

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

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management, returns, and disposal • Distributions of prescription drugs/devices • Shipping, handling, and delivery • Outdated, returned, damaged, or suspect drugs/devices – quarantine process • Drug/device recalls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

SECTION CPD: COMPOUNDING PHARMACY STANDARDS		
CPD. A	General Requirements	Topics include: <ul style="list-style-type: none"> • Qualification • Compliance • Mission statement • Record keeping • Inventory control • Anti-kickback statutes
CPD. B	General Compounding Requirements	Topics include: <ul style="list-style-type: none"> • Supervision • Scope of compounding services • Patient counseling • References • Quality improvement • REMS
CPD. C	Nonsterile Compounding	Topics include: <ul style="list-style-type: none"> • USP <795>, <800>, and Food, Drug, and Cosmetic Act 503A • Policies and procedures • Personnel and training • Facility • Compounding processes • Accountability
CPD. D	Sterile Compounding	Topics include: <ul style="list-style-type: none"> • USP <797>, <800>, and Food, Drug, and Cosmetic Act 503A • Policies and procedures • Personnel and training • Facility • Compounding processes • Accountability

Please contact program staff at compounding@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.