

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.

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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

standards. See 68 FR 60694 (October 23, 2003). These regulations are codified at 45 CFR, parts 160, 162, and 164. This delegation includes authority with respect to the regulations known as follows: the Transaction and Code Set Rule (TCS), 65 FR 50313 (August 17, 2000), the National Employer Identifier Number (EIN) Rule, 67 FR 38009 (May 31, 2002), the Security Rule, 68 FR 8334 (February 20, 2003), the National Provider Identifier Rule, 69 FR 3434 (January 23, 2004), and the National Plan Identifier Rule (currently under development).

This delegation does not include authority with respect to the regulations adopted under section 264 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104–191, as amended, known as the Privacy Rule. The Secretary has delegated to the Office for Civil Rights the authority to receive and investigate complaints as they may relate to the Privacy Rule codified at 45 CFR parts 160 and 164. For the purpose of this notice, “administrative simplification provisions” means the administrative simplification regulatory requirements under HIPAA, other than privacy. For more information about the administrative simplification provisions of HIPAA or what entities the law covers, go to <http://www.cms.hhs.gov/hipaa/hipaa2>.

1. Procedures for Filing Complaints

A person who believes that a covered entity is not complying with the applicable administrative simplification provisions may file a complaint with CMS. The term “covered entity” is defined at 45 CFR 160.103 and includes health plans, health care clearinghouses, and health care providers who conduct certain health care transactions electronically. A fourth type of covered entity, prescription drug card sponsors, was added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173). CMS will not accept complaints until on or after the compliance date for the specific administrative simplification provision in question. (For example, complaints alleging a failure to comply with the Security Rule will not be accepted until after April 20, 2005.)

In order to permit efficient use of CMS resources, complaints must meet all of the following requirements:

- Be filed in writing, either on paper or electronically. CMS will not accept faxed complaints.
- Describe the acts or omissions believed to be in violation of the applicable administrative simplification provisions.

- Provide contact information, including name, address, and telephone number, for the complainant and the covered entity that are the subject of the complaint.

- Be filed within 180 days of when the complainant knew or should have known that the act or omission that is the subject of the complaint occurred, unless this time limit is waived by CMS for good cause shown.

Complainants may, but are not required to, use the CMS complaint form, which can be downloaded at <http://www.cms.hhs.gov>.

2. Procedures for Initial Processing of Complaints

Upon receipt of a complaint, CMS will review the complaint to determine if CMS will accept it for processing. CMS reserves the right to reject complaints. CMS will acknowledge its receipt of a complaint filed within 14 calendar days of receipt. That acknowledgment may be either electronic or on paper.

After CMS receives the complaint, CMS will make a preliminary review of the complaint to determine whether it is complete and appears to allege a failure to comply with an administrative simplification provision. The review will typically proceed as follows:

- If the complaint is complete and appears to allege a failure to comply with the applicable administrative simplification provisions, CMS will notify the complainant that the complaint is accepted for processing and further review. Acceptance of a complaint for processing and further review does not represent a determination that a compliance failure has occurred.

- If additional information is required to make the preliminary determination, CMS will ask the complainant to provide the additional information within a reasonable time, and the complaint will be held in abeyance until that information is received. Failure to provide the requested additional information when requested by CMS may lead to closure of the complaint, without prejudice to the complainant’s right to re-file the complaint.

- CMS will close a complaint if it does not state a claim upon which CMS may act.

A complaint may be withdrawn at any time, upon notice to CMS in such form and manner as CMS may require. Even if a complaint is withdrawn, CMS may nonetheless determine to continue its investigation of the alleged non-compliance complaint. In general, a complaint that has been withdrawn before investigation may be re-filed.

Complainants are, however, cautioned that they must re-file their complaint within 180 days of the date on which the complainant knew or should have known that the act or omission that is the subject of the complaint occurred, and should not assume that this time limit will be waived by CMS.

3. Complaint Processing and Review—Procedures

If after initial processing, as outlined in the previous section, a complaint is accepted for processing and review, CMS will begin an investigation of the complaint. CMS may request from the complainant such additional information and materials as it may require in order to evaluate whether a compliance failure may have occurred, as alleged in the complaint. Failure to provide the information when requested may result in closure of the complaint.

If based on the preliminary review and any additional information gathering CMS ascertains that a compliance failure by a covered entity may have occurred, CMS will advise the covered entity that a complaint has been filed and will inform the covered entity of the alleged compliance failure.

CMS will work with covered entities to obtain voluntary compliance. CMS will ask the covered entity to respond to the alleged compliance failure by submitting in writing: (1) A statement demonstrating compliance; or (2) a statement setting forth with particularity the basis for its disagreement with the allegations; or (3) a corrective action plan. CMS will afford the covered entity a reasonable time to respond to CMS’ request for information, generally 30 days. Extensions may be granted, on a case-by-case basis, at CMS’s sole discretion, and for good cause shown. It is expected that, in most cases, no more than one extension, of an additional 30 days, will be granted.

A covered entity that disagrees with the allegations made should set forth and document, where possible: (1) Compliance; (2) in what respect it believes the allegations to be factually incorrect or incomplete; and/or (3) why it disagrees that its alleged actions or failures to act constitute a failure to comply. Upon receipt of this response from the covered entity, CMS may communicate further with the covered entity and request the opportunity to interview knowledgeable persons or to review additional documents or materials. CMS expects that additional information or access to witnesses will be provided in a timely manner. CMS may also seek additional information from the complainant.

A covered entity may amend or supplement its response at any time and may propose voluntary compliance through a corrective action plan at any time. CMS may require modifications in the terms of a proposed corrective action plan as a prerequisite to accepting the corrective action plan. If a corrective action plan is accepted, CMS will actively monitor the plan, and the covered entity will be required to periodically report to CMS its progress towards compliance. If the covered entity comes into voluntary compliance, CMS will notify the complainant by mail or electronically. The parties to the complaint will be notified, as appropriate, when the complaint is closed.

CMS will make reasonable efforts to secure a timely response from the covered entity. If the covered entity fails or refuses to provide the information sought, an investigational subpoena may be issued in accordance with 45 CFR 160.504 to require the attendance and testimony of witnesses and/or the production of any other evidence sought in furtherance of the investigation.

After finding that a violation exists, the Secretary will pursue other options, such as, but not limited to, civil money penalties.

Collection of Information Requirements

The form associated with this complaint process entitled, "HIPAA Non-Privacy Complaint Form", is currently approved under OMB control number 0938-0948.

Authority: Sections 1102 and 1171 through 1179 of the Social Security Act (42 U.S.C. 1302a and 1320d through 1320d-8).

Dated: December 7, 2004.

Tommy G. Thompson,
Secretary.

[FR Doc. 05-5795 Filed 3-24-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2204-FN]

Medicare and Medicaid Programs; Reapproval of the Deeming Authority of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for Home Health Agencies

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This notice announces our decision to approve the Joint Commission on Accreditation of Healthcare Organizations for continued recognition as a national accreditation program for home health agencies seeking to participate in the Medicare or Medicaid programs.

EFFECTIVE DATE: This final notice is effective March 31, 2005 through March 31, 2008.

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786-0310.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a Home Health Agency (HHA) provided certain requirements are met. Sections 1861(o) and 1891 of the Social Security Act (the Act) establish distinct criteria for facilities seeking designation as an HHA program. The regulations at 42 CFR part 484 specify the conditions that an HHA must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for home health care. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488.

Generally, to enter into an agreement, an HHA must first be certified by a state survey agency as complying with the conditions or requirements set forth in part 484 of our regulations. Then, the HHA is subject to regular surveys by a state survey agency to determine whether it continues to meet those requirements. There is an alternative, however, to surveys by state agencies.

Section 1865(b)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accreditation organization that all applicable Medicare conditions are met or exceeded, we would "deem" those provider entities as having met the requirements. Accreditation by an accreditation organization is voluntary and is not required for Medicare participation.

If an accreditation organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accreditation organization applying for approval of deeming authority under part 488, subpart A must provide us with reasonable assurance that the

accreditation organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning reapproval of accrediting organizations are set forth at § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require accreditation organizations to reapply for continued approval of deeming authority every 6 years or sooner as we determine. The Joint Commission on Accreditation of Healthcare Organizations' (JCAHO's) term of approval as a recognized accreditation program for HHAs expires March 31, 2005.

II. Deeming Applications Approval Process

Section 1865(b)(3)(A) of the Act provides a statutory timetable to ensure that our review of deeming applications is conducted in a timely manner. The Act provides us with 210-calendar days after the date of receipt of an application to complete our survey activities and application review process. Within 60 days of receiving a completed application, we must publish a notice in the **Federal Register** that identifies the national accreditation body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish an approval or denial of the application.

III. Proposed Notice

On September 24, 2004, we published a proposed notice (69 FR 57305) announcing the JCAHO's request for reapproval as a deeming organization for HHAs. In the proposed notice, we detailed our evaluation criteria. Under section 1865(b)(2) of the Act and our regulations at § 488.4 (Application and reapplication procedures for accreditation organizations) and § 488.8 (Federal review of accreditation organization), we conducted a review of the JCAHO application in accordance with the criteria specified by our regulation, which include, but are not limited to the following:

- An onsite administrative review of JCAHO's (1) corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and (5) survey review and decision-making process for accreditation.
- A comparison of JCAHO's HHA accreditation standards to our current Medicare HHA conditions for participation.