that decides to voluntarily terminate its CMS-approved home infusion therapy accreditation program must provide written notice at least 180 days in advance of the effective date of the termination to CMS and each of its accredited home infusion therapy suppliers.

(b) *Involuntary termination of an accrediting organization's approval by CMS.* Once CMS publishes the notice in the FEDERAL REGISTER announcing its decision terminate the home infusion therapy accrediting organization's home infusion therapy accreditation program, the home infusion therapy accrediting organization must provide written notification to all suppliers accredited under its CMS-approved home infusion therapy accreditation program no later than 30 calendar days after the notice is published in the FEDERAL REGISTER announcing that CMS is withdrawing its approval of its home infusion therapy accreditation program and the implications for the home infusion therapy suppliers payment status in accordance with the requirements at §488.1010(f) once their current term of accreditation expires.

(c) *Voluntary and involuntary terminations.* For both voluntary and involuntary terminations—

(1) The accreditation status of affected home infusion therapy suppliers is considered to remain in effect until their current term of accreditation expires;

(2) If the home infusion therapy supplier wishes to avoid a suspension of payment, it must provide written notice to CMS at least 60-calendar days prior to its accreditation expiration date that it has submitted an application for home infusion therapy accreditation under another CMS-approved home infusion therapy accreditation program. Failure to comply with this 60-calendar day requirement prior to expiration of their current home infusion therapy accreditation stations within could result in a suspension of payment; and

(3) The home infusion therapy accrediting organization provides a second written notification to all accredited home infusion therapy suppliers ten calendar days prior to the organization's accreditation program effective date of termination.

(d) *Voluntary withdrawal from accreditation requested by a home infusion therapy supplier.* If a voluntary withdrawal from accreditation is requested by the home infusion therapy supplier, the withdrawal may not become effective until the accrediting organization completes all of the following steps:

(1) The accrediting organization must contact the home infusion therapy supplier to seek written confirmation that the home infusion therapy supplier intends to voluntarily withdraw from the home infusion therapy accreditation program.

(2) The home infusion therapy accrediting organization must advise the home infusion therapy supplier, in writing, of the statutory requirement for accreditation for all home infusion therapy suppliers and the possible payment consequences for a lapse in accreditation status.

(3) The home infusion therapy accrediting organization must submit their final notice of the voluntary withdrawal of accreditation by the home infusion therapy supplier to CMS by 5 business days after the request for voluntary withdrawal is ultimately processed and effective.

§488.1050 Reconsideration.

(a) *General rule.* A home infusion therapy accrediting organization dissatisfied with a determination that its home infusion therapy accreditation requirements do not provide or do not continue to provide reasonable assurance that the suppliers accredited by the home infusion therapy accrediting organization meet the applicable quality standards is entitled to reconsideration.

(b) *Filing requirements.* (1) A written request for reconsideration must be filed within 30 calendar days of the receipt of CMS notice of an adverse determination or non-renewal.

(2) The written request for reconsideration must specify the findings or issues with which the home infusion therapy accrediting organization disagrees and the reasons for the disagreement.

(3) A requestor may withdraw its written request for reconsideration at

any time before the issuance of a reconsideration determination.

(c) *CMS response to a request for reconsideration.* In response to a request for reconsideration, CMS provides the accrediting organization with—

(1) The opportunity for a hearing to be conducted by a hearing officer appointed by the Administrator of CMS and provide the accrediting organization the opportunity to present, in writing and in person, evidence or documentation to refute the determination to deny approval, or to withdraw or not renew designation; and

(2) Written notice of the time and place of the hearing at least 10 business days before the scheduled date.

(d) *Hearing requirements and rules.* (1) The reconsideration hearing is a public hearing open to all of the following:

(i) Authorized representatives and staff from CMS, including, but not limited to, the following:

(A) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts).

(B) Legal counsel.

(C) Non-technical witnesses with personal knowledge of the facts of the case.

(ii) Representatives from the accrediting organization requesting the reconsideration including, but not limited to, the following:

(A) Authorized representatives and staff from the accrediting organization.

(B) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts).

(C) Legal counsel.

(D) Non-technical witnesses, such as patients and family members that have personal knowledge of the facts of the case.

(2) The hearing is conducted by the hearing officer who receives testimony and documents related to the proposed action.

(3) Testimony and other evidence may be accepted by the hearing officer even though such evidence may be inadmissible under the Federal Rules of Civil Procedure.

(4) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(5) Within 45 calendar days after the close of the hearing, the hearing officer will present the findings and recommendations to the accrediting organization that requested the reconsideration.

(6) The written report of the hearing officer will include separate numbered findings of fact and the legal conclusions of the hearing officer.

(7) The hearing officer's decision is final.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

Subpart A—General Provisions

Sec.

Subpart B—Essentials of Provider Agreements

Subpart C—Allowable Charges