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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

To: Board Members

Subject: Agenda Item XI. Executive Officer's Report

Board's Response to COVID-19 Pandemic and Actions Taken by Other Agencies

The Board has dedicated significant resource to its response to the COVID-19 public health crisis; both independently as well as in collaboration with other state and national agencies.

Subsequent to Governor Newson's March 4, 2020 declaration of emergency, the Board developed and implemented a waiver request process consistent with the provisions of Business and Professions Code (BPC) section 4062. This statute provides the Board the authority to waive provisions of Pharmacy Law or its regulations if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care. Consistent with the Board's policy, President Lippe reviews and makes final determination on all waiver approvals. It is important to note that some waiver requests cannot be approved, either because they are outside the scope of the Board's jurisdiction or they seek to expand the scope of practice of a licensee.

Broad Waivers

The first waivers were approved on March 11, 2020. Since that time, the Board has approved 20 broad waivers and 88 site specific waivers. While some broad waivers are developed both in response to site specific waivers that indicate larger applicability, others are developed and recommended by staff or President Lippe. Approval of waivers with broad application are communicated through the Board's subscriber alert system and posted on the website. As these waivers are limited in duration, licensees and others are notified of subsequent extensions or expiration of waivers, also through the Board's website and subscriber alert system. Board staff maintains regular communication with DCA on such waiver actions. Also, Board staff are providing information about waivers and other items of interests to stakeholders at meetings. Staff monitor the use of broad waivers through surveys of licensees as well as through data collection during desk audits and inspections. This information is considered in the decision-making process for extensions or expiration of broad waivers.

Broad waivers typically include conditions for use and recordkeeping requirements to demonstrate compliance with the conditions. In addition, one broad waiver provide authority for the Board to reinstate a license under specified conditions or extend an intern license that would have otherwise expired. As of July 1, 2020, the Board extended 692 intern licenses and reinstated 194 licenses.

Site Specific Waivers

Site specific waivers are also considered and granted. Such waivers typically address a specific challenge at a worksite, that on balance, can be granted without negatively impacting consumers. Members have previously reviewed some site-specific waivers during public meetings. Further, as broad waivers expire, licensees are reminded of the waiver request process to seek a site-specific waiver if conditions in a specific location still require use of the waived provisions.

DCA Director Waivers

In addition to the Board's waiver process, on March 30, 2020, Governor Newsom signed an Executive Order N 39-20, granting the DCA Director the authority to waive licensing requirements and amend scope of practice and any accompanying regulations to facilitate the continued provision of care to individuals. Under the conditions of the Executive Order, this authority extends through the duration of the declared emergency. Similar to the communication used by the Board, DCA also posts information on its website and uses a subscriber alert system to disseminate the information.

Consistent with the provisions of the Executive Order, Board staff partner with DCA in reviewing waiver requests. It is important to note that the Board does not have authority to make decisions on such waivers, but recommendations are offered to the DCA for consideration. Such recommendations are reviewed by President Lippe.

Although many of the DCA Director approved waivers do not impact the Board, others either directly impact Board licensees or serve as a basis for a Board waiver. As an example, the DCA's waiver - Reinstatement of Licensure, could be leveraged for several of the Board's licensees, however, a Board waiver was necessary to allow for the reinstatement of pharmacists licenses because of additional provisions contained within Pharmacy Law.

Further, as part of the approval of the DCA waiver - Order Waiving Restrictions on Pharmacists Ordering and Collecting Specimens for COVID-19 Tests staff partnered with DCA on the development of guidance on this waiver.

California Department of Public Health Waivers

As part of its response to the pandemic, CDPH has released numerous All Facilities Letters (AFL) detailing changes in regulatory practice. In April 2020, CDPH released AFL 20-26.1 notifying general acute care hospitals that CDPH was temporarily waiving licensing requirements and suspending regulatory enforcement of all licensing requirements for hospitals with stated exceptions.

More recently, CDPH released AFL 20-26.3 which served to supersede the prior AFL and extend the provisions of waiver through March 1, 2021.

Resources and Actions by Other Agencies

Other regulators are similarly taking action. Where appropriate Board staff is partnering with the sister agencies in developing policy or guidance. In instances where the Board staff is not involved in of the policy or guidance, we have released the information to licensees on our website.

As an example, Board staff, DCA and the California Department of Public Health partnered to develop and release pharmacy specific workplace guidelines. In addition to these guidelines, the Board posts links to various guidance documents issued. As examples, the link to the Cal/OSHA and Statewide Industry Guidance on COVID-19 is provided as is the FDA's Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products.

Temporary Licenses

As part of California surge capacity planning, Board staff partnered with CDPH, California Office of Emergency Services (OES) and others to issue temporary licenses to facilitate pharmacy services at alternate care sites as well as to facilitate distribution of essential supplies including ventilators and PPE.

Operational Changes

Through the pandemic the flexibility of Board operations has been essential. In March, the Board's office closed to the public and staff transitioned to full time or a rotational teleworking schedule. Prior to reopening offices to the public and resumption of some core functions, including inspections, reopening plans were developed and training provided to all staff. Staff continue to respond to fluidity of the pandemic, by making adjustments to operations to ensure the safety of staff and the public. It is important to note that there are several limiting factors that must be addressed long term to sustain this rotational teleworking schedule, most notably more robust and portable computers and a decreased reliance on paper. Internal assessments are ongoing for both short-term and long-term solutions.

As of July 1, 2020, Board staff estimates it has incurred about $46,000 direct expenses in supplies and equipment and approximately 2,800 staff hours dedicated to the COVID-19 response. Earlier this month, five Board staff were temporarily redirected to perform contact tracing activities for the administration. It is anticipated that this redirection will be necessary for several months and we are working to minimize the operational impact of this redirection.

More recently, in partnership with several other state agencies, inspector staff will begin assessing for compliance with the statewide face mask requirement and other physical distancing and protective measures.

In addition to internal operation, consistent with actions by the Governor to create physical distancing, public meetings have transitioned to a WebEx format. With the partnership of DCA, transition to an online meeting format has ensured the work of the Board continues while allowing public participation and engagement. Should this meeting format be maintained long term, Board staff estimates a cost savings of $70,000 to $75,000 annually.

Included in **Attachment 1** are copies of the Executive Order N-39-20, AFL 20-26.3, and CDPH Updated Testing Guidance.

Update on the CURES System and Implementation of AB 149 (Cooper, Chapter 4, Statutes of 2019

System usage

The CURES system continues to serve a vital tool for healthcare practitioners and regulators. System usage reports are provided on a quarterly basis. Review of the data reveals that over 45,000 California pharmacists are registered in the CURES system.

The data also provides that 5,048,522 searches were conducting using the system in the last three months of the fiscal year, with about 51% of those searches being performed by pharmacists. The second most frequent health care provider performing searches are medical doctors, accounting for about 48% of the searches performed.

Data indicates that 8,240,827 controlled II-V prescriptions were reported to the CURES system in the last quarter of the fiscal year including:

C-II: 3,681,529
C-III: 690,440
C-IV: 3,742,488
C-V: 126,370

Under current reporting requirements, C-V prescriptions are not required to be reported to CURES. It is anticipated there will be a significant increase in C-V prescription volume following the change in reporting requirements in AB 528 (Low, Chapter 677, Statutes of 2019). In addition to other changes resulting from AB 528, beginning January 1, 2021, C-V must be reported. Further, reporting to the CURES system will be required to occur within one business day from dispensing.

AB 149 Implementation

Assembly Bill 1753 changed the security features of controlled substances security forms. The bill amended Health and Safety Code section 11162.1 to require a unique serialized number specified by the Department of Justice. Subsequent legislation, Assembly Bill 149, established a transition period and provided more specificity regarding the serialized number requirement. This also includes a requirement for the serialized number of be compliant with the current National Council for Prescription Drug Program Standards.

The following controlled substance prescription forms will be valid for filling, compounding, or dispensing until January 1, 2021:

- Any prescription written on a form that does not have a unique serialized number but was otherwise valid before January 1, 2019.
- Any prescription written on a form approved by the Department of Justice as of January 1, 2019. This will include the fifteen (15) digit serialized number format approved by the Department of Justice.
- Any prescription written on a form that complies with the new requirements imposed by AB 149, including a compliant serial number and a bar code.

Board staff is partnering with the DOJ and the Board to develop and release information on the transition to ensure continuity and consistency in messaging between the various regulators. It is anticipated that the information will be released in late August or early September to ensure licensees are clear on the transition and requirements moving forward.

Updates on National Issues

FDA Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products

Earlier this year, the FDA released its sample MOU addressing compounded human drug products. Staff have identified problems with the MOU and are concerned with the resource requirements placed on state boards of pharmacy that enter into the agreement. However, staff note that potential restrictions on the business practice of compounding pharmacies could also be problematic.

Staff will continue to monitor actions by other regulators. Ultimately this item should be discussed by the Enforcement and Compounding Committee and the Board. **Attachment 2** is the sample of the MOU.

Summary of the Annual Meeting of the National Association of Boards of Pharmacy

In response to the pandemic, the annual meeting of the NABP was conducted virtually on May 14, 2020. Consistent with the Board's policy, President Lippe served as the voting delegate to the various action items, including election of officers and recommendations for the creation of work groups to evaluate specific items.
During the meeting delegate of the NABP membership adopted five resolutions addressing the following:

- providing guidance to member boards of pharmacy regarding taking disciplinary action against a pharmacy license based solely on observations from Food and Drug Administration (FDA) Form 483;
- consulting with FDA about the legal framework of authorizing manufacturers to ship a biologic containing a patient-specific blood component to a practitioner for

administration to the patient, and determining the appropriate level and type of regulatory oversight to recommend to member boards of pharmacy;
- determining whether and how to incorporate criminal background checks in the NABP e-Profile system; and
- convening a task force on medication reuse for the purpose of identifying the best mechanism to enable the transfer of unused medications to persons in need of financial assistance to ensure access to life-saving therapies.

In addition, participants received updates and presentations on items reviewed and evaluated throughout the year. Provided in Attachment 2 is the report provided by the new Executive Director, Al Carter, as well as workgroup reports provided.

The Report from Report of the Work Group on the Development of an Interstate Endorsement Credential

This workgroup was charged with exploring the feasibility of an interstate endorsement for non-dispensing or cognitive pharmacy practices and to expand the current Electronic Licensure Transfer Program (e-LPT) by creating an interstate endorsement credential that expedites licensure process and a mechanism to integrate mutual recognition among states through an enhanced state-based and uniform process.

Following its work, the work group recommended the following:

1. As e-LTP is providing an efficient system for pharmacists to transfer licensure, NABP should continue to work with states to streamline processes associated with this current license transfer process.
2. NABP should continue to maintain the MPJE and encourage its use by state boards of pharmacy, as it is an important component to evaluate knowledge of pharmacy law.
3. NABP should review MPJE data to determine where knowledge gaps exist with regard to state and federal laws and/or rules, with the goal of correlating those gaps with patient safety issues and concerns.
4. NABP should explore the feasibility of developing a limited pharmacist certification for non-dispensing interstate pharmacist care services that take place outside of a licensed pharmacy. Certification must be recognized by states and maintained for the states by NABP through the e-LTP system. The e-LTP system will serve as a clearinghouse for enforcement actions. with the states maintaining the authority to discipline certified pharmacists.
    - Exploring the feasibility includes surveying the states for the need of such service.
    - Certification would be developed in partnership with states, including the development of criteria for such certification. In addition, where necessary, NABP will develop definitions for terms related to such certification.
    - States may consider making this certification an element of licensure, as opposed to simply recognizing the certification alone.

- Fees would be distributed to states, recognizing the loss in revenue due to fewer nonresident pharmacist obtaining licensure.

Report of the Overview Task Force on Requirements for Pharmacy Technician Education, Practice Responsibilities, and Competence Assessment

This task force evaluated the requirements for technician education, practice responsibilities, and competence assessment. Specifically, the task force was charged with evaluating the current regulatory environment for pharmacy technicians and making recommendations for other task force subgroups to focus on ensuring boards of pharmacy take a more active role in establishing requirements for education, practice responsibilities and competence assessment.

Recommendations from this task force include:

1. The NABP Task Force on Requirements for Pharmacy Technician Education and the Task Force on Pharmacy Technician Competence Assessment should consider establishing minimum standards for pharmacy technician licensure.
2. The NABP Task Force on Pharmacy Technician Competence Assessment should research and evaluate the feasibility of requiring a pharmacy technician entry-level exam for licensure.
3. The NABP Task Force on Pharmacy Technician Competence Assessment should research and evaluate the requirements for minimum standards for an entry-level licensure exam (perform a gap analysis, including state law) and determine if PTCE and ExCPT meet those requirements.
4. The NABP Task Force on Requirements for Pharmacy Technician Education should perform a gap analysis of accreditation standards of accrediting organizations, including those of the ASHP/Accreditation Council for Pharmacy Education (ACPE) and ABHES (Accrediting Bureau of Health Education Schools).
5. The NABP Task Force on Requirements for Pharmacy Technician Education should evaluate and recommend standards for entry-level pharmacy technician education and training programs based on the results of the gap analysis.
6. The NABP Task Force on Requirements for Pharmacy Technician Education and the NABP Task Force on Pharmacy Technician Competence Assessment should recommend revisions, if necessary, to *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* regarding the definitions and scope of practice of entry-level pharmacy technicians.
7. NABP should convene the Task Force on Requirements for Pharmacy Technician Practice Responsibilities scheduled for 2020 to evaluate the various levels of pharmacy technician practice, including but not limited to, levels identified by the current ASHP/ACPE standards, and recommend revisions, if necessary, to the *Model Act*.

Attachment 3 includes a copy of the NABP Press Release regarding the Annual Meeting, the report of the Executive Director and the task force reports.

The next annual meeting is scheduled for May 13-15, 2021 in Phoenix, Arizona.
The upcoming District 6, 7, and 8 virtual meeting to be held on October 13, 2020.

Attachment 1

EXECUTIVE DEPARTMENT
STATE OF CALIFORNIA

EXECUTIVE ORDER N-39-20

WHEREAS on March 4, 2020, I proclaimed a State of Emergency to exist in California as a result of the threat of COVID-19; and

WHEREAS despite sustained efforts, COVID-19 continues to spread at a rapid rate, threatening to overwhelm California's healthcare delivery system; and

WHEREAS California is preparing for a surge in the number of people who will need hospital care during the COVID-19 outbreak by increasing the number of hospital beds and post-acute care facilities that can treat and serve patients; and

WHEREAS this anticipated increase in the use of the healthcare system will require an increase in the health care workforce such as nurses, doctors, medical assistants, and emergency medical technicians; and

WHEREAS maximizing the number of qualified and capable medical and healthcare workers in service in California is imperative to ensure that Californians impacted by COVID-19 can access medical treatment; and

WHEREAS, the anticipated surge requires temporary adjustment of California's staffing and health and safety standards for health providers and health facilities, which are among the strongest in the nation, as numerous professionals are unable to satisfy professional licensing requirements in light of the COVID-19 pandemic that then subsequently prevent them from providing necessary medical and healthcare assistance to the public; and

WHEREAS, our most vulnerable residents who rely on state and local government for social services need additional support during this time; and

WHEREAS the Department of Developmental Services operates Stabilization, Training, Assistance and Reintegration (STAR) community crisis homes to treat individuals with developmental disabilities in acute crisis and additional STAR homes are required to provide treatment to such individuals and to protect the public health during the COVID-19 crisis; and

WHEREAS federal guidance permits monthly caseworker visits with children under court jurisdiction to be accomplished through videoconferencing in limited circumstances, such as a declaration of an emergency that prohibits or strongly discourages face-to-face contact for public health reasons; and

WHEREAS under the provisions of Government Code section 8571, I find that strict compliance with various statutes and regulations specified in this order would prevent, hinder, or delay appropriate actions to prevent and mitigate the effects of the COVID-19 pandemic.

NOW, THEREFORE, I, GAVIN NEWSOM, Governor of the State of California, in accordance with the authority vested in me by the State Constitution and statutes of the State of California, and in particular, Government Code sections 8567 and 8571, do hereby issue the following Order to become effective immediately:

IT IS HEREBY ORDERED THAT:

1) To assist in the care and/or to protect the health of individuals in hospitals and other health facilities, and due to the COVID-19 outbreak, the director of the State Department of Public Health may, to the extent necessary and only for the duration of the declared emergency, waive any of the licensing and staffing requirements of chapters 2 and 2.4 of division 2 of the Health and Safety Code and any accompanying regulations with respect to any hospital or health facility identified in Health and Safety Code section 1250. Any waiver shall include alternative measures that, under the circumstances, will allow the facilities to treat patients while protecting public health and safety. To the extent the facility maintains a disaster and mass casualty plan, the facility granted a waiver shall be established and operate in accordance with that plan. Any waivers granted pursuant to this paragraph shall be posted on the Department's website.

2) To facilitate the continued provision of care due to the COVID-19 outbreak, the director of the State Department of Public Health may, to the extent necessary and only for the duration of the declared emergency, waive any of the professional licensing and certification requirements and amend scopes of practice of chapters 2, 2.35, and 8 of division 2 of the Health and Safety Code and any accompanying regulations with respect to certified nursing assistants, home health aides, and nursing home administrators, and chapter 3, division 2 of the Business and Professions Code and accompanying regulations with respect to certified hemodialysis technicians. The Department shall provide guidance to facilities directing the appropriate qualifications and scope of practice for each classification operating under a waiver based on sound clinical guidelines and the individual's training, education, and work experience. Any waiver shall include alternative measures that, under the circumstances, will allow the facilities to treat patients while protecting public health and safety. Any waivers granted pursuant to this paragraph shall be posted on the Department's website.

3) The certification and permitting requirements of the Radiologic Technology Act (as identified in Health and Safety Code section 27) are, only for the duration of the declared emergency, suspended for all persons:

   (i) whose certificate or permit issued pursuant to the Radiological Technology Act is expired, regardless of expiration date, or has been canceled; or

   (ii) who hold Radiography certification issued by the American Registry of Radiologic Technologists or are an American Registry of Radiologic Technologists Registered Radiologist Assistant; or

   (iii) who are credentialed as Radiology Practitioner Assistants by the Certification Board for Radiology Practitioner Assistants; or

(iv) who are certified, permitted or otherwise authorized to perform radiologic technology by passing a State-required examination by a state other than the State of California; and

(v) who are working under the supervision of a person licensed under the Medical Practice Act, except that the requirement to be under supervision shall not apply to a licentiate of the healing arts, as defined in the Radiological Technology Act; and

(vi) who are deemed by a health facility as necessary workforce for purposes of this Order.

The specific certification requirements of Health and Safety Code section 107110 are suspended for any person who is licensed under the Medical Practice Act (Business and Professions Code sections 2000, et seq.). Except for persons licensed under the Medical Practice Act, this suspension of certification and permitting requirements shall not apply to persons who have never been either certified or permitted by the Department of Public Health, or certified, permitted, or otherwise authorized by the American Registry of Radiologic Technologists, the Certification Board for Radiology Practitioner Assistants, or any other state. This suspension of certification and permitting requirements shall also not apply to persons whose certificate, permit, or other authorization has been revoked or suspended for cause by the Department of Public Health, the American Registry of Radiologic Technologists, the Certification Board for Radiology Practitioner Assistants, or any other state.

4) To ensure hospitals are adequately prepared and staffed to treat COVID-19 patients, the Director of the State Department of Public Health may temporarily waive licensing requirements in Health and Safety Code section 1277 and sections 70203(a)(2), 70701(a)(1)(E), 70703(b), and 70705(a) of Chapter 1, Article 3, of Title 22, that pertain to the credentialing and privileging of physicians. Any waiver shall include alternate measures that, under the circumstances, ensure the competency of physicians providing medical services at the hospital.

5) To facilitate the continued provision of care to individuals affected by the COVID-19 outbreak, the Director of the Department of Consumer Affairs may to the extent necessary and only for the duration of the declared emergency, waive any of the professional licensing requirements and amend scopes of practice in Division 2 of the Business and Professions Code, and any accompanying regulations. Professional licensing requirements should be interpreted broadly to effectuate the purposes of this executive order, and they include, but are not limited to, the examination, education, experience, and training requirements necessary to obtain and maintain licensure, and requirements governing the practice and permissible activities for licensees. The Department, in conjunction with the relevant licensing board, shall provide guidance identifying the appropriate qualifications and scope of practice for each classification operating under a waiver based on sound clinical guidelines and the individual's training, education, and work experience. Any waiver may include alternative measures that, under the circumstances, will allow the regulated individual to treat patients while protecting public health

and safety. Any waivers granted pursuant to this paragraph shall be posted on the Department's website.

6) To ensure the continued operation of the Emergency Medical Services (EMS) system without unduly endangering the people of California during the COVID-19 outbreak, the Director of the California Emergency Medical Services Authority may as necessary and only for the duration of the declared emergency, suspend any licensing, certification, or training requirements for EMS personnel as contained in the EMS Act Chapters 2, 3, and 4, and accompanying regulations, including the authority to permit EMS personnel to provide services in any setting as authorized by the Director for the performance of the current scope of practice. The Authority shall provide guidance to local emergency medical services authorities directing the appropriate qualifications and scope of practice for each classification operating under a waiver based on sound clinical guidelines and the individual's training, education, and work experience. Any waivers granted pursuant to this paragraph shall be posted on the Authority's website.

7) Notwithstanding the Government Code section 14669, or any other law, the Director of the Department of Developmental Services has the authority to enter into a lease, lease-purchase, lease with option to purchase any real or personal property or any other agreement to procure residences or facilities and necessary equipment, goods or services to serve those individuals with development disabilities in crisis, to respond to, mitigate the effects or prevent the spread of COVID-19 to individuals with developmental disabilities or the general community. The leases or agreements may be executed without the review or prior approval of any other state department or agency. The leases or agreements executed pursuant to this provision shall be in effect so long as necessary to address the COVID-19 crisis or its effects.

8) The Department of Social Services may, to the extent the Department deems necessary to respond to the COVID-19 crisis, allow any state monthly face-to-face caseworker visitation requirement, standard, or criteria set forth in the Welfare and Institutions Code sections 16501.1, subdivision (l), 16516.5, and 16516.6, as well as accompanying regulations or other written directives, policies or procedures, to be accomplished through videoconferencing, instead of in-person contact. This flexibility shall only be utilized by caseworkers in keeping with guidance from the Department and after a child-specific decision based on the training and experience of the social worker, considering all available information, that an in-person visit is not necessary to ensure the child's safety and well-being. Any flexibility granted pursuant to this paragraph shall not waive or conflict with applicable federal requirements in United States Code, Title 42, sections 622, subdivision (b)(17) and 624, subdivision (f), as modified for emergency waivers in guidance issued March 18, 2020, in the Child Welfare Policy Manual Title IV-B, section 7.3, question 8and shall expire at the end of the emergency declaration, in 90 days, or sooner as determined by the Department. Any flexibility granted pursuant to this paragraph shall be posted to the Department's website.

IT IS FURTHER ORDERED that as soon as hereafter possible, this Order be filed in the Office of the Secretary of State and that widespread publicity and notice be given of this Order.

This Order is not intended to, and does not, create any rights or benefits, substantive or procedural, enforceable at law or in equity, against the State of California, its agencies, departments, entities, officers, employees, or any other person.

IN WITNESS WHEREOF I have hereunto set my hand and caused the Great Seal of the State of California to be affixed this 30th day of March 2020.

GAVIN NEWSOM
Governor of California

ATTEST:

ALEX PADILLA
Secretary of State

SONIA Y. ANGELL, MD, MPH
State Public Health Officer & Director

State of California—Health and Human Services Agency

California Department of Public Health

GAVIN NEWSOM
Governor

July 3, 2020

AFL 20-26.3

TO: General Acute Care Hospitals

SUBJECT: Suspension of Regulatory Enforcement of Hospital Requirements
(This AFL supersedes AFL 20-26.2)

AUTHORITY: Proclamation of Emergency and Executive Order N-27-20

All Facilities Letter (AFL) Summary

- This AFL notifies hospitals of a temporary waiver of specified regulatory requirements due to the state of emergency related to the Coronavirus Disease 2019 (COVID-19) outbreak.
- This AFL has been updated to extend the waiver until March 1, 2021.
- This AFL provides clarifying changes for downgrading, changing, or eliminating services and conditions for which facilities may request a staffing waiver.

Pursuant to the Governor's declaration of a state of emergency related to COVID-19, the Director of the California Department of Public Health (CDPH) may waive any of the licensing requirements of Chapter 2 of Division 2 of the Health and Safety Code (HSC) and accompanying regulations with respect to any hospital or health facility identified in HSC section 1250. CDPH is temporarily waiving specified hospital licensing requirements and suspending regulatory enforcement of the following requirements as specified below:

Licensing

Hospitals seeking initial licensure or to change beds or services to their license shall submit an application online at the CDPH Health Care Facilities Online Application webpage. This shall not require approval before the hospital may provide care, although CDPH will reach out to provide technical assistance to ensure patient safety and the quality of care.

Space

All statutory and regulatory provisions related to the configuration and use of physical space and classification of beds in a hospital. Hospitals may reconfigure space as needed to accommodate observed or predicted patient surge, patient cohorting, modified infection and source control procedures, and other COVID-19 related mitigation strategies.

Temporary changes of use or modification to the physical environment must be restored to original conditions following expiration of a waiver. Where such temporary changes are to be made permanent, projects must be submitted for Office of Statewide Health Planning and Development's (OSHPDs) review and approval (whether the

changes involve construction or not) no later than two weeks after waiver expiration. Permanent modifications to the physical environment or changes of use must be submitted to OSHPD as projects for review and approval (whether the changes involve construction or not) immediately.

Services

1. Detailed notifications and notification timeframes specified in HSC sections 1255.1, 1255.2, and 1255.25 that are required when a hospital plans to downgrade, change, or eliminate the level of a supplemental service. The notification procedures and timeframes may only be waived if the hospital is modifying services to address patient surge related to COVID-19. A hospital must provide notice to the public regarding the availability of supplemental services at the hospital by posting signage at the entrance of each location and on its internet website. The hospital must provide notice at least 24 hours in advance of the service change to the public and CDPH. Approval is needed if a service is being added or changed.
2. Due to the alternative arrangements available for homeless patients authorized by Executive Order N-32-20 (PDF), detailed discharge planning documentation and the provision of nonmedical services to homeless individuals specified in HSC section 1262.5 is temporarily waived.

Staffing

Hospitals shall bring staffing levels into state ratio compliance within two weeks of this AFL issue date. Only those hospitals experiencing a COVID-19 related surge of patients or staffing shortages resulting from COVID-19 impacts including; increasing community spread, increasing need to meet demand for surge either by regional surge or incoming transfers, daycare or school closures, COVID-19 staffing absenteeism for multiple reasons, or an emergency such as a fire or public safety power shutoff, may request a waiver of minimum nurse-to-patient ratios. A hospital seeking a staffing waiver must submit a CDPH form 5000A (PDF) and provide supporting documentation to the CHCQ Duty Officer at CHCQDutyOfficer@cdph.ca.gov and copy the local district office. CHCQ is able to respond quickly to urgent requests from hospitals seeking a waiver 24/7 and should only mark urgent if needed approval within 8 hours. Pursuant to the Proclamation of Emergency (PDF), all staffing waivers will be posted on the CDPH website. Hospitals must resume mandatory staffing levels as soon as feasible during the waiver period to minimize the need for additional waivers. Temporary staffing waivers will only be approved for 90-days. A hospital may reapply for a waiver if the conditions necessitating the waiver still apply.

This statewide waiver is approved under the following conditions:

- Hospitals shall continue to comply with adverse event and unusual occurrence reporting requirements specified in HSC section 1279.1 and Title 22 California Code of Regulations section 70737(a).
- Hospitals shall report any substantial staffing or supply shortages that jeopardize patient care or disrupt operations.
- Hospitals shall continue to provide necessary care in accordance with patient needs and make all reasonable efforts to act in the best interest of patients.
- Hospitals shall follow their disaster response plan.
- Hospitals shall follow infection control guidelines from the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) related to COVID-19.
- Hospitals shall comply with directives from their local public health department, to the extent that there is no conflict with federal or state law or directives or CDPH AFLs.

CDPH understands the importance of ensuring the health and safety of all Californians and maintaining vital access to acute care services. CDPH encourages facilities to implement contingency plans to address staff absenteeism and the rapid influx of patients. CDPH will continue to promote quality healthcare, provide technical assistance and support compliance with core health and safety requirements, pursuant to Executive Order N-27-20 (PDF). CDPH is taking this unprecedented action due to the significant challenges California's health care system is facing as a result of the COVID-19 outbreak. As a result of this temporary waiver, hospitals do not need to submit individual program flexibility requests for the requirements specified above, except when seeking a staffing waiver.

This waiver is valid until March 1, 2021 and may be extended or reduced based on the conditions of the pandemic and any updated Executive Orders or guidance from CMS or the CDC.

If you have any questions about this AFL, please contact your local district office.

Sincerely,

Original signed by Heidi W. Steinecker

Heidi W. Steinecker
Deputy Director

Resources

- Proclamation of Emergency (PDF)
- Executive Order N-27-20 (PDF)
- CDPH 5000A (PDF)
- CDPH Health Care Facilities Online Application webpage

Center for Health Care Quality, MS 0512 . P.O. Box 997377 . Sacramento, CA 95899-7377
(916) 324-6630 . (916) 324-4820 FAX
Department Website (cdph.ca.gov)

Page Last Updated : July 4, 2020

SONIA Y. ANGELL, MD, MPH
State Public Health Officer & Director

State of California—Health and Human Services Agency
California Department of Public Health

GAVIN NEWSOM
Governor

July 14, 2020

TO: Public health officials, healthcare providers and laboratories

SUBJECT: Updated COVID-19 Testing Guidance

This guidance is an update to the interim COVID-19 testing guidance issued by the California Department of Public Health (CDPH) on May 1, 2020. This updated guidance is intended to support public health officials, health care providers, and laboratories in determining who should be tested given the current context of the COVID-19 pandemic in California.

What's new in this revision compared to May 1, 2020 Testing Guidance?

COVID-19 testing in California has rapidly expanded over the past three months and we have learned much about COVID-19 and which populations and communities it impacts disproportionately.

Consequently, CDPH recommends first prioritizing testing of hospitalized individuals with signs or symptoms of COVID-19 infection followed by testing of other symptomatic individuals and higher risk asymptomatic individuals and then other asymptomatic individuals when certain conditions exist. This guidance should be used for prioritization of patient populations as well as for the purposes of guiding laboratories in managing specimen processing.

Tier One Priority

- Hospitalized individuals with COVID-19 symptoms.
- Investigation and management of outbreaks, under direction of state and local public health departments (includes contact tracing).
- Close contacts of confirmed cases.

Tier Two Priority

- All other individuals with COVID-19 symptoms.
- Individuals who are asymptomatic (having no symptoms of COVID 19), who fall into one of the following categories:

    1. Live in higher risk congregate care facilities including skilled nursing facilities, residential care facilities for the elderly, correctional facilities, or homeless shelters.
    2. Work in the health care sector who have frequent interactions with the public or with people who may have COVID-19 or have been exposed to SARS-CoV-2. The health care sector includes: hospitals; skilled nursing facilities; long-term care facilities; ambulatory surgery centers; health

care providers' offices; health care clinics; pharmacies; blood banks; dialysis centers; hospices; and, home health providers

3. Work in a congregate care facility, including shelters for people experience homelessness and residential care facilities for the elderly.
4. Provide care to an elderly person or a person with a disability in the home, including a person providing care through California's In-Home Supportive Services Program.
5. Work in the emergency services sector who have frequent interactions with the public or with people who may have COVID-19 or have been exposed to SARS-CoV-2. The emergency services sector includes police and public safety departments, fire departments, and emergency service response operations.
6. Work in a correctional facility.
7. Patients requiring pre-operative/pre-hospital admission screening.
8. Patients being discharged from hospitals to lower levels of care.

Tier Three Priority

- Individuals who work in the retail or manufacturing sectors who have frequent interactions with the public or who works in an environment where it is not practical to maintain at least six feet of space from other workers on a consistent basis.
- Individuals who work in the food services sector who have frequent interactions with the public. The food services sector includes grocery stores, convenience stores, restaurants, and grocery or meal delivery services.
- Individuals who work in the agricultural or food manufacturing sector who have frequent interactions with the public or who works in an environment where it is not practical to maintain at least six feet of space from other workers on a consistent basis. The agricultural or food manufacturing sector includes food production and processing facilities, slaughter facilities, harvesting sites or facilities, and food packing facilities.
- Individuals who work in the public transportation sector who have frequent interactions with the public. The public transportation sector includes public transit, passenger rail service, passenger ferry service, public airports, and commercial airlines.
- Individuals who work in the education sector who have frequent interactions with students or the public. The education sector includes public and private childcare establishments; public and private pre-kindergarten programs; primary and secondary schools; and public and private colleges and universities.

Tier Four Priority

Tier Four would be implemented when the state's testing turnaround time, as monitored by CDPH, is less than 48 hours.

- Other individuals not specified above including: those who are asymptomatic but believe they have a risk for being actively infected as well as routine testing by employers.

Testing Discrimination and Inappropriate Workplace Testing

As modifications are made to public health directives and more sectors of the economy open with adaptations, it is important that employers do not use testing to impermissibly discriminate against employees who have previously tested positive for COVID-19 (such as by preventing them from resuming work after they can do so in a manner consistent with public health and safety). This does not mean an employer must allow an employee who currently has COVID-19 to return to work before the employee's infection is resolved. **Further, because PCR tests can**

remain positive long after an individual is no longer infectious, proof of a negative test should not be required prior to returning to the workplace after documented COVID infection. Rather, symptom- or protocol-based criteria should be used in determining when an employee is safe to return to the workplace.

Types of Tests

Diagnostic Tests

Assesses the presence of the virus at a given point in time. A negative means only that an individual was negative at the time the test.

- Polymerase Chain Reaction (PCR) Tests and Nucleic Acid Amplification Testing: Detects the RNA genetic material in the COVID-19 virus and are often collected via nasal pharyngeal, mid turbinate, nasal, oral or throat swab or saliva collection.
- Antigen Tests: Not currently widely utilized. Detects the presence of COVID-19 specific protein particles and is collected via a respiratory sample.

Note: No test is perfect. There is a false negative rate and false positive rate that varies depending on the test and the collection modality

Non- Diagnostic Tests

- Serology (Antibody) Tests: Detect antibodies in the blood indicating possible prior exposure to COVID-19, which may develop 6-14 days after infection. Please see CDPH guidance on Serology Tests for further information.
- **Note:** Commercially available antibody tests have variable performance—see FDA EUA Authorized Serology Test Performance Website.

Reminder - These are statewide guidelines. Local jurisdictions may modify these guidelines to account for local conditions or patterns of transmission.

Center for Health Care Quality, MS 0512 . P.O. Box 997377 . Sacramento, CA 95899-7377
(916) 324-6630 . (916) 324-4820 FAX
Department Website (cdph.ca.gov)

Page Last Updated : July 14, 2020

Attachment 2

MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS BETWEEN THE [insert STATE BOARD OF PHARMACY OR OTHER APPROPRIATE STATE AGENCY] AND THE U.S. FOOD AND DRUG ADMINISTRATION

I. PURPOSE

This Memorandum of Understanding (MOU) establishes an agreement between the [insert State Board of Pharmacy or other appropriate State agency] and the U.S. Food and Drug Administration (FDA) regarding the distribution of inordinate amounts of compounded human drug products interstate[1] and the appropriate investigation by the [insert State Board of Pharmacy or other appropriate State agency] of complaints relating to human drug products compounded in [insert State] and distributed outside such State.[2] This is the MOU provided for by section 503A(b)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 353a), and does not apply to veterinary drug products, biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262), and drugs that are compounded by outsourcing facilities under section 503B of the FD&C Act.

II. BACKGROUND

a. Section 503A of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from three sections of the FD&C Act requiring:

   1. Compliance with current good manufacturing practice (section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B));

   2. Labeling with adequate directions for use (section 502(f)(1) (21 U.S.C. 352(f)(1)); and

   3. FDA approval prior to marketing (section 505 (21 U.S.C. 355)).

[1] For purposes of this MOU, see the definitions of "inordinate amounts" and "distribution of compounded human drug products interstate" (also referred to as "distributed interstate") in Appendix A.

[2] As described herein, the State Board of Pharmacy or other appropriate State agency signatory is agreeing to take certain actions as described in Section III below. For example, if a State Board of Pharmacy signs the MOU, the State Board of Pharmacy agrees to take the actions described in Section III below with respect to drugs compounded by pharmacies in that State; in addition, the State Board of Pharmacy agrees that if it receives information about complaints or becomes aware of information about drugs compounded by physicians in the State and distributed interstate, it will forward the information to FDA and the appropriate State regulator of physicians as described in Section III.

b. To qualify for these exemptions, a compounded human drug product must, among other things,[3] meet the conditions in section 503A(b)(3)(B) of the FD&C Act, under which the drug product is compounded in a State that:

1. Has entered into an MOU with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State (section 503A(b)(3)(B)(i)); or

2. Has not entered into an MOU with FDA and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (section 503A(b)(3)(B)(ii)).

c. Section 503A(b)(3) of the FD&C Act directs FDA to develop a standard MOU, in consultation with the National Association of Boards of Pharmacy (NABP), for use by the States in complying with section 503A(b)(3)(B)(i). This MOU is the standard MOU developed by FDA for this purpose.

III. SUBSTANCE OF AGREEMENT

a. Investigation of Complaints Relating to Compounded Human Drug Products Distributed Outside the State

1. The [insert State Board of Pharmacy or other appropriate State agency] will investigate complaints of adverse drug experiences and product quality issues[4] relating to human drug products compounded at a pharmacy in [insert State] and distributed outside the State. Any investigations will be performed pursuant to the [insert State Board of Pharmacy or other appropriate State agency]'s established investigatory policies and procedures, including those related to prioritizing complaints, provided they are not in conflict with the terms of this MOU.

2. Any investigations performed by the [insert State Board of Pharmacy or other appropriate State agency] under this MOU will include taking steps to assess (1) whether there is a public health risk associated with the compounded drug product; and (2) whether any public health risk associated with the product is adequately contained.

[3] To qualify for the exemptions under section 503A, a compounder must obtain a prescription for an individually identified patient (section 503A(a) of the FD&C Act). This MOU does not alter this condition.
[4] For purposes of this MOU, see the definitions of "adverse drug experience" and "product quality issue" in Appendix A.

3. After the [insert State Board of Pharmacy or other appropriate State agency]'s investigation, if the complaint is substantiated, the [insert State Board of Pharmacy or other appropriate State agency], in accordance with and as permitted by State law, will take the action that the [insert State Board of Pharmacy or other appropriate State agency] considers to be appropriate and warranted to ensure that the relevant pharmacy investigates the root cause of the problem that is the subject of the complaint and undertakes sufficient corrective action to address any identified public health risk relating to the problem, including the risk that future similar problems may occur.

4. The [insert State Board of Pharmacy or other appropriate State agency] will maintain records of the complaint about adverse drug experiences or product quality issues relating to human drug products compounded at a pharmacy, the investigation of the complaint, and any response to or action taken as a result of the complaint, beginning when the [insert State Board of Pharmacy or other appropriate State agency] receives notice of the complaint. The [insert State Board of Pharmacy or other appropriate State agency] will maintain these records for at least 3 years. The 3-year period begins on the date of final action on a complaint, or the date of a decision that the complaint requires no action.

5. As soon as possible, but no later than 5 business days after receiving a complaint involving a serious adverse drug experience or serious product quality issue relating to a drug product compounded at a pharmacy and distributed outside the State, the [insert State Board of Pharmacy or other appropriate State agency] will, by submission to an Information Sharing Network[5] or by email to StateMOU@fda.hhs.gov, provide FDA with the information described in the Submission and Disclosure of Information section of this MOU (section III.c.1.a.i-iii).[6]

6. After the [insert State Board of Pharmacy or other appropriate State agency] concludes its investigation of a complaint assessed to involve a serious adverse drug experience or serious product quality issue relating to a drug product compounded at a pharmacy and distributed outside the State, the [insert State Board of Pharmacy or other

[5] For purposes of this MOU, see the definitions of "serious adverse drug experience," "serious product quality issue," and "Information Sharing Network" in Appendix A.

[6] The information includes the following: (i) Name and contact information of the complainant, if available; (ii) Name and address of the pharmacy that is the subject of the complaint; and (iii) Description of the complaint, including a description of any compounded human drug product that is the subject of the complaint.

appropriate State agency] will share with FDA, as described in the Submission and Disclosure of Information section of this MOU (section III.c.1.a.iv-v),[7] the results of the investigation as permitted by State law.

7. If the [insert State Board of Pharmacy or other appropriate State agency] receives a complaint involving an adverse drug experience or product quality issue relating to a human drug product compounded by a physician and distributed outside the State, the [insert State Board of Pharmacy or other appropriate State agency] will notify the appropriate regulator of physicians within the State. The [insert State Board of Pharmacy or other appropriate State agency] will also notify FDA by submission to an Information Sharing Network or by sending an email to StateMOU@fda.hhs.gov with the information described in the Submission and Disclosure of Information section of this MOU (section III.c.2.a.-c), if available, as soon as possible, but no later than 5 business days, after receiving the complaint.

b. Distribution of Inordinate Amounts of Compounded Human Drug Products Interstate[8]

1. For purposes of this MOU, a pharmacy has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of:

(i) the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus

(ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year.

[7] The information includes: (i) [Insert State Board of Pharmacy or other appropriate State agency]'s assessment of whether the complaint was substantiated, if available; and (ii) Description and date of any actions the [insert State Board of Pharmacy or other appropriate State agency] has taken to address the complaint.

[8] The distribution of inordinate amounts of compounded human drug products interstate is a threshold for the [insert State Board of Pharmacy or other appropriate State agency] to identify and report certain information to FDA, not a limit on the distribution of compounded human drug products interstate.

Figure 1. Calculating an Inordinate Amount

$$\frac{A}{B} = X, \text{ where:}$$

A = Number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year

B = The sum of the number of prescription orders for compounded human drug products (i) that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year

If *X* is greater than 0.5, it is an inordinate amount and is a threshold for certain information identification and reporting under the MOU.

2. On an annual basis, the [insert State Board of Pharmacy or other appropriate State agency] will identify, using surveys, reviews of records during inspections, data submitted to an Information Sharing Network, or other mechanisms available to the [insert State Board of Pharmacy or other appropriate State agency], pharmacies that distribute inordinate amounts of compounded human drug products interstate.

3. For pharmacies that have been identified as distributing inordinate amounts of compounded human drug products interstate during any calendar year, the [insert State Board of Pharmacy or other appropriate State agency] will identify, using data submitted to an Information Sharing Network or other available mechanisms, during that same calendar year:
    a. the total number of prescription orders for sterile compounded human drugs distributed interstate;
    b. the names of States in which the pharmacy is licensed;
    c. the names of States into which the pharmacy distributed compounded human drug products; and
    d. whether the State inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients.

4. The [insert State Board of Pharmacy or other appropriate State agency] will, within 30 business days of identifying a pharmacy that has distributed inordinate amounts of compounded human drug products interstate, notify FDA of such pharmacy, through an Information Sharing Network or by email to StateMOU@fda.hhs.gov, and will include the

information described in the Submission and Disclosure of Information section of this MOU (section III.c.1.b).

5. If the [insert State Board of Pharmacy or other appropriate State agency] becomes aware of a physician who is distributing any amount of compounded human drug products interstate, the [insert State Board of Pharmacy or other appropriate State agency] will notify the appropriate regulator of physicians within the State. The [insert State Board of Pharmacy or other appropriate State agency] will, within 30 business days of identifying a physician who is distributing any amount of compounded human drug products interstate, also notify FDA by submission to an Information Sharing Network or by email to StateMOU@fda.hhs.gov.

c. Submission and Disclosure of Information
    1. When submitting information using StateMOU@fda.hhs.gov regarding complaints relating to human drug products compounded by a pharmacy and distributed outside the State, or regarding distribution of inordinate amounts of human drug products compounded by a pharmacy interstate, the following minimum information will be included. Note, this information can be submitted to an Information Sharing Network for sharing with FDA.

        a. Complaints:

            i. Name and contact information of the complainant, if available;

            ii. Name and address of the pharmacy that is the subject of the complaint;

            iii. Description of the complaint, including a description of any compounded human drug product that is the subject of the complaint;

            iv. [Insert State Board of Pharmacy or other appropriate State agency]'s assessment of whether the complaint was substantiated, if available; and

            v. Description and date of any actions the [insert State Board of Pharmacy or other appropriate State agency] has taken to address the complaint.

        b. Inordinate Amounts:

i. Name and address of the pharmacy that distributed inordinate amounts of compounded human drug products interstate;

ii. The number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year;

iii. The number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year;

iv. The total number of prescription orders for compounded human drug products distributed interstate during that same calendar year;

v. The total number of prescription orders for sterile compounded human drug products distributed interstate during that same calendar year;

vi. The names of States in which the pharmacy is licensed and the names of States into which the pharmacy distributed compounded human drug products during that same calendar year; and

vii. Whether the [insert State Board of Pharmacy or other appropriate State agency] inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients during that same calendar year.

2. When submitting information using StateMOU@fda.hhs.gov regarding complaints relating to human drug products compounded by a physician, or regarding distribution of any amount of human drug products compounded by a physician interstate, the following minimum information will be included, if available. Note, this information can be submitted to an Information Sharing Network for sharing with FDA.

a. Name and contact information of the complainant or notifier;

b. Name and address of the physician that is the subject of the complaint or notification; and

c. Description of the complaint or notification, including a description of any compounded human drug product that is the subject of the complaint or notification.

3. The parties to this MOU will share information consistent with applicable statutes and regulations. The parties recognize that a separate agreement under 21 CFR 20.88 may be necessary before FDA can share information that is protected from public disclosure. Such an agreement will govern FDA's sharing of the following types of information:

- Confidential commercial information, such as information that would be protected from public disclosure under Exemption 4 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4));

- Personal privacy information, such as information that would be protected from public disclosure under Exemption 6 or 7(C) of the FOIA (5 U.S.C. 552(b)(6) and(7)(C)); or

- Information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g., the Trade Secrets Act (18 U.S.C. 1905), the Privacy Act (5 U.S.C. 552a), other FOIA exemptions not mentioned above (5 U.S.C. 552(b)), the Health Insurance Portability and Accountability Act (Public Law 104-191), and FDA's regulations in parts 20 and 21 (21 CFR parts 20 and 21)).

FDA agrees that information provided to FDA by the [insert State Board of Pharmacy or other appropriate State agency] will only be disclosed consistent with applicable Federal law and regulations governing the disclosure of such information, including the FOIA (5 U.S.C. 552(b)), the FD&C Act (21 U.S.C. 301 et seq.), 21 U.S.C. 331(j), 21 U.S.C. 360j(c), the Trade Secrets Act (18 U.S.C. 1905), FDA's regulations in 21 CFR parts 20 and 21, and other pertinent laws and regulations.

IV. ENFORCEMENT AUTHORITIES AND LEGAL STATUS OF AGREEMENT

The parties to this MOU recognize that FDA and the [insert State Board of Pharmacy or other appropriate State agency] retain the statutory and regulatory authorities provided by the FD&C Act, other Federal statutes and attendant regulations, and State statutes and regulations. The parties also recognize that this agreement does not restrict FDA or any other Federal agency from taking

enforcement action, when appropriate, to ensure compliance with Federal statutes, including the FD&C Act and attendant regulations, or prevent the [insert State Board of Pharmacy or other appropriate State agency] from taking enforcement action, as appropriate, to ensure compliance with applicable State statutes and regulations. This MOU does not create or confer any rights for or on any person. By signing this MOU, the [insert State Board of Pharmacy or other appropriate State agency] affirms that it now possesses and will maintain, at the discretion of the State legislature, the legal authority (under State statutes and/or regulations) and the resources necessary to effectively carry out all aspects of this MOU. If State law changes such that the [insert State Board of Pharmacy or other appropriate State agency] no longer has the legal authority or resources necessary to effectively carry out all aspects of this MOU, the [insert State Board of Pharmacy or other appropriate State agency] will notify FDA within 60 calendar days of the change in legal authority.

V. NAME AND ADDRESS OF PARTICIPATING AGENCIES

U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Office of Compliance
Office of Unapproved Drugs and Labeling Compliance
10903 New Hampshire Avenue
Bldg. 51, Suite 5100
Silver Spring, MD 20993-0002
Telephone: (301) 796-3110
Email: StateMOU@fda.hhs.gov

[Insert State Board of Pharmacy or other appropriate State agency and its contact information]

Upon signing the MOU, each party must designate one or more liaisons to act as points of contact. Each party may designate new liaisons at any time by notifying the other party's liaison(s) in writing. If, at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the parties will name a new liaison within 2 weeks and notify the other party's liaison(s).

VI. PERIOD OF AGREEMENT

a. When accepted by both parties, this MOU will be effective from the date of the last signature and will continue until terminated by either party. It may be terminated in writing by either party, upon a 60 calendar day notice of termination. Notice of termination will be sent to the address listed in section V of this MOU.

b. If the [State Board of Pharmacy or other appropriate State agency] does not adhere to the provisions of this MOU, including conducting an investigation of complaints related to compounded human drug products distributed outside the State, the MOU may be terminated upon a 60 calendar day notice of termination.

In case of termination, FDA will post a notice of the termination on its Web site and the [insert State Board of Pharmacy or other appropriate State agency] will notify all pharmacies that compound drug products in the State and notify the State authority that licenses or regulates physicians of the termination and advise them that as of 60 calendar days from the date of the posting of the termination notice, compounded human drug products may be distributed (or caused to be distributed) out of the State only "in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed" by the licensed pharmacy or physician (section 503A(b)(3)(B)(ii) of the FD&C Act).

VII. APPROVALS

APPROVED AND ACCEPTED FOR THE U.S. FOOD AND DRUG ADMINISTRATION	APPROVED AND ACCEPTED FOR [insert State Board of Pharmacy or other appropriate State agency]
By (Type Name)	By (Type Name)
Title	Title
Date	Date

Appendix A. Definition of Terms for the Purposes of this MOU

- **Adverse Drug Experience**: Any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action (21 CFR 310.305(b)).

- **Distribution of compounded human drug products interstate**: Means that a pharmacy or physician has sent (or caused to be sent) a compounded drug product out of the State in which the drug was compounded.

- **Information Sharing Network:** An information sharing network designated by FDA for purposes of this MOU to collect, assess, and allow review and sharing of information pursuant to this MOU.

- **Inordinate Amounts**: A pharmacy has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of: (i) the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year.[9]

- **Product Quality Issue**: Information concerning (1) any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; or (2) any bacteriological contamination; any significant chemical, physical, or other change or deterioration in the distributed drug product; or any failure of one or more distributed batches of the drug product to meet the applicable specifications (21 CFR 314.81(b)(1)). Contamination in general, including but not limited to mold, fungal, bacterial, or particulate contamination, is a product quality issue.

- **Serious Adverse Drug Experience**: Any adverse drug experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital

[9] The definition of *inordinate amounts* in this MOU is separate and distinct from and should not be used in relation to the term *inordinate amounts* as it is used in section 503A(b)(1)(D) of the FD&C Act (pertaining to compounding a drug product that is essentially a copy of a commercially available drug product). The interpretation of this term in each instance necessarily is based on the particular context of the distinct provisions within 503A in which the term appears.

anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse (21 CFR 310.305(b)).

- **Serious Product Quality Issue**: Any product quality issue that may have the potential to cause a serious adverse drug experience (e.g., possible contamination, superpotent product).

Attachment 3

NABP 2020-2021 Executive Committee Inaugurated at Association's 116th Annual Meeting

Delegates to the 116th NABP Annual Meeting, held virtually on May 14, 2020, elected individuals to fill the president-elect, treasurer, and open member positions on the Association's 2020-2021 Executive Committee. The newly elected officers of the NABP Executive Committee are President-elect Caroline D. Juran, BSPharm, DPh (Hon), executive director of the Virginia Board of Pharmacy, and Treasurer Reginald B. "Reggie" Dilliard, DPh, executive director of the Tennessee Board of Pharmacy. Jeffrey J. Mesaros, PharmD, JD, RPh, a member of the Florida Board of Pharmacy, was re-elected to a three-year member term; Fred M. Weaver, RPh, a member of the State of Ohio Board of Pharmacy, was elected to a three-year member term; and Kamlesh "Kam" Gandhi, PharmD, RPh, executive director of the Arizona State Board of Pharmacy, was elected to a three-year member term.

At the conclusion of the Annual Meeting, Timothy D. Fensky, RPh, DPh, FACA, a member of the Massachusetts Board of Registration in Pharmacy, assumed the office of NABP president, and Jack W. "Jay" Campbell IV, JD, RPh, executive director of the North Carolina Board of Pharmacy, assumed the position of chairperson of the Executive Committee. In addition, the following members are continuing to fulfill their terms on the 2020-2021 NABP Executive Committee: Bradley S. Hamilton, RPh, vice president of the Maine Board of Pharmacy; Tejal J. Patel, MBA, PharmD, RPh, member of the Delaware State Board of Pharmacy; Shane R. Wendel, PharmD, RPh, a member of the North Dakota State Board of Pharmacy; Lenora S. Newsome, PD, vice

president/secretary of the Arkansas State Board of Pharmacy; and Nicole L. Chopski, PharmD, BCGP, ANP, executive director of the Idaho State Board of Pharmacy.

Abbreviated biographies for the officers and members of the Association's 2020-2021 Executive Committee are available in the full press release.

Delegates Approve Five Resolutions at the 116th NABP Annual Meeting

Delegates from the member boards of pharmacy adopted five resolutions during the 116th NABP Annual Meeting, held virtually on May 14, 2020. A summary of the approved resolutions is listed in the full press release.

NABP Announces 2020 Leaders at the Forefront of Public Health Protection

NABP has announced its leaders in the protection of public health for 2020. Each year, the Association presents awards to individuals who have worked with unwavering dedication to ensure NABP's continued service to the regulation of pharmacy practice and its efforts to assist the state boards of pharmacy in protecting the public health.

This year's leaders include 2020 Carmen A. Catizone Honorary President recipient Larry L. Pinson, PharmD; 2019-2020 NABP President Jack W. "Jay" Campbell IV, JD, RPh; 2020 Fred T. Mahaffey Award recipient the North Dakota State Board of Pharmacy; 2020 John F. Atkinson Service Award recipient Eric A. Griffin; 2020 Henry Cade Memorial Award recipient Timothy R. Koch, RPh; and 2020 Lester E. Hosto Distinguished Service Award recipient John Clay Kirtley, PharmD.

Biographies for the award winners are available in the full press release.

Lemrey 'Al' Carter, MS, PharmD, RPh, Assumes Position of NABP Executive Director/Secretary

The NABP Executive Committee is pleased to announce that Lemrey "Al" Carter, MS, PharmD, RPh, assumed the position of executive director/secretary at the close of the Association's 116th Annual Meeting, which was held virtually on May 14, 2020. He succeeds Carmen A. Catizone, MS, RPh, DPh, the fourth NABP executive director/secretary. Catizone, who is retiring from NABP after serving the Association for 35 years, will serve in an advisory capacity until December 31, 2020.

More details are in the full press release.

CMS Allows Pharmacies to Temporarily Enroll as Clinical Diagnostic Laboratories to Provide COVID-19 Testing

Centers for Medicare & Medicaid Services (CMS) has released a document detailing a process that allows pharmacies to temporarily enroll as independent clinical diagnostic laboratories. This process will allow those facilities to seek Medicare reimbursement for coronavirus disease 2019 (COVID-19) tests, making it easier for them to provide that service during the pandemic.

"Up until this point in time, most pharmacies could only offer this as a cash service because they were not considered providers through CMS, and really a lot of the third-party payers really didn't have an interest in a fee-for-service type model," Michael E. Klepser, PharmD, FCCP, pharmacy professor at Ferris State University, said in an interview with *Bloomberg Law*. "The fact that CMS is saying we're now authorizing or allowing pharmacists to get reimbursed for these is a great door opening at the federal level and that's a huge, huge thing," he later added.

As previously reported, chain pharmacies such as CVS, Walgreens, and Rite Aid are offering drive-through testing at many pharmacies throughout the country.

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NABP e-News *is a weekly publication prepared by NABP. Please send any comments, questions, or suggestions about the electronic newsletter to commdept@nabp.pharmacy. We look forward to receiving your feedback*

116th NABP Annual Meeting
May 14, 2020

Report of the Executive Director/ Secretary

Presented by:

Lemrey "Al" Carter, MS, PharmD, RPh

I would first like to take this opportunity to thank the National Association of Boards of Pharmacy® (NABP®) Executive Committee for their confidence and trust in me to lead this amazing organization; I am honored and humbled by the opportunity. I would also like to take this occasion to recognize, Carmen Catizone. It is through Carmen's unwavering commitment, foresight, and leadership that NABP is the remarkable organization that it is today. It is my intent to continue in this role with a renewed commitment of passion, vigor, and respect, and to continue to support the member boards of pharmacy and serve our mission to protect public health.

I am a product of Biloxi, MS. I received my doctorate in pharmacy from Xavier University of Louisiana and received my master of science from the University of Florida. Prior to moving to Chicago, IL, every year starting on June 1 until the end of November, the potential to evacuate due to a hurricane was evident and, in many situations, a forced evacuation was mandated. In some way, shape, or form, we programmed it into our brains and had a routine to prepare in the event a hurricane was headed our way. For the last five months and for the undetermined future, we have been dealing and will continue to deal with a pandemic that no one was prepared for. As Chairperson Campbell stated, this pandemic far exceeds any regional hurricane efforts; yet, NABP along with the member state boards of pharmacy have continued to step up to the plate to provide nationwide support through the utilization of NABP Passport and real-time updates to assist members with questions, inquiries, and guidance regarding this deadly virus. We will continue to support all members through this unprecedented time until a vaccine is developed and a solid treatment protocol is implemented.

Due to the coronavirus disease 2019 (COVID-19), the evolution of the practice of pharmacy has been accelerated and will never be the same. NABP will have to respond quickly to comprehend the impact and determine the best way to support our members during these changes. The emerging prevalence and expansion of telehealth and telepharmacy, the change in the role of a pharmacist to align with scope of practice changes, and the desire for a greater digital presence are all factors that will change the pharmacy profession and how you regulate the practice in your state. NABP will support our members during any changes and make sure that this transition is seamless. I, along with the NABP Executive Committee and NABP staff, promise to work tirelessly to minimize disruption in our programs and services we provide.

My three-year plan focuses first on you, the people. It is my priority to develop and strengthen relationships with the Executive Committee, and all state executives and board members to understand how NABP can better serve your interests. We are committed to deliver a seamless transition with no interruption in the services that are provided to our members. Second, we will continue to focus on our programs and make improvements that foster a culture of innovation through technology and the utilization of data and digital solutions to assist member boards in regulating for the purpose of protecting public health. Our

third priority will focus on data integration and the opportunities that exist with the enhanced collection and utilization of e-Profile data. Data integration provides many opportunities for NABP and state boards of pharmacy to create digital solutions to streamline and remove burdensome administrative processes, providing better efficiency and lowering operational costs for state boards of pharmacy and NABP.

I have served as a pharmacist in the community for over 15 years, as a member and chairperson of the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy for six years and have served on numerous tasks forces and committees with pharmacy organizations, including NABP, for the past 12 years. One thing that is consistent is that you are only as strong as the members of your team. With a continued focus on collaborative teamwork and **unity,** adherence to the strategic vision and mission of NABP, and a commitment to servant leadership, we will continue to overcome any pandemic or challenge that is in our path and will continue to see **ideas ignite**. Thank you.

Report of the Work Group on the Development of an Interstate Endorsement Credential

Members Present:

Malcolm Broussard (LA), *chair;* Tracy Collier (SC); Mark Hardy (ND); Virginia Herold (CA); Sam Lanctin (NB); Rich Palombo (NJ); Laura Rang (CO); Steve Schierholt (OH); Ellen Vick (NC); Dennis Wiesner (TX); Cathy Winters (WI).

Others Present:

Jeffrey J. Mesaros, *Executive Committee liaison;* Carmen Catizone; Josh Bolin; Melissa Madigan; Eileen Lewalski; Lawana Lyons; Maureen Schanck; and Romy Schafer, *NABP staff*.

Introduction:

The work group met on September 5, 2019, at the Westin O'Hare hotel in Rosemont, IL. This work group was established in response to NABP President Jack W. "Jay" Campbell's initiative to study the feasibility of an interstate endorsement credential.

Review of the Work Group Charge:

Develop an interstate endorsement credential for non-dispensing or cognitive pharmacy practices and expand the current Electronic Licensure Transfer Program™ (e-LTP™) service by creating:

- interstate endorsement credential that expedites the licensure process by offering credible alternatives to certain, existing requirements; and
- a mechanism to integrate mutual recognition among the states through the enhancement of the state-based and uniform processes currently in place.

Background and Summary:

The work group reviewed the previous work of the Task Force on Mutual-Recognition Licensure and the Task Force on the Regulation of Pharmacist Care Services. As with the previous task forces, work group members called attention to the specific pharmacist role of providing cognitive care services that do not involve the dispensing of prescription products. Members recognized the responsibility of the state boards of pharmacy to oversee pharmacist care services in their state but acknowledged the need for pharmacists to provide care to patients outside of their state. Members agreed that regulatory safeguards should not be so cumbersome that patients are prevented from obtaining care from the most qualified provider. It was acknowledged that burdensome regulation may result in medication therapy management type services being provided across state lines without proper regulatory oversight.

An overview of the paperless e-LTP process was provided to the work group. The overview called attention to the fact that NABP can process 85% of applications, and report applicant information to the requested state, within 24 hours of receipt of the application. The e-LTP process includes a disciplinary review via the NABP Clearinghouse and research of records for

states that do not regularly report discipline to the Clearinghouse. NABP staff reviews the e-LTP data and shares trends about discipline and license transfer with its member boards. Correspondingly, the boards of pharmacy can be assured of a full vetting process with each application, even if the applicant has applied in the past. It was noted that, in the future, NABP will further streamline the e-LTP process through the development of a mobile application so that users can upload information ahead of their application submission.

The work group reviewed steps that can be taken to shorten the application process and discussed potential benefits and risks to patients if certain procedures were eliminated. The members recognized that taking a separate Multistate Pharmacy Jurisprudence Examination® (MPJE®) in each desired state is time consuming and can delay access to patient care. One suggestion was to assess some level of pharmacy law competence through the North American Pharmacist Licensure Examination®. However, aside from Idaho, states seem resolute in maintaining their requirements for a state-specific jurisprudence exam.

The work group also identified state-specific requirements such as personal interviews, criminal background checks, and wet lab exams, which impact the timeliness of the licensure process.

A different approach was noted in Idaho. That state enacted legislation to streamline the licensing of non-resident pharmacists through mutual-recognition licensure; however, the state must first enter into a memorandum of understanding with other states before mutual recognition can occur. To date, Idaho has not developed a mutual-recognition partnership and, therefore, still utilizes the e-LTP process.

The work group reviewed other professional licensure compacts. Although these compacts afford professional license mobility, they may result in delegation of licensure decisions from the individual state boards to an umbrella compact board/committee. This may also apply to professional discipline, which could be delegated to a disciplinary committee that has the authority to promulgate rules for all participating states. In some instances, the individual states must pass compact bills without amendments and there is some loss of autonomy and control. As the state boards must pay into the compact, there is often a loss of revenue. It appears that other health care professions utilize compacts because they do not have a mechanism for license transfer as efficient and thorough as the e-LTP process for pharmacists.

It was noted that multistate recognition currently exists in some state pharmacy laws and rules during declared emergencies. In some states, during an emergency, pharmacists may practice without becoming licensed if licensed by another United States jurisdiction. Members questioned why it was safe to allow a pharmacist to practice without a license during an emergency but not outside of an emergency.

The members also discussed how the practice of pharmacy has changed from dispensing products to providing cognitive services or dispensing knowledge. Specialty pharmacies must include extensive counseling and interactions with patients to adequately provide patient care, as well as to obtain and maintain accreditation. With this in mind, the group reviewed the need to define the provision of cognitive services without dispensing. They asked if an endorsement credential could be developed for cognitive services and if so, when would it apply? They also asked if the requirement for full licensure for medication dispensing would still be needed. Currently, requirements are not uniform across the states. Some states require all pharmacists providing cognitive services to be licensed by the state they are serving, while other states only require the pharmacist-in-charge to obtain additional licensure. In any case, members concurred

that their respective boards would still prefer the reassurance of having an individual license "on the hook" before allowing any type of pharmacist services to be delivered interstate.

After much discussion, the members were asked to ponder "What is the problem you are trying to fix?" They agreed that the issue is complex, and the public would not be justly served by one simple solution or license. In an effort to provide credible alternatives to certain existing requirements, the work group brainstormed about integrating a mutual recognition process through an enhancement of the state-based and uniform processes currently in place. In the end, the work group decided it was most desirable to improve and build on the success of the e-LTP system – one that is already better than what other licensed professionals established for license portability. It was noted that NABP should not consider supporting the "driver's license model" as it does not provide the same level of patient protection as the e-LTP system currently in use.

After careful review and deliberation, the work group recommended the following:

1. As e-LTP is providing an efficient system for pharmacists to transfer licensure, NABP should continue to work with states to streamline processes associated with this current license transfer process.

2. NABP should continue to maintain the MPJE and encourage its use by state boards of pharmacy, as it is an important component to evaluate knowledge of pharmacy law.

3. NABP should review MPJE data to determine where knowledge gaps exist with regard to state and federal laws and/or rules, with the goal of correlating those gaps with patient safety issues and concerns.

4. NABP should explore the feasibility of developing a limited pharmacist certification for non-dispensing interstate pharmacist care services that take place outside of a licensed pharmacy. Certification must be recognized by states and maintained for the states by NABP through the e-LTP system, which will serve as a clearinghouse for enforcement actions, with the states maintaining the authority to discipline certified pharmacists.

    a. Exploring the feasibility includes surveying the states for the need of such service.
    b. Certification would be developed in partnership with states, including the development of criteria for such certification. In addition, where necessary, NABP will develop definitions for terms related to such certification.
    c. States may consider making this certification an element of licensure, as opposed to simply recognizing the certification alone.
    d. Fees would be distributed to states, recognizing the loss in revenue due to fewer nonresident pharmacists obtaining licensure.

Report of the Overview Task Force on Requirements for Pharmacy Technician Education, Practice Responsibilities, and Competence Assessment

Members Present:

Lemrey "Al" Carter (IL), *chair;* Gary Dewhirst (CO); Cindy Fain (AR); John Genovese (NH); Jackie Hall (LA); Jason Hansel (IA); Timothy "Tim" Koch (AR); Gary Merchant (NH); Kristen Snair (AZ); Donna Wall (IN); Anita Young (MA).

Others Present:

Bradley S. Hamilton, *Executive Committee liaison;* Eric Brichto, Accrediting Bureau of Health Education Schools (ABHES); Ryan Burke, Pharmacy Technician Certification Board (PTCB); Jeremy Sasser, National Healthcareer Association; William Schimmel, PTCB; Janet Silvester, American Society of Health-System Pharmacists (ASHP), *guests*; Carmen Catizone; Melissa Madigan; Eileen Lewalski; Maureen Schanck; and Romy Schafer, *NABP staff*.

Introduction:

The task force met on September 11-12, 2019, at NABP Headquarters in Mount Prospect, IL. This task force was established pursuant to Resolution 115-4-19, Task Force on Requirements for Technician Education, Practice Responsibilities, and Competence Assessment, which was approved by the NABP membership at the Association's 115th Annual Meeting in May 2019.

Review of the Task Force Charge:

The charge of the task force will be to:

1. evaluate the current environment for the regulation of pharmacy technicians; and
2. make recommendations for the task force subgroups to focus on ensuring boards of pharmacy take a more active role in establishing requirements for the education, practice responsibilities, and competence assessment of pharmacy technicians.

Background and Discussion:

Members of this task force were charged with reviewing and making general recommendations on various aspects of pharmacy technician education, practice responsibilities, and competence assessment, which will be assessed separately in upcoming task forces dedicated to each of the three topics.

The task force members began their discussion with a review of the charge and request by NABP membership to consider the evolving role of pharmacy technicians and recommend how to ensure that pharmacy technicians are equipped to meet the increasing responsibilities related to their positions, while being mindful of what is in the best interest of public safety and the protection of public health.

The task force members reviewed previous NABP task force reports related to the role of pharmacy technicians and their expanding scope of practice over time. The earliest NABP task force recommendations centered on such topics as the recognition of certified pharmacy technicians and their advanced roles, as well as the requirement for pharmacy technicians to have documented site-specific training. In more recent years, NABP task forces have recommended that all pharmacy technicians become certified, and that pharmacy technician education providers be accredited by a nationally recognized accrediting body to ensure quality technician education.

The task force members emphasized the importance of pharmacy technicians to patient care and recognized that pharmacy technicians are often the primary contact for patients in community pharmacies. The task force also noted that pharmacists are delegating more and more non-clinical tasks to pharmacy technicians so that pharmacists can provide more patient-centered care and advanced clinical services.

In order to fulfill the task force charge, members of the task force felt that the first question to consider was “what should technicians be able to do as an expanded scope and support the pharmacist’s increased patient care scope of practice?” Members noted that some boards of pharmacy are moving away from prescriptive rules outlining what their licensees can do. They agreed that if minimum entry-level educational and competence standards are met, pharmacy technicians should not be prohibited from performing duties within a defined scope in which they have demonstrated competence, considering, of course, the best interest of patients.

On the issue of uniform laws and rules, members also discussed the fact that, although the scope of practice for pharmacists is, for the most part uniform among states, that is not the case for pharmacy technicians. In addition, the requirements for pharmacy technician education and licensure or registration vary significantly. Members grappled with the need for stricter uniform requirements for entry-level pharmacy technicians; for example, the requirement to obtain a background check. The task force engaged in a lively discussion about whether stricter requirements for pharmacy technician licensure would benefit patient safety.

Several members suggested that basic educational requirements and the needed level of competence should be further defined, and the use of a uniform entry-level exam be considered. Members noted that if such an exam was required by all states, then pharmacists and boards could feel confident that pharmacy technicians have the fundamental skills to provide support and ensure patient safety. In addition, members recognized that such uniformity could ensure a level of competence to justify the use of a licensure transfer system similar to that in place for pharmacists.

As part of the discussion about an entry-level licensure exam, members discussed the Pharmacy Technician Certification Examination (PTCE) and the Exam for the Certification of Pharmacy Technicians (ExCPT). Members questioned what these exams assess and at what point certification should occur. Should certification be required before licensure or by a specified time period after licensure? Should it only be required for technicians performing more advanced roles? Some members expressed concern that a new entry-level exam would be redundant to the certification exams. Also of concern was the fact that some states, like Iowa, are currently experiencing a pharmacy technician shortage due to a number of factors related to requirements for entry and career sustaining issues.

The task force pondered the training needed to be eligible to sit for an exam, and if it is important to standardize such training. Task force members discussed whether state boards of pharmacy are equipped to handle the accreditation of pharmacy technician education providers or if that should be left to a third party. If left to a third party, the boards of pharmacy can then define competencies and education standards, perhaps deferring to accrediting organizations' approval processes and defining of pharmacy technician responsibilities supported by the knowledge and skills required to effectively carry out those responsibilities. Overall, members agreed that regulators should be the ones to decide minimum training requirements for all settings, as well as continuing education requirements. In addition, members discussed how boards can support continuing education learning opportunities.

To put the discussions into context, members learned about a new, more advanced level pharmacy technician in New Hampshire – the licensed advanced pharmacy technician. These licensees can independently perform product verification, process refills, and verify the repackaging of drugs. They perform under the supervision of a pharmacist but are held accountable to the board of pharmacy as a mid-level practitioner. Another example mentioned of advanced technician practice was that of military-trained pharmacy technicians. It was noted that they have more advanced responsibilities than their civilian counterparts. Members agreed that these examples should be evaluated further when considering future roles for pharmacy technicians.

The task force noted that any additional burdensome regulatory requirements for pharmacy technician candidates should coincide with an expanded scope of practice, which would allow technicians to broadly utilize their advanced skills. The task force members stressed that the state boards of pharmacy will need to keep in mind their mission to protect public safety while still providing pharmacy technician candidates with a pathway that will enhance future pharmacy care services and meet the needs of patients.

After careful review and deliberation, the task force recommended the following:

1. The NABP Task Force on Requirements for Pharmacy Technician Education and the Task Force on Pharmacy Technician Competence Assessment should consider establishing minimum standards for pharmacy technician licensure.

2. The NABP Task Force on Pharmacy Technician Competence Assessment should research and evaluate the feasibility of requiring a pharmacy technician entry-level exam for licensure.

3. The NABP Task Force on Pharmacy Technician Competence Assessment should research and evaluate the requirements for minimum standards for an entry-level licensure exam (perform a gap analysis, including state law) and determine if PTCE and ExCPT meet those requirements.

4. The NABP Task Force on Requirements for Pharmacy Technician Education should perform a gap analysis of accreditation standards of accrediting organizations, including those of the ASHP/Accreditation Council for Pharmacy Education (ACPE) and ABHES.

5. The NABP Task Force on Requirements for Pharmacy Technician Education should evaluate and recommend standards for entry-level pharmacy technician education and training programs based on the results of the gap analysis.

6. The NABP Task Force on Requirements for Pharmacy Technician Education and the NABP Task Force on Pharmacy Technician Competence Assessment should recommend revisions, if necessary, to *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* regarding the definitions and scope of practice of entry-level pharmacy technicians.

7. NABP should convene the Task Force on Requirements for Pharmacy Technician Practice Responsibilities scheduled for 2020 to evaluate the various levels of pharmacy technician practice, including but not limited to, levels identified by the current ASHP/ACPE standards, and recommend revisions, if necessary, to the *Model Act*.