National Association of Boards of Pharmacy (NABP)
Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)
Accreditation Program

Frequently Asked Questions

1. What is the NABP DMEPOS Accreditation Program?
It is an accreditation program offered by NABP for licensed pharmacies that distribute certain DMEPOS products and services (listed in Question #9 below) and bill Medicare for these products and services. The NABP DMEPOS Accreditation Program is approved by the US Department of Health and Human Services Center for Medicare and Medicaid Services (CMS).

2. Is DMEPOS accreditation mandatory?
Yes, for Medicare. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 mandates that the Secretary of Health and Human Services issue a final rule requiring accreditation and competitive bidding for entities providing DMEPOS, diabetes, and Part B supplies and services.

3. Must I obtain accreditation to acquire or retain my Medicare Part B supplier billing number?
Yes.

4. What happens if my pharmacy does not obtain accreditation?
Your pharmacy will not be able to competitively bid for DMEPOS products and will not be eligible for reimbursement by Medicare for DMEPOS supplies and services.

5. Competitive bidding is scheduled to begin in 2007. Do I have to obtain accreditation by January 1, 2007 to continue billing Part B for DEMPOS supplies and services?
No, but some bidding suppliers will have to obtain accreditation in 2007, others in 2008, and the rest by 2010. Only suppliers from the 10 Metropolitan Statistical Areas (MSAs) selected in 2007 and participating in the competitive acquisition program are required to obtain accreditation, by a yet-to-be determined date in spring 2007. For those suppliers in the first 10 MSAs, to be considered as a bidder, your pharmacy must be accredited by a CMS approved accreditation organization. Bidding suppliers located in the top 10 MSAs will be prioritized by the accreditation organizations.

5a. What are Metropolitan Statistical Areas (MSAs) and how are they determined?
MSAs are ranked in terms of general population, then scored by the greatest number of suppliers and allowed charges per beneficiary. CMS will select the MSAs. The MSAs that were proposed in the NPRM are:

- Charlotte-Gastonia-Concord, NC-SC
- Dallas - Fort Worth – Arlington, TX

- Riverside – San Bernadino – Ontario, CA
- Pittsburg, PA
- Kansas City, MO-KS
- Cincinatti – Middleton, OH – KY – IN
- San Juan – Caguas - Guaynabo, PR
- Cleveland – Elyria – Mentor – OH
- San Francisco – Oakland – Fremont, CA
- Atlanta – Sandy Springs – Marietta, GA
- Houston – Baytown - Sugarland, TX
- Detroit – Warren – Livonia, MI
- Seattle – Tacoma – Bellevue, WA
- Baltimore – Towson, MD
- Philadelphia – Camden - Wilmington, PA- NJ – DE – MD
- Phoenix – Mesa – Scottsdale, AZ
- Boston – Cambridge – Quincy, MA-NH
- Tampa, St. Petersburg- Clearwater, FL

6. When is my pharmacy required to be accredited?

The Center for Medicare and Medicaid Services (CMS) will select 10 MSAs in 2007 and 80 MSAs in 2008. The first round will exclude New York, Los Angeles, and Chicago. NABP will prioritize applications from pharmacies located in the first 10 MSAs, which, as of December 19th, had not yet been identified by CMS. However, CMS did inform all the accrediting organizations on December 18th to begin with DME suppliers in Miami, FL. All DMEPOS suppliers, including non-bidding suppliers, must obtain accreditation sometime before January 1, 2010.

7. Who is eligible to apply for NABP's DMEPOS accreditation?

NABP's DMEPOS accreditation program is targeted specifically to suppliers who possess a current valid state pharmacy license ***and*** who distribute the DMEPOS products and services listed in question #9 below.

8. What are my options if my pharmacy carries products or provides services in addition to those listed in question #9 below?

Such pharmacies may still apply for accreditation with NABP. NABP will establish and maintain relations with other accreditation agencies that have an accreditation focus in areas other than our own. NABP will coordinate with other agencies to complete the accreditation process with these other applicable accreditation agencies.

9. What products has CMS approved for NABP accreditation?

a. Diabetic equipment and supplies, such as:
   - Blood glucose strips;
   - Lancets;
   - Lancet devices;
   - Batteries – replacement;
   - Control solutions;

- Blood glucose monitors;
- Other complementary and related products associated with this group code.

b. Enteral and parenteral nutrients, equipment, and supplies.

c. Orthotics:
- Off-the-shelf orthotics, which are orthotics described in section 1861(s)(9) of the Act that require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit a beneficiary;
- Therapeutic shoes and inserts;
- Other non-custom, off-the-shelf and minimally adjustable orthotic items and supplies.

d. Mobility aids that are non-custom and require minimal assistance or self-adjustment:
- Standard walkers;
- Wheeled walkers;
- Crutches;
- Canes;
- Commode chairs stationary fixed;
- Other complementary and related products associated with this group code.

e. Wound care supplies that are non-custom and are generally purchased off-the-shelf, such as:
- Ostomy skin-barrier items and supplies;
- All A codes in ostomy category;
- Collagen-based wound fillers;
- Collagen dressings;
- Code surgical dressing category: tape, gauze pads, hydrocolloid dressing, hydrogel dressing, skin sealant, eye pads, conforming bandages, compression bandages, elastic bandages;
- Other complementary and related products associated with this group code.

f. Urological supplies that are non-custom and are generally purchased off-the-shelf, such as:
- Bedpans;
- Urinals;
- Urinary catheters;
- Incontinence appliances and supplies;
- Other complementary and related products associated with this group code.

g. Medical supplies that are purchased off-the-shelf, such as:
- Heat/cold applications;
- Compression stockings;

- Other complementary and related product associated with this group code.

h. Respiratory – non-custom, off-the-shelf products and supplies:
- Nebulizers;
- Mouthpieces;
- Tubing administration kits;
- Continuous positive air pressure (CPAP) supplies such as, masks humidifiers, head gear, full face masks;
- Other complementary and related products associated with this group code.

10. What is the cost for DMEPOS accreditation?

Single Pharmacy (small supplier)	
New Application Fee (2007)	$345
Annual Participation Fee (2008)	$150
Annual Participation Fee (2009)	$150
NABP Survey*	$1500
Total 3 year cost	$2,145

*Assumption: One surveyor/survey/day

Contact NABP at dmepos@nabp.net for additional information.

11. How do I apply for NABP's DMEPOS accreditation?

Your pharmacy will be able to apply online at NABP's Web site, *www.nabp.net*, as of January 16, 2007.

12. What are the steps required for a pharmacy to become DMEPOS accredited?

- The pharmacy submits an application to NABP along with the required documentation and the specified fee.
- NABP staff verifies pharmacy and appropriate staff licenses.
- NABP staff checks the NABP Disciplinary Clearinghouse for any disciplinary information regarding the facility or pharmacist-in-charge.
- NABP staff evaluates the application, supporting documents, and sample documentation against the CMS Quality Standards.
- Following the documentation review process, NABP communicates with the applicant to request any outstanding documents not submitted with the application, request revisions to any documents that did not meet the Standards, and, if applicable, inform the supplier that NABP will conduct an unannounced, on-site survey.
- NABP conducts an unannounced survey during normal business hours. Refer to question #16 below for specifics regarding the survey process. For applicant pharmacies that carry related products or provide services in addition to those listed in question #9 above, NABP will conduct, whenever practical, concurrent surveys by NABP and other applicable agencies to best meet the needs of CMS, the pharmacy, and NABP.

Please note that if NABP receives information indicating that there is a serious issue of non-compliance with the applicable Standards, NABP may initiate a procedure to deny accreditation to the applicant prior to conducting a survey.

13. Do I need a manual in order to become accredited by NABP?

A manual, per se, is not required. However, all supporting documentation requested with the application must be submitted to NABP for review. NABP believes the pharmacy should have flexibility in crafting a product that suits its needs while at the same time provides NABP with the necessary information to ensure the pharmacy is in compliance with the CMS Quality Standards.

14. What is the time frame for the accreditation process?

NABP's goal is to complete the DMEPOS accreditation process within 30 to 45 calendar days; however, this is dependent on the submitted application materials and operation of the DMEPOS pharmacy. Providing NABP with a complete application and all accompanying documentation will expedite the process.

15. How long is the DMEPOS accreditation valid?

The DMEPOS accreditation is valid for three years. Accredited suppliers will submit a renewal application to NABP every three years. During the three-year cycle, NABP will monitor accredited facilities on an annual basis by: addressing beneficiary complaints, conducting pharmacy and pharmacist disciplinary screenings through our current national Clearinghouse Database, using self-assessment instruments, requiring the suppliers to conduct evaluation surveys of beneficiaries that will be forwarded directly to NABP, and conducting unannounced surveys of suppliers as part of the accreditation process. Unannounced surveys may also be conducted when the accredited facility is suspected of not complying with the CMS standards, or violation of state and/or federal laws,

16. How often will surveys be performed?

NABP conducts an unannounced survey of the accredited DMEPOS-pharmacy once every three years, in accordance with the following comprehensive schedule, to review, evaluate, and monitor the pharmacy supplier, its performance, and compliance with CMS Quality Standards. 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 prompt an announced on-site survey at other times.

A. Class I – Independent Community DMEPOS-pharmacy supplier: State License Approved or Renewed and State Board of Pharmacy Inspection Conducted within the Prior 12 Months

a. Review of application and submission materials for the DMEPOS-pharmacy supplier.

b. Review of state board of pharmacy report for applicability of compliance to CMS Quality Standards.

c. If the pharmacy is in compliance with CMS Quality Standards, NABP issues the accreditation and schedules an unannounced survey sometime during the three-year accreditation period.
d. If the pharmacy is not in compliance with CMS Quality Standards, NABP conducts an unannounced on-site survey prior to action on accreditation status.

B. Class II - Independent Community DMEPOS-pharmacy supplier: State License Inspection Greater than 12 Months or a New Pharmacy that has not yet been Inspected

a. Review of application and submission materials for the DMEPOS-pharmacy supplier.
b. Review of state board of pharmacy report, if available, for applicability of compliance to CMS Quality Standards.
c. Unannounced on-site survey, prior to action on accreditation status.

C. Class III – Community Chain (chain defined as four or more DMEPOS-pharmacy suppliers under common ownership) DMEPOS-pharmacy supplier

a. Review of application and submission materials for the DMEPOS-pharmacy supplier designated by the chain to provide DMEPOS.
b. On-site meeting with corporate chain personnel responsible for the DMEPOS-pharmacy suppliers designated by the chain to provide DMEPOS. *(Chain is responsible for the costs associated with this meeting.)*
c. Review of state board of pharmacy reports for applicability of compliance to CMS Quality Standards for the prior year for all DMEPOS-pharmacy suppliers designated by the chain to provide DMEPOS.
d. Review of policies and procedures, corporate quality control, and monitoring systems for the DMEPOS-pharmacy suppliers designated by the chain to provide DMEPOS.
e. Unannounced survey of representative sample and statistically valid number (determined by NABP) of DMEPOS-pharmacy suppliers within the chain designated to provide DMEPOS.

17. What is NABP's procedure for addressing disputes?

The Appeals Procedure is available on the NABP Web site at *www.nabp.net*, under "Accreditation Programs" > "DMEPOS" > "Appeals Procedure."

18. Where can I access the list of accredited DMEPOS pharmacies?

A list of accredited DMEPOS pharmacies is accessible on the NABP Web site at *www.nabp.net*, under "Accreditation Programs" > "DMEPOS" > "List of Accredited Pharmacies."

19. Whom can I contact at NABP regarding DMEPOS accreditation questions?
DMEPOS staff is available at dmepos@nabp.net to answer any questions for which you did not find an answer on our Web site.

20. Does NABP administer other types of accreditation programs?
The Verified Internet Pharmacy Practice Sites™ (VIPPS®) Program
Introduced in February 1999 and supported by the Food and Drug Administration (FDA), the voluntary Verified Internet Pharmacy Practice Sites™ (VIPPS®) program is designed to accredit an online pharmacy that is able to appropriately dispense pharmaceuticals to the public, is licensed in good standing by state boards of pharmacy, has passed a rigorous 18-point criteria review, and has successfully completed an on-site inspection.
The Verified-Accredited Wholesale Distributors® (VAWD®) Program
The Verified-Accredited Wholesale Distributors® (VAWD®) program, supported by the FDA, was established in 2004 to help protect the public from the threat of counterfeit drugs affecting the US drug supply. VAWD accreditation provides assurance that the wholesale distribution facility operates legitimately, is validly licensed in good standing, and is employing security and best practices for safely distributing prescription drugs from manufacturers to pharmacies and other institutions. Applicants for VAWD accreditation undergo a criteria compliance review, licensure verification, inspection, background checks, and screening through NABP's Clearinghouse.
More information regarding NABP's accreditation programs is available on NABP's Web site at *www.nabp.net*.

21. Why should my pharmacy select NABP as the DMEPOS accrediting organization?
NABP has over 100 years of regulatory and accreditation experience in pharmacy. NABP's DMEPOS accreditation services are founded on a long history of fostering uniform quality standards for the practice of pharmacy and the safe distribution of medicines and related supplies. Because of its close ties with pharmacy and its experience as an accrediting organization, accrediting DMEPOS suppliers is a natural extension of NABP's services. In addition to their regulatory expertise, NABP's staff members, several of whom are or have been practicing pharmacists, understand the licensing requirements of pharmacies and pharmacies' operations and resources. NABP staff works with pharmacies to streamline the process and provide for effective accreditation procedures.

22. What are NABP's responsibilities as an accrediting organization?
- Prioritize surveys for those suppliers in the 10 Metropolitan Statistical Areas (MSAs) that need to bid in late 2007.
- Prioritize surveys for those suppliers in the 80 MSAs that need to bid in early 2008.
- Consider any previous accreditation, certification, and/or licensure findings that indicate that DMEPOS quality standards are being met at the time the accreditation organization surveys the supplier.

- Use a streamlined process that considers only compliance with CMS' DMEPOS quality standards.
- Notify CMS, in writing, of any supplier that has had its accreditation revoked, withdrawn, revised, or any other remedial or adverse action taken against it by the accreditation organization within 30 calendar days of any such action taken.
- Notify all accredited suppliers within 10 calendar days of CMS' withdrawal of the organization's approval of deeming authority.
- Notify CMS, in writing, at least 30 calendar days in advance of the effective date of any proposed changes in accreditation requirements.
- Submit to CMS, within 30 calendar days of a change in CMS requirements, an acknowledgement of CMS' notification of the change, as well as a revised crosswalk reflecting the new requirements, and inform CMS about how the organization plans to alter its requirements to conform to CMS' new requirements.
- Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.
- Notify CMS, in writing, within 2 calendar days of a deficiency identified in any accreditation entity where the deficiency poses an immediate jeopardy to the entity's beneficiaries or a hazard to the general public.
- Provide, on an annual basis, summary data specified by CMS that relates to the past years' accreditations and trends.
- Attest that the organization will not perform any DMEPOS accreditation surveys of Medicare participating suppliers with which it has a financial relationship or interest.
- Conform accreditation requirements to changes in Medicare requirements.

Created: December 2006