

providers or suppliers accredited under the program:

(1) When a provider or supplier demonstrates full compliance with all of the accreditation program requirements of the accrediting organization's CMS-approved accreditation program, the accrediting organization may recommend that CMS grant deemed status to the provider or supplier.

(2) CMS may deem the provider or supplier, excluding kidney transplant centers within a hospital and ESRD facilities, to be in compliance with the applicable Medicare conditions or requirements. The deemed status provider or supplier is subject to validation surveys as provided at § 488.9.

(b) [Reserved]

[80 FR 29835, May 22, 2015]

§ 488.5 Application and re-application procedures for national accrediting organizations.

(a) *Information submitted with application.* A national accrediting organization applying to CMS for approval or re-approval of an accreditation program under § 488.4 must furnish CMS with all of the following information and materials to demonstrate that the program provides reasonable assurance that the entities accredited under the program meet or exceed the applicable Medicare conditions or requirements. This information must include the following:

(1) Documentation that demonstrates the organization meets the definition of a “national accrediting organization” under § 488.1 as it relates to the accreditation program.

(2) The type of provider or supplier accreditation program for which the organization is requesting approval or re-approval.

(3) A detailed crosswalk (in table format) that identifies, for each of the applicable Medicare conditions or requirements, the exact language of the organization's comparable accreditation requirements and standards.

(4) A detailed description of the organization's survey process to confirm that a provider or supplier meets or exceeds the Medicare program requirements. This description must include all of the following information:

(i) Frequency of surveys performed and an agreement by the organization to re-survey every accredited provider or supplier, through unannounced surveys, no later than 36 months after the prior accreditation effective date, including an explanation of how the accrediting organization will maintain the schedule it proposes. If there is a statutorily-mandated survey interval of less than 36 months, the organization must indicate how it will adhere to the statutory schedule.

(ii) Documentation demonstrating the comparability of the organization's survey process and surveyor guidance to those required for state survey agencies conducting federal Medicare surveys for the same provider or supplier type, in accordance with the applicable requirements or conditions of participation or conditions for coverage or certification.

(iii) Copies of the organization's survey forms, guidelines, and instructions to surveyors.

(iv) Documentation demonstrating that the organization's survey reports identify, for each finding of non-compliance with accreditation standards, the comparable Medicare CoP, CfC, conditions for certification, or requirements.

(v) Description of the organization's accreditation survey review process.

(vi) Description of the organization's procedures and timelines for notifying surveyed facilities of non-compliance with the accreditation program's standards.

(vii) Description of the organization's procedures and timelines for monitoring the provider's or supplier's correction of identified non-compliance with the accreditation program's standards.

(viii) A statement acknowledging that, as a condition for CMS approval of a national accrediting organization's accreditation program, the organization agrees to provide CMS with information extracted from each accreditation survey for a specified provider or supplier as part of its data submissions required under paragraph (a)(11)(ii) of this section, a copy of all survey reports and related information for applicants seeking initial participation in Medicare, and, upon request from CMS,

a copy of the most recent accreditation survey for a specified provider or supplier, together with any other information related to the survey as CMS may require (including corrective action plans).

(ix) A statement acknowledging that the accrediting organization will provide timely notification to CMS when an accreditation survey or complaint investigation identifies an immediate jeopardy as that term is defined at § 489.3 of this chapter. Using the format specified by CMS, the accrediting organization must notify CMS within two business days from the date the accrediting organization identifies the immediate jeopardy.

(x) For accrediting organizations applying for approval or re-approval of CMS-approved hospice programs, a statement acknowledging that the accrediting organization (AO) will include a statement of deficiencies (that is, the Form CMS-2567 or a successor form) to document findings of the hospice Medicare conditions of participation in accordance with section 1822(a)(2)(A)(ii) of the Act and will submit such in a manner specified by CMS.

(5) The criteria for determining the size and composition of the organization's survey teams for the type of provider or supplier to be accredited, including variations in team size and composition for individual provider or supplier surveys.

(6) The overall adequacy of the number of the organization's surveyors, including how the organization will increase the size of the survey staff to match growth in the number of accredited facilities while maintaining re-accreditation intervals for existing accredited facilities.

(7) A description of the education and experience requirements surveyors must meet.

(8) A description of the content and frequency of the organization's in-service training it provides to survey personnel.

(9) A description of the organization's evaluation systems used to monitor the performance of individual surveyors and survey teams.

(10) The organization's policies and procedures to avoid conflicts of interest, including the appearance of con-

flicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

(11) A description of the organization's data management and analysis system for its surveys and accreditation decisions, including all of the following:

(i) A detailed description of how the organization uses its data to assure the compliance of its accreditation program with the Medicare program requirements.

(ii) A statement acknowledging that the organization agrees to submit timely, accurate, and complete data to support CMS's evaluation of the accrediting organization's performance. Data to be submitted includes, but is not limited to, accredited provider or supplier identifying information, survey schedules, survey findings, and notices of accreditation decisions. The organization must submit necessary data according to the instructions and timeframes CMS specifies.

(12) The organization's procedures for responding to, and investigating, complaints against accredited facilities, including policies and procedures regarding referrals when applicable to appropriate licensing bodies and ombudsman programs.

(13) The organization's accreditation status decision-making process, including its policies and procedures for granting, withholding, or removing accreditation status for facilities that fail to meet the accrediting organization's standards or requirements, assignment of less than full accreditation status or other actions taken by the organization in response to non-compliance with its standards and requirements. The organization must furnish the following:

(i) A description of all types and categories of accreditation decisions associated with the program for which approval is sought, including the duration of each.

(ii) A statement acknowledging that the organization agrees to notify CMS (in a manner CMS specifies) of any decision to revoke, withdraw, or revise the accreditation status of a specific deemed status provider or supplier, within three business days from the date the organization takes an action.

(14) A list of all facilities currently accredited by the organization under the program for which CMS approval is sought, including the type and category of accreditation currently held by each provider or supplier, and the expiration date of each provider's or supplier's current accreditation.

(15) A schedule of all surveys expected to be conducted by the organization for the accreditation program under review during the 6-month period following submission of the application.

(16) The three most recent audited financial statements of the organization that demonstrate that the organization's staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(17) A statement that it will:

(i) Provide written notification to CMS and to all providers or suppliers accredited under a CMS-approved accreditation program at least 90 calendar days in advance of the effective date of a decision by the organization to voluntarily terminate its CMS-approved accreditation program, including the implications for their deemed status in accordance with § 488.8(g)(2);

(ii) Adhere to the requirements for written notice to its accredited providers or suppliers at § 488.8(e) in the case of an involuntary termination; and

(iii) Include a written statement that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program, the accrediting organization must continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

(18) A statement that it will provide written notification to CMS of any proposed changes in the organization's CMS-approved accreditation program and that it agrees not to implement the proposed changes without prior written notice of continued program approval from CMS except as provided for at § 488.8(b)(2).

(19) A statement that, in response to a written notice from CMS to the organization of a change in the applicable conditions or requirements or in the survey process, the organization will provide CMS with proposed corresponding changes in the organization's requirements for its CMS-approved accreditation program to ensure continued comparability with the CMS conditions or requirements or survey process. The organization must comply with the following requirements:

(i) The proposed changes must be submitted within 30 calendar days of the date of the written CMS notice to the organization or by a date specified in the notice, whichever is later. CMS will give due consideration to an organization's request for an extension of the deadline.

(ii) The proposed changes will not be implemented without prior written notice of continued program approval from CMS, except as provided for at § 488.8(b)(1)(iv).

(20) A statement acknowledging that, as a condition for CMS's approval of an accreditation program, the organization will agree to permit its surveyors to serve as witnesses in a legal proceeding if CMS takes an adverse action against a provider or supplier on the basis of the organization's accreditation survey findings, and will cooperate with CMS to make surveyors and other staff available when needed.

(b) *Additional information needed.* If CMS determines that additional information is necessary to make a determination for approval or denial of the organization's initial application or re-application for CMS's approval of an accreditation program, CMS will notify the organization and afford it an opportunity to provide the additional information.

(c)(1) *Withdrawing an application.* An accrediting organization may withdraw its initial application for CMS's approval of its accreditation program at any time before CMS publishes the final notice described in paragraph (e)(2) of this section.

(2) *Voluntary termination of a CMS-approved accreditation program.* An accrediting organization may voluntarily terminate its CMS-approved accreditation program at any time. The accrediting

organization must notify CMS of its decision to voluntarily terminate its approved accreditation program at least 90 calendar days in advance of the effective date of the termination. In accordance with the requirement at § 488.4(a)(17)(i), the accrediting organization must also provide written notice at least 90 days in advance of the effective date of the termination to each of its deemed status providers or suppliers.

(d) *Re-submitting a request.* (1) Except as provided in paragraph (d)(2) of this section, an organization whose request for CMS's approval or re-approval of an accreditation program has been denied may resubmit its application if the organization satisfies all of the following requirements:

(i) Revises its accreditation program to address the issues related to the denial of its previous request.

(ii) Demonstrates that it can provide reasonable assurance.

(iii) Resubmits the application in its entirety.

(2) If an accrediting organization has requested, in accordance with subpart D of this part, a reconsideration of CMS's determination that its request for approval of an accreditation program is denied, it may not submit a new application for approval of an accreditation program for the type of provider or supplier at issue in the reconsideration until the reconsideration is administratively final.

(e) *Public notice and comment.* CMS publishes a notice in the FEDERAL REGISTER when the following conditions are met:

(1) *Proposed notice.* When CMS receives a complete application from a national accrediting organization seeking CMS's approval of an accreditation program, it publishes a proposed notice. The proposed notice identifies the organization and the type of providers or suppliers to be covered by the accreditation program and provides 30 calendar days for the public to submit comments to CMS.

(2) *Final notice.* When CMS decides to approve or disapprove a national accrediting organization's application, it publishes a final notice within 210 calendar days from the date CMS determines the AO's applications was com-

plete, unless the application was for a skilled nursing facility accreditation program. There is no timeframe for publication of a final notice for a national accrediting organization's application for approval of a skilled nursing facility accreditation program. The final notice specifies the basis for the CMS decision.

(i) *Approval or re-approval.* If CMS approves or re-approves the accrediting organization's accreditation program, the final notice describes how the accreditation program provides reasonable assurance. The final notice specifies the effective date and term of the approval (which may not be later than the publication date of the notice and which will not exceed 6 years).

(ii) *Disapproval.* If CMS does not approve the accrediting organization's accreditation program, the final notice describes, except in the case of a skilled nursing facility accreditation program, how the organization fails to provide reasonable assurance. In the case of an application for a skilled nursing facility accreditation program, disapproval may be based on the program's failure to provide reasonable assurance, or on CMS's decision to exercise its discretion in accordance with section 1865(a)(1)(B) of the Act. The final notice specifies the effective date of the decision.

(f) *Change of ownership. What Constitutes Change of Ownership.* A description of what could constitute a change of ownership with respect to a national accrediting organization are those activities described in § 489.18(a)(1) through (3) of this chapter.

(1) *Notice to CMS.* Any CMS-approved accrediting organization that is contemplating or negotiating a change of ownership must notify CMS of the change of ownership.

(i) This notice requirement applies to any national accrediting organization with CMS-approved accreditation program(s) that is the subject of a potential or actual change of ownership transaction, including accrediting organizations for Advanced Diagnostic Imaging (ADI) suppliers; Home Infusion Therapy (HIT) suppliers; Diabetic Self-Management Training (DSMT) entities, and clinical laboratories.

(ii) This notice must be provided to CMS in writing.

(iii) This notice must be provided to CMS no less than 90 calendar days prior to the anticipated effective date of the change of ownership transaction.

(iv) CMS will complete their review of the AO's request for approval for the transfer of the existing CMS approval for the accreditation programs to be transferred in the change of ownership within 90 days from receipt of said AO's request.

(2) *Information submitted with the request for approval for change of ownership transaction.* The person(s) or organization(s) acquiring an existing CMS-approved accrediting organization or accreditation programs (that is, purchaser, buyer or transferee) through a change of ownership transaction must do the following:

(i) Seek approval from CMS for the purchase or transfer of the existing CMS approval for the accreditation program(s) to be transferred in the change of ownership event; and

(ii) Meet the requirements of paragraphs (f)(2)(iii) through (f)(4) of this section to demonstrate that the entities that will be accredited with the transferred accrediting program(s) continue to meet or exceed the applicable Medicare conditions or requirements.

(iii) The following information must be submitted to CMS in the purchaser's/buyer's/transferee's request for approval of a transfer of the existing CMS approval for the accreditation program(s) to be transferred in the change of ownership transaction:

(A) The legal name and address of the new owner;

(B) The three most recent audited financial statements of the organization that demonstrate the organization's staffing, funding and other resources are adequate to perform the required surveys and related activities;

(C) A transition plan that summarizes the details of how the accreditation functions will be transitioned to the new owner, including:

(1) Changes to management and governance structures including current and proposed organizational charts;

(2) A list of the CMS-approved accreditation programs that will be

transferred to the purchaser/buyer/transferee,

(3) Employee changes, if applicable,

(4) Anticipated timelines for action;

(5) Plans for notification to employees; and

(6) Any other relevant information that CMS finds necessary.

(D) The prospective new AO's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions, as required by paragraph (a)(10) of this section.

(3) *Written acknowledgements.* The purchaser/buyer/transferee must provide a written acknowledgement to CMS, which states the following:

(i) If the application for the transfer of the existing CMS-approval for the accreditation program(s) to be transferred in the change of ownership transaction is approved by CMS, said purchaser/buyer/transferee must assume complete responsibility for the operations (that is, managerial, financial, and legal) of the CMS-approved accreditation programs transferred, immediately upon the finalization of the change of ownership transaction;

(ii) The purchaser/buyer/transferee agrees to operate the transferred CMS-approved accreditation program(s) under all of the CMS imposed terms and conditions, to include program reviews and probationary status terms, currently approved by CMS; and

(iii) The purchaser/buyer/transferee must not operate the accreditation program(s) it acquired in the change in ownership transaction as CMS approved accreditation programs, until the effective date set forth within the notice of approval from CMS.

(iv) The purchaser/buyer/transferee agrees to operate the transferred CMS-approved accreditation program(s) under all of the terms and conditions found at §§ 488.5 through 488.9.

(4) *Notification.* The following written notifications are required after the change of ownership transaction has been approved by CMS:

(i) All parties to the change of ownership transaction must notify the providers and suppliers affected by such change within 15 calendar days after being notified of CMS's approval of the

transfer of the existing CMS-approval for the accreditation programs to be transferred in the change of ownership transaction.

(ii) If applicable, the purchaser/buyer/transferee must acknowledge in writing to CMS that the accrediting organization or accreditation program(s) being acquired through a purchase or transfer of ownership was under a performance review or under probationary status at the time the change of ownership notice was submitted.

(5) *Federal Register notice.* CMS will publish a notice of approval in the FEDERAL REGISTER of the transfer of the existing CMS approval for the accreditation program(s) to be transferred to the new owner, only after CMS receives written confirmation from the new owner that the change of ownership has taken place.

(6) *Notification to parties in the event that CMS does not approve the transfer of the existing CMS approval.* In the event that CMS does not approve the transfer of the existing CMS approval for the accreditation program(s) to be transferred in the change of ownership transaction, CMS will notify all parties to the change of ownership transaction of such in writing.

(7) *Withdrawal of CMS approval for transferred accreditation programs due to failure to notify CMS of intent to transfer accreditation programs.* In the event that CMS was not made aware of or did not approve the transfer of the existing CMS-approval for the accreditation program(s) to be transferred under a change of ownership:

(i) The existing AO would be permitted to continue operating their existing CMS-approved accreditation programs, if the change of ownership transaction was not completed, unless our review of the transaction revealed issues with the AO that were the subject of the un-finalized change of ownership transaction that was previously unknown to CMS.

(ii) If a change of ownership transaction was completed without notice to CMS or the approval of CMS, CMS would be able to withdraw the existing approval of the AO's accreditation programs in accordance with § 488.8(c)(3)(ii) and (iii).

(8) *Withdrawal of CMS approval for accreditation programs which are transferred notwithstanding CMS' disapproval of the transfer.* In the event that the parties complete the change of ownership transaction, notwithstanding CMS disapproval and the purchaser/buyer/transferee attempts to operate the transferred accreditation program(s) under the CMS-approval granted to the previous owner, CMS will withdraw the existing approval of the transferred accreditation program(s) in accordance with the procedures set out at §§ 488.8(c)(3)(ii) and (iii).

(9) *Requirements for continuation of a deemed status accreditation of Medicare-certified providers and suppliers after CMS withdraws the existing approval of the transferred accreditation program(s).* If CMS withdraws the existing approval of the transferred accreditation program(s) because the change of ownership transaction was completed without notice to CMS or the approval of CMS, an affected Medicare-Certified provider or supplier's deemed status will continue in effect for 180 calendar days if the Medicare-Certified provider or supplier takes the following steps set forth in § 488.8(g).

(i) The Medicare-certified provider or 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 Medicare-certified provider or supplier must 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 in accordance with § 488.8(g).

(iii) Failure to comply with the timeframe requirements specified in § 488.8(g) will place the provider or supplier under the SA's authority for continued participation in Medicare and on-going monitoring.

(10) *Requirements for continuation of accreditation for non-certified suppliers when CMS withdraws the existing approval of the transferred accreditation program(s).* If CMS withdraws its existing approval from a transferred non-certified accreditation program for Advanced Diagnostic Imaging (ADI) suppliers; Home Infusion Therapy (HIT)

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).