

approval status no later than 30 calendar days after the notice is published in the FEDERAL REGISTER. The notification to the accredited home infusion therapy suppliers must inform them of the implications for their payment status once their current term of accreditation expires.

(g) *Change of ownership.* An accrediting organization that wishes to undergo a change of ownership is subject to the requirements set out at § 488.5(f).

[83 FR 56631, Nov. 13, 2018, as amended at 87 FR 25428, Apr. 29, 2022]

**§ 488.1035 Ongoing responsibilities of a CMS-approved home infusion therapy accrediting organization.**

A home infusion therapy accreditation organization approved by CMS must carry out the following activities on an ongoing basis:

(a) Provide CMS with all of the following in written format (either electronic or hard copy):

(1) Copies of all home infusion therapy accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of findings with respect to unmet CMS requirements).

(2) Notice of all accreditation decisions.

(3) Notice of all complaints related to providers or suppliers.

(4) Information about all home infusion therapy accredited suppliers against which the home infusion therapy accreditation organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the providers or suppliers accreditation.

(5) The home infusion therapy accrediting organization must provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

(6) Notice of any proposed changes in the home infusion therapy accrediting organization's accreditation standards or requirements or survey process. If the home infusion therapy accrediting organization implements the changes before or without CMS' approval, CMS may withdraw its approval of the accrediting organization.

(b) Within 30 calendar days after a change in CMS requirements, the home infusion therapy accrediting organization must submit an acknowledgment of receipt of CMS' notification to CMS.

(c) The home infusion therapy accrediting organization must permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(d) Within 2 business days of identifying a deficiency of an accredited home infusion therapy supplier that poses immediate jeopardy to a beneficiary or to the general public, the home infusion therapy accrediting organization must provide CMS with written notice of the deficiency and any adverse action implemented by the accrediting organization.

(e) Within 10 calendar days after CMS' notice to a CMS-approved home infusion therapy accrediting organization that CMS intends to withdraw approval of the home infusion therapy accrediting organization, the home infusion therapy accrediting organization must provide written notice of the withdrawal to all of the home infusion therapy accrediting organization's accredited suppliers.

**§ 488.1040 Onsite observations of home infusion therapy accrediting organization operations.**

(a) As part of the application review process, the ongoing review process, or the continuing oversight of a home infusion therapy accrediting organization's performance, CMS may conduct onsite inspections of the home infusion therapy accrediting organization's operations and offices at any time to verify the home infusion therapy accrediting organization's representations and to assess the home infusion therapy accrediting organization's compliance with its own policies and procedures.

(b) Activities to be performed by CMS staff during the onsite inspections may include, but are not limited to the following:

(1) Interviews with various accrediting organization staff.

(2) Review of documents, survey files, audit tools, and related records.

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(3) Observation of meetings concerning the home infusion therapy accreditation process.

(4) Auditing meetings concerning the accreditation process.

(5) Observation of in-progress surveys and audits.

(6) Evaluation of the accrediting organization's survey results and accreditation decision-making process.

**§ 488.1045 Voluntary and involuntary termination.**

(a) *Voluntary termination by a CMS-approved accrediting program.* In accordance with § 488.1010(a)(23), a home infusion therapy accrediting organization 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

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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