

#### § 488.1030

#### 42 CFR Ch. IV (10–1–23 Edition)

its own investigation of the accreditation survey or any other information related to the survey.

(b) With the exception of home health agency surveys, general disclosure of an accrediting organization's survey information is prohibited under section 1865(b) of the Act. CMS may publically disclose an accreditation survey and information related to the survey, upon written request, to the extent that the accreditation survey and survey information are related to an enforcement action taken by CMS.

#### **§ 488.1030 Ongoing review of home infusion therapy accrediting organizations.**

(a) *Performance review.* CMS evaluates the performance of each CMS-approved home infusion therapy accreditation program on an ongoing basis. This review includes the review of the following:

(1) The home infusion therapy accrediting organization's survey activity.

(2) The home infusion therapy accrediting organization's continued fulfillment of the requirements at §§ 488.1010 and 488.1035.

(b) *Comparability review.* CMS assesses the equivalency of a home infusion therapy accrediting organization's CMS-approved program requirements with the comparable Medicare home infusion therapy accreditation requirements after CMS imposes new or revised Medicare accreditation requirements. When this occurs, the following takes place:

(1) CMS provides the home infusion therapy accrediting organizations with written notice of the changes to the to the Medicare home infusion therapy accreditation requirements.

(2) The home infusion therapy accrediting organization must make revisions to its home infusion therapy accreditation standards or survey processes which incorporate the new or revised Medicare accreditation requirements.

(3) In the written notice, CMS specifies the deadline (no less than 30 calendar days) by which the home infusion therapy accrediting organization must submit its proposed revised home infusion therapy accreditation stand-

ard or survey process revisions, and the timeframe(s) for implementation of these revised home infusion therapy accreditation standards.

(4) CMS may extend the submission deadline by which the accrediting organization must submit its proposed revised home infusion therapy accreditation standards and survey processes, if both of the following occur:

(i) The accrediting organization submits a written request for an extension of the submission deadline.

(ii) The request for extension is submitted prior to the original submission deadline.

(5) After completing the comparability review of the home infusion therapy accrediting organizations revised home infusion therapy accreditation standards and survey processes, CMS shall provide written notification to the home infusion therapy accrediting organization regarding whether or not its home infusion therapy accreditation program, including the proposed revised home infusion therapy accreditation standards and implementation timeframe(s), continues to meet or exceed all applicable Medicare requirements.

(6) If, no later than 60 calendar days after receipt of the home infusion therapy accrediting organization's proposed changes, CMS does not provide the written notice to the home infusion therapy accrediting organization required, then the revised home infusion therapy accreditation standards and program is deemed to meet or exceed all applicable Medicare requirements and to have continued CMS-approval.

(7) If a home infusion therapy accrediting organization is required to submit a new application because CMS imposes new home infusion therapy regulations or makes significant substantive revisions to the existing home infusion therapy regulations, CMS provides notice of the decision to approve or disapprove the new application submitted by the home infusion therapy accrediting organization within the time period specified in § 488.1010(d).

(8) If a home infusion therapy accrediting organization fails to submit its proposed changes to its home infusion therapy accreditation standards and survey processes within the required

timeframe, or fails to implement the proposed changes that have been determined or deemed by CMS to be comparable, CMS may open an accreditation program review in accordance with paragraph (d) of this section.

(c) *Review of revised home infusion therapy accreditation standards submitted to CMS by an accrediting organization.* When a home infusion therapy accrediting organization proposes to adopt new or revised accreditation standards, requirements or changes in its survey process, the home infusion therapy accrediting organization must do the following:

(1) Provide CMS with written notice of any proposed changes in home infusion therapy accreditation standards, requirements or survey process at least 60 days prior to the proposed implementation date of the proposed changes.

(2) Not implement any of the proposed changes before receiving CMS's approval, except as provided in paragraph (c)(4) of this section.

(3) Provide written notice to CMS that includes all of the following:

(i) A detailed description of the changes that are to be made to the organization's home infusion therapy accreditation standards, requirements and survey processes.

(ii) A detailed crosswalk (in table format) that states the exact language of the organization's revised accreditation requirements and the applicable Medicare requirements for each.

(4) CMS must provide a written notice to the home infusion therapy accrediting organization which states whether the home infusion therapy accreditation program, including the proposed revisions, continues or does not continue to meet or exceed all applicable Medicare home infusion therapy requirements within 60 days of receipt of the home infusion therapy accrediting organization's proposed changes. If CMS has made a finding that the home infusion therapy accrediting organization's home infusion therapy accreditation program, accreditation requirements and survey processes, including the proposed revisions does not continue to meet or exceed all applicable Medicare home infusion therapy re-

quirements. CMS must state the reasons for these findings.

(5) If, no later than 60 calendar days after receipt of the home infusion therapy accrediting organization's proposed changes, CMS does not provide written notice to the home infusion therapy accrediting organization that the home infusion therapy accreditation program, including the proposed revisions, continues or does not continue to meet or exceed all applicable Medicare home infusion therapy requirements, then the revised home infusion therapy accreditation program is deemed to meet or exceed all applicable Medicare home infusion therapy requirements and to have continued CMS approval.

(6) If a home infusion therapy accrediting organization implements changes that have neither been determined nor deemed by CMS to be comparable to the applicable Medicare home infusion therapy requirements, CMS may open a home infusion therapy accreditation program review in accordance with paragraph (d) of this section.

(d) *CMS-approved home infusion therapy accreditation program review.* If a comparability, performance, or standards review reveals evidence of substantial non-compliance of a home infusion therapy accrediting organization's CMS-approved home infusion therapy accreditation program with the requirements of this subpart, CMS may initiate a home infusion therapy accreditation program review.

(1) If a home infusion therapy accreditation program review is initiated, CMS will provide written notice to the home infusion therapy accrediting organization indicating that its CMS-approved accreditation program approval may be in jeopardy and that a home infusion therapy accreditation program review is being initiated. The notice will provide all of the following information:

(i) A statement of the instances, rates or patterns of non-compliance identified, as well as other related information, if applicable.

(ii) A description of the process to be followed during the review, including a description of the opportunities for the

home infusion therapy accrediting organization to offer factual information related to CMS' findings.

(iii) A description of the possible actions that may be imposed by CMS based on the findings of the home infusion therapy accreditation program review.

(iv) The actions the home infusion therapy accrediting organization must take to address the identified deficiencies

(v) The length of the accreditation program review probation period, which will include monitoring of the home infusion therapy accrediting organization's performance and implementation of the corrective action plan. The probation period is not to exceed 180 calendar days from the date that CMS approves the AOs corrective action plan.

(2) CMS will review and approve the home infusion therapy accrediting organization's plan of correction for acceptability within 30 days after receipt.

(3) CMS will monitor the AO's performance and implementation of the plan of correction during the probation period which is not to exceed 180 days from the date of approval of the plan of correction.

(4) If CMS determines, as a result of the home infusion therapy accreditation program review or a review of an application for renewal of the accrediting organizations existing CMS-approved home infusion therapy accreditation program, that the home infusion therapy accrediting organization has failed to meet any of the requirements of this subpart, CMS may place the home infusion therapy accrediting organization's CMS-approved home infusion therapy accreditation program on an additional probation period of up to 180 calendar days subsequent to the 180-day probation period described in paragraph (d)(1)(v) of this section to implement additional corrective actions or demonstrate sustained compliance, not to exceed the home infusion therapy accrediting organization's current term of approval. In the case of a renewal application where CMS has already placed the home infusion therapy accreditation program on probation, CMS indicates that any approval of the

application is conditional while the program is placed on probation.

(i) Within 60 calendar days after the end of any probationary period, CMS issues a written determination to the home infusion therapy accrediting organization as to whether or not its CMS-approved home infusion therapy accreditation program continues to meet the requirements of this subpart, including the reasons for the determination.

(ii) If CMS determines that the home infusion therapy accrediting organization does not meet the requirements, CMS may withdraw approval of the CMS-approved home infusion therapy accreditation program. The notice of determination provided to the home infusion therapy accrediting organization includes notice of the removal of approval, reason for the removal, including the effective date determined in accordance with paragraph (d)(4)(iii) of this section.

(iii) CMS publishes in the FEDERAL REGISTER a notice of its decision to withdraw approval of a CMS-approved accreditation program, including the reasons for the withdrawal, effective 60 calendar days after the date of publication of the notice.

(e) *Immediate jeopardy.* If at any time CMS determines that the continued approval of a CMS-approved home infusion therapy accreditation program of any home infusion therapy accrediting organization poses an immediate jeopardy to the patients of the suppliers accredited under the program, or the continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of a CMS-approved home infusion therapy accreditation program of that home infusion therapy accrediting organization and publish a notice of the removal, including the reasons for it, in the FEDERAL REGISTER.

(f) *Notification to home infusion therapy suppliers of withdrawal of CMS approval status.* A home infusion therapy accrediting organization whose CMS approval of its home infusion therapy accreditation program has been withdrawn must notify each of its accredited home infusion therapy suppliers, in writing, of the withdrawal of CMS

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.