suppliers; or Diabetic Self-Management Training (DSMT) entities, because a change of ownership transaction was completed without notice to or the approval of CMS, such affected non-certified supplier's deemed status would continue in effect for 1 year after the removal of the existing CMS accreditation approval, if such non-certified supplier take the steps specified paragraphs (f)(10)(i) and (ii) of this section—

(i) The non-certified supplier must submit an application to another CMS-approved accreditation program within 60 calendar days from the date of publication of the removal notice in the FEDERAL REGISTER; and

(ii) The non-certified supplier must provide written notice to CMS stating that it has submitted an application for accreditation under another CMS-approved accreditation program within the 60-calendar days from the date of publication of the removal notice in the FEDERAL REGISTER.

(iii) Failure to comply with the above-stated timeframe requirements will result in de-recognition of such provider or supplier's accreditation.

[80 FR 29835, May 22, 2015, as amended at 82 FR 38516, Aug. 14, 2017; 82 FR 46143, Oct. 4, 2017; 83 FR 56631, Nov. 13, 2018; 86 FR 62425, Nov. 9, 2021; 87 FR 25427, Apr. 29, 2022; 87 FR 36410, June 17, 2022]

§488.6 Providers or suppliers that participate in the Medicaid program under a CMS-approved accreditation program.

A provider or supplier that has been granted ''deemed status'' by CMS by virtue of its accreditation from a CMS-approved accreditation program is eligible to participate in the Medicaid program if they are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements.

[80 FR 29837, May 22, 2015]

§488.7 Release and use of accreditation surveys.

A Medicare participating provider or supplier deemed to meet program requirements in accordance with §488.4 must authorize its accrediting organization to release to CMS a copy of its most current accreditation survey and any information related to the survey that CMS may require (including, but not limited to, corrective action plans).

(a) CMS may determine that a provider or supplier does not meet the applicable Medicare conditions or requirements on the basis of its own investigation of the accreditation survey or any other information related to the survey.

(b) With the exception of home health agency and hospice program surveys, general disclosure of an accrediting organization's survey information is prohibited under section 1865(b) of the Act. CMS may publicly 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.

(c) CMS posts inspection reports from a State or local survey agency or accrediting organization conducted on or after October 1, 2022, for hospice programs, including copies of a hospice program's survey deficiencies, and enforcement actions (for example, involuntary terminations) taken as a result of such surveys, on its public website in a manner that is prominent, easily accessible, readily understandable, and searchable for the general public and allows for timely updates.

[80 FR 29837, May 22, 2015, as amended at 86 FR 62425, Nov. 9, 2021]

§488.8 Ongoing review of accrediting organizations.

(a) *Performance review.* In accordance with section 1875(b) of the Act, CMS evaluates the performance of each CMS-approved accreditation program on an ongoing basis. This review includes, but is not limited to the following:

(1) Review of the organization's survey activity.

(2) Analysis of the results of the validation surveys under §488.9(a)(1), including the rate of disparity between certifications of the accrediting organization and certifications of the SA.

(3) Review of the organization's continued fulfillment of the requirements in §488.5(a).

(b) *Comparability review.* CMS assesses the equivalency of an accrediting organization's CMS-approved program requirements to the comparable Medicare requirements if the following conditions exist:

(1) CMS imposes new Medicare certification requirements or changes its survey process.

(i) CMS provides written notice of the changes to the affected accrediting organization.

(ii) CMS specifies in its written notice a timeframe, not less than 30 calendar days from the date of the notice, for the accrediting organization to submit its proposed equivalent changes, including its implementation timeframe, for CMS review. CMS may extend the deadline after due consideration of a written request for extension by the accrediting organization, submitted prior to the original deadline.

(iii) After completing the comparability review CMS provides written notification to the organization whether or not the accreditation program, including the proposed revisions and implementation timeframe, continues to meet or exceed all applicable Medicare requirements.

(iv) If, no later than 60 calendar days after receipt of the organization's proposed changes, CMS does not provide the written notice to the organization required in paragraph (b)(1)(iii) of this section, then the revised program will be deemed to meet or exceed all applicable Medicare requirements and to have continued CMS approval.

(v) If an organization fails to submit its proposed changes within the required timeframe, or fails to implement the proposed changes that have been determined by CMS or deemed to be comparable, CMS may open an accreditation program review in accordance with paragraph (c) of this section.

(2) An accrediting organization proposes to adopt new requirements or to change its survey process.

(i) An accrediting organization must provide written notice to CMS of any proposed changes in its accreditation requirements or survey process and must not implement any changes before receiving CMS's approval, except as provided below.

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

(iii) If an organization implements changes that have neither been determined by CMS nor deemed to be comparable to the applicable Medicare requirements, CMS may open an accreditation program review in accordance with paragraph (c) of this section.

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

(1) If an accreditation program review is initiated, CMS provides written notice to the organization indicating that its CMS-approved accreditation program approval may be in jeopardy and that an accreditation program review is being initiated. The notice provides 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 accrediting organization to offer factual information related to CMS's findings.

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

(iv) The actions the accrediting organization must take to address the identified deficiencies including a timeline for implementation not to exceed 180 calendar days after receipt of the notice that CMS is initiating an accreditation program review.

(2) CMS reviews the accrediting organization's plan of correction for acceptability.

(3) If CMS determines as a result of the accreditation program review or a review of an application for renewal of an existing CMS-approved accreditation program that the accrediting organization has failed to meet any of the requirements of this subpart, CMS may place the accrediting organization's CMS-approved accreditation program on probation for a period up to 180 calendar days to implement corrective actions, not to exceed the accrediting organization's current term of approval. In the case of a renewal application where CMS has placed the 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 accrediting organization as to whether or not a CMS-approved accreditation program continues to meet the requirements of this subpart, including the reasons for the determination.

(ii) If CMS has determined that the accrediting organization does not meet the requirements, CMS withdraws approval of the CMS-approved accreditation program. The notice of determination provided to the accrediting organization includes notice of the removal of approval, reason for the removal, including the effective date determined in accordance with paragraph (c)(3)(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 from the date of publication of the notice.

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

(e) *Notification of providers or suppliers*. An accrediting organization whose CMS approval of its accreditation program has been withdrawn must notify, in writing, each of its accredited providers or suppliers of the withdrawal of CMS approval and the implications in accordance with paragraph (g)(1) of this section for the providers' or suppliers' deemed status no later than 30 calendar days after the notice is published in the FEDERAL REGISTER.

(f) *Request for reconsideration*. Any accrediting organization dissatisfied with a determination to withdraw CMS approval of its accreditation program may request a reconsideration of that determination in accordance with subpart D of this part.

(g) *Continuation of deemed status*—(1) *Involuntary termination*. After CMS removes approval of an accrediting organization's accreditation program, an affected provider's or supplier's deemed status continues in effect for 180 calendar days after the removal of the approval if the provider or supplier submits an application to another CMS-approved accreditation program within 60 calendar days from the date of publication of the removal notice in the FEDERAL REGISTER. The provider or supplier must also provide written notice to the SA that it has submitted an application for accreditation under another CMS-approved accreditation program within this same 60-calendar day timeframe. Failure to comply with the timeframe requirements specified in this section will place the provider or supplier under the SAs authority for continued participation in Medicare and on-going monitoring.

(2) *Voluntary termination by accrediting organization*. When an accrediting organization has voluntarily terminated its CMS-approved accreditation program and provides its accredited providers and suppliers the notice required at §488.5(a)(17), an affected provider's or supplier's deemed status continues in effect for 180 calendar days after the termination effective date if

the provider or supplier submits an application to another CMS-approved accreditation program within 60 calendar days from the date of the notice from the accrediting organization. The provider or supplier must also provide written notice to the SA that it has submitted an application for accreditation under another CMS-approved accreditation program within this same 60-calendar day timeframe. Failure to comply with the timeframe requirements specified in this section will place the provider or supplier under the SAs authority for continued participation in Medicare and on-going monitoring.

(h) *Onsite observations of accrediting organization operations.* As part of the application review process, the ongoing review process, or the continuing oversight of an accrediting organization's performance, CMS may conduct at any time an onsite inspection of the accrediting organization's operations and offices to verify the organization's representations and to assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, the review of documents, auditing meetings concerning the accreditation process, observation of surveys, the evaluation of survey results or the accreditation decision-making process, and interviews with the organization's staff.

[80 FR 29837, May 22, 2015]

§ 488.9 Validation surveys.

(a) *Basis for survey.* CMS may require a survey of an accredited provider or supplier to validate the accrediting organization's CMS-approved accreditation process. These surveys are conducted on a representative sample basis, or in response to substantial allegations of non-compliance.

(1) For a representative sample, the survey may be comprehensive and address all Medicare conditions or requirements, or it may be focused on a specific condition(s) as determined by CMS.

(2) For a substantial allegation of noncompliance, the SA surveys for any condition(s) or requirement(s) that CMS determines is related to the allegations.

(b) *Selection for survey.* (1) A provider or supplier selected for a validation survey must cooperate with the SA that performs the validation survey.

(2) If a provider or supplier selected for a validation survey fails to cooperate with the SA, it will no longer be deemed to meet the Medicare conditions or requirements, but will be subject to a review by the SA in accordance with § 488.10(a), and may be subject to termination of its provider agreement under § 489.53 of this chapter.

(c) *Consequences of a finding of noncompliance.* (1) If a CMS validation survey results in a finding that the provider or supplier is out of compliance with one or more Medicare conditions or requirements, the provider or supplier will no longer be deemed to meet the Medicare conditions or requirements and will be subject to ongoing review by the SA in accordance with § 488.10(a) until the provider or supplier demonstrates compliance.

(2) CMS may take actions for the deficiencies identified in the state validation survey in accordance with § 488.24, or may first direct the SA to conduct another survey of the provider's or supplier's compliance with specified Medicare conditions or requirements before taking the enforcement actions provided for at § 488.24.

(3) If CMS determines that a provider or supplier is not in compliance with applicable Medicare conditions or requirements, the provider or supplier may be subject to termination of the provider or supplier agreement under § 489.53 of this chapter or of the supplier agreement in accordance with the applicable supplier conditions and any other applicable intermediate sanctions and remedies.

(d) *Re-instating deemed status.* An accredited provider or supplier will be deemed to meet the applicable Medicare conditions or requirements in accordance with this section if all of the following requirements are met:

(1) It withdraws any prior refusal to authorize its accrediting organization to release a copy of the provider's or supplier's current accreditation survey.

(2) It withdraws any prior refusal to allow a validation survey, if applicable.