



Petition for Waiver


State of Iowa

Submitted On:

June 2, 2020 1:37pm

America/New_York

Licensee/Registrant Name	Northwind Pharmaceuticals, LLC
License/Registration No.:	5698
Address Autocomplete	4838 Fletcher Avenue, Indianapolis, IN, USA
Contact Person for Petition for Waiver	Sara Miller
Direct Phone Number for Contact Person	518-925-4678
Direct Email Address for Contact Person	compliance@nwpharma.com
List each rule you are requesting to be waived:	657-17.3 (155A) Wholesale Distributor license VAWD Accreditation requirement for Non Resident Wholesaler
Describe specifically which requirements you are requesting to be waived	VAWD Accreditation requirement for Non Resident Wholesaler for licensure. VAWD Accreditation is in process with NABP actively reviewing company documentation. VAWD Site Survey canceled due to COVID-19 national emergency.
Start Date	6 1 2020
End Date	12 31 2020
Have you previously requested a waiver of any of the rules listed above?	Yes
If so, what was the outcome?	Waiver granted. Extension required to due National Emergency. VAWD onsite survey canceled until further notice.
If a prior petition for waiver was granted or denied, attach a copy of the Board's prior written ruling or correspondence.	NABP Program Update in Response to COVID-19 Epidemic.msg RE Northwind Pharmaceuticals LLC Indianapolis IN - VAWD Survey Date.msg https://seam.ly/RUC7QyH6 https://seam.ly/3C8GSph1 https://seam.ly/RGqHJkku Iowa Petition for Waiver form .pdf
Explain why following the rule would pose an undue hardship:	Northwind Pharmaceuticals, LLC has been VAWD accredited from 2007 - 2019 at which time a change of location had resulted in a new application for VAWD. Northwind Pharmaceuticals is actively engaged with NABP for VAWD accreditation. Northwind Pharmaceuticals has also been licensed in the state of Iowa since 01/01/1998. The imposed rule would prevent Northwind Pharmaceuticals from shipping the medications to the entities to provide to the patients who require them.
Explain how waiving the rule may impact other people:	Waiving the VAWD requirement temporarily to provide the additional time for Northwind Pharmaceuticals to complete the VAWD accreditation process [which is on hold due to the COVID-19 National Emergency] which will ensure the patients are not impacted by the disruption in the

	medication supply.
Explain how the rule is intended to protect the public health, safety, or welfare:	The VAWD accreditation requirement is intended to ensure the every Wholesale Distributor maintains strict controls to protect the public health and well-being of the end user. The fact that Northwind Pharmaceuticals has been accredited for over ten years and been providing medications to customers in Iowa for over twenty years demonstrates Northwind Pharmaceutical's commitment to protecting the public health.
Explain how the public health, safety, or welfare can still be protected if the rule is waived:	Northwind Pharmaceuticals provides unit of use medications to customers that support the end user / patients. By waiving the VAWD rule, the patients within Iowa will have access to the unit of use medications to protect their health.
Have you spoken to a Board compliance officer or other member of Board staff about your request?	Yes
If so, who?	Sue Mears
Attach copies of any relevant email correspondence	https://seam.ly/oZlaDDWA NABP Program Update in Response to COVID-19 Epidemic.msg https://seam.ly/F1uLt4ua RE Northwind Pharmaceuticals LLC Indianapolis IN - VAWD Survey Date.msg
Do you plan to attend the Board meeting when this Petition will be considered?	No
Sign Here	Sara Miller compliance@nwpharma.com  Signed at: June 2, 2020 1:37pm America/New_York
Receipt	0000016

Sara Miller

From: vawd@nabp.pharmacy
Sent: Friday, March 13, 2020 9:43 AM
To: Northwind Compliance
Subject: RE: Northwind Pharmaceuticals, LLC, Indianapolis, IN - VAWD Survey Date
Attachments: VAWD Focus Items List_060719.pdf

Due to the COVID-19 (coronavirus) impact on business and travel in the United States, NABP onsite survey services may experience unexpected delays and/or cancellations. NABP will try its best to accommodate upcoming scheduled or unscheduled surveys, but must also ensure its staff and contractors are adhering to current CDC Guidelines and recommendations. If you prefer NABP postpone your upcoming survey, please reply to this email immediately. There will be no administrative fees applied and NABP will work on your request to postpone.

Dear Richard,

Your survey date of April 2, 2020 has been confirmed. A tentative agenda detailing the day's activities is provided below. Your facility's business model and size and unforeseen circumstances may necessitate initial and/or ongoing adjustments to the timeline; however, there will be an opportunity to discuss it with the surveyor during the Introduction meeting. If your facility knows of any transportation problems in the area that may impact the surveyor's ability to arrive on time to your facility, please let us know.

As a reminder, a list of documents to have available during the survey is provided here. This list was initially provided as Appendix A of the *Survey Process Guide*.

TENTATIVE AGENDA – VAWD SURVEY
April 2, 2020
Northwind Pharmaceuticals, LLC
4838 Fletcher Ave, Suite 1000, Indianapolis, IN 46203
Contact Name: Richard DeLeon
Phone Number: (317) 522-1637
VAWD Surveyor(s): Zach Roberts

Thursday, April 2, 2020

9:00 – 9:15 AM VAWD Surveyor arrive at Northwind Pharmaceuticals, LLC facility
9:15 – 9:30 AM Introduction meeting: Surveyor and assigned Northwind Pharmaceuticals, LLC staff
9:30 – 12:00 PM Tour of facility

Areas of operational reviews and interviews

- Authorized Trading Partner – Customers, Sources/Vendors
- Common Carrier
- Controlled Substances
- Crisis Operations
- Facility
- Humidity
- In-Bound Product and Receiving
- Inventory

- Laws and Regulations
- Reporting and Notifications
- Personnel
- Policies and Procedures (P&P)
- Product Tracing
- Quality Program
- Quarantine
- Recalls
- Security
- Temperature

12:00 – 1:00 PM Lunch

1:00 – 4:30 PM Continuation of operational reviews and interviews, and summation meeting

4:30 – 5:00 PM Surveyor departs facility

Cordially,

Kelly Kitano

Administrative Coordinator, Distribution Accreditations
P: 847/391-4539
D: 847/391-4536

National Association of Boards of Pharmacy

1600 Feehanville Dr, Mount Prospect, IL 60056
www.nabp.pharmacy | vawd@nabp.pharmacy
vdip@nabp.pharmacy



From: Northwind Pharmaceuticals <Richard.DeLeon@nwpharma.com>

Sent: Thursday, March 12, 2020 11:55 AM

To: vawd@nabp.pharmacy

Cc: Betsy Bigler <betsy.bigler@nwpharma.com>

Subject: RE: Northwind Pharmaceuticals, LLC, Indianapolis, IN - VAWD Survey Date

To Whom It May Concern;

Northwind Pharmaceuticals, LLC is confirming the survey date of April 2, 2020.

Please send all further correspondence to compliance@nwpharma.com.

Thank you for your attention.

Sincerely,

Northwind Compliance

From: vawd@nabp.pharmacy <vawd@nabp.pharmacy>

Sent: Thursday, March 12, 2020 11:33 AM

To: Northwind Pharmaceuticals <Richard.DeLeon@nwpharma.com>

Subject: Northwind Pharmaceuticals, LLC, Indianapolis, IN - VAWD Survey Date

Due to the COVID-19 (coronavirus) impact on business and travel in the United States, NABP onsite survey services may experience unexpected delays and/or cancelations. NABP will try its best to accommodate upcoming scheduled or unscheduled surveys, but must also ensure its staff and contractors are adhering to current CDC Guidelines and recommendations. If you prefer NABP postpone your upcoming survey, please reply to this email immediately. There will be no administrative fees applied and NABP will work on your request to postpone.

Dear Richard,

The National Association of Boards of Pharmacy® (NABP®) has selected **April 2, 2020** as the date(s) for the Verified-Accredited Wholesale Distributors® (VAWD®) survey of your facility.

Please confirm by responding **within three business days**. If your facility or staff cannot accommodate a VAWD survey on these dates, provide written explanation of extenuating circumstances. After confirmation of your survey dates, all costs related to rescheduling or canceling a survey will be at the expense of the facility.

As a reminder, preparedness for the surveyor's visit is a major factor in your facility's potential advancement to accreditation. Familiarizing participants with the VAWD Survey Process Guide and ensuring that your facility is operationally compliant with VAWD criteria are necessary to minimizing post-survey follow-up. Contact NABP IMMEDIATELY if your facility is not currently operational (receiving and shipping prescription drugs and/or prescription devices) or will not be operational during the survey. If the facility is not operational at the time of survey it will not proceed and all costs associated with rescheduling or canceling will be at the expense of the facility.

Thank you for your timely attention to this matter. Please contact NABP at 847/391-4539 if you have any questions or if we can be of assistance to you in preparing for the survey.

Cordially,

Kelly Kitano

Administrative Coordinator, Distribution Accreditations

P: 847/391-4539

D: 847/391-4536

National Association of Boards of Pharmacy

1600 Feehanville Dr, Mount Prospect, IL 60056

www.nabp.pharmacy | vawd@nabp.pharmacy

vdip@nabp.pharmacy



CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Sara Miller

From: vawd@nabp.pharmacy
Sent: Wednesday, March 18, 2020 5:15 PM
To: vawd@nabp.pharmacy
Subject: NABP Program Update in Response to COVID-19 Epidemic



847/391-4406
Fax: 847/375-1114

1600 Feehanville Dr
Mount Prospect, IL 60056
help@nabp.pharmacy

O: NABP ACCREDITATION AND INSPECTION CUSTOMERS

FROM: Kevin McGlynn, Director, Accreditation and Inspection Programs

DATE: March 18, 2020

RE: NABP Program Update in Response to COVID-19 Epidemic

As COVID-19 continues to spread throughout the United States, NABP has continued to monitor the virus' impact on patients, the Association's member boards, customers and staff.

Accreditation Customers:

A careful review of entities holding accreditation through NABP provides assurance that the extension of the current accreditation is possible and in the best interest of patient care. All entities currently holding accreditation with NABP and undergoing reaccreditation or holds an accreditation that will expire prior to June 1, 2020 will have their accreditation automatically extended for three months pursuant to the following conditions:

- NABP is temporarily suspending all accreditation survey activity.
- Any accredited entity that is currently undergoing reaccreditation or whose accreditation will expire prior to June 1, 2020, will need to have submitted their reaccreditation materials, submit the required fee to NABP, and execute an attestation. The attestation will acknowledge further that should NABP find evidence to the contrary the entity may be subject to immediate suspension or revocation of its accreditation.
- NABP will continue to process all new program applications up until the point that a survey is required. At which time, an assessment will be made of whether or not an on-site survey should or can be completed.
- NABP will communicate the status of our survey operations to all states and relevant networks/3rd parties.

Inspection Customers:

- NABP is temporarily suspending all inspection activity.
- NABP will continue to process all new program applications up until the point that an inspection is required. At which time, an assessment will be made of whether or not an on-site inspection should or can be completed.
- NABP will communicate the status of our inspection operations to all states and relevant networks/3rd parties.

NABP will continue to monitor the status of COVID-19 and will keep all parties apprised of any changes to the status of our survey and inspection operations. To that end, we will send out regular, formal updates. We appreciate your patience during this challenging time and hope that collectively, by taking these measures together, we can all accelerate the return to normalcy.

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.