

DMEPOS Accreditation

Durable Medical Equipment, Prosthetics, Orthotics, and Supplies



Accreditation Standards and Applicant Guide



DMEPOS Accreditation Standards and Applicant Guide

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National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, IL 60056
USA
847/391-4406
www.nabp.pharmacy

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

Mission Statement of the National Association of Boards of Pharmacy

NABP is the independent, international, and impartial Association that assists its member boards and jurisdictions for the purpose of protecting the public health.

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Disclaimer

The National Association of Boards of Pharmacy® (NABP®) has been approved by the Centers for Medicare & Medicaid Services to award DMEPOS accreditation since 2006. NABP's DMEPOS Accreditation Standards are inclusive of the CMS Quality Standards governing the accreditation. NABP's DMEPOS accreditation program supports the Association's mission to assist its member boards of pharmacy in protecting public health.

The content of this document is intended to be used as a guide and is not intended to be used as legal advice. The information presented is subject to change and it is the responsibility of the applicant or accredited supplier to comply with all current NABP Accreditation Program requirements along with CMS eligibility, documentation, and billing requirements, along with state and federal regulations and licensure requirements.

The policies and procedures specified in the *DMEPOS Accreditation Standards and Applicant Guide* are subject to change without notice.

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DMEPOS Accreditation With NABP

The Centers for Medicare & Medicaid Services (CMS) established and implemented Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards for suppliers of DMEPOS under the Medicare Modernization Act of 2003 (MMA).

The National Association of Boards of Pharmacy® (NABP®) has been approved by CMS to award DMEPOS accreditation since 2006. NABP accepts applications from licensed pharmacies so that they can dispense and bill Medicare Part B for certain DMEPOS products and services. NABP has accredited over 1,000 organizations and we continue to accredit new pharmacies, allowing them to serve Medicare beneficiaries.

Earning DMEPOS accreditation through NABP demonstrates a pharmacy's commitment to quality health care and a shared mission with NABP to protect the public health.

About NABP

Founded in 1904, the NABP is the impartial professional organization that supports the state boards of pharmacy in protecting public health. With more than 110 years of experience in supporting appropriate pharmacy regulation, NABP understands the complexities of pharmacy practice.

NABP aims to ensure public health and safety through its pharmacist license transfer and pharmacist competence assessment programs, as well as through its Verified Internet Pharmacy Practice Sites®, Verified-Accredited Wholesale Distributors®, Verified-Accredited Device Integrity Program™, Verified Pharmacy Program®, .Pharmacy Verified Top-Level Domain, and DMEPOS programs.

NABP's member boards of pharmacy are grouped into eight districts that include all 50 United States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, the Bahamas, Australia, 10 Canadian provinces, and New Zealand. The Association is governed by its Executive Committee, whose officers and members are elected during the Association's Annual Meeting.

For more on NABP's members and its efforts to protect the public health, visit the About section of the NABP website at www.nabp.pharmacy.



Patients rely on accredited DMEPOS facilities to provide them with quality durable medical equipment, prosthetics, orthotics, and supplies.

Contact DMEPOS staff at DMEPOS@nabp.pharmacy to learn more about NABP's program.

DMEPOS Accreditation Overview

Accreditation is a comprehensive process that requires preparation. Reading and understanding the NABP DMEPOS Accreditation Materials, along with the CMS Quality Standards, and involving all pharmacy staff in the process will help you prepare for the accreditation.

NABP DMEPOS accreditation entails a comprehensive review, including the following:

- **Policy and Procedures Review.** After your online application is submitted, NABP will send a Policy & Procedure Assessment to help you prepare and organize the required documentation. The required documentation must be submitted within 60 days. NABP will review the materials to confirm compliance with both the NABP program standards and the CMS Quality Standards prior to moving to the survey stage.
- **Licensure Verification.** NABP will review and verify that relevant licenses held by the pharmacy and pharmacist-in-charge are current and active.
- **Unannounced On-Site Survey.** An NABP surveyor will conduct an unannounced inspection to confirm the submitted policies and procedures are in place and evident in the day-to-day operation of the pharmacy.

Our surveys are designed with pharmacies in mind, meaning that surveyors take steps to minimize any disruption to the day-to-day operation of the business. In addition, NABP surveyors play a key role in the accreditation process. Their collective skills and expertise ensure fair and objective assessment of compliance with both CMS Quality Standards and NABP requirements for each survey conducted.

Suppliers accredited through the NABP DMEPOS program include national and regional pharmacies, supermarket chains, and independent operators. The NABP DMEPOS accreditation program focuses only on pharmacy suppliers and the 23 product categories for which we can accredit, such as diabetic equipment and supplies, canes and crutches, and surgical dressings (see below for a full list). NABP continues to work with DMEPOS suppliers and CMS to help ensure that Medicare beneficiaries receive the appropriate products, services, and patient care associated with DMEPOS.

Once granted, DMEPOS accreditation is valid for three years. DMEPOS-accredited pharmacies are required to participate in an annual compliance review (see page 15 for more information).

For more information on Medicare enrollment or Part B billing privileges, please visit the National Supplier Clearinghouse at www.palmettogba.com.

DMEPOS Products Approved for Accreditation by NABP

NABP's DMEPOS accreditation program is best suited to pharmacies that distribute DMEPOS products and services that fall within NABP's scope of accreditation. NABP is currently approved by CMS to accredit the following product categories from the Medicare Enrollment Application:

- Blood Glucose Monitors and/or Supplies (mail order)
- Blood Glucose Monitors and/or Supplies (non-mail order)
- Breast Prostheses and/or Accessories
- Canes and/or Crutches
- Commodes/Urinals/Bedpans
- Continuous Positive Airway Pressure (CPAP) Devices and/or Supplies
- Diabetic Shoes/Inserts

- Diabetic Shoes/Inserts-Custom
- Enteral Equipment and/or Supplies
- Enteral Nutrients
- External Infusion Pumps
- External Infusion Pump Supplies
- Heat & Cold Applications
- Insulin Infusion Pumps
- Insulin Infusion Pump Supplies
- Nebulizer Equipment and/or Supplies
- Orthoses: Off-The-Shelf
- Ostomy Supplies
- Parenteral Equipment and/or Supplies
- Parenteral Nutrients
- Respiratory Assist Devices
- Seat Lift Mechanisms
- Surgical Dressings
- Urological Supplies
- Walkers

When selecting product categories, applicants should consider the applicable licensure requirements and know which product categories are included in the Competitive Bidding programs of their service area. For more information on Competitive Bidding, see Appendix A: DMEPOS Resources on page 30.

Eligibility

In order to participate in NABP's DMEPOS accreditation program, applicants must:

- Be a licensed pharmacy that is open and operational, with at least 10 customers for which there are billed prescriptions.
- Seek accreditation only for DMEPOS products and services that fall under NABP's scope to accredit.
- Demonstrate that the entity and appropriate staff are licensed and in good standing with the applicable board(s) of pharmacy or equivalent state agency. In addition, appropriate staff must also be vetted through NABP's Disciplinary Clearinghouse.
- Submit all required documentation demonstrating that the entities' policies and procedures meet the NABP DMEPOS Accreditation Standards and its compliance with CMS requirements for personnel, the pharmacy, record keeping, and patient services as outlined in the CMS Quality Standards.
- Execute a Business Associate Agreement regarding protected health information disclosure prior to the survey stage (this is in conjunction with the Health Insurance Portability and Accountability Act). *Note: The level of protected health information observed during a DMEPOS survey is minimal and only recorded in the event of possible non-compliance.*
- Demonstrate during an unannounced, on-site survey that the written policies and procedures are reflected in actual practice.
- Permit pharmacy staff interviews and provide access to all documentation requested while on site (policies and procedures, human resources personnel and training records, invoices and contracts, etc).

- Meet NABP's performance standards by responding to requests for additional information in a timely fashion. Inability to do so may result in administrative fees or cancellation of application.
- Meet all financial obligations associated with the application and survey process.
- Execute an NABP Letter of Agreement once they successfully achieve accreditation status.

Fee Structure and Timing

NABP's single pharmacy pricing is listed on our website at www.nabp.pharmacy/dmepos. A credit card payment is required for the Year 1 subtotal when the application is submitted. If a pharmacy does not pass the survey, an additional survey and applicable fees will be required to continue with the accreditation process. Administrative fees may be assessed for time extension requests to submit documentation or for excessive document review and remediation cycles. Other fees may apply to process items such as, change of ownership and control notification, mid-cycle product category change requests, or costs to obtain disciplinary action information from state or federal agencies.

A separate fee structure applies to suppliers with more than one facility. For information on fees for two or more facilities that have common ownership and follow the same policies and procedures, please contact DMEPOS staff at DMEPOS@nabp.pharmacy.

The initial accreditation process may take approximately six months to complete, from the time of verified submission of all required documentation. Applicants who demonstrate a high level of compliance with standards that can be evaluated based on document submission will advance more quickly. For best results, the DMEPOS contact person should be active and fully engaged in each stage of the accreditation process.

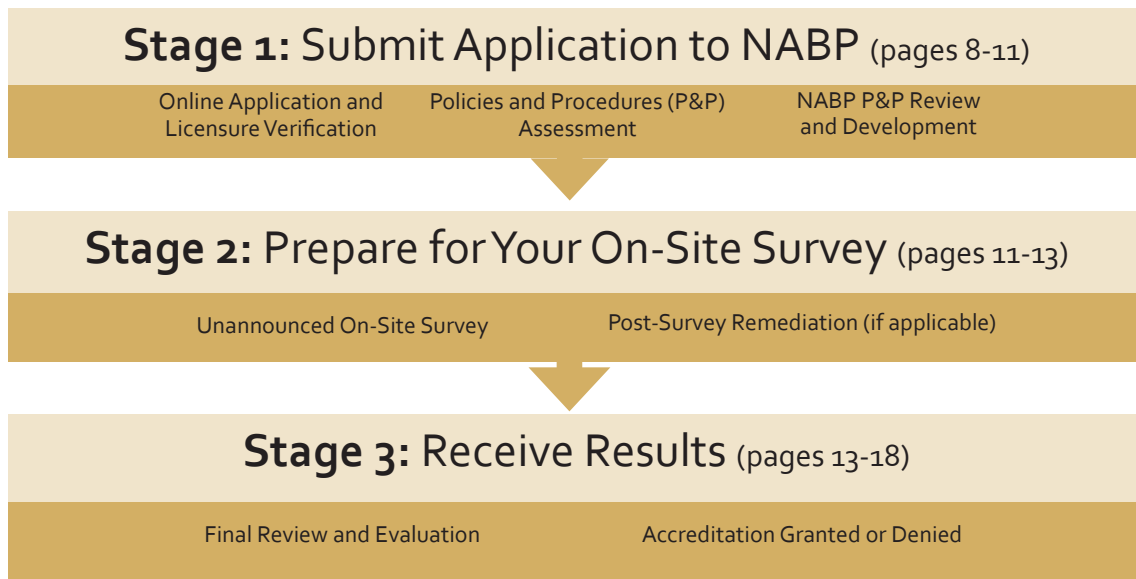
Reaccreditation

Once awarded, DMEPOS accreditation is issued for a three-year term. NABP requires an annual compliance review and program participation fees in Year 2 and Year 3. Reaccreditation prior to the expiration date of the current accreditation is necessary to maintain continuous accreditation. A reaccreditation application, unannounced on-site survey, and fees are required. NABP seeks to make the reaccreditation process convenient and constructive by notifying you well in advance of your accreditation end date and by providing self-assessment materials to help you demonstrate ongoing compliance with NABP DMEPOS Accreditation Standards at survey.



Understanding the NABP Standards and involving all pharmacy staff will help minimize the time needed to achieve DMEPOS accreditation.

Accreditation Process



Stage 1: Submit Application to NABP

Getting started is easy. The steps of the first stage are listed below:

Applicant:

- Completes the brief online application and submits payment;
- Attends a Welcome Call to meet your NABP accreditation contact, share introductory information about the pharmacy, and ask questions about the accreditation process; and
- Completes and submits the NABP Policies & Procedures Assessment along with the pharmacy's corresponding policies and procedures for review and development.

NABP:

- Hosts a Welcome Call following submission of the application to learn more about the pharmacy's accreditation needs and help orient you with NABP's program and process;
- Reviews the Policy & Procedure Assessment and corresponding documents submitted, provides feedback, and confirms compliance with accreditation requirements before advancing to Stage 2 (survey stage); and
- Verifies the licensure information provided.

DMEPOS Online Application

Applicants are required to complete a brief online application and submit payment for the Year 1 subtotal via NABP's website at <https://nabp.pharmacy/programs/dmepos/apply-dmepos>.

The application requires you to:

- Answer pre-application testament questions regarding eligibility and intent
- Provide ownership and control information

- Provide names and licenses (as applicable) for key staff
- Sign a Business Associate Agreement (BAA), pursuant to Health Insurance Portability and Accountability Act (HIPAA) requirements
- Submit NABP affidavits: Financial Management and Product Authentication
- Review a sample Letter of Agreement (which must be executed once accreditation is awarded)

After your application is submitted, you will be partnered with NABP Accreditation staff who will help guide you through the application process. Your accreditation contact will call to review the application with you, answer any questions you may have on the process, and discuss next steps.

 **Note:** Cancelled or withdrawn NABP DMEPOS applications are subject to a handling fee. More information is available upon request.


Communication With DMEPOS Contacts

For your protection and best success, we will only correspond with the DMEPOS contact listed in the application. You may designate a secondary DMEPOS contact for the accreditation application, if it makes sense for your pharmacy. DMEPOS contacts must be full- or part-time employees of the pharmacy and/or corporation.

We are available to assist you Monday through Friday 9 AM to 5 PM CST 847/391-4539 or via email at DMEPOS@nabp.pharmacy. It is important that you periodically check your email for important accreditation news and updates.

Licensure Verification

After you submit your application, records for both the pharmacy and appropriate members of the pharmacy's staff will be thoroughly screened through the NABP Disciplinary Clearinghouse. NABP will verify that the facility and its employees are properly licensed and in good standing with the applicable boards of pharmacy and state regulatory agencies.

 **Note:** Administrative fees may apply to obtain and review Disciplinary Action information.

Policy and Procedure Assessment and Documentation

Applicants will receive an in-depth policy and procedure (P&P) Assessment and Product Category Checklists to use when preparing their accreditation application materials. These items will help the pharmacy meet compliance with NABP's DMEPOS Accreditation Standards, which incorporate the CMS Quality Standards.

A description of the P&Ps and documentation required for NABP's DMEPOS Accreditation can be found on page 20 of this guide. A sample Product Category Checklist can be found in Appendix C. Applicants have 60 days to submit a completed P&P Assessment and corresponding materials.

Summary of NABP DMEPOS Accreditation Materials

P&P Assessment:

A multipurpose document organized by CMS Quality Standards to help pharmacies prepare their P&Ps for review by NABP Accreditation staff.

- Conveys to NABP where specific information can be found in materials submitted and allows for Accreditation staff to easily provide feedback.
- Should be used by applicants to train pharmacy staff on accreditation standards and assist in survey preparation.

Product Category Checklists:

Individual guides outlining product-specific service requirements necessary to obtain DMEPOS accreditation.

- Guide to be used when submitting product-specific P&Ps detailing how your pharmacy will serve Medicare beneficiaries in accordance with the CMS Quality Standards and Medicare requirements.



Note: Additional forms and/or documents may be submitted to support a P&P.

- Should be used by applicants to train pharmacy staff and be kept with your DMEPOS accreditation materials.

Documentation Submission Requirements

All documents required to support your application for DMEPOS accreditation must be submitted electronically. Please note that documentation should only be submitted in the following file formats:

- Adobe PDF (.pdf),
- Microsoft Word (.doc or .docx), and
- Microsoft Excel (.xls or .xlsx).

Submission of other file types may not be accepted or may result in extended processing time and administrative fees.

NABP P&P Review


After receiving the completed application, P&P Assessment, and supplemental documents, NABP will review the submitted materials to verify compliance with NABP DMEPOS Accreditation Standards.

If supporting documentation meets the standards, NABP will notify the applicant via email that they are now ready for Stage 2, the On-Site Survey.

Policy and Procedure Remediation and Development

If your policies and procedures are found to be deficient, you will be asked to provide updated or additional information. **Applications with incomplete or noncompliant documentation cannot advance in the accreditation process.** All requested information and documents are required to be submitted by email to DMEPOS@nabp.pharmacy.

The DMEPOS accreditation team is here to help you through the accreditation process. NABP will work with applicants if document remediation is needed to meet compliance with accreditation requirements before advancing to the next stage.

 **Note:** If you require more time to address a deficiency, please contact NABP as soon as possible to keep us informed of your status. NABP's goal is to help you achieve accreditation as quickly as possible.

While some remediation and development assistance is reasonable, administrative fees may be assessed for multiple time extension requests to submit documentation or if multiple document reviews and remediation cycles are required to confirm compliance. If, after discussion with NABP staff and subsequent remediation cycles, your documentation is still insufficient, NABP may recommend that you consider an outside consultant to help prepare the pharmacy for accreditation or withdraw your application with NABP.

NABP will notify you when Stage 1 is complete by sending a survey notice via email. Although it is permissible for the unannounced on-site survey to be conducted at any time after an application is submitted, NABP will notify you when Stage 1 is complete by sending a survey notice via email so that you may continue to prepare for the unannounced survey.

Stage 2: Prepare for Your On-Site Survey

Unannounced On-Site Survey

After Stage 1 is complete, you will receive a survey notice by email announcing that your pharmacy is at the survey stage. During the on-site survey, the applicant demonstrates that the P&Ps submitted for the accreditation have been implemented and demonstrates compliance with the NABP DMEPOS Accreditation Standards.

Upon arrival, NABP surveyors will introduce themselves to the pharmacist-in-charge and present a NABP badge with photo identification and a business card to establish their official capacity.

DMEPOS On-Site Survey Overview

The surveyor will interview the following people:

- All personnel involved in providing DMEPOS services (pharmacists, technicians, DME fitters, delivery personnel);
- The compliance officer (if available);
- An individual who can address information related to accounting practices, budgeting, and other basic financial information; and
- An individual who can address human resources information related to hiring, training, and education for DMEPOS personnel.

The surveyor will ask to see policies and procedures, documents, or files including the following:

- Personnel files and training records for pharmacy staff: pharmacist-in-charge, pharmacists, pharmacy technicians, delivery persons (if applicable);
- Documentation for contractors utilized for DMEPOS services;

- Medicare B Beneficiary Complaint File/folder containing complaint handling procedures, blank forms, and any completed complaint information;
- Vendor list for DME items and invoices, or other records of sale identifying the source of all DME products on the shelf and in active inventory;
- Equipment Management Plan and Recall file; and
- Medicare B Beneficiary records.



Note: The surveyor may ask to see certain P&Ps and supplemental documentation submitted as part of your DMEPOS accreditation application. In addition, the surveyor may ask to review P&Ps or documentation specific to Medicare.

The surveyor will observe pharmacy processes including:

- Filling a prescription;
- Counseling a patient or training a patient on their DME; and
- Steps to ensuring patient privacy and HIPAA compliance.

Please note that NABP is acting as an agent of CMS, and accordingly NABP surveyors have the right to access and review all relevant pharmacy records. However, the surveyor will not take any copies or documentation from the pharmacy.

If materials such as human resources files (eg, personnel and training files) are not available to view at the pharmacy, an additional survey may be needed, at cost. Please inform NABP Accreditation staff early in the accreditation process if items are not held locally at the pharmacy, but at another location such as a corporate or regional office.

Preparation Checklist

Pharmacies can prepare for the survey by reviewing the P&P Assessment and Product Category Checklists with all pharmacy staff who have a DMEPOS role. Please ensure that the following steps have been taken before the surveyor arrives:

- Pharmacy staff is conversant on the NABP DMEPOS Accreditation Standards.
- DMEPOS accreditation policies and procedures are available at the pharmacy (either as physical copies or available online) and have been implemented, and pharmacy staff has been trained on them.
- Pharmacy staff has been trained on all product categories for which you are seeking accreditation and are able to train beneficiaries in the use of these devices.
- **For reaccreditation:** All action items from the initial accreditation cycle as outlined in a post-survey letter implementation plan, as well as the policies and procedures in the documentation you submitted, continue to be incorporated into your pharmacy's day-to-day operation.

Preparing for the unannounced survey and your attention to any post-survey findings requiring follow-up will help to facilitate the final stages of the accreditation process.

After the Survey

Following the survey, you will receive a letter from NABP that details any actions you need to take to ensure compliance with all NABP DMEPOS Accreditation Standards. The letter may also contain additional documentation needed or policies and procedures that require further remediation.

A post-survey response with a plan to address noncompliance or noncompliant items should be returned to NABP within five business days. This is typically achievable given that applicants strive to complete documentation as quickly as possible in order to move forward in the accreditation process. Additional time can be granted as appropriate. Please let NABP Accreditation staff know if you have questions about the survey findings or if additional time is needed. All materials must be submitted electronically to DMEPOS@nabp.pharmacy. See Appendix A for document submission guidelines.

Additional survey and fees will be required to continue in the accreditation process if:

- Pharmacy staff is not familiar with or not able to demonstrate compliance with the NABP DMEPOS Accreditation Standards during the survey, and
- NABP is unable to ensure your complete remediation with a manageable post-survey action plan due to the large number of deficiencies.

Preparing for the second unannounced survey, and your attention to any post-survey findings requiring follow-up, will help facilitate the final stages of the accreditation process.

Reaccreditation Surveys

Once accredited, NABP conducts an unannounced survey of the accredited DMEPOS pharmacy once every three years during the reaccreditation process to review, evaluate, and monitor the pharmacy supplier, its performance, and compliance with the NABP DMEPOS Accreditation Standards.

Other Unannounced Surveys

NABP performs ongoing compliance monitoring during the accreditation cycle, which could involve an unannounced on-site survey. In addition, complaints (from any beneficiary, regulatory agency, or CMS) and/or a change in critical operations or business structure, such as a change in ownership, could also prompt an unannounced on-site survey.

Stage 3: Accreditation

Final Review and Evaluation

Following the licensure verification, documentation review, and the results of the on-site survey, applicants who have demonstrated compliance with all NABP DMEPOS Accreditation Standards in accordance with the CMS Quality Standards will be granted accreditation.

Accreditation Granted

Pharmacies accredited through the NABP DMEPOS program are doing their part to ensure that Medicare beneficiaries receive the appropriate products, services, and patient care associated with DMEPOS products.

Accreditation is valid for three years, and accredited suppliers will submit a reaccreditation application to NABP every three years.

Accreditation Denied

In reviewing the application, policies and procedures, license verifications, on-site operations, and other documentation, NABP Accreditation staff may discover information indicating the applicant is not in compliance with the NABP DMEPOS Accreditation Standards, CMS Quality Standards, or state or federal law, or that falsified information is found on the application. This would result in a denial of accreditation to a DMEPOS applicant.

Accreditation Disputes and Appeals

In the event that NABP shall deny initial accreditation to a DMEPOS supplier or shall remove such accreditation from a DMEPOS supplier, the DMEPOS supplier may appeal the decision of NABP. See Appendix D for information on procedure to appeal NABP's decision to either deny or remove accreditation.

Accreditation Revocation

If, after accreditation, an applicant is found to be noncompliant with NABP DMEPOS Program Standards or does not complete the Annual Compliance Review process, NABP may revoke the accreditation.

The accredited supplier will be notified of intent to revoke. When a supplier's accreditation is revoked, NABP will terminate the DMEPOS Letter of Agreement (LOA), and the pharmacy (or pharmacies) will be removed from the roster of accredited facilities that NABP provides to CMS.

NABP Letter of Agreement

The NABP DMEPOS LOA represents the agreement between NABP and the pharmacy participating in the accreditation program. The LOA outlines requirements for both parties to the agreement. A draft of the LOA is made available for review prior to applying for NABP DMEPOS accreditation and if accreditation is awarded, must be signed and returned to NABP.

The LOA covers important agreement areas such as:

- Confirmation that all of the information in a pharmacy's completed DMEPOS application and the documentation submitted with the application, as well as all information and documentation subsequently submitted, is accurate and truthful to the best of the pharmacy's knowledge.
- Agreement that the pharmacy will remain in compliance with NABP requirements throughout the three-year accreditation, including completing annual compliance processes or compliance audits and paying all applicable fees.
- Confirmation that the pharmacy agrees to provide NABP and NABP's surveyors with sufficient access to its facility and records for purposes of conducting a compliance review to ensure that the pharmacy is in compliance with the NABP DMEPOS Accreditation Standards. Pharmacy also agrees to permit and facilitate interviews with key personnel in order to evaluate compliance.

Additional agreement areas detailed in the LOA include the following:

- Application confidentiality and when NABP may disclose information or must legally release information
- Subsequent surveys and visits
- Communication with NABP and when to inform NABP of changes
- Accreditation determinations, and an outline of the review and appeals process
- Modification to program requirements
- Publication of pharmacy's accreditation
- Right of publicity by NABP
- Loss of qualification; suspension from program
- Termination of LOA
- Appeals procedure
- Inclusion of the CMS Quality Standards, which the pharmacy agrees to uphold

Accreditation Announcement

Once accredited, NABP will take the following steps to announce your accreditation:

- Provide an NABP Certificate of DMEPOS Accreditation to the accredited supplier for display in the pharmacy
- Include the pharmacy in NABP's accreditation roster, which is issued weekly to the National Supplier Clearinghouse
- Post the name of the pharmacy on NABP's website, www.nabp.pharmacy, in the list of "DMEPOS-Accredited Pharmacies"
- Announce the pharmacy's accreditation in *Innovations*, NABP's newsletter, which is printed and issued to NABP board of pharmacy members 10 times per year (1,400 approximate monthly circulation)


In addition, the use of NABP's DMEPOS Seal is available, upon request, to NABP-accredited pharmacies in good standing. To use the DMEPOS Seal, you will need to agree to NABP's DMEPOS graphic standards requirements.

Annual Compliance Review

Once a year the accredited supplier will confirm its ongoing DMEPOS accreditation compliance. During this time NABP may follow-up on items remediated during the accreditation cycle or provide new information or updates. NABP will also review licensure for the pharmacy and pharmacist-in-charge to confirm good standing.

NABP will send annual compliance review materials via email prior to your accreditation anniversary date. The materials include:

- An annual compliance review form that allows you to confirm or update information and/or documentation on file at NABP.
- An invoice for the annual compliance fee per facility.

 **Note:** Annual compliance fees are not refundable.

Both the fee and completed form must be received by NABP within 30 days. If NABP does not receive a response within 30 days, NABP will assume that you do not wish to renew your DMEPOS accreditation. As such, your accreditation file will be closed and the LOA will be terminated. Please be advised that confirmation of your DMEPOS accreditation will no longer be provided to CMS once the LOA is terminated.

Once your file is closed, you may reapply for accreditation at a later date by submitting a new application, required documentation, and any applicable fees. A minimum of six months is typically required to complete an accreditation.

If accreditation is revoked because annual participation fees were not paid, the National Supplier Clearinghouse (NSC) will revoke the Medicare Billing Number. If a supplier does not respond to the NSC's revocation notice and the Corrective Action Plan during the revocation process, the supplier may be suspended for one year from the Medicare program.



Note: DMEPOS accreditation is required to participate in the DMEPOS Competitive Bidding Program and the Mail Order Competition for diabetic testing supplies.

Reaccreditation Process Overview

DMEPOS suppliers must be reaccredited before the current accreditation expires if DMEPOS accreditation is required for your pharmacy. Unless a pharmacy has applied for pharmacy accreditation exemption from the NSC and has received exemption confirmation, we encourage suppliers to seek reaccreditation for a new, three-year accreditation during the final year of their current accreditation.

Depending on the level of compliance sustained through the current accreditation, reaccreditation typically requires four to six months to complete from the point a reaccreditation application is submitted and required documentation is received. NABP will contact its DMEPOS-accredited pharmacies prior to the expiration date of their current three-year accreditation to begin the reaccreditation process. Accredited suppliers are also welcome to contact NABP at any time to begin the process.

NABP's goal is to provide our DMEPOS-accredited pharmacies continuous accreditation to help avoid any gaps in payment of Medicare Part B claims for products and services subject to the CMS Quality Standards.

The reaccreditation process is similar to the initial DMEPOS accreditation and includes the following three stages.

1. During the application stage, NABP staff will provide reaccreditation applicants with an Assessment Tool and highlight any new or updated P&Ps required. As with the current accreditation, the Assessment Tool will also help reaccreditation applicants prepare for their unannounced survey.
2. An unannounced survey of the pharmacy will be conducted to ensure the pharmacy's continued practice of its DMEPOS policies and procedures and compliance with the NABP DMEPOS Accreditation Standards. *Please note:* If a pharmacy is not successful at survey, a second survey with additional survey fees will be required to continue in the reaccreditation process.

3. Following resolution of any outstanding survey action items, and NABP's verification that licenses are in good standing for the pharmacy and pharmacist-in-charge, DMEPOS staff will recommend that the NABP Accreditation Committee award the pharmacy a new, three-year DMEPOS accreditation.

To ensure continued DMEPOS accreditation compliance during a pharmacy's three-year accreditation cycle, accredited pharmacies should regularly:

- Review their DMEPOS policies and procedures and update them as needed;
- Ensure pharmacy staff are familiar with applicable DMEPOS policies and procedures and the pharmacy's DMEPOS operations; and
- Review the NABP DMEPOS Accreditation Standards, the CMS DMEPOS Quality Standards, and Medicare DMEPOS Supplier Standards in their entirety to ensure compliance.

Maintaining Accreditation Compliance

The DMEPOS LOA contains important information regarding the roles of accredited pharmacies and instances when NABP should be notified. This section highlights common business occurrences where NABP must be informed.

To keep your accreditation current, per the DMEPOS LOA, please advise NABP in writing within ten (10) days of changes to your submitted application that include:

- Change in location;
- Change in ownership;
- Merger with another business;
- Acquisition of another retail business;
- Major change in physical structure of facility; or
- Cessation of supplying the Limited Line of DMEPOS services or cessation of all operations.

Please advise NABP in writing within thirty (30) days of changes to your submitted application that include:

- Change in pharmacist-in-charge; or
- Any significant change in the application information or documentation provided to NABP, including, but not limited to, license or registration numbers, compliance officer, etc.

Additional documentation, a potential on-site survey, and fees may be required with changes listed above. Please contact NABP Accreditation staff for more information.

If an ownership change has occurred, your information will be reviewed and assessed by NABP. If there are no questions or concerns about the request for ownership change, you will be notified by email that NABP agrees to reassign the LOA.

In addition to notifying their accrediting organization of changes, a DMEPOS-accredited supplier must also notify the NSC. Per Supplier Standard #2, the supplier must report changes to the NSC within 30 days of the change. The NSC has information on their website for both the buyer and seller regarding ownership changes and updates necessary via the CMS-855S or Internet-based PECOS. The NSC also outlines the main types of ownership changes (eg, stock or asset) and associated steps to take for each.

- The NSC's website is www.palmettogba.com/nsc (search "ownership").
- The NSC's toll-free phone number is 1-866/238-9652. Customer service representatives are available from 9 AM until 5 PM EST. The automated response system is available 24 hours a day.

Program Standards

NABP's DMEPOS accreditation program supports the Association's mission to assist its member boards of pharmacy in protecting public health. The program standards through which the accreditation process is managed are essential for meeting this mission.

The standards include the validation and assessment of several key areas including:

- Facility and key personnel licensure
- Organizational and administrative structure
- Fiscal and human resources management
- Product safety, vendor and product authentication
- Procurement and inventory
- Information management
- Compliance and performance management
- Intake and assessment, delivery and set-up
- Beneficiary and/or caregiver services, training/instruction and follow-up

NABP's program standards are covered in detail in our Policy and Procedure Assessment and Product Category Checklists.

NABP's DMEPOS Accreditation Standards are inclusive of the CMS Quality Standards. The Quality Standards are guidelines used by the CMS-approved accrediting organizations to which suppliers must comply to attain DMEPOS accreditation. NABP Accreditation Standards cover Section I and Section II of the Quality Standards, along with product-specific service requirements found in Appendix A and Appendix C, for the product categories we accredit.

The CMS Quality Standards are available via the NABP website or can be found on the CMS website. In addition, CMS has released a Quality Standards booklet. The booklet provides tips and additional information to further your understanding of the DMEPOS Quality Standards, as well as the policies and procedures required for accreditation. See Appendix A: DMEPOS Resources.

The CMS DMEPOS Quality Standards consist of two sections and three appendices:

- **Section I:** Supplier Business Services Requirements;
 - » **Addresses:** Administration, financial management, human resources management, consumer services, performance management, product safety, and information management.
- **Section II:** Supplier Product-Specific Service Requirements;
 - » **Addresses:** Intake and assessment, delivery and set-up, training/instruction, and follow-up.
- **Appendix A:** Respiratory Equipment, Supplies, and Services;
- **Appendix B:** Manual Wheelchairs, Power Mobility Devices (PMDs), and Complex Rehabilitative Wheelchairs and Assistive Technology; and
- **Appendix C:** Custom Fabricated and Custom Fitted Orthoses, Prosthetic Devices, External Breast Prostheses, Therapeutic Shoes and Inserts, and Their Accessories and Supplies; Custom-Made Somatic, Ocular, and Facial Prostheses.

CMS Quality Standards Appendices describe the requirements for specific types of DMEPOS items and services.

NABP ensures that DMEPOS suppliers meet program standards by performing:

- A thorough review of submitted DMEPOS documentation such as policies and procedures and supporting information; and
- Unannounced site visits to verify suppliers' submitted documentation and actual business practices are aligned, as demonstrated through record/file reviews and pharmacy staff interviews.

DMEPOS Policies, Procedures, and Supplemental Documentation

The following is a list of policies, procedures, and other documents that are required to complete your application. Applicants receive an NABP DMEPOS P&P Assessment that details focus points for each document to assist in P&P development. The documents listed below are organized according to the CMS Quality Standards.

Section I: Supplier Business Service Requirements

A: Administration

Applicant Item <i>(Materials/Documents, unless noted "applicant process")</i>	Description
Pharmacy Organizational Chart (ORG)	<ul style="list-style-type: none"> • This document details the pharmacy's management structure. • The organizational chart must show clear lines of authority and accountability for the pharmacy. • The organizational chart must list job titles/positions of pharmacy staff and does not need to specify staff names. <ul style="list-style-type: none"> » In particular, the organizational chart should note the pharmacist-in-charge and/or pharmacy manager, as well as the compliance officer for the pharmacy. • The organizational chart should also note contract pharmacy staff, full- and part-time permanent staff, pharmacists, pharmacy technicians, and other nonpharmacist personnel and/or delivery staff.
Vendor Authentication Plan (VAP)	<ul style="list-style-type: none"> • Vendor authentication includes the process to verify vendor licensure with appropriate state or federal agency, screen against the Office of Inspector General (OIG) exclusion list, and ensure the vendor obtains DME directly from the manufacturer or from another wholesaler that obtains directly from the manufacturer.
Vendor List DME (VLD)	<ul style="list-style-type: none"> • This is a list of only those vendors from whom DME products and supplies are obtained.

Compliance Plan (CP)

- The compliance plan addresses compliance with local, state, and federal regulations, and Medicare rules and regulations to include:
 - » References and monitoring of regulations for changes;
 - » Process for developing, revising, and maintaining P&Ps;
 - » Training of staff on P&Ps including Medicare standards and billing;
 - » Fraud, Waste, and Abuse training;
 - » Internal audits and monitoring used to ensure compliance; and
 - » Record retention plan.
- Business practices including risk management initiatives, satisfaction audits, and compliance rules (CMS Administration Quality Standard).
- Detail ways that fraud, waste, and abuse are prevented and controlled.
- Detail how you comply with laws and regulations through training and education of employees, contractors, agents, and directors (if applicable).
 - » Updated manual or internet access to relevant federal and state laws;
 - » In-house training on state laws;
 - » Continuing education for staff; and
 - » Procedures for internal monitoring and auditing.
- Detail consistent enforcement of standards.
- Document records of compliance efforts (eg, training provided, situations reviewed, and actions taken).
- Maintain prescriptions/orders for DME and certifying documentation for seven years from the date of service and provide access to documentation upon request of CMS or a Medicare contractor.

Compliance Officer Job Description (COJD)

- Applicants are required to submit the job description and performance standards for the pharmacy's compliance officer.
- This documentation should address the pharmacy compliance officer's training and education related to risk management and compliance matters.

Licensure (LIC) - Applicant Process

- This addresses the licensure or registration of the facility and the personnel and includes:
 - » Verification of this licensure directly with the licensing agency and documenting the verification (initial and ongoing),
 - » Screening against Medicare exclusion lists (initial and ongoing), **and**
- This applies to employees and contract personnel.

B: Financial Management**NABP DMEPOS
Financial
Management
Affidavit (FMA)**

- Applicants are required to complete the NABP DMEPOS Financial Management Affidavit attesting that the pharmacy has implemented financial management practices that ensure accurate accounting and billing to beneficiaries and the Medicare program. The affidavit requires notarization.
- A copy of the current Operating Budget (budget should exhibit the following: anticipated patient services, market costs, and capital expenditures) must be kept at the pharmacy and be available to the NABP surveyor. (If operating budget was reviewed at a corporate survey, then the pharmacy should be able to provide a performance to budget.)
- Invoices indicating the source of DME products sold to customers must be retained at the pharmacy and be available to the NABP surveyor.

**Medicare Billing Plan
(MBP)**

- Defined billing processes including specific steps or items a third-party processor will perform; processes should address:
 - » Coverage,
 - » Co-pay,
 - » Claims processing,
 - » Rejected claims handling,
 - » Billing only when documentation complete,
 - » Correct use of HCPCS codes and modifiers,
 - » ABN use, and
 - » Reconciliation of remittance advice.
- Detail how your organization complies with Medicare Laws and Standards related to billing. May include reference to:
 - » Compliance Plan,
 - » Role of compliance officer,
 - » Use of third party for Medicare billing, and
 - » Utilization of compliance committee.
- Provide step-by-step instructions of how your organization handles Medicare billing. These instructions should address:
 - » Determination of beneficiary coverage,
 - » Verification of Medicare payment policies,
 - » Claim processing,
 - » Rejected claims, and
 - » Product substitution.
- If applicable, provide a detailed description of the scope of services provided by any third party used for Medicare billing.

C: Human Resources

- Staff Job Description (SJD)**
- Applicants are required to provide job descriptions and requirements for all personnel involved in providing DMEPOS services to beneficiaries. This must include:
 - » Contract pharmacy staff,
 - » Full and part-time permanent staff,
 - » Pharmacists,
 - » Pharmacy technicians,
 - » Other non-pharmacist personnel, and
 - » Delivery staff.
 - Job descriptions should delineate each individual's specific role in the provision of DMEPOS products and services.
 - Job requirements should address training and educational requirements for staff involved in providing DMEPOS services.
 - In addition to providing job descriptions, applicants are required to provide examples of how staff is trained on DMEPOS products and services.

- Personnel File List (PFL)**
- Personnel files and the location of these (hard copy on-site, electronic, etc) should include:
 - » Application or resume (with education and work history);
 - » Current credentials posted (license, registration, certification, etc) and documentation of verification of these credentials;
 - » Results of background checks and/or drug testing (if required by the state);
 - » Screening against exclusion list documentation;
 - » Performance evaluations (including competency assessments);
 - » Disciplinary processes;
 - » Evidence that job descriptions were reviewed by the employee; and
 - » Training records.

- Training Personnel General (TPG)**
- General training includes:
 - » Orientation and job position-specific training;
 - » HIPAA;
 - » OSHA (blood borne pathogen or hazardous/infectious waste handling);
 - » Fraud, Waste, and Abuse; and
 - » Medicare intake and billing (including CMS Quality Standards and Supplier Standards).

- Training Personnel for Equipment Set-up & Beneficiary Training (TPE)**
- Product category-specific training includes:
 - » Product details and features,
 - » Set-up and adjustment,
 - » Maintenance and cleaning, and
 - » Use of the DME including:
 - troubleshooting,
 - hazards and warnings, and
 - infection control.

- Technician Policy/ Scope of Practice (TPS)**
- Either a pharmacy technician policy that defines the tasks a technician may perform (and which are pharmacist-only) or the tasks are included in the technician job description.

Contractor Verification (LIC) - Applicant Process	<ul style="list-style-type: none"> • Includes verifying licensure directly with the licensing agency (initial and ongoing), and • Screening against Medicare exclusion lists such as OIG (initial and ongoing).
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D: Consumer Services

Training/Instruction to Beneficiary/ Caregiver and Follow-Up (TBC)	<ul style="list-style-type: none"> • Process to provide clear written and oral instructions to beneficiaries including content.
Patient Receipt of DMEPOS, Delivery and Set-Up (PRD)	<ul style="list-style-type: none"> • Patient Receipt of DMEPOS that includes: <ul style="list-style-type: none"> » Providing a wait time or delivery time, » Documentation that the beneficiary has received the DME (for in-pharmacy pick-up and items that are delivered, mailed, or sent).
Consumer Services Plan (CSP)	<ul style="list-style-type: none"> • Providing information to the beneficiary regarding: <ul style="list-style-type: none"> » Right to purchase or rent (including capped rental information), and » Information on contacting the supplier 24/7 (including after-hours and emergency contact information). • Process to follow if the supplier is not able to provide the DME.
Beneficiary Complaint Process (BCP)	<ul style="list-style-type: none"> • Beneficiary complaint reporting, response, and notification (CMS Consumer Services Quality Standard): <ul style="list-style-type: none"> » Shall investigate and address patient or beneficiary complaints/concerns regarding DME equipment, supplies, and services provided to the beneficiary, including privacy issues, and maintain documentation of investigation and efforts at resolution. » Within five days of receipt of the complaint/concern, pharmacy shall notify beneficiary of receipt of the complaint and that an investigation is under way. » Within 14 days of receipt of complaint/concern, pharmacy shall provide written notification and result of investigation and response. » Shall maintain documentation of all complaints, investigative documents, and responses to beneficiaries for seven years from the date of service. » May provide sample forms and surveys used for complaint reporting and customer satisfaction.

E: Performance Management

Performance Management Plan (PMP)

Applicants are required to submit a performance management plan with the application. Typically, a performance management plan includes or evidences the following performance-related criteria:

- Data about beneficiary satisfaction and complaints about products and services. For example:
 - » Copies of satisfaction surveys and patient complaint forms
 - » Orientation programs
 - » Policy and procedure manuals
 - » Competency assessments
 - » Performance evaluations
- Data that evidences the timeliness of responses to beneficiary questions, problems, and concerns. For example:
 - » Within five days of receiving a complaint, supplier acknowledges receipt of complaint and that an investigation is proceeding; or
 - » Within 14 calendar days, supplier provides written notification to beneficiary regarding results of investigation and supplier's response.
- Data about the impact of business practices on the adequacy of beneficiary access to equipment, items, services, and information.
 - » For example: how do hours of operation, after-hours services, ordering and out-of-stock procedures impact the beneficiary's access to equipment?
- Data gathered about the frequency of billing and coding errors, the number of Medicare claims denied, and any errors that may be found in the pharmacy's records after being notified of claims denial.
 - » Explain how error situations are handled, resolved, and prevented.
- Data collected about adverse effects to beneficiaries due to inadequate or malfunctioning of equipment, including any injuries, accidents, or hospitalizations. This may be identified through:
 - » Prescribing physician
 - » Other health care team members
 - » Beneficiary or caregiver
- Data about any high-risk, high-volume, and problem-prone areas of beneficiary care and/or service.
 - » For example: Are any of the products and services that the pharmacy provides susceptible to fraud or counterfeiting? Does the pharmacy conduct due diligence on the supplier to ensure the source of DME products dispensed to customers is legitimate?
- Description of the DMEPOS care and services the pharmacy provides to beneficiaries, populations served, performance areas monitored, and data collected, including the frequency, amount, and detail of collection. For example, according to product or service type:
 - » What type of feedback do pharmacy staff solicit (what questions are asked and in what format)?
 - » How often does pharmacy staff actively solicit beneficiary feedback?
- Record of topics that management and leadership identify as performance improvement priorities.
 - » Examples include improved delivery times, improved time of returning patients' calls, and decreased Medicare claim denials.

F: Product Safety**Equipment and Item Management Plan (EMP)**

- Includes training of personnel and beneficiaries regarding safe handling and use of equipment, including infection control.
- A process to ensure equipment and supplies are stored appropriately with regard to temperature and cleanliness. Temperature is maintained and recorded for general storage area, refrigerator, and freezer according to USP guidelines.
- Process for returned rental equipment that includes segregation from clean equipment; cleaning and testing/calibrating to ensure appropriate functioning; identifying and monitoring for defect, malfunction, or failure; and procedure for maintaining and repairing equipment under warranty or rented.

Product Authentication Plan (PAP)

- Includes process to visually inspect product upon receipt for damage, or unusual packaging or labeling, and not allowing such items to be placed into active stock;
- Process for restricting ordering to only authenticated vendors;
- Maintaining invoices or other records identifying the source of DME products; and
- Process for handling specially marked products (restricted sale or restricted use), removing short-dated and expired product from active stock, and initiating recall process.

Incident or Adverse Reaction Investigations Plan (IAR)

- Investigations involving incident/injury resulting in hospitalization/death should be initiated within 24 hours.
- Investigations of incident/injury not involving hospitalization/death should be initiated within 72 hours.
- Investigation should include basic information on the event, conclusions, and whether changes in the systems/process are needed.

Disaster or Crisis Plan (DCP)

- Applicant is required to submit a copy of a disaster/contingency plan.
- The plan should detail how operations will be maintained and how continuity of patient care will be ensured in the event of a disaster or emergency.
- Applicant should also include details about how their DMEPOS staff will be able to provide care for beneficiaries during a crisis.
 - » For example, there may be a call tree in place for employees to provide patient counseling around the clock, even if employees are unable to make it to the physical pharmacy location.
- The plan should be relevant to the pharmacy's geographical area, specifying events to which the area may be susceptible (eg, tornadoes, earthquakes, hurricanes, or blizzards). The contingency plan should include:
 - » Continuity of patient care/services
 - » Risk assessment
 - » Data storage and back-up
 - » Protection of inventory pre/post-disaster
 - » Communications (for internal staff operations and for patients who may experience an adverse event/emergency situation)
- If a patient experiences an adverse event or life-threatening condition and the pharmacy is not open or operational to service its own customers, callers should be directed to local emergency services, such as a hospital or dialing "911."



Note: In many instances, applicants have discovered that a disaster/contingency plan already existed within their organizations, and only minimal updates (if any) were needed to align with DMEPOS accreditation standards.

NABP Product Authentication Affidavit (PAA)

- Affidavit confirming that the supplier is in compliance with the Product Safety Standards as outlined in the CMS Quality Standards.

G: Information Management**Information Management and HIPAA Compliance (IMHC)**

- Process to maintain accurate and pertinent:
 - » Patient records,
 - » Confidentiality of records,
 - » HIPAA policy and agreements, and
 - » Notice of Privacy Practices (NPP) for provision to patients.

Section II: Supplier Product-Specific Service Requirements**Product Category Specifics Policies & Procedures (PCS)**

- Specific information for a product category including:
 - » Products and codes,
 - » Diagnoses for which DME is used,
 - » Additional documentation required for the specific category or product (WOPD/5EO, Face to Face, CMN, DIF, clinical information needed to evidence DME meets criteria).



Note: NABP will provide applicants Product Category Checklists as a guide for the product categories included in the application.

A: Intake and Assessment**DWO, WOPD/5EO**

- Beneficiary documentation that includes:
 - » Patient profile information,
 - » Information from patient that would affect the use of the DME (eg, allergies, blindness, severe arthritis), and
 - » Specific information needed on the DWO, WOPD/5EO.
- Documentation that the beneficiary has
 - » Completed an AOB,
 - » Received the supplier standards,
 - » Received warranty information,
 - » Received the complaint process, and
 - » Received the satisfaction survey (may be in a new beneficiary packet).

B: Patient Receipt of DME, Delivery, and Set-up**Patient Receipt of DMEPOS, Delivery and Set-Up (PRD)**

- The DME provided to the patient is consistent with the physician's order, accurately recorded, and that the beneficiary receipt of the DME is appropriately documented for items picked up in the pharmacy and items that are delivered, mailed, or sent to the beneficiary.
- If the pharmacy does not have the mail order bid contract for blood glucose testing supplies, a process is in place to restrict these DME items to pick-up in pharmacy only (may not be delivered, mailed, or sent).

C: Training/Instruction to Beneficiary and/or Caregiver(s)**Training/Instruction to Beneficiary and/or Caregiver(s) and Follow-Up (TBC)**

- Provide or coordinate the provision of appropriate information related to the set-up, features, routine use, troubleshooting, cleaning, and maintenance of the DMEPOS items provided.
- Advise the beneficiary and caregiver about appropriate safety considerations.
- Provide relevant information and/or instructions about infection control issues related to the use of equipment/items.
- Record in the beneficiary's record that such instruction was provided.
- Training shall commensurate with the risks, complexity, and manufacturer's instructions and/or specification for items.
- Tailor training and instruction materials and approaches to the needs, abilities, learning preferences, language, and readiness to learn of individual beneficiaries/caregivers.
- May provide checklists and forms used to educate in order to verify compliance with this standard.

D: Follow-up**Training/Instruction to Beneficiary and/or Caregiver(s) and Follow-Up (TBC)**

- Follow-up is provided appropriate to the DME product category and may be patient, pharmacy, or physician driven.
- Would include how refills are handled including appropriate documentation of remaining quantities to determine if supply is nearing exhaustion.

Product Category Checklists

The NABP Product Category Checklists contain information and product-specific service requirements necessary to obtain DMEPOS accreditation for each product category that NABP accredits.

NABP requires procedures and forms or documents to detail how your pharmacy will serve Medicare beneficiaries in accordance with the CMS Quality Standards and Medicare requirements. NABP accreditation applicants will receive the Product Category Checklists with the P&P Assessment. The Canes and Crutches Product Category Checklist is provided as an example and can be found in Appendix C.

For your convenience, a sample policy and procedure is available in Appendix E to reference the basic structure of a P&P. It is acceptable to copy information directly from the P&P Assessment to create your pharmacy's plan, provided that the policy and procedure (your plan) has been customized with the organization/pharmacy name, address, etc, and fully reflects your business needs and operation.

Medicare DMEPOS Supplier Standards

In order to obtain and retain a Medicare billing number from the NSC, Medicare DMEPOS suppliers must be compliant with all Medicare DMEPOS Supplier Standards. The NSC is responsible for ensuring compliance with the Supplier Standards.


DMEPOS accreditation applicants should be familiar with the Supplier Standards when going through the accreditation process. A link to the abbreviated version and full Supplier Standards can be found in Appendix A. It is recommended that a supplier review the full Supplier Standards (not just the abbreviated version).

Appendix A: DMEPOS Resources

NABP Document Submission Guidelines

When submitting additional documentation and/or information, please use the following methods only:

- Email documents as attachments to DMEPOS@nabp.pharmacy. Only the following file formats are accepted: Adobe (.pdf), Microsoft Word (.doc or .docx), and Microsoft Excel (.xls). Files may be sent in a zipped folder.

 **Note:** Pasting text into an email is not acceptable.


- Submit a USB flash drive or CD-ROM of the documents via a land carrier, such as Federal Express. We recommend using a priority carrier that provides shipment tracking.

ATTN: DMEPOS Department
National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, IL 60056

Medicare Part B Resources

The following is a list of Medicare Part B resources and contact information that may be helpful to you during the accreditation process and beyond.

- Centers for Medicare & Medicaid Services (CMS), www.cms.gov
 - » DMEPOS Quality Standards booklet – Applicants must demonstrate compliance with the NABP DMEPOS Accreditation Standards and the CMS Quality Standards during the accreditation process.
 - » The Medicare Learning Network (MLN) – Guides/articles/booklets/fact sheets/training presentations
 - » *Medicare Program Integrity Manual*
- National Supplier Clearinghouse (NSC), www.palmettogba.com/nsc or toll-free phone number 1-866/238-9652
 - » Medicare DMEPOS Supplier Standards – Applicants should be familiar with the Supplier Standards. Suppliers must meet these standards to obtain and retain billing privileges.
 - Full Supplier Standards are published in 42 Code of Federal Regulations 424.57(c)
 - Abbreviated Supplier Standards available: www.palmettogba.com/palmetto/providers.nsf/DocsCat/Providers~National%20Supplier%20Clearinghouse~Supplier%20Enrollment~Standards%20Compliance~DMEPOS%20Supplier%20Standards~7GLS7Z1267
 - » CMS-855S Enrollment Application
 - » Licensure Database – A guide to product category licensure requirements by state. (Visit NSC website, search under Licensure Database.)
 - » The following links may be helpful:
 - NSC site visits: www.palmettogba.com/palmetto/providers.nsf/DocsCat/National-Supplier-Clearinghouse~7GNSDY3705
 - Potential documentation requested during NSC site visit: www.palmettogba.com/palmetto/providers.nsf/DocsCat/National-Supplier-Clearinghouse~7GLS773440

- Supplier enrollment basics: www.palmettogba.com/palmetto/providers.nsf/Docs/Providers~National%20Supplier%20Clearinghouse~Supplier%20Enrollment
 - Durable Medical Equipment-Medicare Administrative Contractor (DME-MAC) – Supplier standards manuals/documentation requirements/Product category information/training presentations/claims processing:
 - » Noridian Healthcare Solutions – Jurisdictions A and D
 - Jurisdiction A – (CT, DC, DE, MA, MD, ME, NH, NJ, NY, PA, RI, VT)
 - Jurisdiction D – (AK, AS, AZ, CA, GU, HI, IA, ID, KS, MO, MP, MT, ND, NE, NV, OR, SD, UT, WA, WY)
 - » CGS – Jurisdictions B and C
 - Jurisdiction B – (IL, IN, KY, MI, MN, OH, WI)
 - Jurisdiction C – (AL, AR, CO, FL, GA, LA, MS, NC, NM, OK, PR, SC, TN, TX, VA, VI, WV)
 - Medicare Enrollment Information (after accreditation is awarded):
 - » Suppliers are required by the NSC to obtain/maintain a Medicare Billing number by submitting or updating a Medicare Enrollment Application (also known as the CMS-855S). Please contact the NSC for more information about the CMS-855S form. Call the toll-free phone number 1-866/238-9652 from 9 AM until 5 PM EST to reach a customer service representative. The automated response system is available 24 hours a day.
 - Competitive Bidding Program:
 - » The DMEPOS competitive bidding program is designed to help lower out-of-pocket costs and improve access to certain high-quality DMEPOS products for Medicare beneficiaries. The competitive bidding program was mandated through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 through a statute that requires Medicare to replace its fee schedule with a competitive bid process.
 - » The competitive bid payment amounts are determined by using bids submitted by DMEPOS suppliers. The intent of the competitive bidding program is to set more appropriate payment amounts for DMEPOS items, which will result in reduced beneficiary out-of-pocket expenses and savings to taxpayers and the Medicare program.
 - » To participate in the Medicare DMEPOS competitive bidding program, suppliers must be accredited by a CMS-approved accreditation organization, meet licensing requirements, and, if applicable, get bonded. Additional requirements may apply.
 - » Information about the competitive bidding changes frequently. For up-to-date information, including the bidding timeline and rules, user guides, frequently asked questions, and policy fact sheets and checklists, please visit the Competitive Bidding Implementation Contractor (CBIC) website at www.dmecompetitivebid.com/palmetto/cbic.nsf/DocsCat/Home.
 - Pharmacy Accreditation Exemption:
 - » As of January 1, 2011, pharmacies that meet certain criteria may file an accreditation exemption statement with the National Supplier Clearinghouse (NSC) to seek exemption from the DMEPOS accreditation requirement. Pharmacy exemption information can be found on the NSC website.
 - » The NSC recommends that “you continue accreditation until you have received notice of acceptance of your accreditation exemption statement from the NSC” because “if you are no longer accredited and do not qualify for the exemption, your Medicare billing privileges will be revoked.”
-  **Note:** DMEPOS accreditation is required to participate in the DMEPOS Competitive Bidding Program and the Mail Order Competition for diabetic testing supplies.
- » NABP is not involved in the pharmacy exemption process and questions regarding pharmacy exemption should be directed to the NSC.

Appendix B: DMEPOS Abbreviations

Medicare Abbreviations

ADR	Authorized Distributor of Record
AOB	Assignment of Benefits
BAA	Business Associate Agreement
BoP	Boards of Pharmacy
CAP	Corrective Action Plan
CBIC	Competitive Bidding Implementation Contractor
CMN	Certificate of Medical Necessity
CMS	Centers for Medicare and Medicaid Services
CMS855S	Medicare Enrollment Application (to obtain number for billing DME)
DIF	DME Information Form
DME/DMEPOS	Durable Medical Equipment Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
DME-MAC	Durable Medical Equipment Medicare Administrative Contractor
DWO	Detailed Written Order
FWA	Fraud, Waste & Abuse
HCPCS	Healthcare Common Procedure Coding System
HIPAA	Health Insurance Portability & Accountability Act
HR	Human Resources
ICD-10	International Classification of Diseases 10th Edition
LOA	Letter of Agreement
MMA	Medicare Modernization Act (of 1999)
NABP	National Association of Boards of Pharmacy
NSC	National Supplier Clearinghouse
OSHA	Occupational Safety and Health Administration
P&Ps	Policies and Procedures
PECOS	Provider Enrollment, Chain & Ownership System
USP	US Pharmacopeia
WOPD	Written Order Prior to Delivery
5EO	5 Element Order

NABP Specific Abbreviations

BCP	Beneficiary Complaint Process
COJD	Compliance Officer Job Description
CP	Compliance Plan
CSP	Consumer Services Plan
DCP	Disaster or Crisis Plan
DRIA	Documentation Requirements/Intake and Assessment
EMP	Equipment and Item Management Plan
FMA	Financial Management Affidavit
IAR	Incident or Adverse Reaction Investigations Plan
IMHC	Information Management and HIPAA Compliance
LIC	Licensure
MBP	Medicare Billing Plan

ORG	Organizational Chart
PAA	Product Authentication Affidavit
PAP	Product Authentication Plan
PCS	Product Category Specific Policies and Procedures
PFL	Personnel File List
PMP	Performance Management Plan
PRD	Patient Receipt of DMEPOS Delivery and Set-Up
SJD	Staff Job Description
TBC	Training/Instruction to Beneficiary/Caregiver and Follow-Up
TPE	Training Personnel for Equipment Set-Up & Beneficiary Training
TPG	Training Personnel General
TPS	Technician Policy/Scope
VAP	Vendor Authentication Plan
VAWD®	Verified-Accredited Wholesale Distributors®
VDIP™	Verified-Accredited Device Integrity Program™
VIPPS®	Verified Internet Pharmacy Practice Sites®
VPP	Verified Pharmacy Program®
VLD	Vendor List DME

Appendix C: NABP Product Category Checklist (Sample)

DMEPOS Accreditation

Product Category Checklist:

Canes and Crutches

Guidelines and Instructions

This checklist contains information and product specific service requirements necessary to obtain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation for this product category.

The National Association of Boards of Pharmacy® (NABP®) requires a policy and procedure (P&P) to detail how your pharmacy will serve Medicare beneficiaries in accordance with the Centers for Medicare and Medicaid Services (CMS) Quality Standards and Medicare requirements. Additional forms and/or documents may be submitted to support the P&P.

Groups or Chains: If not all facilities need to be DMEPOS accredited for this category, please list which facilities (store number, city and state) will need to be accredited.

Instructions: Use the checklist below to create a P&P for the product category. The P&P should include all information outlined in the checklist along with any other information deemed necessary to meet your pharmacy's business and operational needs. Pharmacy staff should be trained on the P&P and it should be kept with your DMEPOS accreditation materials. See "Additional Information" at the end for more information.

Product Category Checklist

Products

- Description of products and accessories/supplies that will be billed
- Healthcare Common Procedure Coding System (HCPCS) codes and descriptions
- Filling frequency for each type of item, accessory or supply
- Specific diagnoses for which this category may be billed

Employees

- Specific employees to handle this category (by name, or title such as all pharmacists)
- Indication in employee job descriptions regarding DMEPOS or specific categories
- Specific training for employees that includes:
 - Specific types and features of products
 - Appropriate selection of product for patient
 - How to adjust to appropriate height and use for the individual patient
 - Any accessories such as handles, tips, etc
- Patient training materials in use of product
 - May use information included in product packaging



NATIONAL ASSOCIATION OF BOARDS OF PHARMACY
1600 Feehanville Drive, Mount Prospect, IL 60056
(P) 847/391-4539 • (F) 847/375-1795
www.nabp.pharmacy • dmepos@nabp.pharmacy

The content of this document is intended to be used as a guide and is not intended to be used as legal advice. The information presented is subject to change and it is the responsibility of the pharmacy to comply with all current CMS eligibility, documentation, and billing requirements, along with state and federal regulations and licensure requirements.

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DMEPOS Product Category Checklist: Canes and Crutches

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Intake forms

- Includes any limitations to using the DME
- Specific documentation needed for other than standard cane or crutch (height, weight, severe neurologic disorder or other condition causing the restricted use of one hand, etc)

Order

- May be provided to the patient on a dispensing order, may not be billed to Medicare until a detailed written order (DWO) is received and complete
- DWO required that includes:
 - Beneficiary's name
 - Medicare provider's (physician, etc) name
 - Date of the order and the start date, if start date is different from the date of the order
 - Detailed description of the item(s)
 - Frequency of testing
 - Quantity to be dispensed
 - The number of refills
 - Provider signature and signature date

Additional information

- The patient has a mobility limitation that significantly impairs his/her ability to participate in one or more mobility-related activities of daily living in the home; and
- The patient is able to safely use the cane or crutch; and
- The functional mobility deficit can be sufficiently resolved by use of a cane or crutch.
- It is expected that the patient's medical records will reflect the need for the care provided. These records are not routinely submitted but must be available upon request. Therefore, while it is not a requirement, it is a recommendation that suppliers obtain and review the appropriate medical records and maintain a copy in the beneficiary's file. Record to include:
 - Beneficiary's diagnosis and prognosis
 - Duration of beneficiary's medical condition
 - Clinical course (worsening or improvement)
 - Nature and extent of functional limitations
 - Other therapeutic interventions, results, past experience with related items
- Method to record the make and model of the equipment provided

Setup of DME and training of beneficiary/caregiver

- When picked up by patient or caregiver
 - Who will train patient?
 - Training and setup to include:
 - ◇ Adjusting cane for height of patient, and crutches for height and hand grip
 - ◇ How to use
 - ◇ Maintenance and cleaning
 - ◇ What to look for: hazards, errors, malfunctions



DMEPOS Product Category Checklist: Canes and Crutches

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- ◇ Reporting to pharmacy or provider
- ◇ Copies of training materials used
- Documentation of training
- In residence when delivered/sent
 - Who will train patient?
 - Training and setup to include:
 - ◇ Adjusting cane for height of patient, and crutches for height and hand grip
 - ◇ How to use
 - ◇ Maintenance and cleaning
 - ◇ What to look for: hazards, errors, malfunctions
 - ◇ Reporting to pharmacy or provider
 - ◇ Copies of training materials used
 - Documentation of training

Refill requests

- If additional accessories are needed (worn tips, grips, etc), the frequency of replacement and how it's documented

Follow-up

- May be patient driven

Additional Information

1. Suppliers should refer to the Medicare DMEPOS Supplier Standards and the CMS DMEPOS Quality Standards when creating the product specific P&P. A DMEPOS Quality Standards booklet available on the CMS website provides tips and additional information to further your understanding of the DMEPOS quality standards. When referring to the CMS DMEPOS quality standards, please note that certain product categories have additional requirements:
 - a. Appendix A: Respiratory Equipment, Supplies, and Services
 - b. Appendix C: Custom Fabricated and Custom Fitted Orthoses, Prosthetic Devices, External Breast Prostheses, Therapeutic Shoes and Inserts, and Their Accessories and Supplies; Custom-Made Somatic, Ocular, and Facial Prostheses
2. When adding a product category, the CMS-855S form for each facility on file at the National Supplier Clearinghouse (NSC) will need to be amended with any product category updates. Please await confirmation from NABP that the product has been added or removed to your accreditation prior to updating your CMS-855S.
3. Suppliers are responsible for understanding the requirements pertaining to the products and services for which they bill to Medicare Part B. Please contact the NSC or your DME Medicare Administrative Contractor (DME-MAC) for information on specific items each category contains or other billing questions. The product manufacturer may also provide product category information that may be of assistance in the procedure.



DMEPOS Product Category Checklist: Canes and Crutches

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4. Please ensure the pharmacy is in compliance with licensure requirements if requesting new product categories. The NSC website, www.palmettogba.com/nsc, provides some licensure information via their licensure directory. However, licensure requirements vary, so please check with your state and local governments to ensure the appropriate licenses required for your pharmacy operation have been obtained.
5. The pharmacy should be familiar with the Competitive Bidding Programs of their service area. For up-to-date information, including fact sheets and frequently asked questions, please visit the website of the Competitive Bidding Implementation Contractor (CBIC) at www.dmecompetitivebid.com/palmetto/cbic.nsf/DocsCat/Home. These CBIC website resources serve both contract suppliers and non-contract suppliers.

Please direct questions to DMEPOS staff via email at dmeupos@nabp.pharmacy or by telephone at 847-391-4539.



Appendix D: Appeals Process

DMEPOS Appeals Procedure

This document sets forth key components of the process for DMEPOS suppliers to appeal the NABP decision to either deny accreditation or temporarily suspend a DMEPOS supplier from the accreditation program. This document is for review purposes only and is not binding upon NABP or the DMEPOS supplier. The official DMEPOS Appeals Procedure is incorporated into the DMEPOS Letter of Agreement, which will be provided by NABP upon request.

Procedure

1. In the event that NABP denies initial accreditation to a DMEPOS supplier or temporarily suspends a DMEPOS supplier from the accreditation program, the DMEPOS supplier may appeal the decision of NABP.
2. Provided all fees and expenses invoiced by NABP have been paid, the DMEPOS supplier may file a written Notice of Appeal with the Executive Director/Secretary of NABP within thirty (30) days of the date of the notice of denial or temporary suspension. Such Notice of Appeal shall set forth the specific facts supporting the grounds on which the appeal is based.
3. The DMEPOS supplier agrees to submit with its Notice of Appeal the then-current administrative fee for the appeal hearing. Any costs incurred to convene the DMEPOS Appellate Commission and host the hearing will be invoiced to the DMEPOS supplier.
4. If the written Notice of Appeal and required fee payment are not received by NABP within the designated time period, the temporary suspension converts to disqualification from the DMEPOS accreditation program with no further rights to internal appeal, and the Letter of Agreement shall be terminated.
5. Not more than sixty (60) days from receipt of a Notice of Appeal, NABP shall convene the DMEPOS Appellate Commission, which shall consist of the Chairman, President, and President-Elect of NABP.
6. As part of the DMEPOS supplier's appeal, the DMEPOS supplier may request an audit of its compliance with DMEPOS Accreditation Program Criteria and/or the Letter of Agreement. If the DMEPOS supplier requests an audit, an additional fee shall be submitted that will be applied to the costs of performing the audit. The DMEPOS supplier agrees to pay the then-current audit fee, including any on-site survey fee, as defined by NABP policy. NABP agrees to conduct such an audit at the DMEPOS supplier's expense. A written report of the audit findings will be provided to the DMEPOS supplier, NABP, and members of the Appellate Commission.
7. Unless otherwise agreed by the parties, the Appellate Commission shall set a date, time, and place for a hearing on the appeal not more than sixty (60) days from the date of the convening of the Appellate Commission, or the date after the audit is concluded, whichever may be applicable.
8. NABP and the appealing party shall have the right to representation by counsel throughout the appeal procedure.



9. Failure of the appealing party to pay all of the Appellate Commission's reasonable expenses and, as applicable, audit fee, in full, within seven (7) days of the date of the bill or invoice, shall result in termination of the appeals procedure, disqualification of the appealing party from the DMEPOS program, and termination of the Letter of Agreement.
10. In the event that any person designated as a member of the Appellate Commission shall be disqualified or shall refuse or be unable to serve for any reason at any time, an alternate member shall be selected by the remaining members of the Appellate Commission. The member's service and affiliation with NABP, the NABP Executive Committee, and the Appellate Commission shall not be grounds for disqualification based upon claims of conflict of interest, bias, or the like.
11. Unless otherwise agreed to by the parties not less than ten (10) days before the hearing, the appealing party and NABP shall present written statements of their respective positions to the Appellate Commission.
12. Each party may present evidence at the hearing.
13. Unless otherwise agreed to by the parties, closing arguments shall be submitted to the Appellate Commission within fourteen (14) days of the conclusion of the hearing.
14. Within an additional sixty (60) days thereafter, the Appellate Commission shall render a decision:
 - a. To affirm the decision of NABP;
 - b. To reverse the decision of NABP and not disqualify the DMEPOS supplier from the DMEPOS program;
 - c. Continue the suspension of the DMEPOS supplier's accreditation and establish requirements for reinstatement of accreditation; or
 - d. Take the action the Appellate Commission deems appropriate based upon its findings.
15. The Appellate Commission shall convey its findings and decision to the Executive Director/Secretary of NABP, who will prepare a written report, on behalf of the Appellate Commission, setting forth the Commission's findings and decision. The Executive Director/Secretary will provide a copy of the report to the Appellant, Appellate Commission members, and NABP counsel.
16. The decision of the Appellate Commission, as ratified by the NABP Executive Committee, is final.
17. The DMEPOS supplier has no further rights to internal appeal after the Appellate Commission has rendered a decision.



Appendix E: DMEPOS Policy and Procedure Structure (Sample)

DMEPOS Accreditation Policy & Procedure Structure – Sample Only –

Pharmacy Name/Address:	Policy & Procedure Number: <i>If applicable</i>
Title:	Effective Date:
	Review Date:
Pages:	Revision Date:
Staff or Manager: (Name)	Approved by: (Name)

Purpose

Write a sentence or two describing why the policy and procedure is in place and what it establishes for your pharmacy.

- Note: Creating a “purpose” is optional. It is acceptable to delete the “purpose” and only write a policy and procedure.

Policy

Write a sentence or two to describe what the policy establishes for your pharmacy. A policy provides clear communication to your pharmacy employees on the pharmacy’s expectations regarding a given topic. It is the measure to which they will be held accountable and in compliance.

Procedure

This is the process for pharmacy staff to follow to be in compliance with the policy statement listed above. A good procedure plainly details the process step-by-step. It establishes the methods needed to ensure consistency in the pharmacy’s operation.

The above policy and procedure structure is provided by the National Association of Boards of Pharmacy® DMEPOS Accreditation Program as a sample only.

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