smoking and Health advises the Secretary, Department of Health and Human Services, and the Assistant Secretary for Health in the (a) coordination of all research and education programs and other activities within the Department and with other Federal, State, local and private agencies and (b) establishment and maintenance of liaison with appropriate private entities, Federal agencies, and State and local public health agencies with respect to smoking and health activities.

Matters to be Discussed: The agenda will focus on addressing the Global Tobacco Epidemic.

For Further Information Contact: Substantive program information as well as summaries of the meeting and roster of committee members may be obtained from the Internet at *http://www.cdc.gov/tobacco* in mid-May or from Ms. Monica L. Swann, Management and Program Analyst, Office on Smoking and Health, 200 Independence Avenue, SW., Suite 317B, Washington, DC 20201, (202) 205–8500.

Agenda items are subject to change as priorities dictate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: March 18, 2005.

Alvin Hall,

Director, Management Analysis and Service Office, Centers for Disease Control and Prevention.

[FR Doc. 05–5913 Filed 3–24–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Infectious Diseases

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Board of Scientific Counselors, National Center for Infectious Diseases (NCID).

Times and Dates: 9 a.m.–5:30 p.m., May 12, 2005. 8:30 a.m.–2 p.m., May 13, 2005.

Place: CDC, Auditorium B, Building 1, 1600 Clifton Road, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: The Board of Scientific Counselors, NCID, provides advice and guidance to the Director, CDC, and Director, NCID, in the following areas: program goals and objectives; strategies; program organization and resources for infectious disease prevention and control; and program priorities.

Matters To Be Discussed: Agenda items will include:

1. Opening Session: NCID Update.
2. Futures Initiative Update.
3. Environmental Microbiology.
4. Development of CDC Research Agenda.
5. Veterinary-Human Public Health Interface.
6. Global Disease Detection Initiative.
7. Topic Updates.
   a. Influenza.
   b. Chronic Wasting Disease.
   c. Quarantine Update.
8. Board meets with Director, CDC.

Other agenda items include announcements/introductions; follow-up on actions recommended by the Board December 2004; consideration of future directions, goals, and recommendations.

Agenda items are subject to change as priorities dictate.

Written comments are welcome and should be received by the contact person listed below prior to the opening of the meeting.

Contact Person for More Information: Tony Johnson, Office of the Director, NCID, CDC, Mailstop E–51, 1600 Clifton Road, NE., Atlanta, Georgia 30333, e-mail *tjohnson3@cdc.gov*; telephone 404/498–3249.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: March 18, 2005.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 05–5909 Filed 3–24–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2211–N]

Medicare, Medicaid, and CLIA Programs; Continuance of the Approval of the American Society for Histocompatibility and Immunogenetics as a CLIA Acreditation Organization

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the re-approval of the American Society for Histocompatibility and Immunogenetics (ASHI) as an accrediting organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. We have determined that the accreditation process of this organization provides reasonable assurance that the laboratories accredited by ASHI meet the conditions required by Federal law and regulations. Consequently, laboratories that are voluntarily accredited by ASHI and continue to meet the ASHI requirements will be deemed to meet the CLIA condition-level requirements for laboratories and therefore are not subject to routine inspection by State survey agencies to determine their compliance with Federal requirements. They are, however, subject to validation and complaint investigation surveys conducted by us or our designee.

DATES: *Effective Date:* This notice is effective on March 25, 2005. It will remain in effect for 6 years.

FOR FURTHER INFORMATION CONTACT: Minnie Christian, (410) 786–3339.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Pub. L. 100–578. CLIA replaced in its entirety section 353(e)(2) of the Public Health Service Act, as enacted by the Clinical Laboratories Improvement Act of 1967. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under the CLIA program, we may approve a private, nonprofit organization as an approved accreditation organization to accredit clinical laboratories if the organization meets certain requirements. An organization's requirements for accredited laboratories must be equal to, or more stringent than, the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). The regulations listed in subpart E (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) specify the requirements an organization must meet to be an approved accreditation organization. We approve an accreditation organization for a period not to exceed 6 years.

In general, the approved accreditation organization must:

- Use inspectors qualified to evaluate laboratory performance and agree to inspect laboratories with the frequency determined by us.
- Apply standards and criteria that are equal to or more stringent than those condition-level requirements established by us.
- Assure that laboratories accredited by the accreditation organization continually meet these standards and criteria.
- Provide us with the name of any laboratory that has had its accreditation denied, suspended, withdrawn, limited, or revoked within 30 days of the action taken.
- Notify us at least 30 days before implementing any proposed change in its standards.
- If we withdraw our approval, notify the accredited laboratories of the withdrawal within 10 days of the withdrawal.

CLIA requires that we perform an annual evaluation by inspecting a sufficient number of laboratories accredited by an approved accreditation organization as well as by any other means that we determine to be appropriate.

II. Notice of Continued Approval of ASHI as an Accreditation Organization

In this notice, we approve ASHI as an organization that may continue to accredit laboratories for purposes of establishing their compliance with CLIA requirements. We have examined the ASHI application and all subsequent submissions to determine equivalency with our requirements under subpart E of part 493 that an accreditation organization must meet to be approved under CLIA. We have determined that ASHI complied with the applicable CLIA requirements and grant ASHI approval as an accreditation organization under subpart E, for the period stated in the ''Effective Date'' section of this notice, for the following specialty and subspecialty areas:

- Histocompatibility.
- ABO/Rh typing.

As a result of this determination, any laboratory that is accredited by ASHI during the effective time period for an approved specialty or subspecialty listed above is deemed to meet the CLIA requirements for laboratories found in part 493 of our regulations and, therefore, is not subject to routine inspection by a State survey agency to determine its compliance with CLIA requirements. The accredited laboratory, however, is subject to validation and complaint investigation surveys performed by us, or by any other validly authorized agent.

III. Evaluation of the ASHI Request for Approval as an Accreditation Organization Under CLIA

The following describes the process used to determine that the ASHI provides reasonable assurance that laboratories it accredits will meet the applicable requirements of CLIA.

The ASHI formally reapplied to us for approval as an accreditation organization under CLIA for the specialty of Histocompatibility and the subspecialty of ABO/Rh. We evaluated the ASHI application to determine compliance with our implementing and enforcement regulations, and the deeming/exemption requirements of the CLIA rules.

We verified the ASHI's assurance that it requires the laboratories it accredits to be, and that the organization is, in compliance with the following subparts of part 493 as explained below:

Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

The ASHI submitted the specialty and subspecialty that it would accredit; a comparison of individual accreditation and condition-level requirements; a description of its inspection process; proficiency testing (PT) monitoring process; its data management and analysis system; a listing of the size, composition, education and experience of its inspection teams; its investigative and complaint response procedures; its notification agreements with us; its removal or withdrawal of laboratory accreditation procedures; its current list of accredited laboratories; and its announced or unannounced inspection process.

Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

The ASHI's requirements are equal to or more stringent than the CLIA requirements at § 493.801 through § 493.865.

For the specialty of Histocompatibility, ASHI requires participation in at least one external PT program, if available, in histocompatibility testing with an 80 percent score required for successful participation and enhanced PT for laboratories that fail an event. The CLIA regulations do not contain a requirement for external PT for the specicialty of Histocompatibility.

Subpart J—Facility Administration for Nonwaived Testing

The ASHI requirements are equal to or more stringent than the CLIA

requirements at § 493.1100 through § 493.1105.

Subpart K—Quality System for Nonwaived Testing

The ASHI requirements are equal to or more stringent than the CLIA requirements at § 493.1200 through § 493.1299. For instance, ASHI's control procedure requirements for the test procedures Nucleic Acid Testing and Flow Cytometry are more specific and detailed than the CLIA language for requirements for control procedures. Sections 493.1256(c)(1) and (c)(2) require control materials that will detect immediate errors and monitor accuracy and precision of test performance that may be caused by test system failures, environmental conditions and variance in operator performance. ASHI standards provide detailed, specific requirements for the control materials to be used to meet these CLIA requirements.

Subpart M—Personnel for Nonwaived Testing

We have determined that ASHI requirements are equal to or more stringent than the CLIA requirements at § 493.1403 through § 493.1495 for laboratories that perform moderate and high complexity testing. Experience requirements for Director, Technical Supervisor, and General Supervisor exceed CLIA's personnel experience requirements in the specialty of Histocompatibility.

Subpart Q—Inspections

We have determined that the ASHI requirements are equal to or more stringent than the CLIA requirements at § 493.1771 through § 493.1780. The ASHI inspections are more frequent than CLIA requires. ASHI performs an onsite inspection every 2 years and requires submission of a self-evaluation inspection in the intervening years. If the self-evaluation inspection indicates that an onsite inspection is warranted, ASHI conducts an additional onsite review. In addition, ASHI inspectors provide onsite proficiency testing samples to be processed during the inspection.

Subpart R—Enforcement Procedures

The ASHI meets the requirements of subpart R to the extent that it applies to accreditation organizations. The ASHI policy sets forth the actions the organization takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, the ASHI will deny, suspend, or, revoke accreditation in a laboratory accredited by the ASHI and report that action to us within 30 days. The ASHI also provides an appeals process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that the ASHI's laboratory enforcement and appeal policies are equal to or more stringent than the requirements of part 493 subpart R as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of ASHI accredited laboratories may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by us or our agents, the State survey agencies, will be our principal means for verifying that the laboratories accredited by ASHI remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

Our regulations provide that we may rescind the approval of an accreditation organization, such as that of the ASHI, for cause, before the end of the effective date of approval. If we determine that the ASHI failed to adopt requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its inspection process, we may give it a probationary period, not to exceed 1 year to allow the ASHI to adopt comparable requirements.

Should circumstances result in our withdrawal of the ASHI's approval, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

VI. Collection of Information Requirements

This notice does not impose any information collection and record keeping requirements subject to the Paperwork Reduction Act (PRA). Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the PRA. The requirements associated with the accreditation process for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program, codified in 42 CFR part 493 subpart E, are currently approved by OMB under OMB approval number 0938–0686.

VII. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Authority: Section 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: March 10, 2005.

Mark B. McClellan,

Administrator, Centers For Medicare & Medicaid Services.

[FR Doc. 05–5595 Filed 3–24–05; 8:45 am]

BILLING CODE 4121–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–0014–N]

Procedures for Non-Privacy Administrative Simplification Complaints Under the Health Insurance Portability and Accountability Act of 1996

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice sets forth the procedures for filing with the Secretary of the Department of Health and Human Services a complaint of non-compliance by a covered entity with certain provisions of the administrative simplification rules under 45 CFR parts 160, 162, and 164. It also describes the procedures the Department employs to review the complaints. These procedures are intended to facilitate the investigation and resolution of these complaints.

DATES: *Effective Date:* This notice is effective on April 25, 2005.

FOR FURTHER INFORMATION CONTACT: Michael Phillips, (410) 786–6713.

ADDRESSES: Complaints may be filed with CMS in two ways: (1) By Internet using the Administrative Simplification Enforcement Tool at *http://htct.hhs.gov/.* (2) By mail at: The Centers for Medicare & Medicaid Services, HIPAA TCS Enforcement Activities, P.O. Box 8030, Baltimore, MD 21244–8030.

SUPPLEMENTARY INFORMATION: The Secretary of Health and Human Services delegated to the Administrator, Centers for Medicare & Medicaid Services (CMS), the authority to investigate complaints of noncompliance with, and to make decisions regarding the interpretation, implementation, and enforcement of certain regulations adopting administrative simplification