



Center for Program Integrity, Provider Enrollment & Oversight Group

DMEPOS Accreditation Organizations – Application and Reapplication Instructions

Section 1834(a)(20)(A) of the Social Security Act requires the Secretary to establish and implement quality standards for the suppliers of the items and services described in section 1834(a)(20)(D) of the Act to be applied by recognized independent accrediting organizations. Section 1834(a)(20)(B) requires the Secretary to designate and approve one or more independent AOs for purposes of applying the quality standards referenced in section 1834(a)(20)(A) of the Act. Section 1834(a)(20)(F)(i) requires (and with certain exceptions) the Secretary to mandate that suppliers of the items and services described in section 1834(a)(20)(D) of the Act submit to the Secretary evidence of accreditation by an AO designated under section 1834(a)(20)(B).

The regulations at 42 CFR 424.58 set forth the procedures and requirements for independent AOs applying for approval or reapproval as a CMS-approved DMEPOS accreditation organization. In order to be granted CMS approval as a DMEPOS accreditation organization under 42 CFR 424.58, an AO must apply and demonstrate reasonable assurance that:

- The organization's DMEPOS accreditation program requirements meet or exceed Medicare program requirements.
- DMEPOS suppliers that the organization accredits accrediting organization accredits meet or exceed Medicare program requirements.
- The DMEPOS accrediting organization is compliant with all provisions under 42 CFR 424.58.

To be considered for approval as a DMEPOS accrediting organization under 42 CFR 424.58, an accrediting organization must submit an application to CMS requesting approval of its DMEPOS accreditation program and furnish all required information and statements identified in 42 CFR 424.58(c)(1). An AO's DMEPOS accreditation program should be implemented and operational at the time the application is submitted.

Eligible organizations seeking initial approval or reapproval as a CMS-approved DMEPOS accreditation organization must submit complete applications within 60 calendar days of CMS's submission request. All applications for approval and reapproval must be submitted to CMS via email at DMEAccreditation@cms.hhs.gov. Applications received after the application deadline

will not be considered. Please ensure all required information and materials are included in the application submission to prevent delays or potential denial. The application requirements checklist is included below. Application files should be sent in a .zip format with the application submission email.

Upon receipt of an AO's application submission, CMS will send an acknowledgement email to the AO indicating receipt of the application requesting approval or reapproval of its DMEPOS accreditation program and will conduct a preliminary review of the application for completeness. CMS will then issue a formal notice to the AO of its final decision to approve or deny the AO's application within 210 calendar days from the date CMS determines the application is complete. The decision will also be posted in an announcement on the CMS website. CMS may approve an AO's DMEPOS accreditation program for any period up to a maximum of 6 years.

If CMS determines that additional information is necessary to make a determination for approval or denial of the DMEPOS accrediting organization's application, CMS will notify the accrediting organization and provide an opportunity to submit the requested information.

An AO may withdraw its application for initial approval or reapproval of its DMEPOS accreditation program at any time before the formal notice is issued by CMS. An AO that has been notified that its application or reapplication has been denied may request a reconsideration in accordance with 42 CFR 424.58(l)(1).

For DMEPOS accrediting organizations required to submit reapproval applications under 42 CFR 424.58(d)(1)(ii), failure to submit the application will result in the termination of the DMEPOS accrediting organization's approval.

For any questions regarding the application process or requirements, please contact CMS DMEPOS Accreditation at DMEAccreditation@cms.hhs.gov.

DMEPOS Accreditation Organizations – Application Requirements Checklist

Accreditation Organization Name:

Application Submission Date:

Please indicate ‘Yes’ or ‘No’ for each requirement and cite the reference (document or file name, page number, etc.) where the relevant documentation and information is found in the application submission file(s).

Requirements	Submitted (Y/N)	AO Reference / Comments
The name, address, telephone, and e-mail address of the authorized contact person(s) (one with the ability to make decisions, answer questions, and provide clarifications for the accreditation organization’s application).		
A list of key personnel and resumes for staff critical to the management and oversight of the accreditation organization’s DMEPOS accreditation program.		
§ 424.58(c)(1)(i) A list of the types of DMEPOS suppliers, and a list of products and services for which the organization is requesting approval.		
§ 424.58(c)(1)(ii) A detailed comparison of the organization's accreditation requirements and standards with the applicable DMEPOS quality standards, such as a crosswalk.		
§ 424.58(c)(1)(iii) A detailed description of the organization’s operational, survey, and other accreditation process to confirm that a supplier meets or exceeds the Medicare program requirements. This must include all of the following: (A) Procedures for performing unannounced surveys.		

<p>(B) Frequency of the surveys performed.</p> <p>(C) Copies of the organization's survey forms.</p> <p>(D) Guidelines and instructions to surveyors.</p> <p>(E) Quality review processes for deficiencies identified with accreditation requirements.</p> <p>(F) Dispute resolution processes and policies when there is a negative survey finding or decision.</p> <p>(G) If the DMEPOS accrediting organization has the discretion to perform a survey in certain instances, how it determines whether to perform one. This must include a suggested methodology for sampling locations for surveys under a single tax identification number or organization.</p>		
<p>§ 424.58(c)(1)(iv) Procedures used to notify DMEPOS suppliers of compliance or noncompliance with the accreditation requirements.</p>		
<p>§ 424.58(c)(1)(v) Procedures used to monitor the correction of deficiencies found during an accreditation survey.</p>		
<p>§ 424.58(c)(1)(vi) Procedures for coordinating surveys with another DMEPOS accrediting organization if the organization does not accredit all supplies, products, and services the DMEPOS supplier provides.</p>		
<p>§ 424.58(c)(1)(vii) Detailed professional information about the individuals who perform surveys for the DMEPOS accrediting organization, including the size and composition of accreditation survey teams for each type of DMEPOS supplier accredited, and the education and experience</p>		

<p>requirements that surveyors must meet. The information must also include the following:</p> <p>(A) The content and frequency of the continuing education training provided to survey personnel.</p> <p>(B) The evaluation systems used to monitor the performance of individual surveyors and survey teams.</p> <p>(C) Policies and procedures for a surveyor or institutional affiliate of the DMEPOS accrediting organization that participates in a survey or accreditation decision regarding a DMEPOS supplier with which that individual or institution is professionally or financially affiliated.</p> <p>(D) The organization's policies and procedures to avoid conflicts of interest and the appearance thereof involving individuals who conduct surveys or participate in accreditation decisions. This must include the organization's policies and procedures for all of the following: <i>[See below]</i></p> <p>(E) The organization's policies and procedures for ensuring it has an adequate number of surveyors at all times.</p>		
<p>§ 424.58(c)(1)(vii)(D) The organization's policies and procedures to avoid conflicts of interest and the appearance thereof involving individuals who conduct surveys or participate in accreditation decisions. This must include the organization's policies and procedures for all of the following:</p> <p>(1) The separation of its consulting services from its accreditation services.</p> <p>(2) Protecting the integrity of the DMEPOS accrediting organization's accreditation</p>		

program (including the requirements of paragraphs (m) and (n) of this section).

(3) The prevention and handling of potential or actual conflicts of interest that could arise from situations in which a DMEPOS accrediting organization owner, surveyor, or employee has an interest in, or relationship with, a DMEPOS supplier to which the accrediting organization provides accreditation services. Such interests or relationships include, but are not limited to the following:

- (i) Being employed as a DMEPOS accrediting organization surveyor.
- (ii) Being employed by a DMEPOS supplier that is accredited by the DMEPOS accrediting organization.
- (iii) Having an ownership, financial, or investment interest in a DMEPOS supplier that is accredited by the DMEPOS accrediting organization.
- (iv) Serving as a director of or trustee for a DMEPOS supplier that is accredited by the DMEPOS accrediting organization.
- (v) Serving on a utilization review committee of a DMEPOS supplier that is accredited by the DMEPOS accrediting organization.
- (vi) Accepting fees or payments from a DMEPOS supplier or group of DMEPOS suppliers that is/are accredited by the DMEPOS accrediting organization.
- (vii) Accepting fees for personal services, contract services, referral services, or for furnishing supplies to a DMEPOS supplier that is accredited by the DMEPOS accrediting organization.

<p>(viii) Providing consulting services to a DMEPOS supplier that the DMEPOS accrediting organization accredits.</p> <p>(ix) Having any immediate family member (as defined in paragraph (b) of this section) engaged in any of the activities described in paragraphs (c)(1)(vii)(D)(3)(i) through (viii) of this section.</p> <p>(x) Engaging in any activities during the course of the survey of the facility that would be or cause a conflict of interest.</p> <p>(4) For notifying CMS when a conflict of interest is discovered.</p> <p>(5) For the purposes of this section, a conflict of interest exists when a DMEPOS accrediting organization, the DMEPOS accrediting organization's successors, transferees, or assigns, the DMEPOS accrediting organization owner(s), surveyors, or employees, or the immediate family members of the DMEPOS accrediting organization owners(s), surveyors and other employees have an employment, business, financial or other type of interest in or relationship with a DMEPOS supplier that the DMEPOS accrediting organization accredits.</p>		
<p>§ 424.58(c)(1)(viii) Its processes for identifying and correcting deficiencies within its DMEPOS accreditation program.</p>		
<p>§ 424.58(c)(1)(ix) A description of the organization's data management, analysis and reporting system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system. This must also include a detailed description of how the organization uses its data to ensure the</p>		

<p>compliance of its DMEPOS accreditation program with Medicare program requirements.</p>		
<p>§ 424.58(c)(1)(x) Procedures for responding to, investigating, and (as applicable) closing out complaints against accredited facilities, including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsman programs, the applicable National Provider Enrollment contractor, and CMS. This must also include a detailed outline of all of the following:</p> <p>(A) The steps and research the DMEPOS accrediting organization will undertake in its initial review of the complaint as described in paragraph (e)(3) of this section.</p> <p>(B) How the DMEPOS accrediting organization determines whether, in accordance with a complaint, non-compliance with a DMEPOS quality standard or other applicable CMS requirement exists, including the information it considers in its review and when and how it would take action against the DMEPOS supplier.</p>		
<p>§ 424.58(c)(1)(xi) The organization's policies and procedures for notifying CMS of DMEPOS suppliers that fail to meet the DMEPOS accrediting organization's requirements.</p>		
<p>§ 424.58(c)(1)(xii) A description of all types, categories, and durations of accreditations offered by the organization.</p>		
<p>§ 424.58(c)(1)(xiii) A list of the following:</p>		

<p>(A) All currently accredited DMEPOS suppliers.</p> <p>(B) The types, categories, and product codes of accreditation currently held by each DMEPOS supplier.</p> <p>(C) The effective and expiration dates of each DMEPOS supplier's current accreditation.</p> <p>(D) The upcoming survey cycles for all DMEPOS suppliers' accreditation surveys scheduled to be performed by the organization.</p>		
<p>§ 424.58(c)(1)(xiv) A written presentation that demonstrates the organization's ability to furnish CMS with electronic data in ASCII comparable code.</p>		
<p>§ 424.58(c)(1)(xv) A resource analysis that demonstrates that the organization's staffing, funding, and other resources are adequate to perform fully the required surveys and related activities.</p>		
<p>§ 424.58(c)(1)(xvi) Information that demonstrates the DMEPOS accrediting organization's knowledge, expertise, and experience in DMEPOS.</p>		
<p>§ 424.58(c)(1)(xvii) Information about the DMEPOS accrediting organization's ability to conduct timely reviews of DMEPOS supplier accreditation applications.</p>		
<p>§ 424.58(c)(1)(xviii) A description of the organization's accreditation decision-making process. This includes its policies and procedures for approving, denying, or terminating accreditation status for DMEPOS suppliers that fail to meet the DMEPOS accrediting organization's standards or</p>		

<p>requirements. This must include an explanation of the reasons for which it will deny or terminate a supplier's accreditation.</p>		
<p>§ 424.58(c)(1)(xix) Policies and procedures for both of the following:</p> <p>(A) Determining whether and when a survey is performed (for example, the DMEPOS supplier is providing a new item type). This includes the circumstances under which the DMEPOS accrediting organization will impose a corrective action plan (CAP) in lieu of performing a follow-up survey for an identified DMEPOS supplier deficiency.</p> <p>(B) Ensuring that all onsite surveys are unannounced, including procedures that protect against unannounced surveys becoming known to the DMEPOS supplier before the visit.</p>		
<p>§ 424.58(c)(1)(xx) Policies and procedures regarding when the DMEPOS accrediting organization will apply a CAP to a DMEPOS supplier. This must include the following:</p> <p>(A) The specific circumstances under which the DMEPOS accrediting organization will apply a CAP as opposed to, as applicable, denying or terminating accreditation and the rationale for why the accrediting organization believes a CAP in these situations is more appropriate.</p> <p>(B) How a CAP is developed, implemented, and enforced, including the following:</p> <p>(1) How the DMEPOS accrediting organization determines whether a CAP is acceptable.</p>		

<p>(2) The requirements of (and the timeframe and deadline for) the DMEPOS supplier's resumption of compliance.</p> <p>(3) How the DMEPOS accrediting organization determines whether the DMEPOS supplier has resumed compliance and maintains compliance.</p> <p>(4) The circumstances under which the DMEPOS accrediting organization will impose a CAP in lieu of performing a follow-up survey for an identified DMEPOS supplier deficiency.</p>		
<p>§ 424.58(c)(1)(xxi) An explanation of the following:</p> <p>(A) What the DMEPOS accrediting organization considers to be a DMEPOS supplier deficiency and how it defines the term deficiency.</p> <p>(B) Whether the DMEPOS accrediting organization has different levels of DMEPOS supplier deficiencies.</p>		
<p>§ 424.58(c)(1)(xxii) In performing the functions described in this section, its processes for both of the following:</p> <p>(A) Detecting and addressing potential fraud, waste, and abuse by DMEPOS suppliers (including identifying the accrediting organization's definitions of the terms fraud, waste, and abuse).</p> <p>(B) Reporting this activity to CMS and, as applicable, law enforcement.</p>		
<p>§ 424.58(c)(1)(xxiii) A statement on the DMEPOS accrediting organization's letterhead that is signed and dated by the accrediting organization's chief executive officer (or similar official with authority to</p>		

<p>commit the organization to adhere to Medicare laws and regulations) acknowledging that, as a condition for CMS approval or continued approval of a DMEPOS accrediting organization's accreditation program, the organization agrees to all of the following:</p>		
<p>(A) Provide CMS, within 3 business days of CMS's request, both of the following:</p> <p>(1) Any of the information described in paragraph (e)(1)(i) of this section.</p> <p>(2) Any other information CMS deems necessary to facilitate its oversight of the DMEPOS accrediting organization's accreditation program.</p>		
<p>(B) Provide CMS written notification when an accreditation survey or complaint investigation identifies an immediate jeopardy situation (as that term is defined in paragraph (b) of this section). Consistent with paragraph (e)(1)(iii) of this section, this notice must be provided within 2 business days of the finding.</p>		
<p>(C) Provide written notification to CMS of any proposed changes to the DMEPOS accrediting organization's accreditation program and that it will not implement the proposed changes without prior written notice of continued program approval from CMS consistent with paragraph (e)(2) of this section.</p>		
<p>(D) Notify CMS in writing of any decision to terminate, revoke, withdraw, or amend the accreditation status of a specific DMEPOS supplier within 3 business days of the date the organization took such action.</p>		

<p>(E) Notify CMS of any decision to apply a CAP to a specific DMEPOS supplier within 10 calendar days of the decision. This notification must include the following:</p> <p>(1) The reason for the decision.</p> <p>(2) A detailed explanation and justification as to why the DMEPOS accrediting organization applied a CAP instead of, as applicable, denying or terminating the DMEPOS supplier's accreditation.</p> <p>(3) The details of the DMEPOS supplier's CAP.</p>		
<p>(F) Submit timely, accurate, and complete data to support CMS's evaluation of the DMEPOS accrediting organization's performance.</p> <p>(1) Data to be submitted includes, but is not limited to, DMEPOS supplier identifying information, survey schedules, survey findings, and notices of accreditation decisions.</p> <p>(2) The organization must submit necessary data according to the instructions and timeframes CMS specifies.</p>		
<p>(G) In response to a written notice from CMS to the organization of a change in the CMS quality standards, survey process, or other requirement, provide CMS with proposed corresponding changes in the organization's requirements for its DMEPOS accreditation program to ensure continued comparability with the CMS quality standards, survey process, and requirements. This includes compliance with the following requirements:</p> <p>(1) Submission of the data required in paragraph (e)(7) of this section.</p>		

<p>(2) The proposed changes must be submitted to CMS within 30 calendar days of the date of the written CMS notice to the organization.</p> <p>(3) The organization must not implement its proposed corresponding changes without prior CMS approval.</p>		
<p>(H) Apply and adhere to in its accreditation activities any CMS-established—</p> <p>(1) Definition(s) of deficiency; and</p> <p>(2) Deficiency levels and categories.</p>		
<p>(I) The DMEPOS accrediting organization will permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.</p>		
<p>(J) If CMS permits the DMEPOS accrediting organization to perform surveys via a sampling process, the accrediting organization:</p> <p>(1) Will submit to CMS its planned sampling methodology in detail; and</p> <p>(2) Will not undertake sampling until CMS has approved the accrediting organization's submitted methodology.</p>		
<p>(K) Will not include the following as patient medical records in its DMEPOS supplier surveys:</p> <p>(1) Mock files.</p> <p>(2) Fictional patient records.</p> <p>(3) Simulated documentation.</p> <p>(4) Templates.</p> <p>(5) Duplicate patient records.</p>		

<p>(L) Have a binding written agreement with each DMEPOS supplier the DMEPOS accrediting organization accredits regarding whether the accrediting organization, the supplier in question, or both will assume the costs of a survey that CMS directs the accrediting organization to perform in accordance with paragraph (e)(8)(ii) of this section.</p>		
<p>(M) Submit all required information to CMS both before and after approval of its DMEPOS accreditation program in a truthful, accurate, and complete manner.</p>		
<p>(N) Adhere to all of the requirements of this section at all times, including the policies, procedures, practices, and agreements it outlined in paragraph (c) of this section as part of its initial or reapproval application and any CMS-approved changes thereto under paragraph (e)(2) or (7) of this section.</p>		