National Association of Boards of Pharmacy® (NABP®)  
Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)  
POLICY & PROCEDURE LIST

The following is a summary of the base policies and procedures required for the DMEPOS Accreditation through NABP in reference to the P&P Assessment. After your online application is submitted, NABP will send a Policy & Procedure Assessment (P&P Assessment) to help you prepare the required documentation. The required documentation must be submitted within 60 days. NABP will review the materials to confirm compliance with NABP program standards and the CMS Quality Standards prior to moving to the survey stage.

<table>
<thead>
<tr>
<th>Section I: Supplier Business Service Requirements</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>A: Administration</strong></th>
</tr>
</thead>
</table>
| **Applicant Item**  
(Materials/Documents,  
unless noted "applicant process") | **Description** |
| **Pharmacy Organizational Chart (ORG)**  
(continued on next page) | - 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.  
  - 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 non-pharmacist personnel and/or delivery staff. |
| **Vendor Authentication Plan (VAP)** | - Vendor authentication includes the process to verify a vendor licensure with appropriate state or federal agency, screen against the 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)** | - 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 of relevant federal and state laws,
  - In-house training on state law,
  - Continuing education of staff,
  - Procedures for internal monitoring and auditing. Detail consistent enforcement of standards.

- Document records of compliance efforts (e.g., 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’s 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 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; process should address:  
- Coverage,  
- Copay,  
- 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,  
- 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,  
- 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** | 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 |
| **Staff Job Description (SJD)** (continued on next page) |
| Personnel file list (PFL) | • Personnel files and the location of these (hard copy on-site, electronic, etc.) should include:
  o Application or resume (with education and work history),
  o Current Credentials Posted (license, registration, certificate on, etc.) and
  o Documentation of verification of these credentials
  o Results of Background checks and/or drug testing (if required by the state),
  o Screening against exclusion list documentation,
  o Performance evaluations (including competency assessments),
  o Disciplinary processes,
  o Evidence that job descriptions were reviewed by the employee, and
  o Training records |
| Training personnel general (TPG) | • General training includes:
  o Orientation and job position specific training,
  o HIPAA,
  o OSHA (blood borne pathogen or hazardous/infectious waste handling),
  o Fraud, Waste, and Abuse,
  o Medicare intake and billing (including Medicare Quality and Supplier Standards) |
| Training personnel for Equipment set-up & beneficiary training (TPE) | • Product category specific training including:
  o product details and features,
  o set-up and adjustment,
  o maintenance and cleaning,
  o 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 | • This includes verifying licensure directly with the licensing agency (initial and ongoing), and
  • Screening against Medicare exclusion lists such as OIG (initial and ongoing). |
| **Training/Instruction to Beneficiary/Caregiver and Follow-Up (TBC)** | - Process to provide clear written AND oral instructions to beneficiaries including content |
| **Patient Receipt of DMEPOS, Delivery and Set-Up (PRD)** | - Patient Receipt of DMEPOS which includes:  
  o Providing a wait time or delivery time,  
  o 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)** | - Providing information to the beneficiary regarding:  
  o right to purchase or rent (including capped rental information),  
  o information on contacting the supplier 24/7 (including after hours and emergency contact information),  
  o process to follow if the supplier is not able to provide the DME |
| **Beneficiary Complaint Process (BCP)** | - Beneficiary complaint reporting, response, and notification [CMS Consumer Services Quality Standard]:  
  o 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.  
  o Within five days of receipt of the complaint/concern, pharmacy shall notify beneficiary of receipt of the complaint and that an investigation is underway.  
  o Within 14 days of receipt of complaint/concern, pharmacy shall provide written notification and result of investigation and response.  
  o Shall maintain documentation of all complaints, investigative documents, and responses to beneficiaries for seven years from the date of service.  
  o May provide sample forms and surveys used for complaint reporting and customer satisfaction. |
| **E: Performance Management** | - 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:  
    o Copies of satisfaction surveys and patient complaint forms  
    o Orientation programs  
    o Policy and procedure manuals  
    o Competency assessments  
    o 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;
- 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?

- Identify 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 in general storage, refrigerator and freezer according to USP guidelines, and plan of action is in place to assess integrity of products if an excursion is detected.  
• Process for returned rental equipment that includes segregation from clean equipment, cleaning and testing/calibrating to ensure appropriately functioning, identifying and monitoring for defect, malfunction, or failure and procedure for maintaining and repairing equipment under warranty or rented. |
| Product Authentication Plan (PAP) | Process to visually inspect product upon receipt for damage, unusual packaging or labeling and not allowing the items to be placed into active stock, restrict ordering to authenticated vendors,  
• Maintain invoices or other records identifying the source of DME products,  
• Process for handling specially marked products (restricted sale or restricted use), removing short-dated and expired product from active stock, recall handling 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) (continued on next page) | Applicant is required to submit a copy of a disaster/contingency plan.  
• The plan should detail how operations will be maintained and 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.  
  o 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 in which the area may be susceptible (e.g., tornadoes, earthquakes, hurricanes, or blizzards). The contingency plan should include:  
  o Continuity of patient care/services  
  o 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 with their organizations; hence, it was not necessary to develop the required plan.

### NABP Product Safety 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
- Process to maintain accurate and pertinent:
  - Patient records,
  - Confidentiality of records,
  - HIPAA policy and agreements in place, and
  - Provide NPP to patients.

### Section II: Supplier Product Specific Service Requirements
- 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, 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
- Beneficiary documentation which includes:
  - Patient profile information,
  - Information from patient that would affect the use of the DME (allergies, blindness, severe arthritis),
  - Specific information needed on the DWO/WOPD,
- 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
- 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 for blood glucose testing equipment or supplies (or other items as required by the region), a process 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)

<table>
<thead>
<tr>
<th>Training/Instruction to Beneficiary and/or Caregiver(s) and Follow-Up (TBC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Provide or coordinate the provision of appropriate information related to the setup, features, routine use, troubleshooting, cleaning, and maintenance of the DMEPOS items provided.</td>
</tr>
<tr>
<td>• Advise the beneficiary and caregiver about appropriate safety considerations.</td>
</tr>
<tr>
<td>• Provide relevant information and/or instructions about infection control issues related to the use of equipment/items.</td>
</tr>
<tr>
<td>• Record in the beneficiary’s record that such instruction was provided.</td>
</tr>
<tr>
<td>• Training shall commensurate with the risks, complexity, and manufacturer’s instructions and/or specification for items.</td>
</tr>
<tr>
<td>• Tailor training and instruction materials and approaches to the needs, abilities, learning preferences, language, and readiness to learn of individual beneficiaries/caregivers.</td>
</tr>
<tr>
<td>• May provide checklists and forms use to educate in order to verify compliance with this standard.</td>
</tr>
</tbody>
</table>

### D: Follow-up

<table>
<thead>
<tr>
<th>Training/Instruction to Beneficiary and/or Caregiver(s) and Follow-Up (TBC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Follow up is provided appropriate to the DME product category.</td>
</tr>
<tr>
<td>o May be patient, pharmacy or physician driven.</td>
</tr>
<tr>
<td>• Would include how refills are handled including appropriate documentation of remaining quantities to determine if supply is nearing exhaustion.</td>
</tr>
</tbody>
</table>

**September 2015**

Please contact Jody Barry, Accreditation Manager, at dmepos@nabp.net or 847/391-4484 with any questions.

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.