

## National Association of Boards of Pharmacy® (NABP®) Home Infusion Therapy Pharmacy Accreditation Standards

A pharmacy seeking accreditation through NABP must meet or exceed the standards in each of the following areas: the accreditation standards (Section ACC), which are applicable for all NABP accreditation programs; the pharmacy standards (Section PHY), which are applicable to all NABP pharmacy accreditation programs; and the program specific standards for which the pharmacy is seeking accreditation.

The following is a summary of the standards required for an applicant who is seeking NABP Home Infusion Therapy Pharmacy Accreditation. This tool is to help provide a preview of the standards you can anticipate being required for accreditation.

SECTION ACC: ACCREDITATION STANDARDS		
ACC. A	General Qualifications	Topics include: <ul style="list-style-type: none"> <li>• Terms and conditions</li> <li>• Eligible Entity</li> <li>• Document submission</li> <li>• Business location</li> <li>• Financial management</li> <li>• Shared services/affiliates</li> <li>• Website</li> <li>• Professionalism/ethics</li> </ul>
ACC. B	Licensure	Topics include: <ul style="list-style-type: none"> <li>• Licensed</li> <li>• Scope</li> </ul>
ACC. C	Facility	Topics include: <ul style="list-style-type: none"> <li>• Facility requirements</li> <li>• Disaster plan, emergency preparedness, and recovery</li> </ul>
ACC. D	Personnel	Topics include: <ul style="list-style-type: none"> <li>• Responsible persons</li> <li>• Organizational structure and formal human resources management practices</li> <li>• Personnel qualifications prehire and ongoing</li> <li>• Training</li> </ul>
ACC. E	Compliance with Laws and Regulations	Topics include: <ul style="list-style-type: none"> <li>• General compliance</li> <li>• Disciplinary actions, criminal convictions, and civil settlements</li> <li>• Records</li> </ul>

ACC. F	Drug/Device Procurement, Storage, Distribution, Dispensing, and Delivery	Topics include: <ul style="list-style-type: none"> <li>• Procurement/source</li> <li>• Procurement/receiving</li> <li>• Controlled substances</li> <li>• Storage conditions</li> <li>• Inventory management, returns, and disposal</li> <li>• Distributions of prescription drugs/devices</li> <li>• Shipping, handling, and delivery</li> <li>• Outdated, returned, damaged, or suspect drugs/devices – quarantine process</li> <li>• Drug/device recalls</li> </ul>
ACC. G	Quality Improvement	Topics include: <ul style="list-style-type: none"> <li>• Program</li> </ul>
ACC. H	Policies and Procedures	Topics include: <ul style="list-style-type: none"> <li>• Policies and procedure requirements</li> </ul>
<b>SECTION PHY: PHARMACY STANDARDS</b>		
PHY. A	General Requirements	Topics include: <ul style="list-style-type: none"> <li>• Qualifications</li> </ul>
PHY. B	Facility	Topics include: <ul style="list-style-type: none"> <li>• Appropriate environment</li> </ul>
PHY. C	Personnel	Topics include: <ul style="list-style-type: none"> <li>• Staff requirements</li> </ul>
PHY. D	Compliance with Laws and Regulations	Topics include: <ul style="list-style-type: none"> <li>• Required reporting to state and federal agencies</li> <li>• Patient privacy</li> <li>• Co-location</li> </ul>
PHY. E	Prescription/Order Processing	Topics include: <ul style="list-style-type: none"> <li>• Information Technology</li> <li>• Review of Prescription/order</li> <li>• Drug Use Review</li> <li>• Accuracy of dispensing</li> </ul>
PHY. F	Patient Management	Topics include: <ul style="list-style-type: none"> <li>• Patient communications/counseling</li> <li>• Clinical references</li> <li>• Outcome measures</li> </ul>
PHY. G	Quality Improvement	Topics include: <ul style="list-style-type: none"> <li>• Incident reporting system</li> <li>• Adverse event management</li> <li>• Feedback</li> </ul>

**SECTION HIT: HOME INFUSION THERAPY PHARMACY STANDARDS**

HIT. A	Basis and Scope §486.500	CMS requirement for HIT accreditation
HIT. B	Definitions §486.505	CMS definitions, §§486.520 and 486.525
HIT. C	General Requirements	Topics include: <ul style="list-style-type: none"> <li>• Qualifications</li> <li>• Mission statement</li> </ul>
HIT. D	Sterile Compounding	Topics include: <ul style="list-style-type: none"> <li>• General sterile compounding requirements, including meeting USP &lt;797&gt;, &lt;800&gt;, and Food, Drug, and Cosmetic Act's Section 503A</li> <li>• Policies and procedures</li> <li>• Personnel and training</li> <li>• Facility</li> <li>• Compounding processes</li> <li>• Accountability</li> </ul>
HIT. E	Plan of Care (§486.520)	Topics include: <ul style="list-style-type: none"> <li>• Applicable provider</li> <li>• Individualized plan of care</li> <li>• Periodic review of plan</li> </ul>
HIT. F	Initial Assessment (§486.525 (a)(1)).	Topics include: <ul style="list-style-type: none"> <li>• Medication reconciliation</li> <li>• Appropriateness of home setting</li> <li>• Written order</li> <li>• Drug Utilization Review</li> <li>• Pumps, ancillary drugs and supplies</li> </ul>
HIT. G	Professional Services/ Ongoing Assessment (§486.525 (a))	Topics include: <ul style="list-style-type: none"> <li>• 24/7 professional services, pharmacy and nursing</li> <li>• Patient and family/caregiver education</li> <li>• Remote monitoring</li> <li>• Ongoing assessments and care coordination</li> </ul>
HIT. H	National Standards (§486.525 (b))	Topics include: <ul style="list-style-type: none"> <li>• Policies and procedures related to national standards</li> <li>• Education and training of staff on national standards</li> <li>• National standards are retrievable</li> </ul>
HIT. I	COVID-19 vaccination of facility staff (§486.525 (c))	Topics include: <ul style="list-style-type: none"> <li>• Policies and procedures related to Vaccinations for COVID-19 for all staff</li> <li>• Infection prevention and control</li> <li>• Contingency plan for those not fully vaccinated</li> </ul>

Please contact program staff at [HomeInfusion@nabp.pharmacy](mailto:HomeInfusion@nabp.pharmacy) or 847/391-4539 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 state and federal regulations and licensure requirements.