Accreditation Commission for Health Care, Inc.

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March 13, 2006

Patricia Harris
Executive Officer
California State Board of Pharmacy
1625 N. Market, Suite N 219
Sacramento, CA 95834

Dear Ms. Harris,

I recently received a voice message indicating the need to submit our current pharmacy standards to the California State Board of Pharmacy. Enclosed is an updated program folder outlining the types of programs and process for companies accredited by the Accreditation Commission for Health Care (ACHC) and an Interpretive Guide to Standards for Accreditation for pharmacy services. Please note that all ACHC on-site surveys are done unannounced.

Since we recently have been reviewed by the Center for Medicare and Medicaid Services (CMS) and granted Deeming Authority for Home Health Medicare, I have also enclosed a copy of the Federal Register announcing effective dates of this recognition for Medicare and Medicaid.

We appreciate this opportunity to continue our relationship with the California State Board of Pharmacy. If you have any questions, please contact me.

Sincerely,

Tom Cesar, MPM
President

THE PROVIDER'S CHOICE

ISO 9001:2000

[Federal Register: February 24, 2006 (Volume 71, Number 37)]
[Notices]
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From the Federal Register Online via GPO Access [wais.access.gpo.gov]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2227-FN]

Medicare and Medicaid Programs; Approval of Deeming Authority of the Accreditation Commission for Healthcare (ACHC) for Home Health Agencies

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This notice announces our decision to approve the Accreditation Commission for Healthcare (ACHC) for recognition as a national accreditation program for home health agencies seeking to participate in the Medicare or Medicaid programs.

DATES: Effective Date: This final notice is effective February 24, 2006 through February 24, 2009.

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

SUPPLEMENTARY INFORMATION:

I. Background

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 ACHC's HHA accreditation standards to our current Medicare HHA conditions for participation.

A documentation review of ACHC's survey processes to:

[boxvh] Determine the composition of the survey team, surveyor qualifications, and the ability of ACHC to provide continuing surveyor training.

[boxvh] Compare ACHC's processes to those of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

[boxvh] Evaluate ACHC's procedures for monitoring providers or suppliers found to be out of compliance with ACHC program requirements. The monitoring procedures are used only when the ACHC identifies noncompliance. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at Sec. 488.7(d).

[boxvh] Assess ACHC's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

[boxvh] Establish ACHC's ability to provide us with electronic data in ASCII-comparable code and reports necessary for effective validation and assessment of ACHC's survey process.

[boxvh] Determine the adequacy of staff and other resources.

[boxvh] Review ACHC's ability to provide adequate funding for performing required surveys.

[boxvh] Confirm ACHC's policies with respect to whether surveys are announced or unannounced.

[boxvh] Obtain ACHC's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(b)(3)(A) of the Act, the September 23, 2005 proposed notice (70 FR 55862) also solicited public comments regarding whether ACHC's requirements met or exceeded the Medicare conditions of participation for HHAs. We received no public comments in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between the ACHC's Standards and Requirements for Accreditation and Medicare's Conditions and Survey Requirements

We compared the standards contained in ACHC's accreditation manual for

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HHAs and its survey process in ACHC's Surveyor Training Manual with the Medicare HHA conditions for participation and our State Operations Manual. Our review and evaluation of ACHC's deeming application, which were conducted as described in section III of this final notice yielded the following:

To meet the full intent of all Medicare standards and conditions, ACHC crosswalked the corresponding Medicare standard to each of its standards and stated that HHAs undergoing a deemed status survey from ACHC would meet the ACHC standard as well as the

is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The RFA requires agencies to analyze options for regulatory relief for small businesses. For purposes of the RFA, States and individuals are not considered small entities.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any notice that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we consider a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

This final notice recognizes ACHC as a national accreditation organization for HHAs that request participation in the Medicare program. There are neither significant costs nor savings for the program and administrative budgets of Medicare. Therefore, this final notice is not a major rule as defined in Title 5, United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866. We have determined, and the Secretary certifies, that this final notice will not result in a significant impact on a substantial number of small entities and will not have a significant effect on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act.

In an effort to better assure the health, safety, and services of beneficiaries in HHAs already certified as well as provide relief to State budgets in this time of tight fiscal restraints, we deem HHAs accredited by ACHC as meeting our Medicare requirements. Thus, we continue our focus on assuring the health and safety of services by providers and suppliers already certified for participation in a cost-effective manner.

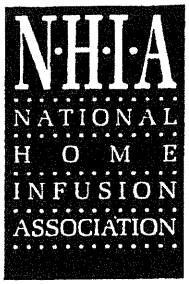
In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget. In accordance with Executive Order 13132, we have determined that this final notice will not significantly affect the rights of States, local or tribal governments.

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb)

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare Hospital Insurance Program; and No. 93.774, Medicare--Supplemental Medical Insurance Program)

Dated: January 30, 2006.
Mark B. McClellan,
Administrator, Centers for Medicare & Medicaid Services.
[FR Doc. 06-1650 Filed 2-23-06; 8:45 am]

BILLING CODE 4120-01-P



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June 2000

To Whom It May Concern:

The National Home Infusion Association (NHIA) represents professionals and organizations providing home and alternate site infusion therapy services. An estimated 85 percent of NHIA members have successfully completed a process of voluntary accreditation for infusion therapy services or are planning to become accredited.

NHIA recognizes the importance of accreditation in setting a high standard of care for the infusion provider community. Currently, there are three accrediting organizations that have developed standards for infusion therapy and provide comprehensive accreditation services. These are:

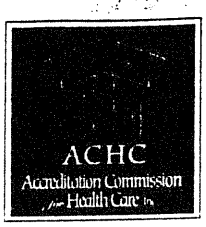
- Accreditation Commission for Health Care (ACHC – www.achc.org)
- Community Health Accreditation Program (CHAP – www.chapinc.org)
- Joint Commission for Accreditation of Healthcare Organizations (JCAHO – www.jcaho.org)

NHIA strongly encourages the recognition of all three accrediting bodies where such accreditation is required for ancillary services contracts.

Sincerely,

Lorrie Kline Kaplan
Executive Director

THE VOICE OF
THE NATION'S
HOME INFUSION
INDUSTRY



Accreditation Commission for Health Care, Inc.

ACCREDITATION POLICIES & PROCEDURES

Accreditation Policies & Procedures

I. Introduction

The Accreditation Commission for Health Care, Inc. (ACHC) is an independent, 501(c)3 non-profit accrediting organization, which is certified to ISO 9001:2000 standards. ACHC is governed by a voluntary Board of Commissioners (Board), which is composed of health care professionals and consumers. The Board is responsible for leadership, governance and oversight of the quality of all services provided by the organization. The Board focuses on the development and maintenance of services that promote excellent outcomes through national health care standards. The Board accepts the ongoing duty to monitor the mission and philosophy of the organization and establish the future direction of ACHC in keeping with its mission. In addition to the expert board members, the organization solicits the support and input from leadership committees such as the Standards and Review Committee, as well as clinical advisors.

The policies and procedures contained in this section pertain to all applicant organizations, whether they are applying for the first time, renewing, or adding or eliminating branches or services. All applicant organizations must follow these accreditation policies and procedures to achieve ACHC accreditation and maintain compliance. Submission of a signed application and contract for survey by an applicant organization constitutes intent to adhere to the policies and procedures in effect on the date on which the application is received by ACHC.

II. Eligibility

Applicant organizations which provide health care services and/or products may apply for accreditation if all of the following eligibility criteria are met:

A. Must be currently operating within the United States and/or its territories;
B. Must have been actively providing health care services for no less than four (4) months and served a minimum of ten (10) clients/patients at the time of survey.
C. Must be serving at least seven (7) clients/patients at the initial survey
D. Is licensed according to applicable state and federal laws and regulations and maintains all current legal authorization to operate;
E. The building in which services are provided/coordinated is identified, constructed, and equipped to support such services;
F. Clearly defines the services it provides under contract or directly;
G. Must be willing to complete and sign attestation to never falsify or misrepresent accredited programs;
H. Must submit all required documents and fees to ACHC within specified time frames;
I. Medicare providers must meet all criteria for participation with Medicare.

Deemed Status Eligibility

Currently, deemed status accreditation is only available to home health applicant organizations. In addition to the above eligibility criteria, applicant organizations applying for deemed status must meet the following requirements:

A. Meet the intent of the definition set forth by Medicare for home health; and

6. **Infusion Nursing**: This service is the administration of parenteral medications via various accesses and ports by an RN specifically trained in these specialized services. This service can be provided in a variety of settings.

7. **Medical Supply Provider**: The storage and delivery of medical supplies designed to meet the needs of a client/patient requiring the product for their medical management in the home care setting. A physician generally prescribes these services. The items sold are usually disposable or semi-durable in nature.

8. **Pharmacy Services**: The infusion therapy continuum of care includes IV drug mixture preparation, IV administration, therapy monitoring, client/patient counseling and education. It is the administration of medications using intravenous, subcutaneous and epidural routes. The IV therapies include IV antibiotics, prescribed primarily for diagnosis such as steomyelitis, sepsis, cellulites, total parenteral nutrition, pneumonia, sexually transmitted diseases and others. ACHC scope of service includes: infusion nursing, home infusion pharmacy, specialty pharmacy, first dose services, ambulatory infusion centers and respiratory nebulizer medications.

9. **Rehabilitation Technology Supplier Services:** Rehabilitation Technology Supplier Services are defined as the application of enabling technology systems designed to meet the needs of a specific person experiencing any permanent or long-term loss or abnormality of physical or anatomical structure or function. These services, prescribed by a physician, primarily address wheeled mobility, seating and alternative positioning, ambulation support and equipment, environmental control, augmented communication and other equipment and services that assist the person in performing their activities of daily living.

10. **Post Mastectomy Fitter Services**: These services include the physical and psychosocial needs of post mastectomy patients, including prosthetic fitting.

III. Purpose or Principals Governing the Accreditation Survey

A. Compliance

Throughout the survey process, ACHC determines whether the organization is meeting the intent of the accreditation standards. Proof of compliance is based upon such things as review of client records, personnel records, policies and procedures, as well as onsite observations and interviews and other activities as necessary.

Standard Revision Compliance

It is the organization's responsibility to ensure compliance with ACHC standards at all times during the accreditation period. Upon revision of standards, ACHC will establish timeframes for the organization to come into compliance. Timeframes for compliance are determined in part by mandatory timeframes required by state/federal regulations, HIPAA, etc. Compliance with revised standards will be 120 days after notification of the revision by ACHC.

B. Education

While the organization is preparing for its onsite survey, ACHC is available to provide assistance in interpretation of standards. During the onsite survey, surveyors will provide education in areas where standards are not fully met, in addition to "best practice" suggestions to help the organization achieve optimum performance.

C. Frequency of Surveys

Accreditation surveys are conducted upon receipt of a new accreditation application and, after receipt of accreditation status, on a triennial basis (upon receipt of a renewal application). All surveys are unannounced. Organizations are allowed to choose up to 10 black out days on which ACHC will not schedule a survey.
Intermittent unannounced surveys are conducted based upon original survey results, random selection of a percentage of accredited organizations, number of branch additions during an accreditation period, or if a grievance/complaint has been received against an accredited organization.

Surveys conducted on applications of organizations applying under ACHC's deeming status with CMS are always unannounced and are initially conducted annually. Home health agencies that have had three consecutive recertification surveys with no conditional level deficiencies, no deficiencies at 42 CFR 484.18 and 42 CFR 484.55 and no complaints resulting in deficiency citations since the previous survey can be surveyed on a triennial basis. ACHC will conduct random unannounced surveys of all agencies to validate the performance of accreditated agencies.

D. Types of Surveys

1. **Initial Survey**: Organizations which apply for ACHC accreditation for the first time will have an initial survey. Applicant organizations must have been in business for four months or more and have served at least ten (10) active clients/patients prior to application submission and have seven (7) clients/patients on service at the time of survey.

2. **Renewal Survey**: Organizations that are accredited by ACHC will receive notification regarding renewal of their accreditation approximately 18 months prior to their expiration date. Renewal surveys are processed the same as an initial survey; however, during the site survey the surveyor also reviews previous deficiencies for compliance.

3. **Deferral Focus Survey**: Organizations that receive a deferral decision may require a focus survey at the applicant organization's expense. A deferral decision requires a plan of correction and evidence demonstrating compliance with the standard(s) in question. A focus survey will be scheduled if a review of personnel or client/patient files, or site observations are required to verify results of the plan of correction.

4. **Interim Survey**: ACHC reserves the right to randomly visit any ACHC accredited organization during the three-year cycle to determine ongoing and continuing compliance with standards. These interim surveys are random and unannounced.

5. **Service Addition Survey**: Organizations adding a service(s) within their accredited program during their three-year accreditation period must notify ACHC of the addition within 30 days and complete a Service Addition Application. Service addition applications follow the same process and survey procedures as Initial and Renewal applications. Organizations requesting a deemed status survey must have all documentation regarding licensure and certification from CMS/State Agency before ACHC can conduct a survey. (See Section VI. D. Service Addition and Section VII. A. Advertising)

6. **Branch Addition Survey**: Organizations adding branches that meet ACHC's branch definition must notify ACHC within 30 days of the opening of that branch, complete a Branch Addition Application for each branch added, and submit required information and applicable branch fees. To qualify as a branch addition, the branch must provide the same services under the organization's current accreditation. Organizations requesting a deemed status survey must have all documentation regarding licensure/certification from CMS/State Agency before ACHC can conduct a survey. ACHC branch surveys consist of a desk review of submitted documentation and photos, and, when necessary, on-site surveys. (See Section VI. C. Branch Office Addition and Section VII. A Advertising)

IV. Accreditation/Survey Process

A. Manual

Prospective applicant organizations can order an ACHC accreditation manual via fax, mail or electronically. ACHC, working with the applicant organization, determines which accreditation manual is most appropriate for services provided. (See Section II. ACHC Programs for guidelines regarding selection of programs and services.) All manuals must be paid for in advance of shipment. Accepted forms of payment are check, cash or credit card (MasterCard, Visa, Discover). Manual sales are non-refundable. Manuals may be exchanged within 90 days of purchase if it is determined that an incorrect program manual was ordered.

B. Organizational Structure and Governance

Based on governance, complexity of corporate structure, tax reporting, and other factors, ACHC will determine the number of applications and number of surveys required. Organizations are required to complete a Location Determination Form to assist in the determination of corporate structure.

C. Application

Applications are located in the accreditation manual. All information submitted and/or reviewed by ACHC is regarded as confidential and in compliance with HIPAA regulations.

Applications are accepted at any time. The Application for Accreditation and other required application attachments must be returned to ACHC with a non-refundable application fee and deposit.

Upon receipt of an application, ACHC will assign an application number. The application is reviewed for completeness and the applicant organization is notified of any missing information. Failure to complete the application in its entirety, including required attachments, will delay or cancel the application process.

Once an application is received by ACHC, the onsite survey will be completed within one year. If an onsite survey is not completed within one year of the application receipt date, by fault of the applicant organization, the application expires and ACHC will require a new application and accreditation fees if the applicant organization wished to continue the accreditation process.

D. Preliminary Evidence Report (PER)

The PER is included in the accreditation manual and must be returned with the completed application. ACHC staff will be available to answer questions during the PER completion process. After ACHC receives the customer's PER(s), accreditation staff prepares and mails a complete PER package to each member of the survey team.

E. Accreditation Fees

As part of the application review process, a quote for accreditation fees is prepared. Fees, number of surveyors/type of surveyors and number of survey days are based upon statistics from the organization's last completed fiscal year prior to application for those program(s)/service(s) indicated on the Application. Relevant statistics include but may not be limited to: (a) number and type of services; (b) number of employees; (c) volume of clients/patients served; and (d) number of branches. Applicant organizations which have not completed at least one fiscal year prior to application must submit year to date statistics.

Full accreditation fees are not refundable. Requests for refunds must be made in writing, detailing the reason for the request. The partial refund amount is determined on an individual basis and is dependent on the stage in the accreditation process where the organization has withdrawn their application.

The applicant organization is held accountable for accurate and timely information. ACHC reserves the right to review and/or adjust accreditation fees based on new or validated information obtained during the survey process which may affect the number of survey days or surveyors required. Continuation of the survey process is contingent upon receipt of total fees prior to the survey.

Accreditation fee structures are reviewed periodically. ACHC reserves the right to adjust accreditation fees and establish the effective date of change based upon the review.

E. Scheduling

Upon completion of the application review and fee determination, the application is forwarded to the Scheduling Department. The Scheduling Department coordinates the survey schedule. A minimum of one surveyor will be scheduled for all programs. A minimum of two surveyors, one nursing and one non- clinical surveyor (MSW or Clergy) will be scheduled for hospice program surveys. Additional surveyors are assigned based on the service(s) provided that is indicated on the application. Surveyors assigned will be discipline specific to the service(s) provided, which may result in a team of surveyors.

ACHC reserves the right to send a surveyor trainee as part of the survey team. Trainees are sent at no charge to the organization.

All ACHC surveyors/preceptors must disclose any potential conflict of interest with the applicant organization to ACHC before the surveyor is assigned to conduct the survey. Surveyors/preceptors with a confirmed conflict are not utilized for the survey being scheduled.

F. Contract for Survey

Once fees and payment schedules are confirmed with the applicant organization, a Contract for Survey is issued. The Contract for Survey identifies, but is not limited to: (1) payment schedule for accreditation fees; (2) rescheduling provisions; (3) contract execution timeframe; and (4) notification timeframes for organizational changes in ownership/governance, facilities, services, etc.

The organization must review the contract in its entirety and sign and return the entire contract to ACHC within seven (7) business days to ensure continuation of the accreditation process. Failure to meet any of the contract terms may result in cancellation of the survey with rescheduling/cancellation fees assessed.

G. Survey

Surveys are conducted by a single surveyor or a team of surveyors. Surveyors are selected based on the services being surveyed.

Entrance Conference

The surveyor(s) will conduct an entrance and exit conference with representatives of the organization. At the entrance conference, the lead surveyor will briefly introduce himself/herself, along with other members of the survey team (if applicable), discuss PER issues and tentative schedule, and answer questions regarding the survey.

Information Gathering

The survey focuses on personnel files, client/patient records, financial management, service contracts, risk management, quality improvement activities, policies and procedures, onsite observations, operational and service delivery outcomes, and staff and client/patient interviews. All applicants will be given explanation of findings/deficiencies throughout the survey process and again during the exit conference.

C. Accreditation Status Criteria

Approval of Accreditation

Full accreditation is awarded to an organization when the overall score and each section score are within a range of 90% or above. Submission of a plan of correction will be required for any standard not fully met. A three-year accreditation period will apply with the exception of deemed status organizations that have not met the criteria listed in Section III (c) under Frequency of Surveys.

Effective accreditation dates for new and renewal organizations are determined as follows:

New organization:

1. First day following the survey, if the organization passes survey on the first review.
2. First day after receipt of plan of correction if the deferral documents clear the corrective document review process.
3. First day after the focus survey, if the deferral is cleared upon review.

Renewal organization:

1. First day following current accreditation expiration date if the organization passes survey on the first review.
2. First day after receipt of plan of correction if the deferral documents clear the corrective document review process.
3. First day after the focus survey, if the deferral is cleared upon review.

Deferral of Accreditation

Deferral accreditation is given to an organization when the overall score or any individual section score is within the deferral range (80% up to 89.99%) or the failure to meet any Medicare Condition of Participation. The organization is advised of the decision in writing and accreditation will be deferred pending submission of a plan of correction within 30 days and corrective documentation within 90 days of the organization's receipt of ACHC's notification. Once all documentation has been received and reviewed, a determination of the need for an onsite survey will be made.

Deferral focus surveys are invoiced at a per-surveyor per-day fee. After the focus survey takes place, if the organization is subsequently found to be in compliance and has a passing score in accordance with approval criteria, full accreditation is awarded and a Certificate of Accreditation will be issued.

If a focus survey is not required, based on the review of the plan of correction and corrective documentation ACHC will determine which deficiencies are cleared and make a final decision regarding accreditation status.

Denial of Accreditation

Denial of accreditation is given to an organization when the total overall score is below 80%. If a determination is made to deny accreditation, the organization is advised in writing.

When accreditation is denied, the applicant organization has the option of reapplying for accreditation no sooner than six months from the date of denial. At the time of re-application, a new application must be submitted with appropriate application fee. Reapplications are processed and accreditation fees charged in accordance with the application process.

D. Accreditation Documentation

All locations for which accreditation has been granted are described in a letter of accreditation which is sent with the Certificate(s) of Accreditation. Certificates of Accreditation are provided for all locations listed in the Application for Accreditation and included in the survey process.

Organizations will be notified in writing of the accreditation decision within six to eight weeks of the last day of the survey. Accreditation survey scores are not sent with the decision letter.

When applicable, the accredited organization should send a copy of the Letter of Accreditation, Summary of Findings and Accreditation Certificate for all locations to the state governing body within 30 days of receipt.

E. Continued Compliance

Accreditation is contingent upon continued compliance with the standards and these accreditation policies and procedures.

Accreditation is not automatically renewable. Approximately 18 months prior to the organization's expiration of accreditation, ACHC will notify the organization in writing and include a renewal application and PER. If renewal applications are not submitted when specified in the renewal letter, sufficient time may not exist to schedule and complete a survey prior to the organization's expiration date. In this event, ACHC will automatically withdraw accreditation at the expiration of the current accreditation period. CMS will be notified if an organization with deemed status loses its accreditation status. Renewal applications are processed through the accreditation process as stated in Section IV Accreditation/Survey Process.

After the organization is officially granted accreditation, ACHC reserves the right to make unannounced onsite visits at any time during a three-year accreditation cycle to determine continuing compliance with standards. If an interim visit reveals a noncompliance with standards, a Plan of Correction and supportive documentation is required. Based on review of this material, if a full survey is required, the organization is responsible for appropriate fees. ACHC conducts interim surveys based on a percentage of currently accredited organizations.

Upon receipt of the appropriate documentation, including licensure and certification documentation from CMS/State Agency, ACHC will review for completeness and determine whether the organization's accreditation certificate is still accurate. If an updated certificate is required, a processing fee will be charged prior to issuance of a new certificate. Change in ownership or control of the organization may result in ACHC conducting onsite survey(s), with applicable survey fees.

Failure of the organization to notify ACHC of post-accreditation changes may result in assessment of fines and other penalties up to and including revocation of accreditation.

A. Name/Location Changes

The organization's notification letter to ACHC must include the following:

1. Effective date of the change
2. Former name, as well as new legal name, if applicable
3. Former location as well as new location, if applicable
4. Any change of services, if applicable
5. Include original certificate of accreditation with the letter only for Name change or relocation to a different city.
6. Include copies of Articles of Incorporation, if applicable
7. Include copies of business license, if applicable

Upon written notification of a change in the organization's name, ACHC will review copies of the Articles of Incorporation and business license, if applicable. A new Certificate of Accreditation with the new name will be issued once ACHC receives the appropriate certificate re-issuance fee.

If the organization is relocated to a new city, ACHC will issue a new Certificate of Accreditation with the new location upon receipt of appropriate certificate re-issuance fees.

B. Merger/Ownership Changes

The organization's notification letter to ACHC must include the following:

1. Effective date of the change
2. Former name, as well as new legal name, if applicable
3. Former location as well as new location, if applicable
4. Any change of services, if applicable
5. Include original certificate of accreditation with the letter, if new certificate is required
6. Include copies of Articles of Incorporation, if applicable
7. Include copies of business license, if applicable

Upon execution of the state required filings of ownership change/merger, a certified letter of transaction shall be submitted to ACHC, postmarked within 2 weeks of the effective date of filing.

Based on a review of documentation submitted, ACHC will make a determination whether an onsite survey, preparation of new Certificate of Accreditation, assessment of fees, and/or other action is required.

C. Branch Office Addition

ACHC defines a branch as serving clients/patients, maintaining client/patient and/or personnel records and accepting referrals and inquiries directly from potential clients/patients. A branch location that is not open at the time of application will be considered a branch addition, and will be processed after the accreditation decision has been rendered. **A branch office that opens after accreditation is granted will not advertise or otherwise consider itself an accredited entity until successfully completing a branch addition survey.**

If an organization adds a branch after its corporate accreditation takes place, ACHC requires the organization to provide written **notification thirty (30) days prior to the opening/acquisition/merger** which resulted in the new location. This letter should include the service(s) to be offered at each branch. Agencies that have deemed status will be surveyed after the CMS regional office approves the branch addition and authorizes ACHC to perform the survey. Questions regarding this process should be directed to ACHC's Accreditation Department.

Upon receipt of the organization's written notification, ACHC will send the organization a Branch Addition Application, Branch Addition Requirements List specific to the organization's services provided, and notification of the fees required. The Branch Addition Requirements List outlines documentation necessary for ACHC to determine/conduct an offsite review or schedule an onsite survey of the new location.

Unless other timeframes are specified by ACHC, the completed application must be returned within 30 days of the date of the notification letter, along with the new branch documentation and applicable branch fee. ACHC reserves the right to conduct an onsite survey of any branch addition. If it is determined an onsite review is necessary, the normal survey scheduling process will apply and additional fees may be assessed.

A review of the documentation is performed and any missing information is requested from the organization in writing via fax/email/mail, along with timeframes for receipt. ACHC will hold the branch addition documentation without further processing until the missing information is received from the organization.

Upon approval, ACHC will mail a letter confirming accreditation of the new location for the duration of the corporate accreditation, and include an accreditation certificate.

D. Service Addition

ACHC requires the organization to provide written **notification thirty (30) days prior to the addition** of any service. Upon receipt of written notification, ACHC will forward the organization a Service Addition Application, which must be completed and returned to

ACHC within timeframe specified on the application along with the specified application fee (to be applied toward accreditation fees).

Upon receipt of the completed application and application fee, accreditation staff follows the application review, scheduling and contract preparation process.

ACHC will require a focused review and an onsite survey to determine if the organization is in compliance with applicable standards for the added service. If the data collected during the onsite survey reflects a passing score for the service(s), a certificate of accreditation for the service is issued for the duration of the current accreditation period.

E. Service Discontinuation

An accredited organization must notify ACHC in writing of any service that has been discontinued. A new Certificate of Accreditation will be issued listing all but the discontinued service. If the organization adds the service at a later date, the organization must follow the instructions for adding a service.

VII. Public Information

A. Logo/Advertising Language

An organization must accurately describe only the program(s), service(s) and branch office(s) currently accredited by ACHC and abide by the Guidelines for Use of ACHC's Logo when advertising its accreditation status to the general public. False or misleading advertising represents noncompliance with accreditation and will result in assessment of fines up to and including withdrawal of accreditation. The Guidelines for Use of ACHC's Logo are sent to organizations in their accreditation notification packet. Branches and services accredited during accreditation cycle can not be advertised as accredited until appropriate applications are submitted and accreditation certificates are received.

B. Press Releases

ACHC encourages organizations to publicize their accreditation status and provides a sample press release in the accreditation notification packet.

C. Public Information Requests

Upon receipt of a written request, ACHC will release the organization's Summary of Findings to the public. This information is released without written authorization from or notification to the organization.

VIII. Handling of Complaints

A. ACHC will investigate and/or review, and follow up on complaints from any source where an ACHC accredited organization or pending applicant organization appears to be out of compliance with its accreditation standards. As required by ACHC standards, accredited

organizations must provide ACHC's telephone number to their clients/patients as part of their client/patient hand-out for purposes of reporting a complaint.

B. ACHC will receive complaints via telephone, mail, e-mail, facsimile or in person. If requested, a complainant's identity will be held confidential whenever possible.

C. If the complaint involves (1) possible abuse, neglect, or exploitation of a child or a disabled adult, (2) professional conduct, or (3) compliance with state or federal laws, ACHC will notify the appropriate regulatory authority.

D. Information documented as part of the grievance process includes:

- date complaint received
- name, address and phone number of the person making the complaint (anonymous complaints will not be accepted)
- documentation of whether or not complainant's identity is to remain confidential
- brief narrative description of the complaint

E. If upon review of information it is determined that immediate jeopardy to the client/patient is present and ongoing, ACHC will notify the CMS regional office (RO) and conduct its investigation within two (2) business days of authorization from the RO. If it is determined the situation is non-immediate jeopardy, the complaint will be prioritized within two (2) business days of receipt and ACHC will conduct an investigation of the matter within 30 days to determine the exact nature of the complaint and the action warranted. Depending upon the nature of the complaint, one or both of the following actions may be taken:

1. ACHC will contact the organization and address the following:

   - notify the organization that a complaint has been received.
   - provide a description of the complaint(s).
   - request the organization's cooperation in resolving the complaint.
   - request the organization respond to the complaint within the identified time frame
   - ask the organization if they were aware of the complaint and if they have taken action.

2. ACHC may contact the organization via phone and/or fax or designate personnel to go unannounced to the organization and request immediate access to information and data related to the standards indicated in the complaint.

F. ACHC will review all the information and data collected relative to the complaint. If necessary, a summary report will be sent to the Standards and Review Committee for a final decision.

G. If an investigation reveals the complaints allegations are substantiated and the patient's health, safety and welfare are in jeopardy, accreditation may be withdrawn or suspended.

H. If ACHC makes the decision to withdraw accreditation, ACHC will notify the appropriate regulatory bodies of its decision.

INTERPRETIVE GUIDE
STANDARDS FOR ACCREDITATION

CORE: SECTIONS 100 - 700

SECTION 100: ORGANIZATION AND ADMINISTRATION

Standard 101. Legal Authority. The organization is an established entity with legal authority to operate.

Standard 101, Criterion A: There is appropriate licensure, Articles of Incorporation, or other documentation of legal authority.

Note: Failure to meet this criterion will result in automatic deferral.

Interpretation: Legal authority is granted to one individual, members of a limited liability corporation, a board of directors, or a board of health; usually referred to as the governing body, and as allowed in state statutes for the appropriate type and structure of the organization. Whether private or public entity, the individual, or organization will have a copy of the appropriate authorization(s) to conduct business. All required license(s) and or permit(s) must be current and posted in a prominent location accessible to public view in all locations/branches and/or in accordance with appropriate regulations or law.

Evidence: Copy of Articles of Incorporation/Bylaws and all applicable amendments
Copy of all current applicable license(s)/permit(s) for each premise

For Medicare certified home health agencies: The home health agency must comply with CFR 484.12(b) and 484.14(b). See appendix A for the full text of the regulation.

Standard 101, Criterion B: Information or change in authority, ownership, or management.

Interpretation: The organization's written policy and procedure describe the required action and timeframes if a request for information is received from a regulatory or accrediting body, or there is a change in ownership, governing body, or management.

Evidence: Written Policies and Procedures
Response to Interviews

For Medicare certified home health agencies: The home health agency must comply with CFR 484.12(b). See appendix A for the full text of the regulation.

Standard 102. The organization is directed by a governing body, which assumes full legal authority and responsibility for the operation of the organization.

Standard 102, Criterion A: Governing body duties and accountabilities must be clearly defined.

Interpretation: A governing body assumes full legal authority and responsibility for the operation of the organization consistent with acceptable standards of practice. Activities of the governing body may include but are not limited to the following: decision making, appoints a qualified administrator, arranges for professional advice, reviews the annual program evaluation, adopts and periodically reviews written bylaws or equivalent, establishes or approves written policies governing operations, human resource management, quality improvement, community needs planning and oversight of the management and fiscal affairs of the organization.
Policies must be reviewed and revised on an ongoing basis as needed and reviewed/revised as part of the annual evaluation.

Although many governing bodies delegate authority for some of these functions to individual staff members or to an advisory committee, the ultimate responsibility continues to rest with the governing body. In situations where the board of directors serves as the governing body for a large, multi-service organization, board activities will address the overall organization; however, oversight of the organization's program must be evidenced in some manner such as reports to the board documented in minutes of board meetings.

Evidence: Written Policies and Procedures
Minutes of Board of Directors Meetings
For privately owned organizations whose owners serve as leader/executive, records of organizational decisions including dates and participants
Response to Interviews

For Medicare certified home health agencies: The home health agency must comply with CFR 484.12(b) and 484.14(b). See appendix A for the full text of the regulation.

Standard 102, Criterion B: There is a description of the governing body.

Interpretation: Legal documents and/or policies must describe the governing body's structure, type, and size, which may vary according to the organization's type, clients/patients served and communities served. Legal documents and/or policies must also describe the governing body's term of office, frequency of meetings, attendance requirements, and definition of a quorum, conflict of interest disclosure requirement, and overall responsibilities. Sole proprietorships or partnerships may have single or two-member governing bodies rather than boards. A private corporation's governing body may consist of officers and stockholders. Governmental units will have boards as specified by State statute. Programs that are part of a larger organization do not require a separate governing body.

Evidence: Written Policies and Procedures
Articles of Incorporation/Bylaws or Statutes

Standard 102, Criterion C: There is a list of governing body members.

Interpretation: Legal documents and/or policies must list the governing body members including the name, address, telephone number, occupation, title, and employer of each person.

Evidence: List of Governing Body Members
For Medicare certified home health agencies: The home health agency must comply with CFR 484.12(b). See appendix A for the full text of the regulation.

Standard 102, Criterion D: Governing body members must receive an orientation to their responsibilities and accountabilities.

Interpretation: There is evidence that the governing body members received an orientation to their responsibilities and accountabilities as defined by the organization. Governing body members are provided the opportunity to evaluate the orientation process.

Orientation must include but not be limited to, the following: (1) organizational structure; (2) a review of the organization's values, missions, and/or goals; (3) overview of programs and initiatives; (4) philosophy of service/care; (5) employee and client/patient grievance policy and procedure; (6) confidentiality agreement; and (7) their responsibilities in the quality improvement activities.

Evidence: Orientation Checklists
Signed Attendance Records
Meeting Minutes
Response to Interviews

Standard 103. The governing body arranges for a professional advisory committee with representation from the organization, professionals having expertise in the program service areas and the lay community.

Note: This Standard is required for organizations that provide clinical/professional services. This Standard is preferred, but not required for organizations that do not provide clinical/professional services.

Standard 103, Criterion A: Organizational and administrative policy and procedures describe the function of the professional advisory committee.

Interpretation: The Organizational and administrative policy and procedures will describe the function, duties, and activities, frequency of meetings and evaluation of the professional advisory committee. The major function of the advisory committee shall be to advise the organization on clinical and professional issues, to participate in the evaluation of the organization's program and to assist the organization in maintaining liaison with other health care providers in the community and in the community served by the organization.

The committee shall have appropriate representation for the service provided. For example, Clinical Respiratory Care Services shall have a Respiratory Care Practitioner; Pharmacy services shall have a Pharmacist, Home Health Agencies, shall consist of at least one Physician and one Registered Nurse, and representation from other professional disciplines. At least one member of the group is neither an owner nor is an employee of the organization.

Evidence: Written Policies and Procedures

For Medicare certified home health agencies: The home health agency must comply with CFR 484.16(a) and 484.14(b). See appendix A for the full text of the regulation.

Standard 103, Criterion B: There is a list of professional advisory members.

Interpretation: Policies and/or other documents must list the advisory committee members including the name, address, telephone number, occupation, title, and employer of each person.

Evidence: List of Advisory Committee Members

For Medicare certified home health agencies: The home health agency must comply with CFR 484.16(a). See appendix A for the full text of the regulation.

Standard 103, Criterion C: Advisory committee members must receive an orientation to responsibilities and accountabilities in advising the governing body.

Interpretation: There is evidence that the professional advisory committee members received orientation to their responsibilities and accountabilities as defined by the organization.

Orientation must include but not be limited to, the following: (1) organizational structure; (2) employee and client/patient grievance policy and procedure; (3) responsibilities for quality improvement activities; (4) a review of the organization's values, missions and/or goals; and (5) a confidentiality agreement.

Evidence: Orientation Checklists
Signed Attendance Records
Response to Interviews

Standard 103, Criterion D: The Advisory committee meets on a regular schedule and meetings are documented by dated minutes.

Interpretation: There is evidence that the professional advisory committee meets on a regular schedule to discuss items brought before the committee and to advise the organization on clinical direction.

Evidence: Schedule of Meeting Dates
Dated meeting Minutes

For Medicare certified home health agencies: The home health agency must comply with CFR 484.16(a). See appendix A for the full text of the regulation.

Standard 104. The organization has a written policy and procedure which defines conflict of interest and the procedure for disclosure.

Standard 104, Criterion A: The organization's written policy defines conflict of interest.

Interpretation: The organization's policy defines conflict of interest and the procedure for disclosure and conduct in relationships with personnel, customers, and clients/patients. The policy must include the required conduct of any affiliate or representative of the governing body, professional advisory committee, and/or employee having an outside interest in an entity providing services to the organization and/or other client/patient relationships.

In the event of proceedings that require input, voting, or decisions, the individual(s) with a conflict of interest must be excluded from the activity.

Evidence: Written Policies and Procedures
Written Minutes of Meetings

Standard 104, Criterion B: The written policy and procedure for conflict of interest disclosure will be shared and understood.

Interpretation: The conflict of interest disclosure policy and procedure must be shared with and understood by the governing body, professional advisory committee, staff members, and organization representatives.

Evidence: Response to Interviews
Board Meeting Minutes
Orientation Records
Signed Conflict of Interest Disclosure Statements

Standard 105. There is a designated individual, accountable to the governing body, who is responsible for the overall operations and services of the organization.

Standard 105, Criterion A: There is an individual who is designated as responsible for the overall operation and services of the organization. The administrator organizes and directs the agency' s ongoing functions; maintains ongoing liaison among the governing body, the group of professional personnel and the staff; employees qualified personnel and ensures adequate staff education and evaluations; ensures the accuracy of public information materials and activities; and implements an effective budgeting and accounting system.

Interpretation: The leader/executive *is responsible for all programs* and services and must be accountable to the governing body. There will be written policies and procedures that specify the responsibilities and authority of this individual.

The resume and/or application of the current leader/executive verify that the individual who holds this position meets the minimum education and experience requirements as defined by the organization and any applicable state and federal laws and regulations.

The organization must also provide information regarding changes in the administrator position to ACHC and other required agencies.

Evidence: Written Policies and Procedures
Leader/Executive Resume/Application

For Medicare certified home health agencies: The home health agency must comply with CFR 484.12 (b), 484.14(b) and 484.14(c). See appendix A for the full text of the regulation.

Standard 105, Criterion B: There are annual written evaluations of the leader/executive by the governing body.

Interpretation: The organization conducts annual reviews of the leader/executive. The governing body may delegate the evaluation function to a specific person or entity such as an advisory or personnel committee. The evaluation is reviewed with the leader/executive and documented.

This criterion does not apply to sole proprietorships or to limited liability corporations (LLC) where the president and leader/executive is also the owner and governing body. A proprietary organization's annual outcome evaluation could serve as an evaluation of the leader/executive.

This criterion is not applicable if the organization has been in operation less than one year at the time of accreditation survey.

Evidence: Written and dated evaluations of the Leader/Executive
Other documentation that demonstrates evaluation of the Leader/Executive
Response to Interviews

Standard 105, Criterion C: An individual is appointed to assume the role of the leader/executive during temporary absences and/or vacancies.

Interpretation: There must be a person or designated position appointed to assume the role of the leader/executive for temporary absences and/or vacancies. This appointment must be written into operations policy and must be included in the job description of the position intended to perform this responsibility. The duties that the individual assumes during the absence of the leader/executive must be written into operations policy and into the orientation of this individual.

Evidence: Written Policies and Procedures

For Medicare certified home health agencies: The home health agency must comply with CFR 484.14(c). See appendix A for the full text of the regulation.

Standard 106. The organization's structure is such that responsibility and accountability for programs are clearly defined.

Standard 106, Criterion A: The organization chart shows the relationship of all positions within the organization.

Interpretation: The Board of Directors and all personnel are clearly identified on the organization chart. The organization chart must show the position responsible for each service the organization provides. Titles for the position(s) may include director, manager, coordinator, supervisor, etc. Large organizations will probably have several positions responsible for services, while small organizations may have only one position responsible for all services. If supervision of personnel is divided so that task supervision is provided by one person and administrative supervision by another, it must be shown on the organization chart. Lines of supervision are clearly identified on the organization chart.

Evidence: Organization Chart

For Medicare certified home health agencies: The home health agency must comply with CFR 484.14. See appendix A for the full text of the regulation.

Standard 106, Criterion B: The organization will designate a person responsible for direction, coordination, and overall supervision of each type of service provided by the organization either directly or by contract. For home health agencies, all skilled nursing and therapeutic services are furnished under the supervision and direction of a physician or a registered nurse. This person, or a similarly qualified alternate, is available at all times during business hours and participates in all activities relevant to the professional services furnished.

This individual may be the supervisor of one or more services and may serve as the leader/executive. There will be written policies and procedures that specify the responsibilities and authority of this individual(s).

The person responsible for the direction, coordination, and supervision of services takes steps to assure: (a) the quality of services is maintained; (b) staffing of the program is appropriate; and (c) services are available.

Evidence: Written Policies and Procedures
Organization Chart

For Medicare certified home health agencies: The home health agency must comply with CFR 484.14 and 484.14(d). See appendix A for the full text of the regulation.

Standard 106, Criterion C: Service personnel can accurately describe the chain of command.

Interpretation: Personnel must be able to provide a description of the organization's chain of command that is consistent with the organization chart.

Evidence: Response to Interviews
For Medicare certified home health agencies: The home health agency must comply with CFR 484.14. See appendix A for the full text of the regulation.

Standard 107. The organization will establish a written mission and philosophy statement.

Standard 107, Criterion A: There is a written organization mission and philosophy statement that directs the services and goals of the organization.

Interpretation: There is a written organization mission and philosophy statement that directs the goals and service/care delivery activities of the organization. The organization regularly reviews the mission and philosophy statements. The mission and philosophy are communicated to all staff.

Evidence: Written Mission and Philosophy Statement
Response to Interviews

Standard 107, Criterion B: The goals of the organization are identified.

Interpretation; Short term and long-term goals are identified and may be developed with input from staff. Goals will be established as part of the strategic planning for the organization. Leadership utilizes the

goals to monitor effectiveness of the organization. The goals of the organization are communicated to all staff.

Evidence: Strategic Plans and/or other Evidence of Written Goals
Response to Interviews

Standard 108. The organization complies with all federal, state, and local laws and regulations and reports compliance outcomes.

Standard 108, Criterion A: There are written policies and procedures established and implemented by the organization regarding compliance with all applicable federal, state, and local laws and regulations. The organization also complies with accepted professional standards and practices.

Note: Failure to meet this criterion will result in automatic deferral.

Interpretation: This standard requires compliance with all laws and regulations such as local and state licensure, professional licensure/certification, practice standards, the Americans with Disabilities Act, Equal Employment Opportunities Act, Fair Labor Standards Act, Title VI of the Civil Rights Act of 1964, Occupational Safety and Health Standards, Medicare regulations, Medicaid regulations, Omnibus Budget Reconciliation Act 1987, Balanced Budget Act of 1997, occupational licensure laws, Public Health regulations relating to infectious diseases, HIPAA regulations and other laws and regulations as applicable to the service/care provided by the organization.

Compliance with Civil Rights and Equal Employment Opportunity Acts is required for organizations receiving State or Federal funds (Medicare, Medicaid, Title III, Title XX, etc.).

Compliance with OSHA, FDA, DEA, Dept. of Transportation, State Dept. of Agriculture, all appropriate occupational licensing boards, and all required business licenses for city, county, and state are required for all organizations as applicable to the service/care provided.

Accepted standards of practice and occupational licensure acts are utilized by the organization to guide the provision of service/care.

Copies of all required federal and state posters are placed in a prominent location for easy viewing by staff.

For Medicare certified home health agencies, the agency must disclose information regarding ownership and management and any changes thereof.

Evidence: Written Policies and Procedures
Copies of Appropriate Licenses
Copies of all Applicable Occupational Licensure Acts, Rules, and Standards of Practice
Copies of Required Posters in a prominent location

For Medicare certified home health agencies: The home health agency must comply with CFR 484.12 (a), 484.12(b) and 484.12(c). See appendix A for the full text of the regulation.

Standard 108, Criterion B: The organization will inform the accrediting body and Board of Directors of any negative outcomes from review/audits.

Interpretation: Negative outcomes affecting accreditation or licensure will be reported to the governing body and to ACHC within 30 days. All responses and actions to the outcomes will be included in the report.
Outcomes that must be reported to ACHC include, but are not limited to: license suspension(s); license probation; conditions/restrictions to license(s); civil penalties of ten thousand dollars ($10,000.00) or more; and third party payer recovery of insurance payments of ten thousand dollars ($10,000.00) or more.

Evidence:
- Board Meeting Minutes
- Response to Interviews
- Reports to ACHC
- Federal Agency and State Licensure Agency Report(s) and/or Inspections from authorized regulatory and accrediting bodies

SECTION 200: PROGRAM/SERVICE OPERATIONS

Standard 201. Descriptions of specific service/care provided by the organization are available to all staff, clients/patients, and the community.

Standard 201, Criterion A: There are descriptions of service/care, available for distribution to staff, clients/patients, and the community.

Interpretation: Written policies and procedures will address, at a minimum the following: (1) types of service/care available; (2) service/care limitations; (3) charges or client/patient responsibility for service/care and/or products before or at time of delivery (or indication that charges are available upon request); (4) eligibility criteria; (5) hours of operation, including on call availability (if applicable); and (6) contact information and referral procedures.

Written descriptions of service/care with detailed information must be available to staff members. Marketing and instructional materials must use lay language and provide a more general description of services offered.

Descriptions must include each service/care provided to the client/patient. The contact information and referral procedures must provide instructions for telephoning the organization or an answering service and procedures to make a referral for services. Hours of operation must be included.

Evidence: Written Policies and Procedures
Written Description of Services
Marketing Materials to include Electronic Media
Documents that include Service Descriptions

Standard 201, Criterion B: All staff members are familiar with service/care to the extent that a clear and accurate description is provided in response to inquiries.

Interpretation: All staff members are aware of service/care provided and can accurately describe service/care and contact information. It is preferred that there be an ongoing plan for informing prospective clients/patients, referral sources, and the public about current service/care and new service/care, as they become available.

Evidence: Response to Interviews

Standard 201, Criterion C: A description of service/care is given to clients/patients and their families.

Interpretation: The client/patient responsible party will receive verbal and written program service/care descriptions prior to receiving service/care with evidence documented in the client/patient record.

Evidence: Response to Interviews
Client/Patient Records

***Standard 201, Criterion D is applies to certified home health agencies only.**

Standard 201, Criterion D: The agency must provide at least one qualifying service directly through agency employees.

Interpretation: An agency is considered to be providing a service directly when the person providing the service is an employee of the agency. An individual who works for a home health agency on an hourly or per-visit basis may be considered an agency employee if the agency is required to issue a W-2 form in their name.

Evidence: **Personnel files**
Contracts

For Medicare certified home health agencies: The home health agency must comply with CFR 484.14(a). See appendix A for the full text of the regulation.

Standard 202. A written Client/Patient Bill of Rights is reviewed with and distributed to each recipient of in-home service/care. The agency protects and promotes the exercise of these rights.

Standard 202, Criterion A: There are written policies and procedures established and implemented by the organization regarding the rights and responsibilities of clients/patients.

Interpretation: Written policies and procedures outline the client/patient rights and responsibilities. The policy shall require that the organization provide the client/patient with a written copy of their rights before initiation of service/care. The policy must state that if a client/patient cannot read the statement of rights, it shall be read to the client/patient in a language the client/patient understands. For a minor or a client/patient needing assistance in understanding these rights, both the client/patient and the parent, legal guardian, or other responsible person must be fully informed of these rights. An agency required to provide advance directives information must provide written information concerning its policies on advance directives, prior to care being provided.

The Client/Patient Bill of Rights must include, but not be limited to the right to:

- Be fully informed in advance about service/care to be provided, including the disciplines that furnish care and the frequency of visits as well as any modifications to the service/care plan.
- Participate in the development and periodic revision of the plan of service/care.
- Informed consent and refusal of service/care or treatment after the consequences of refusing service/care or treatment are fully presented.
- Be informed, both orally and in writing, in advance of service/care being provided, of the charges, including payment for service/care expected from third parties and any charges for which the client/patient will be responsible.
- Have one's property and person treated with respect, consideration, and recognition of client/patient dignity and individuality.
- Be able to identify visiting staff members through proper identification.
- Voice grievances/complaints regarding treatment or care, lack of respect of property or recommend changes in policy, staff, or service/care without restraint, interference, coercion, discrimination, or reprisal.

- Have grievances/complaints regarding treatment or care that is (or fails to be) furnished, or lack of respect of property investigated.
- Choose a health care provider.
- Confidentiality and privacy of all information contained in the client/patient record and of Protected Health Information.
- Be advised on agency's policies and procedures regarding the disclosure of clinical records
- Receive appropriate service/care without discrimination in accordance with physician orders.
- Be informed of any financial benefits when referred to an organization.
- Be fully informed of one's responsibilities.
- Be informed of provider service/care limitations.

Note: The following rights must be included for organizations that provide Clinical/Professional Services:

- Be informed of client/patient rights under state law to formulate advanced care directives.
- Be informed of anticipated outcomes of service/care and of any barriers in outcome achievement.
- Be informed of client/patient rights regarding the collection and reporting of OASIS information.

When state or federal regulations exist regarding client/patient Bill of Rights, the organization's Bill of Rights statement must include those components. The client/patient has the right to be informed of his or her rights. The organization must protect and promote the exercise of these rights.

Evidence: Written Policies and Procedures
Client/Patient Bill of Rights
Response to Interviews

For Medicare certified home health agencies: The home health agency must comply with CFR 484.10, 484.10(a), 484.10(b), 484.10(c), 484.10(d), 484.10(e). See appendix A for the full text of the regulation.

Standard 202, Criterion B: All staff members are provided training and understand the client/patient Bill of Rights and Responsibility policy and procedures.

Interpretation: All staff members are provided training during orientation and at least annually thereafter concerning the organization's client/patient Bill of Rights.

Evidence: Orientation and In-Service Records
Response to Interviews

Standard 202, Criterion C: The written client/patient Bill of Rights and Responsibility statement will be discussed and distributed to the client/patient at the time of the admission or development of the plan of service/care before the initiation of care/treatment.

Interpretation: The Client/Patient Bill of Rights and Responsibility statement must be reviewed with the client/patient or responsible party. Documentation of receipt and understanding of the information must be placed in the client/patient record. This must be done prior to care/treatment being provided. This evidence may be provided either by obtaining signatures of the client/patient/responsible party or by noting in the client/patient record that the Client/Patient Bill of Rights was reviewed and understood by

the client/patient/responsible party. A copy of the Bill of Rights and Responsibilities is made available to others in the community upon request.

It is preferred that the Client/Patient Bill of Rights be reviewed with the client/patient or the responsible party on an annual basis as a reminder of the client/patient rights and responsibilities.

Evidence: Client/Patient Records
Response to Interviews

For Medicare certified home health agencies: The home health agency must comply with CFR 484.10 and 484.10(a). See appendix A for the full text of the regulation.

Standard 202, Criterion D: DMEPOS Supplier Standards are distributed to and reviewed with each Medicare recipient of service/care.

Note: Applicable to organizations providing HME, Medical Supplies, Prosthetics, and Orthotics.

Interpretation: A copy of the DMEPOS Supplier Standards must be distributed to the client/patient/responsible party with documentation of receipt and understanding of the information. This evidence may be provided either by obtaining signatures of the client/patient/responsible party or by noting in the client/patient/responsible party record that the DMEPOS Supplier Standards were reviewed and understood by the client/patient/responsible party.

Evidence: Client/Patient Records
Response to Interviews

Standard 203. The organization will maintain and follow their written grievance, complaint, and concern policy and procedure.

Standard 203, Criterion A: The organization written policies and procedures require that the client/patient be informed at the initiation of service/care how to report grievances, complaints, or concerns and explain how they will be investigated and resolved.

Interpretation: The organization must have a written procedure that describes how client/patient grievances, complaints, and concerns will be investigated and resolved. Policy and procedure will describe at a minimum: (1) the appropriate person to be notified of the grievance/complaint/concern; (2) time frames for investigation activities, to include after hours; (3) reporting of information; (4) review and evaluation of the collected information; (5) effective action taken and outcome; (6) communication with the client/patient/caregiver/family; and (7) documentation of all activities involved with the grievance/complaint/concern, investigation, analysis and resolution. The organization will investigate and attempt to resolve all client/patient grievance/complaint/concern and document the results within a described time frame as defined in policy.

Evidence: Written Policies and Procedures

For Medicare certified home health agencies: The home health agency must comply with CFR 484.10(b). See appendix A for the full text of the regulation.

Standard 203, Criterion B: All personnel are knowledgeable of the policy and procedure for handling a grievance/complaint/concern during any contact with clients/patients.

Interpretation: Personnel will be oriented and familiar with the client/patient grievance/complaint/concern policy and procedure. Staff will assist in implementing the resolution process when needed.

Evidence: Personnel Orientation Checklist
Response to Interviews

Standard 203, Criterion C: The organization will investigate, document and resolve all client/patient grievances/complaints and document the results in a timely manner.

Interpretation: The organization will maintain records of grievances/complaints and their outcomes, and include this information in the annual program service/care review/evaluation. A summary of the grievances/complaints will be reported quarterly to the governing body.

Evidence: Grievance/Complaint Logs
Governing Body Minutes
Observation

For Medicare certified home health agencies: The home health agency must comply with CFR 484.10(b). See appendix A for the full text of the regulation.

Standard 203, Criterion D: The organization must provide the client with written information concerning how to contact the organization, appropriate state agencies, and ACHC concerning grievances/complaints at time of admission.

The organization must provide all client/patient with written information listing a telephone number, contact person, and the organization's process for receiving, investigating and resolving grievances/complaints about its service/care.

The agency must advise the patient in writing of the telephone number of the appropriate state regulatory body's hot-line telephone number(s), the hours of operations and the purpose of the hotline. This may be a separate information sheet given to the client/patient or incorporated with the Client/Patient Bill of Rights information. If the agency is a certified home, the patient must also be made aware that they can use the hotline to lodge complaints concerning the implementation of advance directives requirements. ACHC's telephone number must be provided. ***Note: The ACHC phone number requirement is not applicable to organizations if this is their first ACHC survey.***

Evidence: Client/Patient Records

For Medicare certified home health agencies: The home health agency must comply with CFR 484.10(b), and 484.10(f). See appendix A for the full text of the regulation.

Standard 204. There are written policies and procedures regarding confidentiality and privacy of client /patient information.

Standard 204, Criterion A: There are written policies and procedures for securing and releasing confidential and Protected Health Information (PHI) and Electronic Protected Health Information (EPHI).

Interpretation: Confidentiality policies address, at a minimum, the following: (1) a definition of protected health and confidential information, the types of information that are covered by the policy, including electronic, and computerized information, telephone and cell phone communications, and verbal and faxed information; and (2) persons/positions authorized to release PHI/EPHI and confidential information and person's to whom it may be released; (3) conditions which warrant its release; (4) persons to whom it may be released; (5) signature of the client/patient or someone legally authorized to act on the client/patient's behalf; (6) a description of what information the client/patient is authorizing the organization to disclose; (7) securing client/patient records and identifying who has authority to review or access clinical records; (8) when records may be released to legal authorities pursuant to subpoenas with appropriate documentation; (9) the storage and access of records to prevent loss, destruction or tampering of information; and (10) the use of confidentiality/privacy statements and who is required to sign a confidentiality/privacy statement. The organization has clearly established written policies and procedures that address the areas listed above which are clearly communicated to staff.

Evidence: Written Policies and Procedures

For Medicare certified home health agencies: The home health agency must comply with CFR 484.11. See appendix A for the full text of the regulation.

Standard 204, Criterion B: Personnel, governing body, and advisory committee members are knowledgeable about and consistently follow confidentiality and privacy policies and procedures.

Interpretation: There is evidence that personnel, governing body, and advisory committee members have been trained and practice confidentiality policies. The organization must designate an individual to be responsible for seeing that the confidentiality and privacy procedures are adopted and followed.

Evidence:
- Signed Confidentiality Agreements
- Orientation Checklists
- Job Descriptions
- Response to Interviews

Standard 204, Criterion C: The client/patient and/or responsible party receive and understand information related to the confidentiality policy prior to the receipt of services/care.

Interpretation: The individual visiting the client/patient/responsible party for the first time will provide written information and will discuss confidentiality/privacy of client/patient-specific information as included in the client/patient rights and responsibilities. Client/patient records must contain signed release of information statements/forms when the organization bills a third party payer or shares information with others outside the organization as required by HIPAA and other applicable law and regulations.

Evidence: Client/Patient Records
Response to Interviews

For Medicare certified home health agencies: The home health agency must comply with CFRs 484.10(a), 484.10(d) and 484.11. See appendix A for the full text of the regulation.

Standard 204, Criterion D: The organization has Business Associate Contracts for all Business Associates that may have access to Protected Health Information as required by HIPAA and other applicable law and regulations.

Interpretation: A copy of all Business Associate Contracts will be on file at the organization.

Evidence: Business Associate Contracts

For Medicare certified home health agencies: The home health agency must comply with CFR 484.11. See appendix A for the full text of the regulation.

Standard 205. There are written policies and procedures describing the client/patient's rights to accept or refuse medical or surgical treatment and the right to formulate advance care directives and written policies about client/patient resuscitation.

Standard 205, Criterion A: Written policies and procedures include the client/patient's right to accept or refuse service/care and the right to formulate advance care directives.

Note: Formulation of Advance Care Directives is applicable when in home clinical/professional service/care is provided.

Interpretation: The organization's policy and procedure must describe client/patient's rights under law to make decisions regarding medical care, including the right to accept or refuse service/care and the right to formulate advance directives.

Policies and procedures must include at a minimum: (1) determining the existence of advance care directives; (2) educating clients/patients and families about advance directives; (3) facilitating advance directives; (4) rendering of service/care in the absence or presence of advance directives; (5) education of staff and the community. Client/patient service/care is not prohibited based on whether or not the individual has an advance directive.

Evidence: Written Policies and Procedures

Standard 205, Criterion B: Advance Care Directive information must be provided to the client/patient or responsible party prior to the initiation of service/care and documented in the client/patient record.

Interpretation: Advance care directive information must be provided to the client/patient/family/responsible party prior to the initiation of services. The client/patient's decision regarding advance care directives must be documented in the client/patient record.

The organization's staff respects the client's/patient's wishes and assists the client/patient in completing advance directives if requested.

Evidence: Client/Patient Records
Response to Interviews

Standard 205, Criterion C: Written policies and procedures describe resuscitative guidelines and the responsibilities of staff.

Interpretation: The organization has written policies and procedures for staff responsibilities regarding client/patient resuscitation and the response in the event of a medical emergency. The policies must identify which staff, if any, may perform resuscitative measures, response to medical emergencies and utilization of "911" services (EMS) for emergencies. Successful completion of appropriate training, such as CPR course(s) must be defined in the policies and procedures. Clients/patients and families are provided information about the organization's policies for resuscitation, medical emergencies and accessing "911" services (EMS).

Evidence: Written Policies and Procedures
Response to Interviews

Standard 206. The organization has written policies and procedures for the reporting of suspected abuse, neglect, or exploitation of clients/patients and suspected abuse or neglect of children in accordance with state law.

Standard 206, Criterion A: The written policies and procedures define and outline the process for reporting suspected abuse, neglect, or exploitation of clients/patients and suspected abuse or neglect of children.

Interpretation: Written policies and procedures incorporate state law in relation to reporting suspected abuse, neglect, or exploitation of clients/patients and suspected abuse or neglect of children.

Evidence: Written Policies and Procedures

Standard 206, Criterion B: All staff members are knowledgeable of the policy and procedure for reporting suspected abuse, neglect, or exploitation of clients/patients and suspected abuse or neglect of children.

Interpretation: Personnel will be oriented and familiar with the process for reporting suspected abuse, neglect, or exploitation of clients/patients and suspected abuse or neglect of children.

Evidence: Employee Orientation Checklist
Response to Interviews

Standard 206, Criterion C: The organization will report suspected abuse, neglect, or exploitation of clients/patients and suspected abuse or neglect of children to the appropriate authorities.

Interpretation: All staff members are knowledgeable of and will report suspected abuse, neglect, or exploitation of clients/patients and suspected abuse or neglect of children to the designated organization staff member who is responsible for reporting to the appropriate authorities.

Evidence: Incident Reports
Response to Interviews

Standard 207. The organization has mechanisms in place to investigate and make recommendations on specific ethical concerns and issues related to client/patient service/care.

Standard 207, Criterion A: The organization has written policies and procedures that address identification, evaluation, and discussion of ethical issues.

Interpretation: The organization provides service/care within an ethical framework that is consistent with applicable professional and regulatory bodies. Written policies and procedures must address the mechanisms utilized to identify, address, and evaluate ethical issues in the organization. Examples of mechanisms utilized to consider and discuss ethical issues may include: (1) professional advisory groups; (2) ethics committees; (3) ethics forums; (4) access to professional experts; and/or (5) quality improvement committees.

Evidence: Written Policies and Procedures

Standard 207, Criterion B: All personnel are knowledgeable of the policy and procedure for reporting ethical concerns to the organization's management.

Interpretation: Orientation and annual training of personnel must include a list of potential ethical issues and the process to follow when an ethical issue is identified. Personnel are trained regarding professional relationships, conflict of interest, and professional boundaries.

Evidence: Personnel Orientation Checklist
In-Service Records
Response to Interviews

Standard 207, Criterion C: The organization will monitor and report all ethical concerns to the governing body.

Interpretation: A summary of any ethical issues and actions must be presented to the governing body/organization leaders at least quarterly.

Evidence: Incident/Variance Reports-Observation
Reports and/or Minutes of Meetings for Governing Body/Organization Leaders
Response to Interviews

Standard 208. The organization has mechanisms in place to provide service/care to clients/patients and families from various cultural backgrounds, beliefs, and languages.

Standard 208, Criterion A: The organization has written policies and procedures that address the provision of service/care to clients/patients and families from various cultural backgrounds, beliefs, and languages.

Interpretation: Written policies and procedures describe the mechanism the organization will utilize to communicate to clients/patient and families of different nationalities. The policies and procedures will also describe any actions expected for staff members providing service/care to clients/patients who have different cultural backgrounds and beliefs.

Evidence: Written Policies and Procedures

Standard 208, Criterion B: All personnel are knowledgeable of the written policy and procedure for the provision of service/care to clients/patients and families from various cultural backgrounds, beliefs, and languages.

Interpretation: Different cultural backgrounds and beliefs impact the client's/patient's lifestyles, habits, view of health, healing, terminal illness, and dying. Organization staff must identify differences in their own beliefs and the client's/patient's beliefs and find ways to support the client/patient. Staff members must make efforts to understand how the client/patient and family's cultural beliefs impact their perception of his illness approach to health and home care. If applicable, staff also considers the impact on end of life service/care issues, loss, and bereavement.

All staff members are provided with annual education and resources to increase their cultural awareness of the clients/patients/families they serve.

Evidence: Personnel Orientation Checklist
In-Service Training Records
Response to Interviews

Standard 208, Criterion C: Staff members can communicate to the client/patient in the appropriate language or form understandable to the client/patient.

Interpretation: Mechanisms are in place to assist with language and communication barriers. This may include the availability of bilingual staff or interpreters. Staff members can communicate with the client/patient/family by using special telephone devices for the deaf or other communication aids such as picture cards or written materials in the client/patient's language.

Evidence: Response to Interviews

Standard 209. The organization has a Compliance Program to prevent violations of the fraud and abuse laws.

Standard 209, Criterion A: There is an established Compliance Program.

Interpretation: The organization will have an established Compliance Program that provides both general and specific guidance as to various internal anti-fraud and abuse controls. The Compliance Program identifies and discusses numerous compliance risk areas particularly susceptible to fraud and abuse.

The Compliance Program must detail actions the organizations must take to prevent violations of the fraud and abuse laws. The guidelines include the following: (1) implementation of written policies, procedures, and standards of conduct; (2) designation of a compliance officer and compliance committee; (3) conducting effective training and education programs; (4) development of open lines of communication between the compliance officer or compliance committee and organization employees for receiving complaints and protecting callers from retaliation; (5) performance of internal audits to monitor compliance; (6) establishing and publicizing disciplinary guidelines for failing to comply with organization standards and policies and applicable statutes and regulations; and (7) prompt response to detected offenses through corrective action.

Evidence:
- Written Policies and Procedures
- Compliance Plan
- Internal Audits
- Quality Improvement Activities
- Orientation and In-Service Education Records
- Response to Interviews

SECTION 300: FISCAL MANAGEMENT

Standard 301. There is an annual budget that includes all projected revenue and expenses for the organization's programs.

Standard 301, Criterion A: The organization has written policies and procedures that address the budgeting process. The organization's annual budget is developed in collaboration with management and staff members and under the direction of the governing body, if applicable.

Interpretation: The organization has a budget that includes projected revenue and expenses for all programs and service/care it provides. The budget is reflective of the organization's service/care, strategic plan, and programs.

The organization's leaders and the individuals in charge of the day-to-day program operations must be involved in developing the budget and in planning and review of periodic comparisons of actual and projected expenses and revenues for the service/care.

Evidence: Written Policies and Procedures
Copy of Current Annual Budget

For Medicare certified home health agencies: The home health agency must comply with CFR 484.14(i)(1) and 484.14(i)(3). See appendix A for the full text of the regulation.

Standard 301, Criterion B: There is a review of the annual budget.

Interpretation: The budget is reviewed and updated at least annually by the governing body and leadership staff of the organization.

Evidence: Copy of Annual Budget(s)
Governing Body Minutes
Response to Interviews

For Medicare certified home health agencies: The home health agency must comply with CFR 484.14(i)(4). See appendix A for the full text of the regulation.

Standard 301, Criterion C: There is a written capital expenditure plan.

Note: This criterion is required for organizations that have a capital expenditure item in the budget. Organizations such as sole proprietorships, in which the leader/executive is the governing body, are not subject to this criterion.

Interpretation: The plan defines capital expenditures and details the proposed expenditures for the current budget year. Home Health/Medicare/Medicaid Certified Agencies are required to have a written capital expenditure plan for at least a 3-year period, including the operating budget year. The plan includes and identifies in detail the anticipated sources of financing for, and the objectives of each anticipated expenditure that would exceed the limit as defined in the Home Health Conditions of

Participation. All other organizations are required to have a written capital expenditure plan for at least a 1-year period, if there is a capital expenditure in the budget.

Evidence: Capital Expenditure Plan

For Medicare certified home health agencies: The home health agency must comply with CFR 484.14(i)(2). See appendix A for the full text of the regulation.

Standard 301, Criterion D: Written policy sets the limit for expenditures that require approval of the governing body.

Interpretation: The written policies and procedures must address the maximum level of expenditure that may be incurred without specific approval and the process for obtaining approval for expenditures above the stated limit. In organizations where the leader/executive has full discretion over expenditures, there must be a written policy confirming this authority.

Evidence: Written Policies and Procedures

Standard 302. Fiscal policies and procedures describe activities to ensure sound business practices for program service/care operations.

Standard 302, Criterion A: There are written policies and procedures, which ensure sound business practices.

Interpretation: There must be written policies and procedures that address each of the following: (1) receipt and tracking of revenue; (2) billing of clients/patients/transmission to third party payers; (3) notification to the client/patient/family of changes in reimbursement from third party payers; (4) collection of accounts/reconciliation of accounts; (5) extension of credit; (6) consequences of non-payment, if applicable; (7) acceptance of gifts and/or restricted funds, if applicable; (8) process for receiving, recording and acknowledging mailed contributions, if applicable; and (9) assignment of revenue to the appropriate program. An organization which does not extend credit must state that there is no extension of credit and specify procedures for dealing with non-payment and partial payment situations.

Evidence: Written Policies and Procedures

Standard 302, Criterion B: There is an accounting system that tracks all revenue and expenses.

Interpretation: Organizations must have an accounting system or process that tracks all revenue and expenses.

A large, multi-faceted organization is not required to maintain a separate accounting system for the service/care program(s) being accredited.

Evidence: Accounting System

Standard 302, Criterion C: Fiscal policies and procedures describe activities to ensure safe, timely and accurate collection and transmission of OASIS data.

Note: OASIS data required for Medicare-certified home health agencies.

Interpretation: The agency must encode and transmit OASIS data for each patient within 7 days of completing an OASIS data set. The agency must encode and transmit OASIS data using software from CMS or software that conforms to the CMS standard electronic record layout. The agency has policies and procedures for conducting clinical and data entry audits and a process to verify that collected OASIS data is consistent with reported OASIS data. The agency has policies and procedures for identifying and addressing any discrepancies in data collected and reported.
OASIS data is being transmitted no later than the last day of the current month. The agency has a policy that addresses the alternate plan when it is unable to submit OASIS data to the state agency. The agency has policies and procedures to ensure the confidentiality of OASIS data. The agency must submit OASIS data to the state agency or CMS OASIS contractor at least monthly

Evidence: Written Policies and Procedures
OASIS Data

For Medicare certified home health agencies: The home health agency must comply with CFR 484.20(a) 484.20(b), 484.20(c) and 484.20(d). See appendix A for the full text of the regulation.

Standard 303. The organization establishes the necessary time frames for keeping financial records and requires an annual audit/review.

Standard 303, Criterion A: All financial records are kept for the time frames described in financial record management policies and procedures and in compliance with regulatory standards.

Interpretation: Written policies and procedures reflect applicable statutes, IRS regulations, and/or Medicare/Medicaid program service/care requirements of maintaining financial records for at least five years after the last audited cost report.

Evidence: Written Policies and Procedures

Standard 303, Criterion B: There are quarterly reviews by the organization's leaders and an annual audit/review of the organization's finances by a person independent of the organization.

Interpretation: Quarterly reviews of financial information are conducted by organization leaders. The annual audit or review is prepared by a Certified Public Accountant (CPA) or accounting firm. Financial reviews are used to assess compliance with budget, needed budgetary changes, timeliness, and accuracy of accounting processes and compliance with applicable regulations.

Evidence: Financial Audit or Review Report for the last fiscal year
Quarterly Reviews of Financial Information for the last fiscal year
Response to Interviews

Standard 304. There are written policies and procedures that require established rates for all program service/care and define methods for providing full reimbursement disclosure to the client/patient or other interested parties.

Standard 304, Criterion A: Written policies and procedures require established service/care rates and describe the method(s) for conveying charges to the public, consumers, and referral sources.

Interpretation: There are written policies and procedures for establishing and conveying the charges for the products and services/care provided to clients/patients. Written charges for services/care are available upon request.

Evidence: Written Policies and Procedures
A list of Services/Care with Corresponding Charges

Standard 304, Criterion B: All staff members responsible for conveying charges are knowledgeable of the policy and procedure.

Interpretation: Current charges for services/care are available in writing for reference by employees when conveying information to the client/patient, public, consumers, and referral sources.

All staff members responsible for conveying charges are oriented and provided with education concerning the conveying of charges.

Evidence: Orientation Checklist
Response to Interviews

Standard 304, Criterion C: The client/patient and/or responsible party is advised orally and in writing of the charges for service/care at or prior to the receipt of services. The client/patient also has the right to be informed of changes in payment information no later than 30 days after the agency becomes aware of the change.

Interpretation: The client/patient/responsible party will be provided written information concerning the charges for service/care at or prior to the receipt of service/care. Client/patient records contain written documentation that the client/patient was informed of the charges, the expected reimbursement for third party payers, and the financial responsibility of the client/patient.

Evidence: Client/Patient Records
Response to Interviews

For Medicare certified home health agencies: The home health agency must comply with CFR 484.10(e). See appendix A for the full text of the regulation.

Standard 304, Criterion D: There are criteria for the use of sliding fee scale.

Note: This criterion is required for organizations that utilize a sliding scale fee.

Interpretation: If the organization utilizes a sliding scale fee, there must be written criteria for determining eligibility for adjusted rates and methods used to determine the rate the client/patient would be expected to pay for service/care.

Evidence: Written Criteria for utilizing the Sliding Fee Scale

SECTION 400: PERSONNEL MANAGEMENT

The standards in this section apply to all categories of personnel in the organization unless otherwise specified. Direct service/care personnel include anyone who has direct responsibility for client/patient/family service/care, including, but not limited to: contract personnel, nurses, home health aides, personal care and home maker workers, social workers, chaplains, volunteers in hospice, bereavement counselors, delivery technicians, respiratory care practitioners, pharmacists, clinical supervisors, case managers, and physicians.

Standard 401. There are written personnel policies and procedures describing the activities related to personnel management.

Standard 401, Criterion A: There are written policies and procedures that describe personnel policy management and the review of personnel policies.

Interpretation: Personnel policies must address: (1) wages; (2) benefits; (3) grievances; (4) recruitment, hiring and retention of personnel; (5) disciplinary action/termination of employment; (6) staff conflict of interest; and (7) performance expectations and evaluations. Personnel policies are reviewed at least annually and updated as needed and are in accordance with applicable law and regulations. Personnel policies and procedures show evidence of non-discriminatory practices.

It is preferred that wage information be available in the form of salary scales, with information about beginning salaries for each position classification, salary ranges, overtime, on-call and holiday pay.

An explanation of benefits must be shared with all benefit eligible employees. Organizations, which provide no benefits to some categories of employees, must communicate this fact in writing to affected employees. For example, the contract/agreement with home care staff who is utilized on an "as needed" basis may address that benefits are not available to persons employed in that classification.

Written grievance information must address options available to employees who have work-related complaints, including steps involved in the grievance procedure.

Disciplinary action and termination of employment policies must clearly define time frames for probationary actions, conditions warranting termination, steps in the termination process, and appeal procedures.

Evidence: Written Policies and Procedures and/or Employee Handbook
Response to Interviews

For Medicare certified home health agencies: The home health agency must comply with CFR 484.14(e). See appendix A for the full text of the regulation.

Standard 401, Criterion B: Personnel policies are accessible to employees.

Interpretation: Each employee must receive a copy of the company employee handbook or copies of all personnel policies. Any employee handbook and all personnel policies are reviewed at least annually and updated as needed.

Evidence: Employee Handbook and/or Personnel Policies
Personnel Files
Response to Interviews

Standard 402. There is a job description for each position within the organization.

Standard 402, Criterion A: There is a job description for each position within the organization which is consistent with the organization chart with respect to function and reporting responsibilities.

Interpretation: The job description lists: (1) job duties; (2) reporting responsibilities; (3) minimum job qualifications, experience requirements, education, and training; (4) requirements for the job; and (5) physical and environmental requirements with or without reasonable accommodation.

Written job descriptions are reviewed at least annually and updated as needed.

The organization's job descriptions are consistent with the organization chart with respect to function and reporting responsibilities.

Evidence: Job Descriptions
Organization Chart

Standard 402, Criterion B: Each employee reviews and/or receives a copy of their current job description upon hire and whenever the job description changes.

Interpretation: Receipt and/or review of the job description with the employee is a necessary part of the orientation process and must be repeated during the annual performance evaluation and whenever the job description changes. The organization will verify the receipt and review by giving each employee a copy of the job description and requiring the employee to sign a copy of the job description and placing it in the employee's personnel file.

Evidence: Personnel Files
Response to Interviews

Standard 403. Employees are qualified for the positions they hold by meeting the education, training, and experience requirements defined by the organization.

Standard 403, Criterion A: Written policies and procedures describe the activities required to verify education, training, and experience when selecting a new employee.

Interpretation: Persons hired for specific positions within the organization must meet the minimum qualifications for those positions in accordance with applicable laws or regulations, as well as the organization's policies and the job description.

Prior education, training, and experience will be verified prior to employment. This can be accomplished by obtaining copies of resumes, applications, references, diplomas, licenses, certificates, and workshop attendance records.

Evidence: Written Policies and Procedures
Personnel Files

For Medicare certified home health agencies: The home health agency must comply with CFR 484.14(e). See appendix A for the full text of the regulation.

Job Descriptions

Standard 403, Criterion B: All new employee qualifications will be reviewed through previous employer reference checks.

Note: This criterion will not be scored for employees who have been with the organization greater than 3 years at the time of initial accreditation survey.

Interpretation: At least two references will be obtained prior to hire. All employer references will address position held, dates of employment and eligibility for rehire if the reference is allowed to disclose this information. A minimum of one employer reference and one personal reference is required. In the case of an applicant with no previous work experience, educational or personal references may be accepted. In the case of an applicant who was a prior employee of the organization, the applicant's previous employment history may serve as their reference.

While written reference checks are preferred, documentation of telephone references is acceptable.

Evidence: Personnel Files

Standard 403, Criterion C: Personnel credentialing activities are conducted at the time of hiring and annually to verify qualifications of all credentialed/licensed staff in the positions they hold.

Interpretation: The personnel file or other employee records will contain validation that credentialing information is obtained on an annual basis. Credentialing information includes a procedure for the review of professional occupational licensure, certification, registration or other training as required by state boards and/or professional associations for continued credentialing.

Evidence: Personnel Files

For Medicare certified home health agencies: The home health agency must comply with CFR 484.14(e). See appendix A for the full text of the regulation.

Standard 404. Employees will have appropriate TB screening, Hepatitis B vaccination or declination, a valid driver's license, and a criminal background check.

Standard 404, Criterion A: TB screening or verification that the employee is free of symptoms will be mandatory for direct care employees.

Interpretation: Tuberculin skin testing (PPD) must be performed on all direct care staff as recommended by CDC and OSHA guidelines based upon community and company TB incidence and prevalence rates. The organization's written policy and procedure must describe this process.

Evidence: Written Policies and Procedures
Personnel Files or other Confidential Employee Records

Standard 404, Criterion B: All direct care personnel will have access to Hepatitis B vaccine as each job classification indicates and as described in federal CDC and OSHA standards.

Interpretation: Hepatitis B vaccination program and post-vaccination antibody titer must be performed in accordance with CDC and OSHA guidelines. Employees must sign a declination statement for the Hepatitis B vaccination within 10 working days of employment if they choose not to become vaccinated.

The following are circumstances under which an employer is exempted from making the vaccination available: (a) the complete Hepatitis B vaccination series was previously received; (b) antibody testing shows the employee to be immune; or (c) the vaccine cannot be given to the individual for medical reasons or the individual cannot receive antibody testing.

Evidence: Personnel Files or other Confidential Employee Records

Standard 404, Criterion C: All personnel, who are required to operate a motor vehicle in the course of their duties, are required to have a valid state driver's license appropriate to the type of vehicle being operated in compliance with state laws and the organization's policies.

Interpretation: Evidence of valid drivers' licenses must be kept in personnel files, along with record of all inquiries made on individual driving records (MVR) through the State Department of Motor Vehicles. The organization must conduct a MVR check on each staff member who is required to operate a motor vehicle in the course of his/her duties at the time of hire. It is preferred that the organization recheck the MVR at least every 3 years to insure the driving records of the staff member are clear of violations that may be of concern to the organization. Copies of valid Commercial Drivers License (CDL), HAZMAT Endorsement and valid DOT physicals must be kept on file for employees that require CDL's.

Evidence: Personnel Files

Standard 404, Criterion D: The organization and staff must carry the appropriate amount of vehicle insurance when required to operate a motor vehicle in the course of their duties and in compliance with state laws and the organization's policies.

Interpretation: The organization must carry the appropriate amount of insurance on all company vehicles. The organization's insurance carrier will instruct the company on what is an appropriate amount of insurance based on risk assessments. Staff must follow the organization's policies and procedures for the appropriate amount of insurance on personal vehicles used in the provision of service/care.

Evidence: Written Policy and Procedures
Personnel Files
Company Vehicle Insurance Documents

Standard 404, Criterion E: All personnel providing direct client/patient service/care will have a criminal record background check.

Interpretation: The organization must perform a criminal background check and a national sex offender registry check, at the time of hire, for each employee providing direct client/patient's service/care. It is preferred that the organization recheck criminal background history and the sex offender registry on all staff that provide direct client/patient service/care at least every 3 years.

The organization must have a policy regarding special circumstances, if any, for hire of a person convicted of a crime. The policy may include, but not be limited to: documentation of special considerations, restrictions, or additional supervision.

Evidence: Written Policies and Procedures
Personnel Files

Standard 405. The organization maintains a personnel file for each employee.

Standard 405, Criterion A: Written policies and procedures describe the procedures to be used in the management of personnel files and confidential records for each employee.

Interpretation: Written policies and procedures will describe: (1) employee positions having access to the personnel file; (2) proper storage; (3) the required contents; (4) review requirements; and (5) time frames for retention of personnel files.

The organization maintains a personnel file for each employee that will contain, at a minimum, an application, dated, and signed withholding statements, verification of citizenship status, and all other items noted in the standards/criterions.

The organization is required to have complete personnel records available for inspection by federal, state regulatory agencies and accreditation agencies.

Evidence: Written Policies and Procedures
Personnel Files

Standard 406. The organization assures that all employees receive orientation.

Standard 406, Criterion A: The organization has a written orientation plan for all new employees.

Interpretation: The written orientation plan must include the following, at a minimum: (1) review of the individual's job description and duties to be performed and their role in the organization; (2) organization chart/supervision; (3) mission/philosophy; (4) record keeping and reporting; (5) confidentiality and privacy of protected health information; (6) client/patient's rights; (7) advance directives; if applicable (8) conflict of interest; (9) written policies and procedures; (10) training specific to job requirements; (11) additional training for special populations (i.e.: nursing homes, pediatrics, disease processes with specialized care); (12) cultural diversity; (13) ethical issues; (14) professional boundaries; (15) quality improvement plan; and (16) OSHA requirements, safety and infection control.

Medicare certified Home Health agencies must include OASIS and other required documentation in the orientation.

Hospice orientation must also include the following: (1) introduction to hospice; client/patient, family, caregiver as a unit of service/care; (2) concepts of death and dying and bereavement; (3) emotional support, psychosocial, and spiritual issues; (4) pain and symptom management; (5) diseases and medical conditions common to hospice; and (6) stress management.

The organization must have a checklist or other method to verify that the topics have been discussed with individual workers; and written policies and procedures describing the orientation process.

Evidence: Written Policies and Procedures
Orientation Checklist/Orientation Plan

Standard 406, Criterion B: The organization will designate trained personnel responsible for conducting orientation activities.

Interpretation: The orientation process includes a description of position(s)/qualifications representing trained personnel responsible for conducting orientation activities.

Evidence: Written Policies and Procedures and/or Job Description

Standard 406, Criterion C: All staff members participate in an orientation program appropriate to the classification of the employee and the service/care he/she will provide prior to assuming client/patient responsibilities.

Interpretation: Orientation is conducted with all staff and volunteers prior to their assuming client/patient service/care responsibilities. Staff members are oriented to their specific client/patient assignments.

The orientation is documented in the personnel files for all staff members and volunteers.

Evidence: Orientation Checklist or other Documentation of Attendance
Personnel Files
Response to Interviews

Standard 407. The organization assures that all employees receive training and/or demonstrate competence appropriate to job requirements.

Knowledge and skills can be acquired through a variety of methods such as classroom instruction, on-the-job observation and demonstration, self-instruction, internships, etc. The focus and type of training is directly related to the goals of the employee and/or the organization.

Standard 407, Criterion A: The organization assures that all staff members have received training and/or education and can competently perform the required client/patient service/care activities prior to being assigned to work independently.

Interpretation: The organization's written policies must define the minimum education and training, licensure, certification, experience, and the minimum competencies, required for each service/care

offered, as well as the method for documenting that personnel have received the required training (i.e. certificates, diplomas, etc).

The organization designs and implements a competency assessment program based on the service/care provided. Competency assessment must be an ongoing process and focus on the primary service/care, and/or therapies being provided. Competency assessment is conducted initially during orientation and annually thereafter. Validation of skills is specific to the staff member's/volunteer's role and job responsibilities.

Procedures for determining that staff are competent to provide quality service/care must be in place and may be accomplished through clinical observation, skills lab review, supervisory visits, knowledge-based tests, situational analysis/case studies, and self-assessment. All competency assessments and training must be sufficiently documented. A self-assessment tool alone is not acceptable. Peer review of clinical staff competency by like disciplines will be acceptable if defined by the organization. There must be a plan in place for addressing performance and education of staff when staff does not meet competency requirements.

A Home Health agency must ensure that home health aides have successfully completed an approved training program before providing care. A home health aide training program may be offered by any organization if the organization has not been cited with a correction level deficiency within the last two years.

Evidence: Written Policies and Procedures
Evidence of Competency Assessment
Response to Interviews

For Medicare certified home health agencies: The home health agency must comply with CFR 484.36, 484.39(a)(1),484.36(a)(2),484.36(a)(3),484.36(b)(1), 484.36(b)(3),484.36(b)(5) and 484.36(b)(6). See appendix A for the full text of the regulation.

Standard 407, Criterion B: Staff members are trained and/or have demonstrated competence to perform any new tasks/procedures prior to performing those tasks independently. Direct care staff are not allowed to perform any task for which they have been evaluated as unsatisfactory.

Interpretation: The organization has a process that assures that each direct service staff member has demonstrated competency in any new task before being assigned to that task. The organization also has a process to ensure that staff have been proven competent to perform task(s) after re-training has been provided. A qualified registered nurse must determine if a home health aide is competent in all required skills.

Evidence: Written Policies and Procedures
Evidence of Competency Assessment for New Tasks/Procedures
Response to Interviews

For Medicare certified home health agencies: The home health agency must comply with CFR 484.36, 484.36(a)(1),484.36(a)(2),484.36(a)(3),484.36(b)(1),484.36(b)(3),484.36(b)(4),484.36(b)(5)and 484.36(b)(6). See appendix A for the full text of the regulation.

Standard 408. The organization implements an education plan for all personnel.

Standard 408, Criterion A: The organization has an in-service education plan that provides ongoing in-service education for all staff members.

Interpretation: In-service education refers to ongoing training provided by the employer to develop and maintain skills necessary for all staff members to perform their current job responsibilities. Organizations may provide this training directly or arrange for staff to attend sessions offered by outside sources. The in-service education plan is a written document that may outline program topics to be offered or designate how program topics will be identified for personnel throughout the year. The plan must be based on reliable and valid assessment of needs relevant to individual job responsibilities. Ongoing education activities include methods for obtaining information about staff learning needs, outcome data from competency assessments, and staff input about the effectiveness of the in-services provided. Education activities also include a variety of methods for providing staff with current relevant information to assist with their learning needs. These methods include provision of journals, reference materials, books, internet learning, in house lectures and demonstrations, and access to external learning opportunities.

The organization must have a written policy defining the number of hours of in-service or continuing education required for each classification of personnel. Non direct care staff must have a minimum of 8 hours of in-service/continuing education per year. Direct care staff, including home health aides, must have a minimum of 12 hours of in-service/continuing education per year. In-service training for home health aides may be conducted while the aide is providing care to a patient. It is preferred that organizations encourage supervisors to attend in-service education programs to improve their supervisory skills. The organization must comply with all professional or occupational licensure laws for continuing education requirements and organization policy requirements regarding continuing education.

There is written documentation confirming attendance at in-service and/or continuing education programs.

As applicable, education programs must be designed to assist staff with work related issues of grief, loss and change, and pain and symptom management.

Evidence: Written Policies and Procedures
Documentation of In-service Education Programs and Attendance
Documentation of Staff Attendance at Continuing Education Programs
Response to Interviews

For Medicare certified home health agencies: The home health agency must comply with CFR 484.36(b)(2). See appendix A for the full text of the regulation.

Standard 409. All staff members are supervised by qualified personnel.

Standard 409, Criterion A: The organization has written policies and procedures relating to the supervision of new and experienced staff members.

Interpretation: Supervision involves the direction, observation, and evaluation of the performance of new and experienced staff members. This may be accomplished through documented individual and group conferences dealing with job-related issues, observation, and evaluation of work performance, and telephone contacts to review job assignments. New employees are defined as either new to the organization or new to the program or service/care provided.

There are written policies and procedures for ongoing supervision, appropriate to the service/care provided, directly or through contract during all hours of operation. The written policies and procedures include a mechanism for accessing supervisors and for assuring that staff members know how to contact a supervisor when needed. Written policies and procedures must differentiate between the supervision of new and experienced staff members. Supervision of new employees will include closer monitoring and more frequent supervision of performance than those with experience. (Examples of closer monitoring may include more frequent observation and feedback regarding employee's performance during the first several months of employment).

Evidence: Written Policies and Procedures

Standard 409, Criterion B: The qualifications and current competence of the individuals supervising staff members are appropriate to the scope of program and the services/care provided.

Interpretation: The following elements are present for each individual who supervises direct service/care staff, whether the supervisor is employed directly or through contract: (a) evidence of verification of education and training requirements in accordance with applicable law or regulation and the organization's policy; (b) evidence that he or she has clinical and supervisory knowledge and experience appropriate to his or her assigned supervision responsibilities; and (c) evidence of ongoing in-services and training pertinent to their roles.

When a supervisor does not have appropriate clinical training and experience for a clinical specialty area the organization provides access to qualified consultation. Supervisors can describe the process for obtaining consultation and describe the types of assistance that is available to them.

Evidence: Personnel Files
Job Descriptions
Response to Interviews

Standard 409, Criterion C: Supervision is available during all hours, that program service/care is provided.

Interpretation: An adequate number of individuals provide appropriate administrative and clinical supervision of staff in all service/care areas. Supervision will be consistent with the appropriate occupational licensure requirements.

Evidence: Observation
On-call Schedules
Response to Interviews

Standard 410. Qualified personnel evaluate all staff members.

Standard 410, Criterion A: Qualified personnel observe and evaluate each direct service/care staff performing their job duties at least annually and/or in accordance with state or federal regulations. Competency assessments of home health aides must be conducted by a qualified registered nurse. All patient care is provided in compliance with professional standards and principals.

Note: This criterion is applicable to organizations that are providing direct client/patient service/ care.

Interpretation: Qualified personnel observe and evaluate each direct service/care staff performing their job duties at frequencies required by state or federal regulations. Industry principles and professional standards also used to determine appropriate staffing and care. If no regulation exists the evaluation must be performed at least once annually to assess that quality service/care are being provided. This activity may be performed as part of a supervisory visit. Written policies and procedures must define assessment items/standards. The evaluation(s) shall become part of the personnel record.

Evidence: Written Policies and Procedures
Personnel Files

For Medicare certified home health agencies: The home health agency must comply with CFR 484.12(c). See appendix A for the full text of the regulation.

Standard 410, Criterion B: Written annual performance evaluations are completed for all personnel based on specific job descriptions.

Interpretation: The organization has written policies and procedures addressing individual performance evaluations for all staff and/or volunteers. These policies describe how performance evaluations are conducted, who conducts them, and when they are to be conducted. The policy must also identify any deviations to their policy, i.e. if the organization's annual evaluation serves as the performance evaluation for the leader(s)/executive(s) of the organization. Evaluations involve both the supervisor and the individual in rating work performance based on performance criteria for their specific job description.

Annual performance evaluations are required for part-time staff members that have worked for six months or longer in a year.

Evidence: Written Policies and Procedures
Personnel Files

For Medicare certified home health agencies: The home health agency must comply with CFR 484.12(c). See appendix A for the full text of the regulation.

Standard 410, Criterion C: The results of annual performance evaluations are shared with personnel.

Interpretation: A copy of the performance evaluation must be reviewed by the employee and signed by the individual performing the evaluation and the employee. Performance evaluation results must be shared with the employee by a face-to-face conference with the supervisor.

Evidence: Personnel Files
Response to Interviews

Standard 410, Criterion D: Action is taken when negative client/patient outcomes are directly related to staff performance.

Interpretation: An assessment is completed to determine the best course of action when negative client/patient outcomes are experienced due to staff performance. Based on this assessment, actions may include remedial training of the staff, reassignment of the staff, or limitation of the staff's involvement in client/patient service/care or other appropriate actions. The actions taken must be documented in personnel records, variance reports or other appropriate documents.

Evidence: Organization Documentation
Personnel Files
Response to Interviews

Standard 411. Written contracts and/or agreements govern the components of services/care that are purchased from another entity resulting in shared responsibility for service/care delivery.

Note: This criterion is applicable to organizations that have contracts/agreements for shared responsibility components.

Medicaid waiver program agreements are not subject to these standards if enrolled in the state provider network. Personal Care Services (PCS) and the Community Alternatives Program (CAP) agreements are not subject to this standard.

Standard 411, Criterion A: Written contracts/agreements are on file within the organization.

Interpretation: A contract or agreement is required whenever the organization sells or purchases services, personnel, training, or supervision from another organization/individual for direct or indirect client/patient service/care on an on-going or individual client/patient basis.
Evidence: Written Contracts and/or Agreements

For Medicare certified home health agencies: The home health agency must comply with CFR 484. 14, 484.14(a), 484.14 (f), 484.14(h) and 484.38 (d)(4). See appendix A for the full text of the regulation.

Standard 411, Criterion B: Service/care contracts/agreements are reviewed and renewed as required in the contract.

Interpretation: The organization has an established process to review and renew contract/agreements as required in the contract. A mechanism to indicate that the review and or renewal have been accomplished may be evidenced by either a notation of the review dates on the initial contract/agreement or development of an updated contract/agreement.

Evidence: Written Contracts and/or Agreements

For Medicare certified home health agencies: The home health agency must comply with CFR 484.14(a).. See appendix A for the full text of the regulation.

Standard 411, Criterion C: There are copies of professional liability insurance certificates of coverage on file for any personnel providing direct service/care and/or organizations providing shared responsibility service/care.

Interpretation: The organization maintains current copies of professional liability insurance certificates of coverage for all personnel providing direct service/care and/or organizations providing shared responsibility service/care. The certificates should be maintained with the respective contract.

Evidence: Copies of current Insurance Certificates confirming liability coverage

Standard 411, Criterion D: Contracts/agreements contain the required items.

Interpretation: The following items must be included in the contract/agreement: (1) Name and type of service/care to be provided; (2) duration of contract/agreement; (3) responsibilities of each organization; (4) the manner in which service/care will be controlled; coordinated, and evaluated by the primary organization; (5) the amount and procedures for payment for service/care furnished under the contract; (6) compliance with all organization policies including applicable personnel policies; (7) requirements to meet Medicare Conditions of Participation; if applicable, (8) overall responsibility for supervision of staff, if applicable and (9) other applicable law and regulations.

Evidence: Written Contracts and/or Agreements

For Medicare certified home health agencies: The home health agency must comply with CFR 484.14(f), 484.14(h), 484.36(d)(4), 484.36(d)(4)(i), 484.36(d)(4)(ii) and 484.36(d)(4)(iii). See appendix A for the full text of the regulation.

Standard 411, Criterion E: The organization monitors all service/care provided under contract and/or agreements to ensure that service/care are delivered in accordance with the terms of the contract/agreement.

Interpretation: The organization has implemented a process for monitoring all service/care provided under a contract or agreement. Processes may include satisfaction surveys, routine record reviews, on-site observations and visits, customer comments and other quality improvement activities. Data and outcomes from monitoring activities are reported to the organization leadership.

Evidence: Quality Improvement Activities
Board Minutes or Leadership Meeting Documentation

For Medicare certified home health agencies: The home health agency must comply with CFR 484.12(c), 484.14 and 484.14(a). See appendix A for the full text of the regulation.

SECTION 500: CLIENT/PATIENT RECORD MANAGEMENT

Standard 501. An accurate record is maintained for each client/patient.

Standard 501, Criterion A: The organization has written policies and procedures relating to the required contents of client/patient records.

Interpretation: The organization's written policies and procedures must define the required contents of the client/patient records the organization maintains. The contents must include, but are not limited to the following: (1) identification data; (2) names of next of kin or legal guardian; (3) emergency contact; (4) name of primary caregiver(s); (5) source of referral; (6) admission and discharge dates from hospital or other institution, if applicable; (7) name of physician responsible for care; (8) diagnosis; (9) physician's orders; (10) signed release of information and other documents for protected health information; (11) admission and informed consent documents; (12) assessment of the home, if applicable; (13) initial assessments; (14) ongoing assessments, if applicable; and (15) a written plan of service/care, as applicable.

For programs providing clinical service/care (i.e.: Hospice, Home Health, Clinical Respiratory Care), the client/patient record must also include: (16) advance directives; (17) names of power of attorney and/or healthcare power of attorney; (18) evidence of coordination of service/care provided by the organization with others who may be providing service/care; (19) physician orders that include medications and dietary, treatment and activity orders; (20) signed and dated clinical and progress notes; (21) copies of summary reports sent to physicians; (22) client/patient/family response to service/care provided; and (23) a discharge summary.

Written policies must define any circumstances where a separate client/patient record is not required, e.g. retail cash sales of supplies and products.

Evidence: Written Policies and Procedures

For Medicare certified home health agencies: The home health agency must comply with CFR 484.48. See appendix A for the full text of the regulation.

Standard 501, Criterion B: Written policies and procedures address access, storage, removal, and retention of client/patient records and information.

Interpretation: Organizational policies must be consistent with HIPAA standards. Policies must define who can have access to client/patient records, including persons authorized to enter information and review the records. Original copies of all active client/patient records must be kept in a secure location on the organization's premises. Current electronic client/patient records must be stored in an appropriate secure manner as to maintain the integrity of the client/patient data through routine backups on or off site. The organization's policies specify any circumstances and the procedure to be followed to remove client/patient records from the premises or designated electronic storage areas. Policies describe the protection and access of computerized records and information, including back-up procedures, electronic transmission procedures, storage of back-up disks and tapes and methods to replace information if necessary.

Clinical record information is safeguarded against loss of unauthorized use. An organization must have written consent from the patient to release information not authorized by law. Written procedures govern use and removal of records and the conditions for release of information.

All client/patient records must be retained for a minimum of five years from the date of the most recent discharge of the client/patient, five years after the month the cost report to which the records apply is filed or per state law. Records of minor clients/patients (or clients/patients with guardians) must be retained until at least one year following the client/patient's eighteenth birthday or according to state laws and regulations.

Portions of client/patient records may be copied and removed from the licensed premises to ensure that appropriate service/care staff will have information readily accessible to them to enable them to provide the appropriate level of service/care.

The organization must have specific written policies and procedures delineating how these copies will be transported and stored to preserve confidentiality of information.

Evidence: Written Policies and Procedures

For Medicare certified home health agencies: The home health agency must comply with CFR 484.48(a) and 484.48(b). See appendix A for the full text of the regulation.

Standard 501, Criterion C: There is a client/patient record for each client/patient who receives service/care that contains the required items.

Interpretation: A separate client/patient file must be maintained for each client/patient requiring ongoing service/care. The original client/patient record must be maintained on the premises where the service/care is provided. The client/patient record must content the items as required by organization policy.

Evidence: Client/Patient Records

Standard 501, Criterion D: Client/patient records contain documentation of all service/care provided with entries dated and signed.

Interpretation: The client/patient record must contain documentation of all service/care provided, directly or by contract, with entries dated and signed by the appropriate staff member. Each home visit, treatment, or service/care must be documented in the record and signed by the individual who provided the service/care. Signatures must be legible, legal and include the proper designation of any credentials.

Evidence: Client/Patient Records

Standard 501, Criterion E: There is demonstrated consistency between the service/care performed by the organization, the service/care plan and the services billed.

Note: Failure to meet this criterion will result in automatic deferral.

Interpretation: The organization must be able to verify that clients/patients are properly billed for service/care provided. The surveyor will conduct an audit of billing records for client/patient charts that are chosen at random for the client/patient record review.

Evidence: Client/Patient Records
Billing Records

Standard 502. There is a process for client/patient referral and acceptance.

Standard 502, Criterion A: There are written policies and procedures, which describe the referral process.

Interpretation: Written policies and procedures describe the referral process including the required referral information. Written policies and procedures designate the positions in the organization that may receive referrals.

Referrals containing verbal orders must be given by the referring physician, by others approved by law to prescribe, or the individual directly designated to convey orders and will be referred to a designated staff member(s) for verification and documentation of verbal orders.

Evidence: Written Policies and Procedures

Standard 502, Criterion B: There are written policies and procedures for service/care guidelines, which define eligibility for all service/care and programs.

Interpretation: There are written policies and procedures that designates the staff member(s) that are assigned to assess the level and type of service/care required by clients/patients referred to the organization, and determine whether the client/patient is eligible for admission based on the organization's criteria and availability of service/care to meet the client/patient's needs.

Eligibility guidelines must identify the following: (1) target population(s); (2) geographic area served; (3) service/care limitations; and (4) method of payment. Eligibility guidelines may vary for different service/care programs. Eligibility criteria are periodically reviewed for appropriateness and continued accessibility to the organization's programs. Specialized populations may be defined generally as anyone needing the service/care, or in some cases, may be defined by special funding sources, specific ages (elderly, infants, children, etc.), special service/care needs (medical care, homemaking, personal care, etc.), or specific diseases/disabilities (Alzheimer's, arthritis, etc.). The organization shall identify the geographic area served.

Service/care may have limitations such as client/patient-related restrictions (provided only to ambulatory patients, provided only when client/patient cannot perform personal care tasks independently, limited life expectancy, availability of a responsible caregiver, safety restrictions etc.), or organization-related restrictions (ability of staff, hours of operation, etc.). Policies describe eligibility guidelines and procedures to follow for clients/patients who have no ability to pay for service/care.

Evidence: Written Policies and Procedures

Standard 502, Criterion C: There are written policies and procedures that address the organization's compliance with federal, state, and local anti-discrimination laws in the acceptance of clients/patients.

Interpretation: There must written policies and procedures verifying the organization's intent to abide by anti-discrimination legislation which must include, but not be limited to the following: age, race, nationality, creed, sex, sexual orientation, diagnosis/infectious disease, disability, ability to pay, and DNR status.

Evidence: Written Policies and Procedures

Standard 502, Criterion D: Verification of license/certification of the referring physician or others approved by law to prescribe medical services, treatments, and/or pharmaceuticals will be conducted prior to providing service/care.

Interpretation: Written policies and procedures describe the process for verification of physician credentials. Ongoing periodic assessments of current physician license/other license/certification may be obtained from the state Licensing Board of Medicine or other Licensing/Certification Boards, or verification of physician privileges at the local or regional accredited hospital. The organization must have a mechanism to ensure that orders are only accepted from currently licensed physicians.

Evidence: Written Policies and Procedures
Approved Physician List
Response to Interviews

Standard 502, Criterion E: Client/patient records and other sources provide verification that the clients/patients receiving service/care meet eligibility requirements.

Interpretation: Client/patient records and other sources provide verification that clients/patients receiving service/care meet eligibility requirements.

Evidence: Client/Patient Records

Standard 503. The organization coordinates planning and service/care delivery efforts with other community agencies.

Standard 503, Criterion A: There are written policies and procedures for addressing client/patient needs, which cannot be met by the organization. Clients/patients are referred to other agencies when appropriate.

Interpretation: Service/care needs which cannot be met by the organization will be addressed by referring the client/patient to other organizations when appropriate. Client/patient records or referral or intake forms must indicate a referral was made to another organization or communication was provided to the physician or referral source when client/patient needs could not be met.

Evidence: Written Policies and Procedures
Client/Patient Records or Referral Log or Intake Form

Standard 503, Criterion B: All staff members are knowledgeable about other service/care available in the community.

Interpretation: All staff members are aware of other community service/care and make an effort to work cooperatively with these organizations to promote a full range of home and community based service/care options in the communities served. Service/care needs, either identified by staff, referring physicians, or requested by clients/patients/families/responsible party, which cannot be met by the organization will be addressed by referring the client/patient/family to other community agencies. Unmet service/care needs will be communicated to the governing body at least quarterly.

Evidence: Client/Patient Records
Reports to Governing Body
Response to Interviews

SECTION 600: QUALITY OUTCOMES/IMPROVEMENT

Standard 601. There is organizational participation and involvement in quality improvement activities by all staff members.

Standard 601, Criterion A: The organization ensures the implementation of a quality outcome/improvement plan by the designation of a person or persons responsible for quality improvement coordination activities.

Interpretation: Duties and responsibilities relative to QI coordination include: assisting with the overall development and implementation of the QI plan; assisting in the identification of goals and related client/patient outcomes; and coordinating, participating, and reporting of activities and outcomes results.

The individual(s) responsible for quality improvement coordination activities may also be the owner, manager, supervisor, or other organization employee.

Evidence: Job Description

Standard 601, Criterion B: There is evidence of involvement of the governing body and organizational leaders in the quality improvement process.

Interpretation: The governing body and leaders are ultimately responsible for all actions and activities of the organization; therefore, their role in the evaluation process and the responsibilities delegated to staff must be clearly documented. There must be evidence that the results of quality improvement activities are communicated to the governing body and organizational leaders. For organizations that require a professional advisory committee, there must also documented involvement of this committee in the quality improvement process.

The organization's leaders allocate resources for implementation of the quality improvement program. Resources may include but are not limited to training and education programs regarding quality improvement, staff time, information management systems, and computer programs.

Evidence: Minutes of Governing Body Meetings
Minutes of Professional Advisory Committee meetings
Response to Interviews

For Medicare certified home health agencies: The home health agency must comply with CFR 484.52. See appendix A for the full text of the regulation.

Standard 601, Criterion C: There is evidence of staff involvement in the quality improvement process.

Interpretation: Personnel will receive training related to quality improvement activities and their involvement. Training may include, but not be limited to, the purpose of quality improvement activities, person(s) responsible for coordinating quality improvement activities, the staff's individual role in quality improvement, and performance improvement outcomes resulting from previous activities.

The staff must be involved in the evaluation process through carrying out quality assessment activities, evaluating findings, recommending action plans, and/or receiving reports of findings. Staff must be informed of results of quality improvement activities that directly impact or reflect the service/care they provide.

Evidence: Minutes of Staff Meetings
Response to Interviews

For Medicare certified home health agencies: The home health agency must comply with CFR 484.52. See appendix A for the full text of the regulation.

Standard 602. There is a quality improvement program that includes all quality aspects of the program and service/care provided.

The quality improvement program will be comprehensive and will include activities that assess and improve the quality of service/care offered by the organization based on identified priorities and identified undesirable trends and patterns noted in collected data. All data is protected and confidentiality of the individual is maintained.

Standard 602, Criterion A: Quality improvement activities must include an annual evaluation of the program service/care.

Note: For organizations providing non-clinical services, this criterion is not scored if this is the organization's initial survey.

Interpretation: An annual evaluation is a process that measures the organization's performance in relation to its mission, philosophy, goals and objectives and in meeting the needs of the clients/patients and communities served. As part of the evaluation process, the policies and administrative practices of the agency are reviewed to determine the extent to which they promote quality patient care. The annual evaluation is summarized in a written report which includes: (1) the effectiveness of the quality improvement program; (2) the effectiveness, quality and appropriateness of service/care provided to the clients/patients, service/care areas and community served, including culturally diverse populations; (3) effectiveness of the overall administrative and fiscal operations; (4) effectiveness of all programs including service/care provided under contractual arrangements; (5) utilization of staff; and (6) review and revision of policies and procedures, and forms used by the organization.

It is preferred that the quality improvement program incorporates a mechanism to elicit community input into the annual evaluation of the organization's service/care.

Evidence: Annual Program Evaluation

For Medicare certified home health agencies: The home health agency must comply with CFR 484.52(a). See appendix A for the full text of the regulation.

Standard 602, Criterion B: Quality improvement activities must include an assessment of processes that involve risks.

Interpretation: A review of all variances, which may include incidents, accidents, and worker compensation claims, must be conducted at least quarterly for detection of trends, patterns of behavior, and for an action plan to decrease occurrences.

Evidence: Quality Improvement Reports
Incident/Variance Reports

Standard 602, Criterion C: Quality improvement activities must include ongoing monitoring of at least one important aspect related to the service/care provided.

Interpretation: The organization must conduct monitoring of at least one important aspect of the service/care provided by the organization. An important aspect of service/care reflects a dimension of activity that may be high volume (occurs frequently or affects a large number of clients/patients), high risk (causes a risk of serious consequences if the service/care is not provided correctly), or problem-prone (has tended to cause problems for staff or clients/patients in the past.

Examples of activities may include, but not be limited to: delivery of service/care (timeliness, incorrect product deliveries, etc.), medication administration, and clinical procedures.

Evidence: Quality Improvement Reports

Standard 602, Criterion D: Quality improvement activities must include ongoing monitoring of at least one important administrative aspect of function or service/care of the organization.

Interpretation: The organization must conduct monitoring of at least one important administrative/operational aspect of function or service/care of the organization. Examples of QI activities may include, but not be limited to, monitoring compliance of conducting performance evaluations, in-service hours, or billing audits.

Evidence: Quality Improvement Reports

Standard 602, Criterion E: Quality improvement activities must include satisfaction surveys.

Interpretation: The QI plan identifies the process for conducting client/patient satisfaction surveys. The QI plan also identifies the process for conducting staff, physician, and referral source satisfaction surveys.

Evidence: Quality Improvement Reports

Standard 602, Criterion F: The quality improvement plan includes a review of the client/patient record.

Interpretation: The client/patient record review is conducted by all disciplines or members of the client/patient service/care team. An adequate sampling of open and closed records is selected to

determine the completeness of documentation.

An adequate sample of records is one that represents statistically significant sample as defined in the Interpretive Guide glossary.

Evidence: Quality Improvement Reports

For Medicare certified home health agencies: The home health agency must comply with CFR 484.52(b). See appendix A for the full text of the regulation.

Standard 603. The organization uses appropriate methods to collect data and monitor performance.

Standard 603, Criterion A: Each quality improvement activity or study contains the required items.

Interpretation: Each quality improvement activity/study must include the following items: (1) a description of indicator(s)/activities to be conducted; (2) frequency of activities; (3) designation of who is responsible for conducting the activities; (4) methods of data collection; (5) acceptable limits for findings; (6) who will receive the reports; and (7) plans to re-evaluate if findings fail to meet acceptable limits in addition to any other activities required under state or federal laws or regulations.

Evidence: Quality Improvement Activities/Studies

For Medicare certified home health agencies: The home health agency must comply with CFR 484.52(a) and 484.52(b). See appendix A for the full text of the regulation.

Standard 603, Criterion B: Quality improvement activities include participation in external benchmarking.

Note: This criterion is preferred only and will not be scored at this time.

Interpretation: It is recommended that the organization participate in external benchmarking activities either at the state, regional, or national level.

Evidence: Quality Improvement activities

Standard 603, Criterion C: There is an annual written quality improvement report.

Note: For organizations providing non-clinical services, this criterion is not applicable to organizations who have been in business less than one year or who have not completed 12 months of QI activities prior to their initial survey.

Interpretation: There is a comprehensive, written annual report that describes the quality improvement activities, findings and corrective actions that relate to the service/care provided. In a large multi-service organization, the report may be part of a larger document addressing all of the organization's programs.

While the final report is a single document, improvement activities must be conducted at various times

during the year. Data for the annual report may be obtained from a variety of sources and methods, i.e., audit reports, client/patient questionnaires, feedback from referral sources, outside survey reports, etc.

Evidence: Written Quality Improvement Reports

Standard 604. Information gained from the quality improvement activities and evaluation is utilized by the organization.

Standard 604, Criterion A: There is a written plan of correction developed in response to any quality improvement findings that do not meet an acceptable threshold.

Interpretation: A written plan of correction is developed in response to any quality improvement activity that does not meet an acceptable threshold. The plan of correction may identify changes in policy, procedure, or processes that will improve performance.

The plan of correction may require governing body action or approval or may be within the scope of authority already delegated to organization staff.

Evidence: Written Corrective Action Plans

For Medicare certified home health agencies: The home health agency must comply with CFR 484.52(a). See appendix A for the full text of the regulation.

Standard 604, Criterion B: Plan of correction outcomes indicates changes or revisions in the service/care, policies, and/or procedures.

Interpretation: A written summary describes changes made as part of a corrective action plan. This summary may be found as a separate document, as part of the minutes of governing body meetings, or as part of quality assessment reports.

Evidence: Quality Improvement Reports
Minutes of Governing Body Meetings

For Medicare certified home health agencies: The home health agency must comply with CFR 484.52(a). See appendix A for the full text of the regulation.

Standard 604, Criterion C: The organization investigates all adverse events.

Interpretation: The organization investigates all adverse events and develops a plan of correction to prevent the same or similar events from occurring again.

Adverse events include but are not limited to: (1) unexpected death, including suicide of client/patient/caregiver; (2) any act of violence, including rape of staff and/or client/patient/caregiver; (3) a serious injury (specifically includes loss of limb or function); (4) psychological injury; (5) a significant adverse drug reaction or significant medication error; or (6) other untoward events or undesirable outcome as defined by the organization.

Evidence: Adverse Event Reports and Action Plans

SECTION 700: RISK MANAGEMENT: INFECTION AND SAFETY CONTROL

Standard 701. The organization has a program designed to identify, prevent, and control infections.

Standard 701, Criterion A: The organization has written policies and procedures that address infection control and the compliance with regulatory standards.

Interpretation: Written policies and procedures, in accordance with CDC, Health Department, APIC (Association for Professionals in Infection Control Epidemiology) and OSHA standards, address education of staff, volunteers, clients/patients and caregivers about: (1) general infection control measures appropriate for service/care provided; (2) hand washing; (3) use of universal precautions and personal protective equipment; (4) needle-stick prevention and safety plan; if applicable (5) appropriate cleaning/disinfecting procedures; (6) infection surveillance, monitoring and reporting of employees and clients/patients; (7) disposal and transportation of regulated waste, if applicable; (8) precautions to protect immune-compromised clients/patients; (9) employee health conditions limiting their activities; and (10) assessment and utilization of data obtained about infections and the infection control program.

The organization has written policies and procedures that detail OSHA Blood borne Pathogen and TB Exposure Control Plan training for all direct care staff. The exposure control plans must be reviewed annually and updated to reflect significant modification in tasks or procedures that may result in occupational exposure. The Exposure Control Plan must include engineering and work practice controls that eliminate occupational exposure or reduce it to the lowest feasible extent, i.e. use of safer medical devices, and appropriate respiratory protection devices. A copy of the plans must be made available to the employee at the workplace during the work shift.

The TB Exposure Control plan must include a current organization assessment indicating the community and company TB incidence and prevalence rates as recommended by CDC guidelines.

Written policies and procedures identify the staff member who has the responsibility for the implementation of the infection control activities, and staff education.

Written policies and procedures describe the conditions limiting the employee's assignments to office or home. Examples may be impetigo, communicable disease, fevers, respiratory diseases, etc.

Evidence: Written Policies and Procedures
Observation
Home Visits

Standard 701, Criterion B: All staff members, volunteers, clients/patients, and caregivers are knowledgeable of the policies and procedures for infection control.

Interpretation: The organization must ensure staff members, volunteers, clients/patients and caregivers receive instruction about basic and high-risk infection control procedures as appropriate to the services/care provided. Training is consistent with OSHA and CDC recommendations: Clinical staff

must provide infection control instructions to the client/patient/family and caregivers.

Evidence: Orientation Records
In-Service Education Records
Personnel Files
Response to Interviews

Standard 701, Criterion C: All staff members and volunteers must consistently follow infection control procedures in the provision of service/care to the organization's clients/patients.

Interpretation: All staff members and volunteers demonstrate infection control procedures in the process of providing service/care to clients/patients as described in OSHA and CDC standards and as adopted into program service/care policies and procedures.

Evidence: Observation

Standard 701, Criterion D: The organization reviews and evaluates the effectiveness of the infection control program.

Interpretation: The organization monitors infection statistics of both clients/patients and personnel and implements other activities (such as infection tracking records or logs) to ensure that staff follow infection control procedures and report infection outcomes.

Infection control tracking must be used to collect and trend data on infections of both personnel and clients/patients. The organization identifies what infections will be reported in personnel and clients/patients using criteria appropriate to the populations served and in accordance with applicable law and regulations.

Surveillance data is analyzed for trends and related factors that may contribute to the trends and for correlations between employees, volunteers, clients/patients, and infection control practices.

Data must be utilized to assess the effectiveness of the infection control program. A written summary of the evaluation of the infection control program must be communicated to leadership and staff, Corrective action plans and steps for improvement are to be implemented as needed. Data and action plans must be included in the Quality Improvement activities and reported to the administrative staff and direct care personnel at regular intervals.

The organization must report all communicable diseases, as required by the local county health department, to the local county or state department of health.

Evidence: Reports of Infection Tracking Records or Logs
Quality Improvement Reports

Standard 702. The organization has a system designed to identify, prevent, and control safety hazards related to the service/care provided to the client/patient.

Standard 702, Criterion A: The organization has written policies and procedures that address safety issues relating to service/care provision and education of staff members concerning safety.

Interpretation: Written policies and procedures must include types of safety training as well as the frequency of training. Safety training is included at orientation and ongoing training. Safety training activities may include but not be limited to: (1) body mechanics; (2) workplace fire safety management and evacuation plan; (3) workplace or office security; (4) personal safety techniques; (5) common environmental hazards, (i.e. icy parking areas and walkways, blocked exits, cluttered stairways, etc.); (6) office equipment safety; and (7) safety and compliance monitoring measures relating to the client/patient's medication, when applicable.

For programs providing in-home service/care, the safety training activities may also include: (1) personal safety techniques relating to in home service/care; (2) safety measures relating to oxygen use, if applicable; (3) client/patient medical equipment safety; if applicable (4) basic home safety measures (i.e., household chemicals, throw rugs, furniture layout, cluttered stairways, blocked exits, bathroom safety, electrical safety, etc.); and (5) use of restraints, if applicable.

Evidence: Written Policies and Procedures

Standard 702, Criterion B: The organization educates all personnel about safety issues relating to service/care provision.

Interpretation: The organization has a process in place to educate personnel about home and work place safety measures. Safety measures address building safety and security, staff safety and security, equipment safety, client/patient/family safety and security and home safety.

Evidence: Orientation Records
In-service Records
Response to Interviews

Standard 703. The organization has a plan to meet client/patient needs in a disaster or crisis situation.

Standard 703, Criterion A: The organization has written policies and procedures that outline the process for meeting client/patient needs in a disaster or crisis situation.

Interpretation: The written policies and procedures describe a process to organize and mobilize staff adequate to secure resources needed to meet client/patient needs in the event of a disaster or crisis. The process includes a system to identify alternative methods for contacting staff and mobilizing resources to meet critical client/patient needs. The process includes alternative methods, resources, and travel options for the provision of service/care and safety of staff and identified time frames for initiation of the plan.

The process includes specific measures for anticipated emergencies typical or appropriate for the geographical area served (i.e., hurricanes, tornadoes, floods, earthquakes, chemical spills, and inclement weather). The organization must have, at a minimum, an annual practice drill to evaluate the adequacy of their plan.

The emergency plan also describes access of 911 services in the event of needed emergency services/care for clients/patients, personnel, and visitors.

The program also has a method to identify and prioritize clients/patients based upon their need so that service/care is ensured for clients/patients who would otherwise be at risk of threat to their health or safety.

Evidence: Written Policies and Procedures

Standard 703, Criterion B: The organization educates all staff members about the process to meet client/patient needs in a disaster or crisis situation.

Interpretation: The organization educates all staff members about the process to meet client/patient needs in a disaster or crisis situation. The staff education requirements must include at a minimum; (1) orientation to the emergency plan; and (2) annual review of the emergency plan.

Evidence: Orientation Records
In-Service Records
Response to Interviews

Standard 704. The organization implements a utilities management plan in the office site, and client/patient service/care environments.

Standard 704, Criterion A: The organization conducts regular assessments of its utility systems for potential risks or failures.

Interpretation: The organization ensures adequate back up systems and processes are in place in the event of power or utility failure. Utilities management may include, but not be limited to: (1) heating and cooling in the office or warehouse or other work site; (2) refrigeration; (3) water supply; (4) telephone, electronic and other communication devices, electrical systems, and computer systems; and (5) routine checks and maintenance of utility systems.

Evidence: Utilities Management Plan
Utilities Assessment Logs or Reports

Standard 705. Services/care is provided in a safe and secure environment.

Standard 705, Criterion A: The organization has written policies and procedures that address the organization's fire safety and emergency power systems.

Interpretation: The written policies and procedures or fire safety plan address fire safety and management for all client/patient service/care areas, office and worksite environments. The written policies and procedures include the organization's policies for providing emergency power to critical areas that must include at a minimum: alarm systems, illumination of exit route, and emergency communication systems.

Evidence: Written Policies and Procedures
Observation

Standard 705, Criterion B: The organization implements its fire safety and emergency power system plan.

Interpretation: Smoking is prohibited throughout the building(s) and the nonsmoking policy is communicated to all personnel, clients/patients, and visitors. Fire exits and escapes routes are identified throughout the building.

Smoke detectors, fire alarms, and extinguishers are present and placed in secure areas to meet NFPA and LSC Code, (National Fire Protection Agency and Life Safety Code). These items are inspected, maintained and tested on a regular basis and as recommended by the manufacturer. Fire drills are conducted at least annually. The organization evaluates their response to the fire drill and communicates these results to personnel.

The organization must test its emergency power system at least twice per year.

Evidence: Observation
Inspection/Maintenance Logs

Standard 706. The organization has a procedure for the safe transportation and labeling of hazardous chemicals and/or materials used in the provision of service/care.

Standard 706, Criterion A: The organization has written policies and procedures for the acceptance, transportation, and pick-up of hazardous chemicals and/or materials used in the provision of client/patient service/care.

Interpretation: Written policies and procedures include safe methods of handling, labeling, storage, transportation, disposal, and pick-up of hazardous wastes and hazardous chemicals and/or materials used in the home and organization. The organization must follow state and federal guidelines.

Evidence: Written Policies and Procedures

Standard 706, Criterion B: The organization has written policies and procedures following OSHA's Hazard Communication Standard that describe appropriate labeling of hazardous chemicals and/or materials, instructions for use, storage and disposal requirements.

Interpretation: The organization has written policies and procedures following OSHA's Hazard Communication Standard detailing: (1) the labeling of containers of hazardous chemicals and/or materials with the identity of the material and the appropriate hazard warnings; (2) the use of current Material Safety Data Sheet (MSDS) which must be maintained on file for each chemical used at the facility; and (3) the proper use, storage, and disposal of hazardous chemicals and/or materials, and (4) the use of appropriate personal protective equipment (PPE).

Evidence: Written Policies and Procedures
Review of MSDS Log

Standard 707. The organization has a system for identifying, monitoring, reporting, investigating, and documenting all variances.

Standard 707, Criterion A: The organization has written policies and procedures for identifying, monitoring, reporting, investigating, and documenting all incidents, accidents, variances, or unusual occurrences.

Interpretation: Written policies and procedures describe the process for reporting, monitoring, and investigating and documenting a variance. Procedures must describe: (1) action to notify the supervisor or after hours' personnel; (2) time frame for verbal and written notification; (3) appropriate documentation and routing of information; (4) guidelines for notifying the physician; and (5) follow-up reporting to the administration/board.

There will be written policies and procedures for the organization to comply with the OSHA guidelines to include recording of information about every work-related injury or illness that involves loss of consciousness, restricted work activity, or job transfer, days away from work, or medical treatment beyond first aid.

There will be written policies and procedures for the organization to comply with the FDA's Medical Device Tracking program and to facilitate any recall notices submitted by the manufacturer, if applicable.

Written policy identifies the person(s) responsible for collecting incident data and monitoring for patterns or trends, investigating all incidents, taking necessary follow-up actions and completing appropriate documentation.

The organization defines incidents to be reported, including but not limited to: (1) Adverse client/patient service/care outcomes; (2) Medication and treatment errors, complications or reactions, if applicable; (3) Personnel injury or endangerment; (4) Client/Patient/family injury, including falls; (5) Motor vehicle accidents when conducting agency business; (6) Environmental safety hazards, malfunctions or failures, including equipment; (7) Unusual occurrences; and (8) Suicide threats or attempts.

There is an incident report form and identification of the types of situations that must be reported and documented. These would include but not be limited to personnel or client/patient injury during service provision, and adverse events.

Evidence: Written Policies and Procedures
Incident Report Form

Standard 707, Criterion B: Personnel demonstrate knowledge of the procedure for reporting and documenting variances involving self or client/patient.

Interpretation: The organization educates all personnel about examples of incidents/variances that may occur and the organizations policies and procedures for documenting and reporting incidents/variances.

Evidence: Orientation Records
In-Service Records
Response to Interviews

Standard 707, Criterion C: All incidents, accidents, variances, or unusual occurrences will be documented and reported. Reports must be tracked to collect and trend data on all incidents, accidents, and variances that occur.

Interpretation: The organization documents all incidents, accidents, variances, and unusual occurrences. The reports are distributed to management; the governing body and are reported as required by applicable law and regulation. The organization must record significant work-related injuries and illnesses that are diagnosed by a physician or licensed health care professional and any work-related injuries and illnesses that meet any of the specific recording criteria listed in 29 CFR 1904.8 through 1904.12, if applicable to the organization.

This data must be included in the Quality Improvement plan. The organization assesses and utilizes the data for reducing further safety risks.

Evidence: Incident/Variance Report Logs
OSHA 300, 300A and 301 Forms, if applicable
Quality Improvement Reports

Standard 708. The organization follows procedures for waived tests under the Clinical Laboratory Improvement Amendment (CLIA) and state regulations when staff performs waived tests.

Standard 708, Criterion A: The organization will obtain and maintain a current certificate of waiver from the Department of Health and Human Services. The organization also ensures that referral laboratories are certified in the appropriate services areas.

Interpretation: Organizations that conduct waived tests under CLIA will obtain and maintain a current certificate of waiver from the Department of Health and Human Services. Examples of several waived tests are blood glucose monitoring, fecal occult blood and dipstick urinalysis. If an organization refers specimens for lab testing to an outside laboratory, the referral lab must be CLIA certified. The agency should have a copy of the referral lab's CLIA certificate in its administrative records.

Evidence: Current DHH Certificate of Waiver

For Medicare certified home health agencies: The home health agency must comply with CFR 484.14(j). See appendix A for the full text of the regulation.

Standard 708, Criterion B: The organization has policies and procedures that define utilization purposes and staff training requirements for using waived tests.

Interpretation: The organization has policies and procedures that address how waived test will be utilized in patient care, i.e. for screening, treatment, or diagnostic purposes.

The organization identifies which staff may perform waived test and conducts appropriate training for these individuals.

Evidence: Written Policies and Procedures
Personnel files – Training Documentation

For Medicare certified home health agencies: The home health agency must comply with CFR 484.14(j). See appendix A for the full text of the regulation.

Standard 708, Criterion C: The organization has written policies and procedures for equipment utilized in the performance of conducting waived tests.

Interpretation: Policies and procedures for equipment utilized in the performance of conducting waived tests include: (1) instructions for using the equipment; (2) the frequency of conducting equipment calibration, cleaning, testing and maintenance; and (3) quality control procedures.

Evidence: Written Policies and Procedures
Calibration and Maintenance Logs
Quality Control Logs

For Medicare certified home health agencies: The home health agency must comply with CFR 484.14(j). See appendix A for the full text of the regulation.

INTERPRETIVE GUIDE
STANDARDS FOR ACCREDITATION

Glossary

Accident

Bodily injury to an employee or client on the premises which might require an insurance claim or worker's compensation

Advance Care Directive

A legal document, either a Living Will or Health Care Power of Attorney, that specifies the desires of a client when the client can no longer make his/her wishes known regarding life support and/or health care related decisions.

Advisory Committee

A group of individuals charged with the responsibility to advise an organization's program(s). Membership, which often includes consumers, is usually representative of the community served. Functions of the advisory committee may include serving as liaison with other community programs, making recommendations on professional issues, participating in evaluation of specific services, reviewing policies and procedures, identifying unfilled service needs in the community, and planning programs to close identified service gaps.

Aide Services

A public or private organization or a subdivision of an organization which is primarily engaged in providing supportive personal care and/or home management services to clients in their homes. Aide services are offered by paraprofessionals with titles that may include but not be limited to: Home Care Aide, Nursing Assistant, Personal Care Provider, Home Health Aide, or Community Health Technician.

Alternate Site

Any site other than the client's home where home care services are delivered, e.g. LTC facility, home outpatient clinic, schools, physician office, AIC, ED, etc. Federal, state or local regulations and third-party payers may define alternate sites that are recognized for reimbursement.

Allied Health Personnel

Licensed practical nurses (LPN), physical therapy assistants (PTA), occupational therapy assistants (COTA), speech therapy assistants, or other health professionals as defined in occupational licensure laws that are subject to supervision by a health professional.

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Ambulatory Infusion Center

Ambulatory Infusion Center is defined as a centralized location where a patient can receive infusion therapy. The facility will be staffed by a nurse(s) and in some cases, a pharmacist. Services provided are directed by a physician. A pharmacist must compound and provide medications and the nurse must administer the medication.

Assessment

A systematic and comprehensive evaluation of physical, mental, social, environmental, and economic functional areas to determine the client's strengths and weaknesses, which must be considered in developing the plan of care. Assessments are conducted for all home care service clients at the beginning of care and repeated periodically (reassessments) to determine client needs.

Breast Prosthetic

An external silicone or equivalent material appliance used to replace surgically removed breast tissue; or to symmetrically align reconstructed breast tissue.

Bylaws

Rules, regulations, or laws adopted by the organization for the regulation of its internal affairs and dealings with external entities.

Case Management

The ongoing monitoring and assessment of the needs of the client in relation to the plan of care developed at the time of initial assessment. Management of the case includes, but is not limited to the following activities:

1. Screening to identify individuals who need services
2. Initial assessment to determine the client's strengths, problems, and care needs in major functional areas
3. Service planning, the link between assessment and service delivery whereby a case manager uses the assessment data, along with recommendations of a multi-disciplinary team of professionals, to develop a package of services for each client
4. Arranging for delivery of services
5. Monitoring of the client's service plans, including appropriate follow-ups
6. Periodic reassessment of the client's condition and situation and revision of the plan of care
7. Implementation of the plan of care

Certified Fitter

An individual who has received industry certification to fit and dispense breast prosthetics, surgical bras and related products.

Certified Occupational Therapy Assistant (COTA)

Any person who assists in the practice of occupational therapy in accordance with applicable occupational licensure laws and regulations and works under thee supervision of an occupational therapist by performing patient-related activities assigned by an occupational therapist, which are commensurate with the occupational therapist assistant's education and training. COTA's employed are graduates of an accredited two (2) year Occupational Therapist Assistant program and currently certified by the state Board of Occupational Therapy Examiners, as applicable.

Chief Executive Officer

The person who heads an organization and has the authority and responsibility, as delegated by the governing body, to accomplish program-specific goals and objectives, implement program policy, and manage personnel and resources.

Client Care Evaluation

Process which focuses on assessing the effect of the service on the client's well being. Client care evaluation measures the outcomes (results) of care against predetermined standards. Suggested activities for client care evaluation include: 1) surveying the level of client satisfaction; 2) monitoring the client's functional status; 3) assessing changes in the family caregiver's stress level; 4) evaluating the client's well-being; and 5) monitoring particular service tasks.

Client Record

File of information relative to a client. Client records usually contain the initial assessment and periodic reassessments, the plan of care, documentation of visits and other contacts with the client, notes made by the home care staff on the condition of the client, referrals for other services, and other information pertinent to the care of a particular client.

Clinical Coordination

Ongoing monitoring and assessment of the needs of the client in relation to the service provision. Coordination activities include, but are not limited to:

1. Screening to identify individuals who need services.
2. Service planning, the link between assessment and service delivery whereby the organization uses the assessment data, along with recommendations of a multi-disciplinary team of professionals, to develop a package of services for each client.
3. Coordinating delivery of services.
4. Monitoring of the client's service plans, including appropriate follow-ups.
5. Oversees the periodic reassessment of the client's condition and the revision of services.

Clinical Respiratory Care Services

Clinical Respiratory Care Services pertain to assessment, monitoring, treatment and care of a client in need of respiratory care services. Examples of Clinical Respiratory Care Services include: (1) performing respiratory care assessments, (2) clinical testing, (3) administration of medications and treatments, (4) patient/caregiver respiratory care education, and (4) monitoring of care provided.

Community

The individuals, groups, agencies, facilities or institutions located within the geographical area served by an organization.

Conflict of Interest

A situation existing between an organization and an individual in which the individual stands to achieve personal gain from an action of the organization, e.g. a member of the organization's governing body profits, or is subject to profit, from a real estate transaction.

Consumer

A direct recipient of service, a potential recipient of service, a responsible party (person with authority to act on the client's behalf), or a representative of a consumer organization. A consumer is neither an owner nor an employee of the organization.

Contracted Services

Services made available via a formal agreement with another organization, agency, or individual. The contract/agreement specifies the services, personnel, and space to be provided and the consideration to be expended in exchange.

Direct Care Staff

Staff, including contract, that provide hands on care or direct care to the patient in his/her home or alternate site location, i.e., in-home aides, nurses, therapists, ministers, counselors, etc. It does not include office or support staff.

Director of Clinical Respiratory Service

An individual who is a Licensed Respiratory Care Practitioner (RCP) with sufficient education and clinical experience to direct the scope of clinical respiratory services being offered.

Direct Service Staff

Employees who have direct contact with clients in his/her home or alternate site location, i.e., HME Technicians, Service Technicians, Repair Technicians, etc. It does not include office or support staff.

Discharge

The point at which the agreement to provide home care services is canceled so that the organization no longer has responsibility for care of the client.

Disclosure

A public statement of an individual's conflict of interest. The statement may be made in writing, orally, or both.

Experienced Professional

A professional with at least one year of work experience.

Fiduciary Relation

The legal relation that exists when one person justifiably places reliance on another whose aid or protection is sought in some matter.

Financial Audit

An independent review certifying that an organization's financial reports reflect its financial status.

Financial Management

Procedures used to plan and control an organization's overall financial operations.

First Dose Pharmacy Services

First Dose Pharmacy Services refer to organizations that provide a limited number of doses of medication for another organization. The organization that provides the first dose is not responsible for the clinical monitoring or billing for the patient.

Fitter Services

Fitter services include the provision of breast forms, prosthesis and related supplies to individuals in a specialty designed fitter area of the facility providing the services.

Governing Body

Person(s) or group which has ultimate responsibility for the overall operation of the organization.

Hazardous Material

Any substance or material defined by OSHA as hazardous to a person's health.

Health Professional

A licensed health care provider authorized to supervise other personnel as defined in applicable occupational licensure laws and regulations.

Home Care License

License issued by the state licensing authority to home care providers that have met licensure requirements.

Home Medical Equipment Services

Home Medical Equipment (HME) services include the provision of medical equipment to individuals in their place of residence, along with ongoing monitoring of its use. Examples of HME include but are not limited to beds, ambulatory aids (walkers, canes, and crutches), wheelchairs, bathroom aids, and oxygen delivery systems.

Home Pharmaceutical Care

In terms of ACHC accreditation, home pharmaceutical care is care that is provided to a client in the home or at an alternate site. Home Pharmaceutical Care has four functions: 1) collecting, organizing and evaluating information; 2) formulating a course of action; 3) providing medications and counseling patients; and 4) monitoring and managing patient outcomes.

Home Respiratory Care Practitioner

A licensed respiratory care practitioner (RCP) with documented training and experience in the deliver of home respiratory care. In states without RCP licensure the therapist must be credentialed by the National Board for Respiratory Care (NBRC) as a Certified Respiratory Therapist (CRT) or Registered Respiratory Therapist (RRT). Health care professionals such as LPN's, RN's, and PT's may be utilized to deliver respiratory care services, within their scope of practice, provided there is adequate documentation to support supplemental training and experience in providing home respiratory care.

Hospice Services

Hospice Services are defined as a coordinated program of palliative and supportive care in a variety of settings from the time of admission through bereavement care. Hospice care includes the provision of core and non-core services.

Incident

Any interruption in the normal and defined policy and procedure of an organization that might require documentation reporting, investigation, and follow-up.

Infusion Nursing Services

Infusion Nursing Services is defined as professional services provided by a registered nurse certified in infusion nursing (CRNI) or other acceptable certifications as approved by the state nursing board.

Infusion Pharmacy

An infusion pharmacy provides parenteral (e.g. intravenous, subcutaneous, intramuscular) medications for patients in alternate settings. The service includes clinical monitoring by the pharmacy, and may include nursing services as well.

Infusion Services

Refers to Nursing and Pharmacy Services provided to an individual in a temporary or permanent residence used as the individual's home or in an alternate site setting. Examples of such services include but are not limited to preparation and administration of IV antibiotics, pain management, parenteral and enteral nutrition, hydration and electrolyte replacement, chemotherapy, blood products, cardiac and pulmonary medications, antiemetic therapy, etc. Services also include line maintenance (e.g., implanted ports, various central lines, PICC, epidural, intrathecal, etc.)

In-Home Aide

A paraprofessional person who has received special training in providing home-based services.

In-Home Aide Service Program

A public or private organization or a subdivision of an organization which is primarily engaged in providing supportive personal care and/or home management service to patients in their homes.

In-Home Aide Services

Services that are necessary for the maintenance of the patient in his/her home, including the following:

Assistance with the Activities of Daily Living

- Care of the teeth and mouth
- Grooming, such as shaving and care of the hair and nails
- Bathing
- Toileting
- Changing bed linens with client in bed
- Ambulation indoors and outdoors
- Transfers
- Preparing and meals
- Dressing
- Relearning household skills lost because of disability
- Accompanying client to clinics, physicians, or other places, for the purpose of obtaining medical diagnosis or therapy

Assistance with a Therapeutic Regimen

- Helping with and monitoring prescribed exercises
- Assisting with medications that can be self-administered
- Assisting with simple procedures such as an extension of physical, speech, or occupational therapy
- Measuring and recording oral and rectal temperature, radial pulse, and respirations

Maintenance of a Safe and Healthy Environment

- Care of the client's room and other areas used through sweeping, vacuuming, and dusting
- Maintaining general cleanliness of the kitchen and bathroom
- Care of the client's laundry and bed linens
- Necessary bed making and changing of bed linens
- Shopping for food and household supplies needed for the health and maintenance of the client
- Planning, preparing, and serving meals

Support of Effective Home Management and Family Development Skills

- Demonstrating, reinforcing, and teaching family budgeting techniques
- Teaching comparison shopping
- Organizing household routines
- Planning and assisting with moving activities
- Teaching and reinforcing appropriate housekeeping skills
- Assisting with and teaching basic mending and repair skills
- Demonstrating, reinforcing, and teaching routine child care techniques and positive parenting skills
- Assisting family members in relating effectively with significant community figures, i.e., landlords, physicians, merchants, and school personnel

In-home Services

Services provided to an individual in a place of temporary or permanent residence used as an individual's home or in an alternate site location.

In-patient Care Services

Defined as palliative and support care provided in an institutional setting that is owned and managed directly by the hospice. This includes hospice respite care, as well as, general in-patient care for pain centered on symptom management which cannot be managed in the home setting.

In-service Education

Ongoing education/training provided by the employer to enhance the skills and knowledge of professional staff and in-home Unlicensed Assistive Personnel (UAP) or to teach them new skills relevant to their responsibilities and disciplines.

Interdisciplinary Team Plan of Care

A collaboration of all hospice direct care staff done on an ongoing basis to develop and maintain an individualized patient plan of care which, at a minimum, includes the following: (1) identified problems/needs; (2) achievable goals and objectives; (3) frequency and mix of services; (4) outcomes; and (5) prescribed HME and supplies.

License

Authorization to practice in the professional discipline for which an individual has been prepared. License is granted by the authority having jurisdiction in the state where the individual practices.

Licensed Physical Therapist (LPT)

A person who practices physical therapy in accordance with the provisions of the State Physical Therapy Practice Act. All physical therapists employed with an organization have graduated from an accredited school of Physical Therapy and currently licensed by the State Board of Physical Therapy Examiners.

Licensed Physical Therapist Assistant (LPTA)

A person who assists in the practice of physical therapy in accordance with the provisions of the State Physical Therapy Practice Act, and works under the supervision of a physical therapist by performing such patient-related activities as assigned which are commensurate with the physical therapist assistant's education and training. LPTA's have graduated from an accredited two (2) year Physical Therapist Assistant program and currently licensed by the State Board of Physical Therapy Examiners.

Medical Social Work Services

Defined as the professional application of social work values, principles, and techniques to one or more of the following ends: helping people obtain tangible services; counseling and psychotherapy with individuals and families; helping communities provide or improve social and health services. The practice of social work requires knowledge of human development and behavior; of social and economic, and cultural institutions; and of the interaction of all these factors.

Medical Supply Provider Services

The storage and delivery of home medical equipment and/or medical supplies designed to meet the needs of a client requiring the product for their medical management in the home care setting. These services are generally prescribed by a physician and may be reimbursable through a third party payer or contract. These items are sold to the client and are usually disposable or semi durable in nature. The supplier does not provide in-home care. Any equipment provided must not require ongoing maintenance by the provider.

Nursing Services

Professional services provided by a registered nurse or a licensed practical nurse under the supervision of a registered nurse.

OASIS

The OASIS is a key component of Medicare's partnership with the home care industry to foster and monitor improved home health care outcomes. The Outcome and Assessment Information Set is a group of data elements that:

- Represent core items of a comprehensive assessment for an adult home care patient; and
- Form the basis for measuring patient outcomes for purposes of outcome-based quality improvement (OBQI).

Occupational Therapy Services

Occupational therapy is skilled treatment that helps individuals achieve independence in all facets of their lives. It gives people the "skills for the job of living" necessary for independent and satisfying lives.

Orientation

The introduction to roles and responsibilities of the job and work setting. Orientation must be provided upon employment and any time significant changes occur in a worker's role and/or responsibility.

Orthotics and Prosthetic Services

Orthotics services are defined as the fitting of orthoses, which are braces intended to support or correct any defect of form or function of the human body. Prosthetic services are defined as the fitting of prostheses, which are artificial limbs that replace all or any part of any extremity. These services, prescribed by a physician, promote the welfare of the physically challenged. Orthotics and Prosthetic services facilitate and/or enhance independence thereby improving the person's quality of life.

Paraprofessional

A trained aide who assists a professional person (i.e. home care aide, nursing assistant)

Patient

A direct recipient of service, a potential recipient of service, or a responsible party (person with authority to act in the client's behalf)

Patient/Family

The total focus of hospice care according to its philosophy

Patient Record

A file of information relative to a patient. It usually contains the initial assessment and periodic reassessments, the plan of care, documentation of visits and other contacts with the patient, notes made by the staff on the condition of the client, referrals for other services, and other information pertinent to the care of a particular patient.

Pharmacy Services

Refers to Pharmacy Services provided to an individual in a temporary or permanent residence used as the individual's home or in an alternate site setting. Examples of such services include, but are not limited to, preparation and administration of IV antibiotics, pain management, parenteral and enteral nutrition, hydration and electrolyte replacement, chemotherapy, blood products, cardiac and pulmonary medications, antiemetic therapy, etc. Services may also include Nursing Services which consist of line maintenance (e.g., implanted ports, various central lines, PICC, epidural, intrathecal, etc.)

Pharmacy Technician

An individual that compounds and maintains medication and supply inventory under the direction of a Registered Pharmacist. Certification preferred.

Physical Therapy Services

The treatment of physical dysfunction or injury by the use of therapeutic exercise and the application of modalities, intended to restore or facilitate normal function or development.

Physician

A person with a current license to practice medicine in the state

Plan of Care

A written description of the client's major physical and psychosocial problems to be addressed in the provision of care, and the strategy for intervention. A written plan of care includes at a minimum: (1) start of care date; (2) certification period; (3) patient demographics; (4) principle diagnoses and other pertinent diagnoses; 5) medications: dose/frequency/route; 6) safety measures; (7) nutritional requirements; (8) allergies; (9) functional limitations; (10) activities permitted; (11) mental status; (12) prognosis; (13) orders for discipline and treatments (specify amount/frequency/duration); (14) goals/outcomes; and (15) physician's name, signature and date.

A copy of the plan of care plan must be signed in accordance with state regulations and kept in the patient's permanent record. May be called a plan of care, care plan, plan of treatment or other special title furnished by the organization.

Plan of Service

A written description of the client's problems, needs, and goals related to the service provided to the client/patient. A written plan of service includes at a minimum: (1) start of service date; (2) principle diagnoses and other pertinent diagnoses; (3) home safety assessment; (4) functional limitations; (5) physician orders, and (6) problems, needs and goals. A copy of the plan of service is kept in the patient's permanent record.

Preferred Standard

A preferred standard is a standard that ACHC recommends organizations are compliant with or are striving toward compliance. ACHC does not score a preferred standard during survey. New standards are frequently introduced as preferred standards prior to being required.

Professional

Refers to a licensed registered nurse, licensed registered pharmacist, licensed respiratory care practitioner, licensed physical therapist, licensed speech therapist, certified occupational therapist, or a person with a bachelor's degree in social work, home economics or closely related helping profession.

Program/Service Evaluation

A process that measures the organization's performance in relation to the established goals and objectives. The evaluation concentrates on comparisons from year-to-year and statistical analysis. Suggested activities for program evaluation include the following: 1) review of the organization's mission/philosophy statement and the purpose and goals to ensure consistency; 2) review of job descriptions for appropriateness; 3) review of the organization chart for consistency with current operations; 4) review of service descriptions and eligibility criteria for appropriateness and consistent application; 5) review of service related and personnel policies and procedures for ensuring appropriateness and consistency; and 6) reviews of the cost per service unit against current charges. The statistical review would concentrate on following: 1) number of clients receiving each service; 2) number of visits/hours for each service; 3) client outcomes; 4) adequacy of employees to meet client needs; 5) numbers and reasons for non-acceptance of clients; and 6) reasons for discharge.

Qualified Physician

An individual who is licensed to practice medicine in the organization's service area and who is knowledgeable about the level of care/services that can be safely and effectively provided in the home setting

Qualified Staff

An individual that has had appropriate training and experience for the position held with evidence of education and training in accordance with applicable laws or regulations.

Qualified Supervisor

Employed directly or through contract and possesses: 1) evidence of verification of education and training requirements in accordance with applicable laws or regulations, and the organization's policy, and 2) evidence that clinical and supervisory knowledge and experience are appropriate to his/her assigned supervision responsibilities.

RCP

The acronym for Respiratory Care Practitioner

Rehabilitation Technology Supplier Services

Defined as the application of enabling technology systems designed to meet the needs of a specific person experiencing any permanent or long-term loss or abnormality of physical or anatomical structure or function. These services, prescribed by a physician, primarily address wheeled mobility, seating and alternative positioning, ambulation support and equipment, environmental controls and other equipment and services which assist the person in performing their activities of daily living. Rehabilitation technology services facilitate and/or enhance access and independence thereby improving the person's quality of life.

Registered Occupational Therapist (OTR)

Occupational Therapist is an individual who practices occupational therapy in accordance with the provisions of the State Occupational Therapy Practice Act. All occupational therapists employed with the agency are currently licensed by the state Board of Occupational Therapy Examiners and have graduated from an accredited school of Occupational Therapy.

Respiratory Nebulizer Medication Pharmacy Program

A Respiratory Nebulizer Medication Pharmacy program is a program that dispenses aerosolized single patient dose respiratory medications. The medications may be prepackaged or compounded by the pharmacy. These medications are usually delivered directly to the client's home by use of outside delivery services such as UPS, FedEx or US Mail, but may also be delivered by the organization itself. These medications usually benefit a targeted patient population with a chronic disease such as Emphysema, Chronic Bronchitis or Asthma. Examples of Respiratory Medications include Beta Adrenergic Bronchodilators, Anticholinergic Bronchodilators, Cortico Steroids (Anti-inflammatory Agents), Cromolyn Sodium, Mucolytics, and Antibiotics.

Responsible Party

A family member or other person who has authority to make decisions on the client's behalf

Risk Management

A prevention activity intended to protect the assets and profits of an organization by reducing the potential for loss resulting from Acts of God, human error, or court judgments. Suggested activities for risk management include, at a minimum: 1) monitoring to assure that confidentiality procedures are adequate and consistently followed; 2) monitoring for consistency between minimum qualifications for personnel and hiring practices; 3) monitoring the need for training for new services and service delivery problem areas; 4) monitoring of incident reports; 5) monitoring of high frequency service procedures, e.g. transportation of clients, or high risk situations for clients or staff, e.g. Alzheimer's or protective services clients

Social Work Assistant

A person who has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has at least one year social work experience in a health care setting; or has two years of appropriate experience as a social work assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a state or seeking initial qualification as a Social Work Assistant after December 31, 1977.

Social Worker

A person who has a Master's degree from a school of social work accredited by the Council on Social Work Education, and has one year of social work experience in a home care setting.

Specialty Pharmacy Services

Specialty Pharmacy Services dispense medications (usually self injectable biotechnology drugs) to a client's home, physician's office, or clinics specializing in certain chronic disease states. These medications benefit a targeted patient population with a chronic and sometimes life-threatening disease. Examples of Specialty Pharmacy drug classifications and medications include growth factor, such as Genotropin and Humatrope; antihemophilics, such as Hemofil; and Bioclate interferons, such as Avonex and Rebetron; or HIV/Aides such as Eqivir or Viracept.

Speech-language Pathologist (S-LP)

A qualified S-LP is a professional who holds an academic Master's or Doctorate degree in Speech-Language Pathology, and holds or is eligible for the Certificate of Clinical Competence by the American Speech-Language Hearing Association (ASHA) and has a current state license in speech-language pathology.

Speech Therapy Services

Speech Therapy Services are the treatment of speech defects and disorders, especially through use of exercises and audio-visual aids that develop new speech habits.

Supervision (Personnel)

Involves the direction, observation, and evaluation of the performance of personnel. Personnel supervision may be accomplished through individual and group conferences dealing with job-related issues, visits to homes of clients to observe and/or evaluate work performance, telephone contacts to review job assignments, etc.

Supervision (Case)

Monitoring and assessment of the needs of a client in relation to the plan of care being followed by the home care employees. Case supervisory visits to the client's home may be made when the Unlicensed Assistive Personnel (UAP) or allied health personnel is present to observe and assist, or when the UAP is absent, to assess relationships and determine whether goals are being met.

Surgical Bra

A specially-made/adapted bra equipped with pockets to specifically hold breast prosthetics.

Therapeutic Services

Therapeutic services or those skilled and non-skilled services requiring orders by the appropriate licensed or certified individual for payment of Medicare/Medicaid certified services

Unlicensed Assistive Personnel (UAP)

Non-licensed health care personnel that provide services to clients under the direction of a licensed health care professional.

Unmet Care Needs

Client needs that an organization cannot meet. Unmet care needs could be needs assessed initially and the client is not served, but referred to another organization. Unmet care needs may be assessed during the time that other services are being provided. The organization may refer the client for only the services it cannot provide or it may be necessary to refer the client to another organization for unmet care needs.

Utilization Review

The periodic review of a sample of active and closed home care service records to determine the adequacy of the plan of care and the appropriateness of care. Utilization review activities also seek to address specific questions about the use of the organization's resources. Suggested activities for utilization review include: 1) monitoring that eligibility criteria are consistently applied and client service policies and procedures are consistently followed e.g., discharge, information and referral, acceptance of clients; 2) monitoring that services provided were appropriate to client needs; 3) monitoring timeliness in service delivery; and 4) reviewing applications of clients not accepted for service.

Variance

Any interruption in the normal and defined policy and procedure of the organization that might require documentation reporting, investigation, and follow-up

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INTERPRETIVE GUIDE
STANDARDS FOR ACCREDITATION

SECTION 1700: PHARMACY SCOPE OF SERVICES

These standards are applicable to all the Pharmacy Scopes of Practice including Infusion Pharmacy, Ambulatory Infusion Center, Specialty Pharmacy, First Dose Pharmacy and Respiratory Nebulizer Medication Pharmacy, except where noted.

Infusion Pharmacy *is defined as a pharmacy that provides parenteral (e.g. intravenous, subcutaneous, intramuscular) medications for patients in alternate settings. The service includes clinical monitoring by the pharmacy, and may include nursing services as well.*

Ambulatory Infusion Center *is defined as a centralized location where a patient can receive infusion therapy. The facility will be staffed by a nurse(s) and in some cases, a pharmacist. Services provided are directed by a physician. A pharmacist must compound and provide medications and the nurse must administer the medication.*

Specialty Pharmacy *is defined as a pharmacy that dispenses medications (usually self injectable biotechnology drugs) to a client's home, physician's office, or clinics specializing in certain chronic disease states. These medications benefit a targeted patient population with a chronic and sometimes life-threatening disease. Examples of Specialty Pharmacy drug classifications and medications include growth factor, such as Genotropin and Humatrope; antihemophilics, such as Hemofil; and Bioclate interferons, such as Avonex and Rebetron; or HIV/Aides such as Eqivir or Viracept.*

First Dose Pharmacy *refers to an organization that provides a limited number of doses of medication for another organization. The organization that provides the first dose is not responsible for the clinical monitoring or billing for the patient.*

Respiratory Nebulizer Medication Pharmacy *is defined as a pharmacy that dispenses aerosolized single patient dose respiratory medications. The medications may be prepackaged or compounded by the pharmacy. These medications are usually delivered directly to the client's home by use of outside delivery services such as UPS, FedEx or US Mail, but may also be delivered by the organization itself. These medications usually benefit a targeted patient population with a chronic disease such as Emphysema, Chronic Bronchitis or Asthma. Examples of Respiratory Medications include Beta Adrenergic Bronchodilators, Anticholinergic Bronchodilators, Cortico Steroids (Anti-inflammatory Agents), Cromolyn Sodium, Mucolytics, and Antibiotics.*

All equipment services are provided in accordance the HME Standards section of this manual and apply to organizations that provide medical equipment in the provision of care to the client/patient, e.g. infusion pumps and medication compressors.

Standard 1701. All Pharmacy Services will be provided by qualified pharmacists in accordance with state laws, regulations and recognized professional practice standards.

Standard 1701, Criterion A: All Pharmacy Services will be provided by qualified personnel and administered in accordance with the organization's policies and job descriptions, federal, state

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and local laws and established regulatory guidelines as dictated by the Board(s) of Pharmacy of the state(s) into which medications are dispensed.

Interpretation: Pharmacists and pharmacy technicians will function in accordance with the organization's job description, accepted ethical and professional practice standards and in accordance with all applicable federal, state and local laws and guidelines set by the Board of Pharmacy.

If Pharmacy Services are dispensing in other states, a pharmacy license or permit for states serviced will be obtained if required by that state (many states require a nonresident license). Current copies of applicable rules and regulations are available to appropriate organization staff.

Evidence:
State Board of Pharmacy Regulations
Resident State Board of Pharmacy Permit/License
Non-resident Board of Pharmacy Permit/License as required
USP Chapter 797 or USP 27 NF 22 Reference Book
DEA Registration
State Controlled Substance License (when required))
Pharmacist(s) Licenses
Pharmacy Technician(s) Licenses/Certificates, where required
Job Descriptions
Personnel Record Reviews

Standard 1701, Criterion B: All required licenses and/or permits for the physical facility are current and placed on display in an appropriate public area.

Interpretation: The organization will display all licenses and/or permits required in the operation of the pharmacy services in an area of public view.

Evidence:
Licenses displayed in an appropriate place for public view (if required)
Device Dispensing Permit (if required)
State Board of Pharmacy License or contract with a locally licensed pharmacy (contract will be available for review during survey)

Standard 1702. There are written policies and procedures relating to pharmacy services.

Standard 1702, Criterion A: There are written policies and procedures describing the scope of services offered by the pharmacy program.

Interpretation: The pharmacy program has written and implemented policies and procedures addressing the scope of services offered by the organization. These services should include, but not be limited to, types of services provided, target client/patient populations and goals of the program.

Evidence: Written Policies and Procedures

Standard 1702, Criterion B: Pharmacy Services are provided according to the client/patient's plan of care with access to a Registered Pharmacist available 24 hours a day, 7 days a week.

Interpretation: The organization provides Pharmacy Services 24 hours a day, 7 days a week when necessary to meet client/patient needs. An on-call coverage system may be used to provide this coverage during evenings, nights, weekends and holidays.

Evidence: On-Call Schedule/Log

Standard 1703. Qualified personnel supervise the pharmacy services.

Standard 1703, Criterion A: All Pharmacy Services are provided under the direction of a Registered Pharmacist.

Interpretation: All Pharmacy Services must be provided under the direction of a registered pharmacist with sufficient education and experience in the scope of services offered. State regulations may dictate pharmacist requirements.

Evidence: Personnel Record Review

Standard 1703, Criterion B: A Registered Pharmacist supervises Pharmacy Technicians in accordance with organizational policy and the state Board of Pharmacy.

Interpretation: The pharmacy follows their state Board of Pharmacy regulations and organizational policies and procedures that demonstrate supervision of services provided by pharmacy technicians. The policies and procedures identify the method and frequency for assessing pharmacy technician practice to ensure that services are provided appropriately.

Evidence: Written Policies and Procedures
Documentation of Supervision Activities - Client/patient Record and/or Personnel Record Review
Response to Interviews

Standard 1704. Patients will have an assessment of need and plan of care.

This standard and criterions are not applicable to First Dose Pharmacy.

Standard 1704, Criterion A: Written policies and procedures describe the process for assessment and the plan of care.

Interpretation: The Pharmacy Services program has written policies and procedures that describe the process for a patient assessment, the development of the plan of care and the frequency and the process for the plan of care review.

Evidence: Written Policies and Procedures

Standard 1704, Criterion B: All clients/patients referred for Pharmacy Services will have an assessment of appropriate therapy.

Interpretation: An assessment will be performed and information documented in the client/patient's record for clients/patients referred for pharmacy services. The assessment shall focus on appropriateness for therapy in the home, safety in the home, and method of drug delivery.

Evidence: Client/Patient Record Reviews

Standard 1704, Criterion C: There is a written plan of care for each client/patient accepted for services and based upon assessment data.

Interpretation: The plan of care specifies: (1) problems; (2) interventions; (3) monitoring expectations; (4) expected client/patient outcomes; and (5) resolutions.

Physician orders are needed to provide any services requiring the administration of medication, treatment(s), ongoing assessments or other activities as governed by state law. Physician orders may also be required under certain program requirements (i.e., Medicare, Medicaid, Managed Care, and other third party payers). The organization has a responsibility to obtain physician orders as applicable.

Evidence: Client/Patient Record Reviews

Standard 1704, Criterion D: The organization will show evidence of the client/patient/caregiver participation in the plan of care.

Interpretation: The client/patient/responsible parties have a right to be involved in the development of the plan of care and any changes in that plan. However, the degree of involvement may vary depending on the ability of the client/patient. At a minimum, the client/patient or responsible party must agree to the plan of care prior to the beginning of services and as subsequent changes occur.

The client/patient record must show involvement of the client/patient/family/caregiver in the development or at least agreement to the plan of care and any revisions made to the plan. The following are suggestions as to how organizations may document this information: (1) the plan of care may be signed by the client/patient/responsible party; (2) a notation may be made in the client/patient record that the client/patient/responsible party participated in the development of the plan of care; (3) there may be documentation in the client/patient record that the plan of care was reviewed and accepted by the client/patient/responsible party; or (4) there is evidence that the plan of care was provided to the patient for review and change.

Evidence: Client/Patient Record Reviews
Response to Interviews

Standard 1704, Criterion E: Pharmacy services are delivered in accordance with the written plan of care.

Interpretation: The client/patient record reflects that pharmacy services are delivered in accordance with the plan of care and directed at achievement of established goals.

Evidence: Client/Patient Record Reviews

Standard 1704, Criterion F: There is evidence that the plan of care is reviewed.

There is documentation in the client/patient record that reflects the plan of care is reviewed for: (1) appropriateness (care being provided is still needed); (2) effectiveness (client/patient outcomes/response to care); and (3) to determine if all needed services are being provided. Included in this review is a discussion with the client/patient/responsible party to determine the level of satisfaction with the care

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being provided. Notation of a review may be made in the client/patient record, in minutes of meetings, such as team meetings, or case conferences.

The organization follows program policies and any applicable laws and rules for the frequency of plan of care review. The plan of care review would occur more frequently based on the patient's need for changes.

Evidence: Client/Patient Record Reviews
Responses to Interviews

Standard 1704, Criterion G: There is evidence of changes in the plan of care based on reassessment data.

Interpretation: Changes are noted on the plan of care and/or in the progress notes based on client/patient requests, client/patient's condition, client/patient's response to therapy, and when physician orders indicate changes.

There is evidence of communication to the physician regarding the client/patient's condition. If new or revised client/patient or treatment goals are indicated, they must be reflected in a revised plan of care. Revised plans of care shall be approved by the client/patient's physician.

Evidence: Client/Patient Record Reviews

Standard 1705. Client/patient and/or caregiver education focus on goal and outcome achievement.

Standard 1705, Criterion A: Written policies and procedures describe the process for client/patient and/or caregiver education.

Interpretation: The Pharmacy services program has written policies and procedures that describe client/patient and/or caregiver education. The policies and procedures must include: (1) treatment and disease management education; (2) proper use, safety hazards and maintenance of any equipment provided; (3) plan of care; and (4) how to notify the company of problems, concerns and complaints.

Evidence: Written Policies and Procedures

Standard 1705, Criterion B: Client/patient and/or caregiver education must focus on goal and outcome achievement as established in the plan of care.

Interpretation: Client/patient education is an integral part of pharmacy services. Assessment of the client/patient and/or caregiver's knowledge deficits and learning abilities are evaluated during the initiation of services. Client/patient education/instruction will proceed in accordance with the client/patient's willingness and condition to learn.

Education must be coordinated with the client/patient/caregivers and the health care team and must focus on goal and outcome achievement as established in the plan of care. Elements of client/patient education may include, but not be limited to: (1) ongoing assessment of client/patient and caregiver's learning needs; (2) communication of needs to other health care team members; and (3) incorporating client/patient needs into the plan of care. The client/patient records will include documentation of all

teaching, client/patient's response to teaching, and the client/patient's level of progress/achievement of goals/outcomes. Written instruction will be provided to the client/patient as appropriate.

Evidence: Client/Patient Record Reviews
Response to Interviews

Standard 1706. Pharmacy Services discharge client/patients as appropriate and in accordance with established policies and procedures.

Standard 1706, Criterion A: Pharmacy Services follow discharge policies and procedures.

Interpretation: The organization has a process, which assesses the client/patient's ongoing appropriateness for therapy/services. The discharge policy will define the activities that represent client/patient discharge.

The client/patient record should reflect discharge planning activities, the client/patient's response and understanding to these activities, client/patient care instructions and a reasonable notice prior to discharge whenever possible.

There is a discharge summary report or notation in the progress notes or a software section dedicated to discharge that includes: (1) a summary of the services provided; (2) the date and reason for the discharge; (3) a brief description of ongoing needs that could not be met; (4) any instructions or referral information given to the client/patient/responsible party. A copy of the discharge summary is made available to the physician and a copy is placed in the client/patient record.

Evidence: Written Policies and Procedures
Client/Patient Record Reviews

Standard 1707. All pharmaceuticals are administered in accordance with applicable laws/regulations and organization policies and procedures.

Standard 1707, Criterion A: A Registered Pharmacist must review all client/patient medications and consult with other health care professionals caring for the client/patient, including the physician. All OBRA counseling is completed as specified by law.

This criterion is not applicable to respiratory nebulizer medication and specialty pharmacy services unless mandated by the state Board of Pharmacy or internal policy.

Interpretation: A licensed pharmacist must review all prescription and non-prescription medications that a client/patient is currently taking prior to dispensing medications.

A medication profile is established at the start of therapy. This profile is updated and kept current through ongoing review and revision of client/patient data.

A licensed pharmacist is specifically responsible for recognizing the following as they pertain to infusion related diagnosis and infusion drugs: (1) side effects; (2) toxic effects; (3) allergic reactions; (4) desired effects; (5) unusual and unexpected effects; (6) drug interactions; (7) appropriateness of the drug for the client/patient's diagnosis; (8) appropriateness of the dose; (9) changes in the client/patient's condition that contraindicate continued use of the drug. In addition, the pharmacist, in conjunction with

other health care professionals caring for the client/patient, must be able to anticipate those effects which may rapidly endanger a client/patient's life or well being, and instruct the client/patient, family member and/or caregiver, as necessary, in following the prescribed regimen.

Evidence: Client/Patient Record Reviews
Response to Interviews

Standard 1707, Criterion B: Medications and supplies are accurately labeled and dispensed to the patient for whom they are ordered.

Interpretation: Medications dispensed to client/patients are appropriately labeled according to applicable law and regulation and standards of practice.

There is a process to verify that the correct medication(s) and supplies, if applicable, were dispensed and delivered to the correct client/patient.

Evidence: Pharmacy Logs
Delivery Tickets or Logs

Standard 1707, Criterion C: There are written policies and procedures relating to special education, experience, or certification requirements for pharmacy staff to prepare pharmaceuticals and dispense devices.

Interpretation: The organization must have written guidelines defining any special education, experience or certificates necessary for pharmacy staff to prepare pharmaceuticals and dispense devices. Qualifications may vary based upon classifications of drugs as well as State Board of Pharmacy requirements.

Evidence: Written Policies and Procedures
Personnel File Reviews

Standard 1707, Criterion D: There are written policies and procedures that address response to adverse drug reactions.

Interpretation: The organization has written policies and procedures that address the steps taken should an adverse drug reaction occur.

Policies and procedures should address the standard protocol for managing and reporting Adverse Drug Reactions (ADR) internally and to outside state agencies as required by law. This may include standing orders to treat anaphylaxis and recommended dosages of drug per age group.

Evidence: Written Policies and Procedures
Response to Interviews
ADR Record Book
MedWatch Records

Standard 1707, Criterion E: There are written policies and procedures to ensure that the right patient receives the right treatment at the right time.

Interpretation: There is a process to verify the identity of the patient and the treatment the patient is to receive.

Evidence: Written Policies and Procedures
Response to Interviews

Standard 1708. The pharmacy has a system for the recall of medications.

Standard 1708, Criterion A: The organization has written policies and procedures for medication recall.

Interpretation: There are written policies and procedures for tracking medications or products dispensed to patients. There are written procedures for external reporting of medication product defects. There are written procedures for the safe disposition of recalled medications or products dispensed to client/patients.

Evidence: Written Policies and Procedures

Standard 1708, Criterion B: Records are maintained to identify each client/patient who is receiving or has received recalled medications.

Interpretation: Documentation will include, but not be limited to, the manufacturer of each client/patient's medication, lot numbers and expiration dates.

Evidence: Dispensing/Recall Records
Client/Patient Record Reviews
Response to Interviews

Standard 1708, Criterion C: Staff implements organization's policies and procedures for the safe disposition of recalled medications and external reporting.

Interpretation: Staff implements the organization's written policies and procedures for the safe disposition of recalled medications or products stocked and dispensed to client/patients.

Staff implements the organization's written policies and procedures for external reporting of medication product defects. Client/patient's physicians are notified when medications are discontinued, expire, or are recalled.

Evidence: Dispensing/Recall Records
Client/Patient Record Reviews
Response to Interviews

Standard 1709. All parenteral/sterile medications are prepared and compounded by qualified personnel in a suitable environment using appropriate aseptic technique.

This standard and criterions only apply if the organization performs sterile compounding.

Standard 1709, Criterion A: The organization has a written policies and procedures for drug compounding.

Interpretation: The written policies and procedures for drug compounding defines quality control procedures for monitoring aseptic technique and the compounding environment to comply with established standards, Board of Pharmacy regulations or Federal law. The written policies and procedures defines processes for preparing/compounding sterile products and includes: (1) aseptic technique; (2) validation of aseptic processing procedures (media fills or end product testing); (3) appropriate attire for personnel who compound (gown, mask, sterile gloves and booties); (4) hand washing procedures; (5) environmental considerations (security, temperature, ventilation); (6) preparation of parenteral drugs; (7) preparation of cytotoxic drugs; (8) preparation of sterile drugs from non-sterile products, (9) use, maintenance, accuracy and precision of compounding equipment, and (10) HPLC

Evidence: Written Policies and Procedures

Standard 1709, Criterion B: The organization has written policies and procedures for cleaning and disinfection.

Interpretations: Written policies and procedures for cleaning of the work surfaces, equipment, and compounding/anteroom areas to reduce the risk of particulate matter in the work area and contamination of the compounding environment include: (1) process and frequency for cleaning work surfaces, equipment and work areas; (2) using dedicated cleaning tools specific to the area; (3) appropriate disinfectant solutions, rotated regularly with another sanitizing solutions of a different action; (4) documentation of the cleaning process.

Evidence: Written Policies and Procedures

Standard 1709, Criterion C: Qualified personnel comply with aseptic technique when compounding sterile preparations.

Interpretation: Personnel demonstrate knowledge and understanding of contamination control and aseptic techniques in accordance with written policies and procedures, state specific Board of Pharmacy and Federal law. Personnel qualifications include initial and follow-up training for periodic evaluation of performance.

Evidence: Observation
Quality Control Records
Personnel File Reviews
Response to Interviews

Standard 1709, Criterion D: Sterile products are compounded in an ISO 5 (formerly Class 100) environment (e.g. ISO 5 room and/or laminar airflow workbench (LAFW, Biological Safety Cabinet (BSC) or barrier isolator) used within an ISO Class 7 buffer zone or clean room environment, using the appropriate compounding equipment. Hazardous drugs are only prepared in a Biological Safety Cabinets (BSCs) or negative-pressure barrier isolators.

Interpretation: The ISO Class 5 and ISO Class 7 environment are certified every 6 months or in accordance with ISO 14644 standards, NSF 49, state Board of Pharmacy regulations, USP Chapter <797> and/or Federal law. A qualified independent contractor performs certification according to accepted standards for operational efficiency. Procedures are maintained for monitoring the proper operating conditions for all equipment used in accordance with manufacturer guidelines.

Evidence: Observation
Engineering Control Certification Reports and Certification Certificates
Quality Control Records
Response to Interviews

Standard 1710. The pharmacy assures pharmaceuticals are stored under appropriate conditions.

Standard 1710, Criterion A: There are written policies and procedures relating to pharmaceutical storage.

Interpretation: The written policies and procedures must include, but are not limited to: (1) Storage of pharmaceuticals; (2) monitoring of storage room temperatures; (3) accessibility of legend drugs; (4) storage during deliver; (5) cleaning and disinfecting of any reusable containers; and (6) pharmaceutical labeling as to the appropriate storage

Evidence: Written Policies and Procedures

Standard 1710, Criterion B: The pharmacy stores pharmaceuticals under appropriate conditions of security, sanitation, light and temperature.

Interpretation: Pharmaceuticals are stored in accordance with manufacturer or USP requirements. Temperatures are monitored wherever pharmaceuticals are stored to assure the requirements are met. Prescription and legend drugs are stored in the licensed pharmacy, which is accessible only under the supervision of licensed pharmacist(s).

Evidence: Observation
Quality Control Records

Standard 1710, Criterion C: The pharmacy uses delivery containers that assure pharmaceuticals are maintained under appropriate conditions of sanitation, light and temperature in the course of deliveries.

Interpretation: The pharmacy assures pharmaceuticals are maintained under appropriate conditions of sanitation, light and temperatures in the course of deliveries. Where appropriate, the pharmacy uses delivery containers such as coolers and ice packs to maintain the storage conditions in accordance with manufacturer or USP requirements.

The policies and procedures for the cleaning and disinfecting of any reusable containers are implemented. Shipping methods are tested periodically to ensure that containers stay within specified temperature requirements.

Evidence: Observation
Shipping Records

Standard 1710, Criterion D: The pharmacy ensures that pharmaceuticals are stored under appropriate conditions of sanitation, light and temperature in the client/patient's home.

Interpretation: The pharmacy has and acts upon information affecting the maintenance of appropriate conditions of sanitation, light and temperature in the client/patient's home. Where necessary, the pharmacist intervenes appropriately to ensure that appropriate conditions are achieved or maintained. Pharmaceuticals dispensed to the patient are clearly labeled as to the appropriate storage.

Evidence: Prescription Labeling
Response to Interviews

Standard 1711. The pharmacy will have access to a reference library appropriate to the level of the services provided.

Standard 1711, Criterion A: The Pharmacy staff will have access to a reference library appropriate to the level of services provided.

Interpretation: The pharmacy staff will have access to a reference library appropriate to the level of services provided. The pharmacy has available reference books, journals, Internet access, etc. appropriate for the client/patient population served. The library will contain, at a minimum: (1) drug compatibility and stability; (2) drug interactions; (3) general clinical references; and (4) pharmacy regulations for any state into which medications are dispensed.

Evidence: Observation
Response to Interviews

Rehabilitation Technology Supplier Services

Defined as the application of enabling technology systems designed to meet the needs of a specific person experiencing any permanent or long-term loss or abnormality of physical or anatomical structure or function. These services, prescribed by a physician, primarily address wheeled mobility, seating and alternative positioning, ambulation support and equipment, environmental controls and other equipment and services which assist the person in performing their activities of daily living. Rehabilitation technology services facilitate and/or enhance access and independence thereby improving the person's quality of life.

Registered Occupational Therapist (OTR)

Occupational Therapist is an individual who practices occupational therapy in accordance with the provisions of the State Occupational Therapy Practice Act. All occupational therapists employed with the agency are currently licensed by the state Board of Occupational Therapy Examiners and have graduated from an accredited school of Occupational Therapy.

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Responsible Party

A family member or other person who has authority to make decisions on the client's behalf

Risk Management

A prevention activity intended to protect the assets and profits of an organization by reducing the potential for loss resulting from Acts of God, human error, or court judgments. Suggested activities for risk management include, at a minimum: 1) monitoring to assure that confidentiality procedures are adequate and consistently followed; 2) monitoring for consistency between minimum qualifications for personnel and hiring practices; 3) monitoring the need for training for new services and service delivery problem areas; 4) monitoring of incident reports; 5) monitoring of high frequency service procedures, e.g. transportation of clients, or high risk situations for clients or staff, e.g. Alzheimer's or protective services clients

Social Work Assistant

A person who has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has at least one year social work experience in a health care setting; or has two years of appropriate experience as a social work assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a state or seeking initial qualification as a Social Work Assistant after December 31, 1977.

INTERPRETIVE GUIDE
STANDARDS FOR ACCREDITATION

SECTION 1800: AMBULATORY INFUSION CENTER SCOPE OF SERVICES

In addition to all 1700 pharmacy standards, the following standard(s) and criteria apply to Ambulatory Infusion Center Programs.

Standard 1801. The facility housing the Ambulatory Infusion Center will be staffed by qualified health care providers in accordance with state laws, regulations and recognized professional practice standards.

Standard 1801, Criterion A: The Ambulatory Infusion Center services will be provided by qualified personnel and administered in accordance with the organization's policies and procedures, federal, state and local laws and established regulatory guidelines. The Ambulatory Infusion Center will meet laws/regulations for facilities that provide services/care to patients on site.

Interpretation: The Ambulatory Infusion Center will meet all guidelines specified by law or regulation relating to the facility, pharmacy and nursing, including but not limited to: (1) OSHA; (2) Federal, State, and local laws: (3) Fire department regulations; (4) Americans with Disabilities Act and (5) National Fire Protection Agency and Life Safety Code

Evidence: Observation
Inspection Reports
Response to Interviews

Standard 1801, Criterion B: The Ambulatory Infusion Center has written policies and procedures that describe the resuscitation equipment/supplies required in the facility and its use.

Interpretation: The Ambulatory Infusion Center has written policies and procedures that describe the resuscitation equipment/supplies required by the facility. The resuscitation equipment/supplies required shall include but not be limited to; (1) oxygen and accessories, (2) resuscitation bag and mask, (3) medications for adverse reaction and/or resuscitation with protocols for use and (4) current CPR posters.

Evidence: Written Policies and Procedures
Medication Protocols

Standard 1801, Criterion C: The Ambulatory Infusion Center implements its policies and procedures for resuscitation equipment/supplies.

Interpretation: The Ambulatory Infusion Center implements the written policies and procedures that describe the resuscitation equipment/supplies required by the facility. The facility educates the professional staff members in the use of resuscitative equipment/supplies on at least an annual basis. The cart(s) and/or box(s) that store the resuscitative equipment/supplies are inventoried on a regular basis to insure correct inventory and non-expired products.

Unmet Care Needs

Client needs that an organization cannot meet. Unmet care needs could be needs assessed initially and the client is not served, but referred to another organization. Unmet care needs may be assessed during the time that other services are being provided. The organization may refer the client for only the services it cannot provide or it may be necessary to refer the client to another organization for unmet care needs.

Utilization Review

The periodic review of a sample of active and closed home care service records to determine the adequacy of the plan of care and the appropriateness of care. Utilization review activities also seek to address specific questions about the use of the organization's resources. Suggested activities for utilization review include: 1) monitoring that eligibility criteria are consistently applied and client service policies and procedures are consistently followed e.g., discharge, information and referral, acceptance of clients; 2) monitoring that services provided were appropriate to client needs; 3) monitoring timeliness in service delivery; and 4) reviewing applications of clients not accepted for service.

Variance

Any interruption in the normal and defined policy and procedure of the organization that might require documentation reporting, investigation, and follow-up