

INNOVATIONS

ADAPTING,
ADVANCING

2021

IN REVIEW



NABP

National Association of
Boards of Pharmacy

05



Feature News
Adapting, Advancing:
2021 in Review

12



118th Annual Meeting
A Primer for the Annual
Meeting Business Processes

01 Letter From the Chairperson

02 Policy Perspectives

Compounding Update: FDA's
Revised Draft Compounding
Guidance for Hospitals

04 Interview With a Board Inspector

Dennis DeLaBarre, RPh

05 Feature News

08 Licensure Transfer Requests
Reach Nearly 18,000 in 2021

10 Accreditation and
Verification Program
Growth Rebounds in 2021 as
Pandemic Restrictions Ease

11 118th Annual Meeting

Official Voting Delegate
Submissions Due by April 19

14 Interview With a Board Member

Amy Fore, MHSA, FACMPE, FACHE

16 State Board News

Alabama Rule Changes Impact
Pharmacy Technicians and Off-Site
Vaccine Order Entry Processing

17 Professional Affairs Update

New Study Examines Increased
Threat of Online Medication
Sales From Social Media and
COVID-19

INNOVATIONS

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NABP Mission Statement

NABP is the independent, international, and
impartial Association that assists its member
boards in protecting the public health.



NABP

National Association of
Boards of Pharmacy

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*NABP Executive
Committee elections
are held each year
at the Association's
Annual Meeting.*



Timothy D. Fensky,
RPh, DPh, FACA
NABP Chairperson

My Fellow Members,

2021 presented many continued and new challenges to providers and regulators across all areas of the health care field. And for NABP, it was also full of opportunities for the Association and its member boards. Opportunities were created from not only adapting to a changing health care landscape, but from also advancing our shared mission of protecting the public health.

In pharmacy practice, we have seen this in the form of improved access to telehealth and telepharmacy services, which are now available in most of the country. We have also seen changes in the way so many pharmacies have been adapting to labor shortages. At the Association level, we see this adaptability in relation to the performance of various NABP programs and services over the last year.

This issue of *Innovations* features highlights of how NABP programs and services were adapted and performed in 2021, including several articles providing annual metrics and trends. These include information about examinations, licensure transfer, the NABP Clearinghouse, and accreditation and inspection services. One goal of this issue is to keep all members informed as to how the member boards are utilizing NABP's offerings and how the Association ensures that these services continue to fill the needs of the boards of pharmacy.

This issue also includes updates about our Annual Meeting. Your Executive Committee and the NABP staff are hard at work to make sure this year's event in Phoenix, AZ, will be productive, safe, and exciting. I am very much looking forward to the opportunity to meet with so many colleagues to discuss important regulatory

One goal of this issue is to keep all members informed as to how the member boards are utilizing NABP's offerings and how the Association ensures that these services continue to fill the needs of the boards of pharmacy.

matters. I look forward to spending time getting to know our members in person.

While 2021 required extended efforts to adapt, I believe the collaboration among board of pharmacy colleagues was a significant strengthening factor that helped us continue to advance for the protection of public health. I am continually impressed by the energy and resilience of this Association's members, and I am proud to count myself among them. ●

Sincerely,

A handwritten signature in dark ink, appearing to read 'Timothy D. Fensky', written over a light blue background.

Timothy D. Fensky, RPh, DPh, FACA
NABP Chairperson

Compounding Update: FDA's Revised Draft Compounding Guidance for Hospitals



Jonathan A. Keller, PharmD, JD, RPh
Faegre Drinker Biddle & Reath LLP



Genevieve M. Razick, JD
Faegre Drinker Biddle & Reath LLP

This article is part two of a two-part series. The first article was published in the February 2022 issue of Innovations and provides information about the status of Food and Drug Administration's (FDA's) compounding memorandum of understanding.

Updated Compounding Guidance for Hospitals

On October 6, 2021, FDA issued a draft guidance document to revise for the third time its guidance on hospital and health system compounding under Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This draft guidance revised the draft guidance issued in 2016 by FDA, titled *Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act*. FDA noted that it revised the prior draft guidance to address stakeholder feedback and provide further clarification on policies regarding hospital and health system compounding.

Notably, the draft guidance reiterates that, to the extent hospitals or health systems have a need for compounded drug products, the hospital pharmacy should obtain such products from outsourcing facilities, rather than compounding the product itself. FDA, however, also recognized that outsourcing facilities may not always be able to meet the medical needs for non-patient-specific compounded drug products to be used in hospitals and health systems. Therefore, the revised guidance describes the circumstances under which FDA will not take action against a hospital or health system pharmacy that: (1) compounds and distributes drugs without first receiving a valid prescription or order for an identified individual patient; or (2) compounds a drug product regularly or in inordinate amounts that are essentially copies of commercially available drug products.

Compounding Based on Receipt of Valid Prescriptions for Individually Identified Patients

The draft guidance describes FDA's risk-based enforcement approach for

circumstances in which a hospital or health system pharmacy might deviate from the outlined circumstances regarding the individually identified patient prescription requirement. To focus attention on compounded drug products that pose the greatest risk to public health, the agency proposed a two-part enforcement policy. The first part of the enforcement policy describes the limited circumstances under which FDA generally does not intend to take action with respect to compounding when the pharmacy does not first receive a valid prescription order for an individually identified patient. FDA explained that this practice must be limited with certain circumstances present:

- The compounded drug products are administered only to patients within the hospital or health system.
- The compounded drug products are used or discarded within 24 hours of transfer out of the pharmacy.
- The drug products are compounded in accordance with all other applicable requirements of the FD&C Act and FDA regulations.

With respect to a hospital or health system pharmacy that does not compound drug products within the controls specified in the guidance document, the agency will prioritize its regulatory actions to focus on those instances that have the highest potential for harm to the public health. FDA noted that it will assess the following considerations when determining how to prioritize its enforcement resources:

- evidence of poor compounding practices or lack of sterility assurance;
- non-patient-specific compounded drugs not for emergency uses;
- routine, large amounts of non-patient-specific compounded drugs;
- routine interstate distribution of large amounts of non-patient-specific

compounded drugs, particularly when the hospital or health system pharmacy is not located near a state border or when it distributes such products to multiple states; and

- no procedures to obtain non-patient-specific compounded drugs from outsourcing facilities where such products are available and appropriate.

Compounding of Drug Products That Are Essentially Copies

The revised draft guidance also describes the circumstances under which FDA does not intend to take action against a hospital or health system pharmacy for compounding drug products regularly or in inordinate amounts that are essentially copies of a commercially available drug product. The circumstances are when:

- the compounded drug product is administered only to patients within the hospital or health system.
- the pharmacy obtains from the prescriber a statement that:
 - specifies a change between the compounded drug product and the commercially available drug product;
 - indicates that the compounded drug product will be administered only to patients for whom the change produces a significant difference from the commercially available drug product; and
 - describes the intended patient population for the compounded drug product.
- a statement is on file for each prescriber that covers each drug product that is compounded.
- the statement is maintained in the hospital or health system pharmacy to address routine orders for patients for whom the change produces a significant difference.

To focus attention on compounded drug products that pose the greatest risk to public health, the agency proposed a two-part enforcement policy.

What Comes Next?

Interested parties and stakeholders were invited to submit written comments regarding the revised draft guidance by December 6, 2021.

The majority of submitted comments focus on the requirement in the revised guidance that the “compounded drug products are used or discarded within 24 hours of transfer out of the pharmacy.” Many of the comments recommended that the beyond-use date should be based on United States Pharmacopeia Chapter <795> and <797> guidelines, and not limited to 24 hours. Additionally, several comments requested clarification regarding what FDA considers to be the “transfer[red] out of the pharmacy” requirement. For example, one stakeholder questioned whether this means when the compounded drug leaves the pharmacy where the compounded preparation was compounded, or the physical hospital where the pharmacy is located. Another stakeholder questioned whether the compounded drug will need to be discarded within the 24-hour time frame should it not actually leave the pharmacy within that time frame. We expect the comments received by FDA will help clarify the agency’s final guidance document when it will be issued.

This article was written by Jonathan A. Keller, PharmD, JD, RPh, and Genevieve M. Razick, JD, with Faegre Drinker Biddle & Reath LLP. Please note, the opinions and views expressed by Faegre Drinker Biddle & Reath do not necessarily reflect the official views, opinions, or policies of NABP or any member board unless expressly stated. ●



Dennis DelaBarre, RPh

Compliance Officer, North Dakota State Board of Pharmacy

How long have you been serving as an inspector for the Board?

I became a compliance officer for the Board in 2015. I had recently retired from an assistant director of pharmacy position at a 286-bed, full-service hospital, having worked in that capacity for about 18 years. Before that, I was director of pharmacy, materials management, and central supply at a 160-bed facility. Prior to my hospital experience, I was manager of a retail chain drugstore.

What tools or skills are a must-have in a pharmacy inspector's toolkit?

My inspection assignments are for hospital pharmacies and compounding retail pharmacies providing both sterile and nonsterile products. For these duties, I would say that previous hospital experience is very helpful, and the compounding education provided by CriticalPoint, LLC, and the United States Pharmacopeial Convention (USP) is essential.

What are some common issues that you have witnessed and addressed as an inspector with the Board?

Incorrect beyond-use dating on unit-dose prepackaging was an issue that was easily corrected with education. Timely updating of policies and procedures is an area that often needs improvement, especially in the absence of a full-time pharmacist-in-charge. Manual recording of refrigerator and freezer temperatures was problematic, but North Dakota now requires continuous temperature monitoring of cold storage equipment that contains medications. We frequently have both our retail and hospital pharmacies audit a drug from its last required Drug Enforcement Administration (DEA) inventory. My fellow compliance officers and I find that this is frequently done incorrectly, with too much reliance on inventory systems. In the compounding area, many hoods used to prepare hazardous materials were placed too close to the walls, making it difficult, if not impossible, to complete the required monthly cleaning in a satisfactory manner.

In North Dakota, do inspectors also conduct investigations for other health regulatory boards?

I inspect one nuclear pharmacy, while medical gases and veterinary supplies are assigned to another compliance officer.

What is one of the most challenging or surprising cases you have investigated?

Two hospice nurses were diverting drugs from their patients over a period of two years, from 2012 to 2014. In September 2014, DEA and the North Dakota Board of Nursing investigated, and both nurses eventually surrendered their licenses. In March 2016, a DEA diversion investigator noticed that the case had not been resolved and contacted the local police in January 2017. The police started investigating and no charges were filed until August 31, 2017. In the meantime, both nurses had completed drug addiction treatment and one license was reinstated. After the police investigation, both nurses were charged, and both pleaded guilty to a Class B felony charge of endangering a vulnerable adult and a Class C felony charge of criminal conspiracy. At the sentencing hearing, it was estimated that as many as 106 patients could have suffered as a result of the nurses' actions. Both received a three-year sentence.

What advice would you give to a new board inspector?

A new board inspector assigned to hospitals and compounding pharmacies should take advantage of educational opportunities on medication safety, the compounding guidelines in USP chapters, and controlled substance diversion. Be careful to distinguish the differences between what is required and what is considered best practice. ●

North Dakota State Board of Pharmacy



Number of Board Members

5 pharmacists,
1 public member,
1 pharmacy technician



Number of
Compliance
Officers/Inspectors
4



Rules & Regulations
Established by
State Board of
Pharmacy



Number of
Pharmacist Licensees
2,238



Number of
Pharmacies
921



Number of Wholesale
Distributors
1,392



ADAPTING,
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2021

IN REVIEW

Recovering and learning from the challenges faced in the first year of the coronavirus disease 2019 (COVID-19) pandemic, NABP quickly adapted its business practices and programs throughout 2021 to continue supporting member boards of pharmacy and their needs.

The COVID-19 landscape continues to evolve and impact public health and, therefore, continues to affect the boards of pharmacy. Thus, NABP approached 2021 with flexibility but kept its eye on the future of its programs and services. From holding meetings in a hybrid or virtual format to the evolution of the NABP Passport being used to support other emerging issues such as hurricane relief, the Association is committed to staying flexible to take on new challenges while maintaining its mission of protecting the public health.

In this issue of *Innovations*, NABP is pleased to report the results and successes of 2021 for its Clearinghouse, licensure transfer, examination, accreditation, and inspection programs.

2021 Exam and Assessment Volume

This table provides the volume of 2021 administrations for the following programs:

- North American Pharmacist Licensure Examination® (NAPLEX®);
- Pre-NAPLEX®;
- Multistate Pharmacy Jurisprudence Examination® (MPJE®);
- Pre-MPJE®;
- Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®);
- Pre-FPGEE®; and
- Pharmacy Curriculum Outcomes Assessment® (PCOA®).

More information on NABP examinations and assessments is located in the Programs section of the NABP website. ●



Volume of Examination and Assessment Administrations		
	2020	2021
NAPLEX	17,177	18,432
Pre-NAPLEX	13,868	14,759
MPJE	30,715	32,882
Pre-MPJE	8,939	10,349
FPGEE	912	516
Pre-FPGEE	349	270
PCOA	16,479	11,115
Program Year 1	733	976
Program Year 2	1,564	1,268
Program Year 3	14,028	8,680
Program Year 4	154	191



NABP Clearinghouse 2021

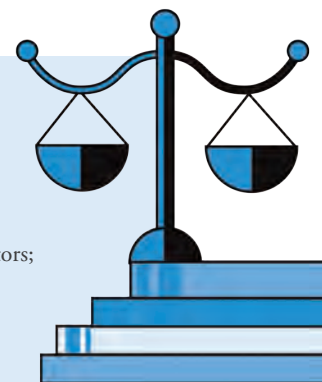


Over 5,000 Disciplinary Actions Recorded

The Association's year-end data results for 2021 showed that a total of 5,226 disciplinary records were submitted to the NABP Clearinghouse by state boards of pharmacy on 4,263 individual and business NABP e-Profiles.

Of the 5,226 actions reported in 2021:

- 2,115 (40%) were on pharmacists;
- 1,390 (27%) were on pharmacies;
- 1,341 (26%) were on pharmacy technicians;
- 147 (3%) were on wholesalers, manufacturers, and distributors;
- 80 (1.5%) were on other individuals;
- 71 (1.4%) were on pharmacy interns;
- 55 (1.1%) were on other licensees;
- 16 (0.3%) were on controlled substance licenses; and
- 11 (0.2%) were on Drug Enforcement Administration and Food and Drug Administration registrations. ●



Year 2021 Action Code Categories INDIVIDUALS

	COUNT	%		COUNT	%
Publicly Available Fine/Monetary Penalty	1,019	22.8%	Reprimand or Censure	299	6.7%
Other Licensure Actions - Not Classified	550	12.3%	Reduction, Modification, or Extension of Previous Licensure Action	171	3.8%
Probation of License	548	12.3%	Summary or Emergency Action, Limitation, Suspension, or Restriction on License	162	3.6%
Revocation of License/Certificate	436	9.8%	Denial of Initial License or Renewal License/Certificate	151	3.4%
Suspension of License/Certificate	393	8.8%	Limitation or Restriction on License	71	1.6%
License/Certificate Restored or Reinstated, Complete, Conditional, Partial, or Denied	328	7.3%	Miscellaneous	20	0.4%
Voluntary Surrender of License/Certificate	321	7.2%			

TOTAL 4,469

Year 2021 Action Code Categories BUSINESSES

	COUNT	%		COUNT	%
Publicly Available Fine/Monetary Penalty	1,185	59.8%	License/Certificate Restored or Reinstated, Complete, Conditional, Partial, or Denied	27	1.4%
Reprimand or Censure	385	19.4%	Suspension of License/Certificate	16	0.8%
Probation of License	111	5.6%	Monitoring, Closure, or Other Operational Business Modification	15	0.8%
Other Licensure Actions - Not Classified	71	3.6%	Reduction, Modification, or Extension of Previous Licensure Action	3	0.2%
Revocation of License/Certificate	68	3.4%	Summary or Emergency Action, Limitation, Suspension, or Restriction on License	1	0.1%
Voluntary Surrender of License/Certificate	56	2.8%			
Denial of Initial License or Renewal License/Certificate	42	2.1%			

TOTAL 1,980

Year 2021 Bases for Action Code Categories INDIVIDUALS

	COUNT	%		COUNT	%
Noncompliance With Requirements	1,816	43.1%	Unsafe Practice or Substandard Care	271	6.4%
Improper Prescribing, Dispensing, Administering Medication/Drug Violation	832	19.7%	Fraud, Deception, or Misrepresentation	247	5.9%
Other Actions - Not Classified	488	11.6%	Improper Supervision or Allowing Unlicensed Practice	121	2.9%
Criminal Conviction or Adjudication	329	7.8%	Misconduct or Abuse	87	2.1%
			Confidentiality, Consent, or Disclosure Violation	24	0.6%

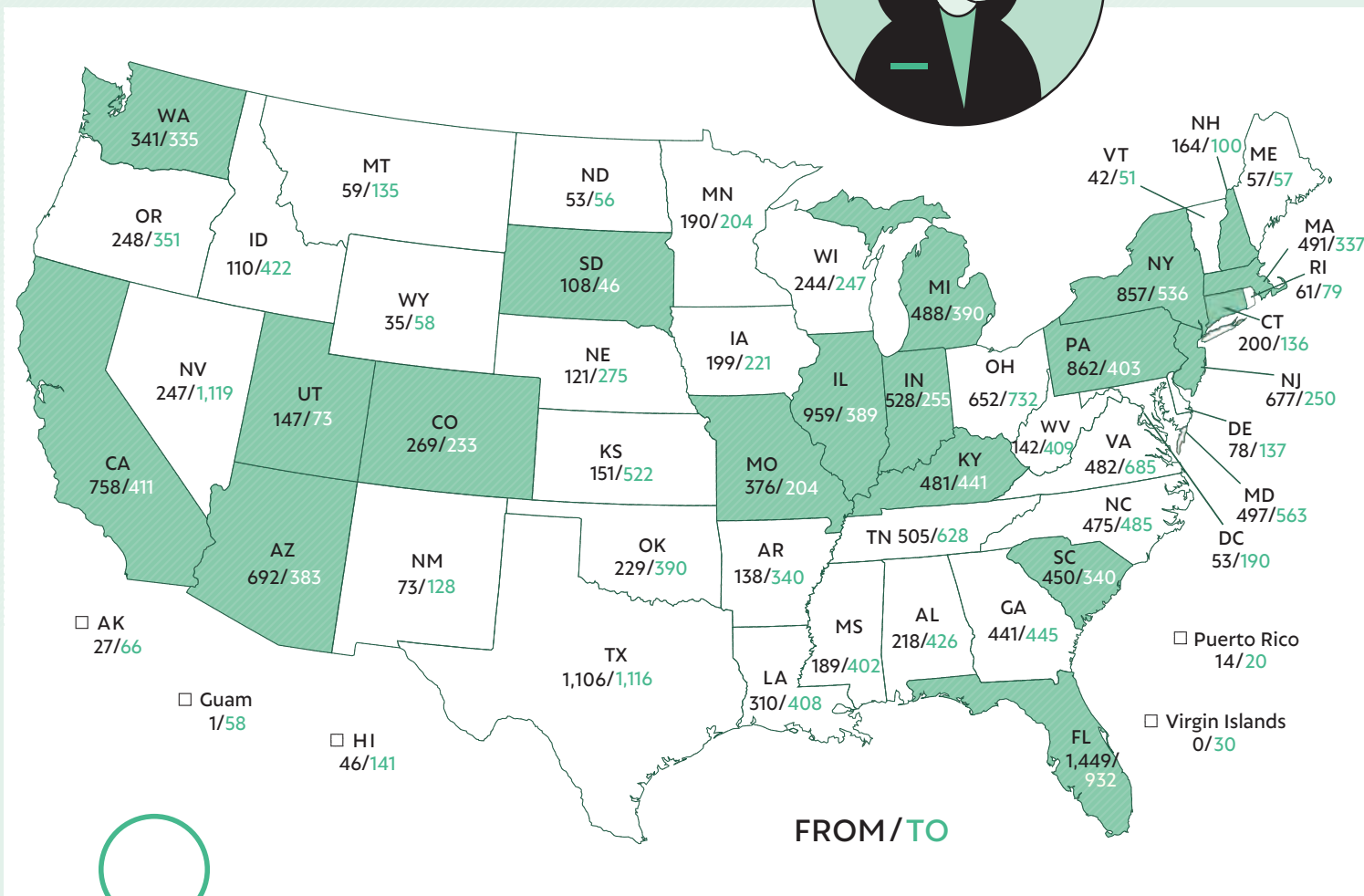
TOTAL 4,215

Year 2021 Bases for Action Code Categories BUSINESSES

	COUNT	%		COUNT	%
Noncompliance With Requirements	1,485	72.4%	Other Actions - Not Classified	49	2.4%
Improper Supervision or Allowing Unlicensed Practice	293	14.3%	Confidentiality, Consent, or Disclosure Violations	18	0.9%
Improper Prescribing, Dispensing, Administering Medication/Drug Violation	141	6.9%	Criminal Conviction or Adjudication	7	0.3%
Fraud, Deception, or Misrepresentation	51	2.5%	Substandard Care or Patient Neglect/Abuse	7	0.3%

TOTAL 2,051

Licensure Transfer Requests Reach Nearly 18,000 in 2021



Shaded areas denote states where the number of applications for transfer from the state is greater than the number of applications requesting transfer to the state.

Licensure transfer requests submitted through the NABP Electronic Licensure Transfer Program® (e-LTP™) reached 17,790 in 2021, representing an approximate 2% increase over the requests submitted in 2020. This increase, which is also somewhat

higher than the 16,740 requests submitted to NABP in 2019, may indicate that changes brought by the coronavirus disease 2019 pandemic may no longer be having as significant an impact on licensure transfer requests.

e-LTP Transfer Requests to States

In 2021, Nevada was the state with the highest number of requests to transfer licensure to the state, with a total of 1,119 requests submitted over the year.

2021 Supply Chain Inspection Totals

Due to the impact of the coronavirus disease 2019 pandemic, Supply Chain Inspection applications started out slow in 2021. However, they are on the rise as states begin to require the inspection. The Supply Chain Inspection program fulfills NABP's contract obligations to conduct state distribution inspections and is used to determine Drug Distributor Accreditation eligibility. Two inspections were completed in 2020 and 17 in 2021, with 15 of them occurring in the fourth quarter. Twenty-four additional inspections were in queue at the close of

2021 for completion before year-end or in early 2022. NABP's Supply Chain Inspection program is best suited for participants in the medical supply chain that store, handle, and ship prescription drugs and devices. More information about the program can be found in the Programs sections of the NABP website. ●

Supply Chain Inspections	2021	Since Inception (2019)
Total Inspections	17	64

Additional states with the highest number of licensure transfer requests to the state in 2021 are:

- Texas – 1,116 requests;
- Florida – 932 requests;
- Ohio – 732 requests; and
- Virginia – 685 requests.

Texas, Virginia, and Florida were among the five states with the most licensure transfer requests in 2020. As in previous years, many states with the highest number of transfer requests are states with the highest reported populations of licensed pharmacists, including Texas and Florida, according to NABP's 2022 *Survey of Pharmacy Law*.

Nevada's status as the state with the greatest number of transfer requests is new this year. In 2020, Nevada had 186 requests for licensure transfer to the state. The massive increase in transfer requests in 2021 may be driven by a policy change from the Nevada State Board of Pharmacy requiring all pharmacists engaged in compounding or dispensing activities for residents to be licensed in Nevada following a review of Nevada Revised Statutes 639.100(1)(a).

Previously, only nonresident pharmacies and the pharmacist-in-charge were required to register with the Board. The Board began notifying nonresident pharmacies of this change on July 22, 2021.

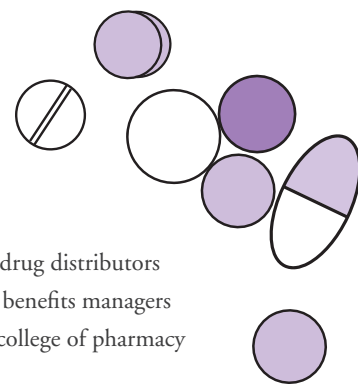
e-LTP Transfer Requests From States

Licensure data from 2021 show Florida, Texas, Illinois, Pennsylvania, and New York as having the highest number of requests to transfer from states. The total number of requests to transfer licenses from these states was:

- Florida – 1,449 requests;
- Texas – 1,106 requests;
- Illinois – 959 requests;
- Pennsylvania – 862 requests; and
- New York – 857 requests.

In 2021, the average processing time for e-LTP requests was two days. However, most e-LTP requests are processed in 24 hours and sent directly to the boards. In 2021, NABP received 12,658 e-LTP applications and processed 17,921 license transfer requests. To learn more about e-LTP, visit the NABP website at www.nabp.pharmacy. ●





Accreditation and Verification Program Growth Rebounds in 2021 as Pandemic Restrictions Ease

Drug Distributor Accreditation

A total of 725 facilities held Drug Distributor Accreditation by the end of 2021. This figure includes 17 new accreditations and 70 reaccreditations awarded in 2021. The number of states currently requiring or recognizing NABP Drug Distributor Accreditation is 31.

DMEPOS Pharmacy Accreditation

DMEPOS Pharmacy Accreditation continues to receive a steady number of applications, resulting in 87 new accreditations and reaccreditations in 2021. Currently, 184 companies representing almost 24,083 facilities are accredited by NABP for DMEPOS.

OTC Medical Device Distributor Accreditation

NABP's OTC Medical Device Distributor Accreditation is for business entities that distribute medical devices often designated as medium to high risk by Food and Drug Administration, specifically, diagnostic over-the-counter (OTC) devices such as diabetes medical supplies eligible for reimbursement. By the end of 2021, one facility had received OTC Medical Device Distributor Accreditation.

Digital Pharmacy Accreditation

Digital Pharmacy Accreditation awarded 19 new accreditations and three reaccreditations by the end of 2021. Eighty-eight businesses that account for tens of thousands of pharmacies across the United States were accredited and overall participation in Digital Pharmacy Accreditation has steadily increased since the program's inception in 1999.

.Pharmacy Verified Websites Program

NABP verified the websites of 418 customers, and 601 .pharmacy domain names were registered through the .Pharmacy Verified Websites Program. This includes:

- 456 pharmacies
- 48 boards of pharmacy and regulatory agencies
- 31 resource and referral sites
- 24 associations and consumer advocacy sites
- 22 professional sites
- 9 pharmacy automation distributors
- 5 pharmaceutical manufacturers

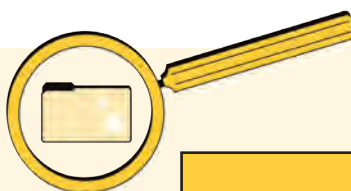
- 3 wholesale drug distributors
- 2 pharmacy benefits managers
- 1 school or college of pharmacy

Compounding Pharmacy Accreditation

In 2020, NABP launched a compounding pharmacy accreditation for facilities wishing to demonstrate compliance with US Pharmacopeia standards for Chapters <795>, <797>, and <800>. As of the end of 2021, 56 pharmacies have received this accreditation.

Newest Accreditations

Several of the Association's newer accreditations demonstrated success in 2021, including Specialty Pharmacy Accreditation, Community Pharmacy Accreditation, and Home Infusion Therapy Pharmacy Accreditation. In 2021, seven new pharmacy accreditations were awarded through these programs, including one Community Pharmacy Accreditation and the first Specialty Pharmacy Accreditation and Home Infusion Therapy Pharmacy Accreditation. ●



VPP Inspections Continue as Valuable Resource

Verified Pharmacy Program® (VPP®) totals for 2021 were impacted by various closures and travel restrictions caused by the coronavirus disease 2019 pandemic. However, after a period of not conducting inspections, NABP was able to proceed as normal in most jurisdictions where facilities met Centers for Disease Control and Prevention, federal, state, local, and NABP guidelines for safety. For facilities that have not yet met the requirements, NABP continues to offer virtual inspections until a physical on-site inspection can be done safely. More information about VPP can be found in the Programs sections of the NABP website. ●

VPP Inspections*	2021	Since Inception (2013)
General Retail Pharmacy Only	79	327
General and Nonsterile Compounding Only	80	616
General and Sterile Compounding Only	64	316
General, Nonsterile, and Sterile Compounding	125	635
Nuclear	24	74

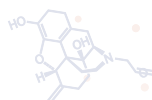
* The totals above represent facilities whose inspections have already been completed in 2021 and do not include applicants who are awaiting an inspection or who recently submitted an application.

Official Voting Delegate Submissions Due by April 19

In order to vote during the Final Business Session and qualify for the Annual Meeting travel grant, active member state boards of pharmacy must submit their signed Official Delegate Certificates by April 19, 2022.

- Chief administrative officers of the boards may submit the completed and signed Official Delegate Certificate to NABP Executive Office via mail to NABP Headquarters or via email to ExecOffice@nabp.pharmacy.
- Only current board of pharmacy members or chief administrative officers qualify to serve as delegates or alternate delegates.
- Only one individual may serve as the official voting delegate; however, there is no limit on how many individuals may serve as alternate delegates.

For more information, contact ExecOffice@nabp.pharmacy. ●



NALOXONE

Online registration is now available! See our new, improved schedule, travel details, and more at www.NABPAnnualMeeting.pharmacy.



Important Deadlines

- **Proposed CBL Amendments** – Due April 4, 2022
- **Voting Delegate Submissions** – Due April 19, 2022
- **Early Annual Meeting Registration Rate** – Ends April 22, 2022
- **Early Hotel Reservation Rate** – Ends April 28, 2022
- **Annual Meeting Registration Refund** – Ends April 29, 2022
- **Annual Meeting Registration** – Closes May 9, 2022



A Primer for the Annual Meeting Business Processes

Much of the foundation for issues addressed at the Annual Meeting is laid at the district level. District meetings provide a voice for each district to take part in the decision-making processes of NABP and, in turn, shape the business processes for the Annual Meeting.

It All Starts at the District Meetings

During the district meetings, board delegates vote on candidates seeking nomination for NABP Executive Committee open member positions in their district. Also, during these meetings, members may submit resolutions for consideration by their district. Resolutions passed at the district meetings are then submitted to NABP and are reviewed by the Committee on Resolutions before being voted on at the Annual Meeting. These resolutions have the potential to result in NABP actions, such as the development of task forces to explore or address an issue or revisions to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)*, which provides the boards with model language that may be used when developing state laws or board rules. In addition, once approved by the membership, resolutions document the Association's stance on issues affecting the practice of pharmacy and public health. They can also express NABP's intention to work with other key stakeholders.

Voting

When there is an open NABP Executive Committee member position for a district, the district may nominate up to two candidates at its district meeting. After the district meeting, there is also an opportunity for individuals to be nominated outside the district process. Nominees for Executive Committee officer positions of president-elect and treasurer submit their interest and qualifications for these positions directly to NABP. NABP then determines if they meet the criteria to be candidates. At the Annual Meeting, the membership votes on the slate of candidates, including the open member positions and officer positions of president-elect and treasurer. The president and chairperson positions are progressively assumed. Amendments to the

NABP Constitution and Bylaws are also voted on at the Annual Meeting. These amendments may be submitted by any active member board, the Committee on Constitution and Bylaws, or the Executive Committee within a specific time frame prior to the Annual Meeting. Although newly proposed amendments to the Constitution may be presented during any Annual Meeting business session, they may not be discussed and voted on until the next succeeding Annual Meeting. By contrast, proposed amendments to the Bylaws may be presented and voted on at the same Annual Meeting. Finally, resolutions that were submitted by the districts, active member boards, or NABP committees are discussed and voted on at the Annual Meeting.

Business Sessions

So that the member boards can be provided with the opportunity to thoroughly review what the Association has accomplished and plans to accomplish for the upcoming year, this year's business processes have been divided into **three** sessions during the Annual Meeting.

At the First Business Session, candidates will be announced for the open Executive Committee officer and member positions. Attendees will hear reports of the NABP Executive Committee chairperson and president.

During the Second Business Session, attendees will hear the report of the treasurer and NABP executive director/secretary. The resolutions that were submitted by the districts, active member boards, or committees of the Association, and proposed amendments to the Constitution and Bylaws (if any) are also read during this session.

Finally, attendees hear the candidate and seconding speeches for the open Executive

Committee positions. After the business session, attendees have the opportunity to interact with the candidates during the Informal Member/Candidate Discussion and share their thoughts about each candidate with their board's voting delegate.

During the Final Business Session, elections will take place for the open executive committee officer and member positions. Attendees will also hear the remarks of the incoming president. Election results will then be announced followed by the installation of the new 2022-2023 Executive Committee. The final reports of the Committee on Constitution and Bylaws and the Committee on Resolutions are presented. During these reports, the proposed amendments to the Constitution and Bylaws, if applicable, and resolutions that were read during the Second Business Session are discussed and voted on. Although only designated voting delegates from active member boards may vote, any affiliated member may participate in the discussion portion of the Final Business Session's agenda. An affiliated member is any individual who is a current or former member or administrative officer of an active or associate member board of the Association. With important outcomes such as new Executive Committee officers and members, amendments to the NABP Constitution and Bylaws, and adoption of policy-setting resolutions, attendees can see the significance of the business sessions to the NABP member boards. It is through participation in these sessions that members have the opportunity to help shape the Association's actions for the coming year. ●

In 2021, NABP commissioned three task forces and one work group, which were established in response to resolutions voted on during the 117th Annual Meeting. Visit the Resources section of the NABP website under Reports for more details about these task forces.

NABP Business Session Processes

NABP/AACP District Meetings

- Board of Pharmacy delegates nominate individuals to run for the open Executive Committee positions in their district.
- Board of Pharmacy delegates discuss and vote on proposed resolutions to be submitted to NABP for consideration by the full membership.



Annual Meeting

First Business Session

- Candidates for open Executive Committee member and officer positions introduced.



Second Business Session

- Proposed amendments to the NABP Constitution and Bylaws presented.
- Proposed resolutions presented.
- Candidate speeches.



Final Business Session

- Board of Pharmacy delegates vote for new Executive Committee members and officers on behalf of their board.
- Board of Pharmacy delegates vote on proposed Constitutional and bylaw amendments, if applicable, and resolutions.
- Members invited to discuss proposed Constitutional and bylaw amendments, if applicable, and resolutions.

Annual Meeting Outcomes

- Newly elected officers and Executive Committee members are installed during the Final Business Session.
- The NABP Constitution and Bylaws is updated on the website to reflect approved amendments, and background on the changes is provided in *Innovations*.
- Resolutions approved by the membership are posted on the NABP website and announced in *Innovations*.
- Single-issue task forces may be convened, and/or potential revisions made to the NABP *Model Act*.



Amy Fore, MHSA, FACMPE, FACHE

Public Member, Arkansas State Board of Pharmacy

When were you appointed to the Board of Pharmacy? Are you a pharmacist, technician, public member, or other type of member?

I was appointed to the Arkansas State Board of Pharmacy in 2017 as a public member.

What steps should a board member take to be successful in their role?

From my perspective, one of the most important things a board member can do is stay centered in the fact that our purpose is to protect the public. While we want to support the advancement of the practice of pharmacy, to me, the greatest charge we have is to protect the residents of the state of Arkansas and, as an extension of that, promote public health and welfare. If board members can keep this as their true north in all conversations and decisions, they will be successful contributors to their state board of pharmacy.

What are some recent policies, legislation, or regulations that your Board has implemented or is currently working on?

One thing we are seeing in pharmacy that is mirroring other sectors of health care is how pharmacies are bringing innovative ways to meet the needs of their patients while facing reimbursement challenges, increasing costs, and staffing shortages. This includes everything from central fill sites to remote order entry. As a board member, it is encouraging to see industry leaders finding ways to continue to provide high-quality pharmacy services to patients in new and innovative ways.

Has the Board encountered any challenges to developing and/or implementing these new policies, legislation, or regulations?

Using innovative approaches to the delivery of pharmacy services as the example, it challenges us, as board members, to really understand the purpose and processes of

these new innovations to ensure that they meet our state regulations and are true to our charge of protecting the public.

What advice would you give to a new board member?

Whether you are a pharmacist, technician, or public member, ask questions. There have been so many times that the answer to a single question completely changes the understanding of a situation, no matter the topic – policies, regulations, legislative, discipline, or licensing – based on the information we have available. By asking questions, we can ensure that we have the most information possible before making the decision. And, of course, always keep your purpose of protecting the public as the core of all decisions.

Have you served as a member of any NABP task forces or committees, or attended NABP or district meetings? If so, in your experience, what are the benefits of participating in these NABP activities?

I attended an NABP District 6 meeting in 2019. As a public member who works in health care, it was an invaluable experience. I met board members from other states and was able to network with people who have similar challenges but sometimes address them with different or unique approaches. Being able to take those ideas back to the Board, adapt them to our situation, and implement them, improves the quality of care, specifically pharmacy services, for all. ●

Arkansas State Board of Pharmacy



Number of Board Members

6 pharmacist members and 2 public members



Number of Compliance Officers/Inspectors

5



Rules & Regulations Established by State Board of Pharmacy



Number of Pharmacist Licensees

6,540



Number of Pharmacies

1,363



Number of Wholesale Distributors

1,754

In Memoriam: NABP Mourns Passing of Former Honorary President



NABP is sad to announce that Past Honorary NABP President Carl W. Aron, RPh, passed away on January 5, 2022. A licensed pharmacist for

the state of Louisiana since 1962, he took ownership of his family business, Aron's Pharmacy, in 1971. For more than 50 years, he served on the Louisiana Board of Pharmacy, with 25 of those years serving as president. Aron was the longest serving member on any board of pharmacy in the country.

At the 109th NABP Annual Meeting, Aron was awarded the 2013 Honorary NABP President Award in recognition of

his commitment to the Association and the boards of pharmacy, and for his diligence and dedication to the practice of pharmacy and patient care. Aron showed his ongoing dedication to the Association by serving on multiple examination committees, including the Blue Ribbon Committee of Item Writers, to ensure that NABP's examinations remained valid and effective. He also served on the NABP Advisory Committee on Examinations (ACE), including as chairperson of ACE from 2004 to 2005; on the NABP Committee on Law Enforcement/Legislation in 2008; and as chairperson of the NABP Task Force on Emergency Preparedness, Response, and the US Drug Distribution System. For his service to the Association, Aron received the NABP Distinguished Service Award in 2006.

An active member of several pharmacy associations, Aron was a member of the board of directors of the Fifth District Pharmaceutical Association, which recognized his service with the Grant Collins Award in 2006. He was also a member of the Louisiana Pharmacists Association (LPA) and served on the organization's executive committee. He was honored by the LPA with the Independent Pharmacist of the Year Award in 2012, and with the Bowl of Hygieia award in 1985. As a member of the National Community Pharmacists Association (NCPA), Aron served on NCPA's Professional Affairs Committee. He also sat on the Dean's Advisory Council for the University of Louisiana Monroe, School of Pharmacy, as well as on the university's President's Advisory Council. ●

Coming Soon! Digital Issue of *Innovations*

Beginning with its April 2022 issue of *Innovations*, NABP will be launching a digital version of the newsletter that will be accessible via the NABP website. *Innovations* will continue to be printed as a monthly newsletter and mailed to subscribers and the NABP membership. However, as an additional benefit, an interactive digital version of the newsletter will also be available. Compared with the current pdfs, all dynamic digital *Innovations* issues will include new navigation options and be mobile-friendly. In addition, future digital issues will include access to some of the following "digital-only" content:

- audio and video of interviews, meetings, and public service announcements,
- extended article content and resources,
- shareable infographics,
- interactive visuals, and more.



Keep a lookout in your email inbox for the upcoming digital issue this spring!

Alabama Rule Changes Impact Pharmacy Technicians and Off-Site Vaccine Order Entry Processing

The Alabama State Board of Pharmacy has adopted rule changes that impact the role of pharmacy technicians and off-site vaccine order entry processing. Below is a brief summary of the changes.

- **680-X-2-.12 Supervising Pharmacist**

This rule was amended to provide a specific process by which pharmacists who will no longer be acting as supervising pharmacists shall notify the Board.

- **680-X-2-.14 The Role of Technicians in Pharmacies in Alabama**

This rule was amended to allow for more disciplinary options for noncompliance of required technician training. This change went into effect on October 15, 2021.

- **680-X-2-.47 Off Site Vaccine Order Entry Processing**

The new rule is to provide standards for off-site order entry processing for immunizations by any pharmacy in the state of Alabama. This rule went into effect on December 13, 2021.



District of Columbia Updates Opioid Labeling Requirements

In response to the Opioid Labeling Amendment Act of 2020 that became effective on March 16, 2021, the District of Columbia now requires prescription opioid medications to include a statement that the drug is an opioid and that with opioids there is a risk of overdose and addiction. The statement must be affixed to the container in which an opioid is sold or dispensed.

Massachusetts Allows Schedule II Prescriptions From Nonresident Practitioners

Massachusetts now allows pharmacies to fill Schedule II prescriptions from any nonresident practitioners (eg, nurse practitioners, dentists) who are authorized to prescribe in the state where they are located. This change is in response to “An Act Promoting a Resilient Health Care System That Puts Patients First,” which was signed into law in Massachusetts.

There have been no other changes to out-of-state Schedule II prescription validity. The following rules remain:

- All Schedule II prescriptions issued from out of state are only valid for five days from the date of issuance.
- Schedule II nonnarcotic prescriptions may be filled from any state.
- Schedule II narcotic prescriptions may only be filled if issued from Maine or states contiguous to Massachusetts (Connecticut, New Hampshire, New York, Rhode Island, and Vermont).

Oregon's Physician Assistant Modernization Bill Impacts Pharmacy Practice

Oregon's 2021 House Bill (HB) 3036 modernizes physician assistant (PA) practice and impacts pharmacy practice. The changes to PA practice provided in 2021 HB 3036 are operational in phases on January 15, 2022, and July 15, 2022. The November 2021 issue of the *Oregon State Board of Pharmacy Newsletter* includes a summary of the areas that impact pharmacy licensees and registrants as of January 15, 2022. ●



Most articles published in State Board News are selected from the newsletters of state boards that participate in the NABP State Newsletter Program. Issues are posted on the NABP website on each participating state's page.

New Study Examines Increased Threat of Online Medication Sales From Social Media and COVID-19

Due to the emerging prevalence of drug availability on social media and an increase in demand stemming from the coronavirus disease 2019 (COVID-19), the threat of illegal medication sales online is getting worse, a new study shows. The study, which was performed as part of a collaboration by Butler University and Michigan State University, found that about 18% of survey participants buy their medications online because they are “a good deal” or they believe they are getting legitimate medications. In addition, online platforms that survey participants perceived as least trustworthy for purchasing medications (Kik and TikTok) trended toward being considered generally safe from survey participants.

According to NABP’s findings, nearly 95% of websites offering prescription-only drugs online operate illegally. NABP is currently running a consumer awareness campaign to inform consumers about the dangers of buying medicine from unlicensed pharmacies online and through social media accounts. Boards of pharmacy and other health care organizations and providers are encouraged to use NABP’s patient education kit to share important online medication safety information with patients in their state.

DEA’s October 2021 Take Back Day Collects Nearly 745,000 Pounds of Unneeded Prescription Drugs

Nearly 745,000 pounds of unwanted medications were collected across the country at the 21st Drug Enforcement Administration (DEA) National Prescription Drug Take Back Day on October 23, 2021. These results reflect the positive trend that Americans value these efforts and have dedicated their time to prevent addiction and/or potential overdoses by removing old prescription drugs from their homes.

And, as DEA reminds us all, if you did not make it to a Take Back Day event, every day is Take Back Day. More than 9,600 locations can be found by using NABP’s Drug Disposal Locator Tool, available on the consumer website, www.safe.pharmacy. By entering a zip

code or city and state, consumers can find the nearest drug disposal sites on a map.

Operation Dark HunTor Disrupts Opioid Trafficking on the Darknet

Operation Dark HunTor, a coordinated international effort on three continents to disrupt opioid trafficking on the darknet, resulted in the arrest of 150 alleged darknet drug traffickers and other criminals who engaged in tens of thousands of sales of illicit goods and services across Australia, Bulgaria, France, Germany, Italy, the Netherlands, Switzerland, the United Kingdom, and the United States. The 10-month long operation was a coordinated effort between the Department of Justice (DOJ), through the Joint Criminal Opioid and Darknet Enforcement team, and Europol. The DOJ and its international partners will continue efforts to crack down on counterfeit opioids that are being purchased through the darknet.

SAMHSA’s 2020 National Survey on Drug Use and Health Shows COVID-19’s Impact on Substance Abuse

Americans’ mental health has suffered during the COVID-19 pandemic, which had an impact on people’s use of drugs and alcohol, according to the 2020 National Survey on Drug Use and Health. This survey, released annually by the Substance Abuse and Mental Health Services Administration (SAMHSA), showed that more than 59.3 million people 12 years of age or older used illicit drugs in 2020.

The survey also revealed that about 4.2 million adolescents received mental health services and an estimated 41.4 million adults received mental health services or took prescription medication for a mental health issue.

More information can be found on the SAMHSA website at www.samhsa.gov/newsroom/press-announcements/202110260320.

CDC Provisional Data Show Record-High Drug Overdoses Driven by Fentanyl

The Centers for Disease Control and Prevention (CDC) released new provisional data indicating that overdose deaths have

jumped to a new record high with an increase of 28.5% from the same period a year earlier, doubling over the past five years. According to CDC, over 100,000 people in the US have died from drug overdoses during the 12-month period ending in April 2021. Data from CDC also found that 64% of deaths were caused by synthetic opioids, primarily fentanyl, an increase of 49% from the same period a year earlier.



Drug Diversion Prevention Bill Signed Into Law

The Ensuring Compliance Against Drug Diversion Act of 2021 (PL 117-53) was signed into law on November 10, 2021, by President Joseph R. Biden. The act will close the loophole that is enabling illegal opioid distribution and provide more transparency and accountability for pharmacies seeking to distribute controlled substances. The new law will codify current drug regulations to make clear that DEA registrations may not be transferred or passed from one entity to another after that entity (possessing the registration) dies, ceases legal existence, discontinues professional practice, or surrenders the registration. ●



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UPCOMING EVENTS

Advisory Committee on Examinations

April 7, 2022 | NABP Headquarters

Committee on Constitution and Bylaws

April 11, 2022 | Virtual Meeting

118th NABP Annual Meeting

May 19-21, 2022 | Phoenix, AZ

NABP Program Review and Training

June 15, 2022 | Virtual Meeting

NABP/AACP District 5 Meeting

August 3-5, 2022 | Custer, SD

NABP/AACP District 3 Meeting

August 7-10, 2022 | Flowood, MS

NABP/AACP Districts 6, 7, and 8 Meeting

August 28-30, 2022 |
Oklahoma City, OK

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