# California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100 Sacramento, CA 95833

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



# LICENSING COMMITTEE REPORT January 27, 2021

Debbie Veale, Licensee Member, Chairperson Seung Oh, License Member, Vice-Chairperson Lavanza Butler, Licensee Member Jignesh Patel, Licensee Member Jason Weisz, Public Member Albert Wong, Licensee Member

- I. Call to Order and Establishment of Quorum
- II. Public Comment for Items Not on the Agenda, Matters for Future Meetings

\*(Note: the committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a).)

III. Approval of the October 20, 2020, Licensing Committee Meeting Minutes

**Attachment 1** includes the draft minutes from the October 20, 2020 meeting.

IV. Presentation by the University of California Schools of Pharmacy related to Academic Dishonesty

### Background

As part of its July 2020 Board Meeting, the Board received a presentation on recently published research regarding academic dishonesty in the California Schools of Pharmacy. Subsequent to that presentation, the Licensing Committee as part of its October 2020 meeting, discussed the issue and possible actions the Board could take to address the issue. As the minutes reflect, no action was taken during the committee, but the committee indicated its desire to continue its discussion.

## During the Meeting

During the meeting members will receive a presentation from representatives of the University of California, including its approach to academic dishonesty and best practices for creating an environment that discourages such behavior.

# V. Discussion and Consideration of Proposal to Expand the Authority for Pharmacists to Order and Administer CLIA Waived Tests for Influenza and COVID

#### Relevant Law

Business and Professions Code (BPC) 4052(a)(12) establishes the authority for a pharmacist to order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. As included in this provision, the pharmacist performing such functions must ensure such testing is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate.

BPC 4052.1(a)(2) establishes the authority for a pharmacist to order drug therapy-related laboratory tests in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, as specified.

BPC 4052.2(a)(2) establishes the authority for a pharmacist to order drug therapy-related laboratory tests as part of the care provided in a licensed health care facility, licensed home health agency, licensed correctional clinic, a licensed clinic with physician oversight, or other provider as specified, in accordance with the policies, procedures, or protocols of that facility, home health agency, etc.

BPC 4052.4 establishes the authority for a pharmacist to perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under BPC 1206.5 or BPC 1206.6. The section provides that "routine patient assessment procedures," includes CLIA waived tests as authorized under BPC 1206.5 and 1206.6.

BPC 1206.5(a)(11) establishes the authority for a pharmacist to perform a clinical laboratory test or examination classified as waived under CLIA as long as the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel.

BPC 1206.6 provides authority for pharmacist at a community pharmacy who, performs only blood glucose, hemoglobin A1c, or cholesterol tests that are classified as waived under CLIA in the course of performing assessments as provided in BPC 4052.4. This section also requires the pharmacy to obtain a CLIA certificate of waiver and comply with all other requirements for the performance of waived clinical laboratory tests under applicable federal regulations. Further, the section provides that the pharmacist-in-charge (PIC) is responsible for directing and supervising testing oversight, decision making and ensures the pharmacy has obtained a registration as required by BPC 1265.

BPC 1265 establishes the licensing requirements for a clinical laboratory as specified. BPC 1265(k) provides authority for the PIC to serve as the laboratory director for registration required under BPC 1206.6.

# Background

On August 25, 2020, the DCA Director issued an order that waives specified professional licensing requirements and amends the scopes of practice of pharmacists and pharmacy technicians to allow them to perform waived, point-of-care tests used to detect SARS-CoV-2. Along with the waiver, guidance was released to inform and educate pharmacies, pharmacists and pharmacy technician of clinical laboratory requirements that apply under the DCA Order.

More recently, as part of the October Licensing Committee Meeting and subsequent Board Meeting, the Board approved the following policy statement:

The CDC has acknowledged that the flu and COVID-19 are both respiratory illnesses that are caused by different viruses that may be difficult to differentiate based on symptoms alone without testing to confirm a diagnosis. The Board also recognizes that community pharmacies provide unique access for patients to obtain tests in a safe and convenient location. In recognition of these facts and the existing authority pharmacists already may provide certain CLIA waived tests, the Board hereby declares its support for all efforts to secure temporary authority for pharmacists to perform CLIA-waived tests for influenza and COVID during the declared disaster, as well as a more permanent solution through statutory changes that facilitate authority for pharmacists to perform CLIA-waived COVID and influenza testing in a safe manner.

### For Committee Discussion and Consideration

During the meeting members will have the opportunity to review the draft statutory proposal to ensure the proposal is consistent with its prior discussion and includes the appropriate provisions to pursue the permanent authority consistent with the policy statement.

**Attachment 2** includes the draft statutory proposal.

# VI. <u>Discussion and Consideration of Statutory Proposal to Expand the Authority for Pharmacy</u> <u>Technicians to Administer COVID-19 and Influenza Vaccines</u>

## Relevant Law

BPC 4115 provides that a pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. This section further requires the board to adopt regulations that a pharmacy technician may perform.

Title 16, California Code of Regulations section 1793.2 establishes the nondiscretionary tasks to include removing the drug or drugs from stock; counting, pouring, or mixing pharmaceuticals, placing the product into the container, affixing the label or labels to the container; and packaging or repackaging.

# Background

Existing law provides authority for pharmacists to independently initiate and administer vaccines lists on the routine schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP) under specific conditions (BPC 4052.8). Effective January 1, 2021, this authority was expanded to include COVID-19 vaccines that are FDA authorized or FDA approved.

As part of the October Committee meeting and subsequent discussions during the October and November 2020 Board meetings, the Board approved the following policy statement related to pharmacy technician administered vaccinations.

# <u>Policy Statement – Expand Authority to Allow Pharmacy Technicians to Administer</u> COVID-19 and Influenza Vaccinations

In recognition of the current COVID-19 crisis and consistent with the recommendations from health experts, including the CDC, on the importance of influenza and COVID-19 vaccinations, the Board supports all efforts to facilitate influenza and COVID-19 administration in a safe manner. Further, in recognition of the unique access patients have to community pharmacies, such locations provide a safe and convenient option to receive such vaccinations. The Board further believes that influenza and COVID-19 vaccine administration may be safely performed by a specially trained licensed pharmacy technician under specified conditions and as such supports efforts to secure such temporary authority under waivers during the declared disaster, as well as a more permanent solution through statutory or regulatory changes.

## For Committee Discussion and Consideration

Consistent with the approved policy statement, during the meeting, members will have the opportunity to review the draft statutory proposal. As drafted the proposal includes the prior provisions identified by the committee an approved by the Board including:

- Specificity that the task must be delegated by the supervising pharmacist
- Completion of a training program approved by ACPE and CPR certification
- Ongoing requirement for 1 hour of CE
- Authority to administer epinephrine, if delegated by the supervising pharmacist.
- Recordkeeping requirements

**Attachment 3** includes a copy of the relevant laws and draft statutory proposal.

# VII. Discussion and Consideration of Board's Current Policy related to Authority for Pharmacy Technicians to Administer Vaccines to Determine if Inclusion of Additional Vaccines is Appropriate

#### Background

The history of prior policy discussion is provided under the prior agenda item.

# For Discussion and Consideration

During the meeting members will have the opportunity to discuss if the current policy statement should be expanded to include vaccines included on the ACIP recommended schedule.

Should the Committee determine that it is appropriate to expand the policy, it is recommended that the policy statement be updated to reflect this expansion and conforming changes made to the draft statutory proposal discussed as part of the prior agenda item.

**Attachment 4** includes a copy of the Recommended Child and Adolescent Immunization Schedule and Recommended Adult Immunization Schedule.

## VIII. Discussion and Consideration of Draft Pharmacist Workforce Survey

### Background

As indicated in the Board's responses to Sunset Issues, the issue of medication errors must be addressed to improve patient health. The issue warrants study in California, where conditions within a pharmacy may be different than on a national level. Further, consideration should be given to determine if the Board or some other entity should receive reports of medication errors to gain a better understanding of the scope of the issue and report on the findings. It appears appropriate to conduct a survey on working conditions to ascertain if conditions in California may be a contributing factor.

## For Discussion and Consideration

During the meeting members and stakeholders will have an opportunity to review a draft survey. The draft survey is being developed in collaboration with an expert from the Department of Consumer Affairs and will be provided as supplemental meeting materials when complete.

# IX. Discussion and Consideration of Waiver Request of Business and Professions Code Section 4131(b) Related to the Location of the Supervising Pharmacy and Remote Dispensing Site Pharmacy

Subsequent to the release of the agenda, the request for consideration was withdrawn. No action is required at this time.

### X. Review and Discussion of Licensing Statistics

The quarterly licensing statistics for fiscal year 2020/2021, are provided in **Attachment 5.** 

As of December 31, 2020, the Board has received 7,623 initial applications, including:

• 1,348 intern pharmacists

- 1,525 pharmacist exam applications (451 new, 1,074 retake)
- 104 advanced practice pharmacists
- 2,218 pharmacy technicians
- 211 community pharmacy license applications
- 62 sterile compounding pharmacy license applications (LSC, LSE, SCP, SCE)
- 63 nonresident pharmacy license applications
- 16 hospital pharmacy license applications

As of December 31, 2020, the Board has received 275 requests for <u>temporary</u> site license applications, including:

- 135 community pharmacy license applications
- 38 sterile compounding pharmacy license applications
- 39 nonresident pharmacy license applications
- 18 hospital pharmacy license applications

As of December 31, 2020, the Board has issued 4,525 individual licenses, including:

- 1,324 intern pharmacists
- 1,493 pharmacists
- 75 advanced practice pharmacists
- 1,473 pharmacy technicians

As of December 31, 2020, the Board has issued 241 site licenses without temporary license requests, including:

- 82 automated drug delivery systems
- 44 community pharmacies
- 0 hospital pharmacies

As of December 31, 2020, the Board has issued 193 temporary site licenses, including:

- 98 community pharmacies
- 11 hospital pharmacies

#### **Processing Times**

The general application and deficiency mail processing times by license type are provided below reflecting data current as of January 15, 2021. The data reflects the time from when an application or deficiency response is received by the Board through to the time it is reviewed by licensing staff. The standard performance processing time is within 30 days for initial applications and is within 10 days for deficiency mail. The term "Current" means there are no items to review or staff is currently reviewing the items within 1-5 days for that specific license type.

Staff continue to work diligently and make adjustments to review applications and mail electronically during this pandemic. Processing times exceed the standard processing times resulting from a combination of factors, including impacts resulting from the pandemic.

Premises Application Types	Application Processing Times as of 10/2/2020	Application Processing Times as of 1/15/2021	Deficiency Mail Processing Times as of 10/2/2020	Deficiency Mail Processing Times as of 1/15/2021
Pharmacy	28	47	10	47
Nonresident Pharmacy	14	58	10	65
Sterile Compounding	28	16	22	33
Nonresident Sterile Compounding	22	Current	21	38
Outsourcing	Current	Current	Current	Current
Nonresident Outsourcing	17	19	Current	25
Hospital Satellite Compounding Pharmacy	Current	Current	Current	Current
Hospital	2	16	Current	Current
Clinic	22	42	10	3
Wholesaler	23	15	Current	18
Nonresident Wholesaler	24	22	Current	25
Third-Party Logistics Provider	Current	Current	Current	Current
Nonresident Third-Party Logistics Provider	8	11	Current	22
Automated Drug Delivery System	8	7	Current	Current
Automated Patient Dispensing System	Current	Current	Current	Current
Emergency Medical Services Automated Drug Delivery System	Current	Current	Current	Current

Individual Application Type	Application Processing Times as of 10/2/2020	Application Processing Times as of 1/15/2021	Application Processing Times as of 10/2/2020	Deficiency Mail Processing Times as of 1/15/2021
Exam Pharmacist	24	30	7	18
Pharmacist Initial	Current	Current	n/a	n/a
Licensure				
Advanced Practice	Current	28	Current	28
Pharmacist				

Individual Application Type	Application Processing Times as of 10/2/2020	Application Processing Times as of 1/15/2021	Application Processing Times as of 10/2/2020	Deficiency Mail Processing Times as of 1/15/2021
Intern Pharmacist	42	37	9	28
Pharmacy Technician	51	54	Current	34
Designated	Current	31	Current	25
Representative				
Designated	Current	29	Current	25
Represenatives-3PL				
Designated	Current	Current	Current	Current
Representatives-Reverse				
Distributor				
Designated Paramedic	Current	Current	Current	Current

# **IX. Future Committee Meeting Dates**

- April 21, 2021
- July 14, 2021
- October 27, 2021

# X. Adjournment

# **Attachment 1**



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# LICENSING COMMITTEE MEETING DRAFT MEETING MINUTES

DATE: October 20, 2020

LOCATION: Teleconference

MEMBERS PRESENT: Deborah Veale, Licensee Member, Chair

Seung Oh, License Member, Vice-Chairperson

Jignesh Patel, Licensee Member Jason Weisz, Public Member Albert Wong, Licensee Member

MEMBERS NOT PRESENT: Lavanza Butler, Licensee Member

STAFF PRESENT: Anne Sodergren, Executive Officer

Eileen Smiley, DCA Staff Counsel Norine Marks, DCA Staff Counsel

### I. Call to Order and Establishment of Quorum

Chairperson Veale called the meeting to order at 9:03 a.m. and advised all individuals observing or participating in the meeting that the meeting is being conducted consistent with the provisions of Governor Gavin Newsom's Executive Order N-29-20. Participants were advised that individuals watching the web cast would only be able to observe the meeting and that anyone interested in participating in the meeting would need to join the WebEx meeting as indicated on the agenda.

Roll call was taken and a quorum established.

### II. Public Comment for Items Not on the Agenda, Matters for Future Meetings

Ms. Veale announced the Board has contracted with the Office of Professional Examination Services (OPES) to conduct an analysis of the pharmacist licensure examination. She reported this item will be agendized for discussion after the analysis is completed and a report published. It is anticipated this item will be placed on the January 2021 Licensing Committee Meeting agenda.

The committee received no public comment for future items.

# III. Approval of the July 8, 2020, Licensing Committee Meeting Minutes

Having received no comments on the draft minutes from committee members, Ms. Veale provided the public with the opportunity to comment on the draft minutes. The members received no public comment on the draft minutes.

**Motion:** To approve the July 8, 2020, meeting minutes as written.

M/S: Oh/Wong

Support: 4 Oppose: 0 Abstain: 1 – Jason Weisz

# IV. Discussion and Consideration of Proposal to Expand the Authority for Pharmacists to Order and Administer CLIA Waived Tests for Influenza and COVID

Ms. Veale reported existing law establishes limited authority for pharmacists to perform routine patient assessment procedures including routine drug-therapy related patient assessment procedures and referred members to the meeting materials which detail the existing legal provisions. In addition to the provisions in Pharmacy Law, other provisions related to pharmacist authority reside in other areas of the Business and Professions Code sections generally under the purview of the Department of Public Health's Laboratory Field Services.

Ms. Veale reported on the waiver issued on May 12, 2020, by DCA Director Kirchmeyer to allow for a pharmacist to order and administer COVID-19 tests in California. Along with the waiver, a guidance document was issued that provided additional details regarding the temporary authorities. Ms. Veale noted the waiver did not allow for the processing of the specimen at a pharmacy.

Furthermore, Ms. Veale indicated more recently, on August 25, 2020, the DCA Director issued an order that waived specified professional licensing requirements and amended the scopes of practice of pharmacists and pharmacy technicians to allow them to perform waived, point-of-care tests used to detect SARS-CoV-2. Along with the waiver, guidance was released to inform and educate pharmacists and pharmacy technician of clinical laboratory requirements that apply under the DCA Order. Ms. Veale referred members to the waiver and guidance documents provided in the meeting materials.

Ms. Veale continued to report that the CDC notes that both the flu and COVID-19 are respiratory illnesses caused by different viruses, coupled with the fact that it may be hard to tell the difference based on symptoms alone, testing may be needed to help confirm a diagnosis.

Additionally, Ms. Veale reported as we are entering flu season, and COVID-19 positive tests appear to be on the rise nationally, it appears appropriate to consider the benefits

to patients if pharmacist authority is expanded to allow pharmacists to perform CLIA waived point-of-care tests for both COVID-19 and influenza.

Ms. Veale reported to aid in the discussion today, several policy questions were provided. She suggested the committee start the discussion with the large policy question; "Is there a benefit to patients if pharmacist authority is expanded to allow pharmacists to perform these CLIA waived point-of-care tests?".

Ms. Veale expressed her belief that pharmacists have unique access, especially in community pharmacies and in rural areas, and that taking advantage of these factors can create an additional access point for patients that may not otherwise have ready access to such testing. Ms. Veale noted that if the committee does not believe in the larger policy issue, it may not be necessary to further discuss.

All members were in support of the larger policy issue expressing the benefit of the expanded authority for consumers to receive a quick diagnosis, as well as expanding the patient access in rural areas. The members requested more information on how this would be accomplished.

Ms. Veale indicated with the members agreeing on the larger policy issue, the committee would then move to discuss several policy questions.

Ms. Sodergren provided additional clarification that a change in law would be needed to facilitate this policy change permanently, but that the board could issue a policy statement and pursue a waiver from the DCA Director to request such changes immediately in response urgency of the COVID-19 pandemic.

In addition, Ms. Sodergren encouraged the committee to think long term regarding the discussion and not only the urgent issue of COVID-19 but what the long-term benefit could be to a more permanent solution.

The committee considered several policy questions as part of its discussion.

1. What, if any, additional training requirements should be required?

Member Wong suggested required training could include a seminar class or a one hour continuing education class.

Member Patel agreed with requiring some type of training since the influenza test requires you to insert a swab into one nostril and is not aware of a current pharmacy course that includes this type of training. He suggested a 30-minute training course on specimen collection as well as protection provisions such as use of PPE.

Member Oh agreed with the need for training and indicated his belief that pharmacy students receive some training for point-of-care testing in their curriculum.

Ms. Veale noted if this type of training is included in the pharmacy student's curriculum then this should be sufficient training, with which Mr. Wong agreed.

Member Weisz agreed with the members comments.

The members then heard comments from the public.

Danny Martinez, California Pharmacist Association (CPhA), advised members that the CPhA's website offers information on COVID-19 as it relates to pharmacists including training on specimen collection that is offered, free of charge, by the American Pharmacists Association (APhA) as well as other pharmacy groups. He also reported the manufactures of the tests include instructions on how to process the specimens. Mr. Martinez indicated he does not believe that additional training beyond what is already provided is necessary.

Lindsey Gullahorn, California Retail Association (CRA) and National Association of Chain Drug Stores (NACDS), supported the larger policy goals to pursue statutory change. She agreed with Mr. Martinez' comment that no additional training would be required because the test comes with instructions from the manufacture.

Member Wong indicated that he does not believe a one-hour training course is overly burdensome and believed it is important to ensure the specimen collection is done correctly.

Steven Gray, California Society of Health-System Pharmacist (CSHP), supported permanence and emergency regulation. In addition, he agreed with Mr. Martinez' comment. Dr. Gray indicated other states are already allowing this and have seen a dramatic reduction in overall use of antibiotics.

Mark Johnston, CVS Health, reported the federal government already regulates CLIA waived training requirements and requires the CDC to print training for each CLIA waived test. Mr. Johnston indicated that he does not support adding to the training.

Lori Walmsley, Walgreens, supported the proposal to create permanency and suggested not requiring additional training. She also suggested allowing prescribing of antiviral would be appropriate.

Ms. Veale indicated the consensus is training is necessary and noted federal requirements probably cover the training needed. She noted it is not the intent for the Board to duplicate and complicate training requirements if defined federally.

Mr. Oh agreed after hearing comments from the public if the training requirements are outlined federally then the Board should not make it more complicated.

Mr. Weisz requested information on what type of training is already being provided.

Ms. Veale directed staff to research the federal CLIA waived training requirements including trying to obtain a copy of the manufacture inserts that provide instructions.

2. Should we specify how test results should be communicated to the patient's PCP?

Ms. Veale noted agreement with written comments provided by CPhA, in supporting the same type of requirement of referral services outlined in current California Code of Regulation section 1746.3(c)(7) wherein the pharmacist, with patient consent, can notify the patient's primary care provider of any test performed on the patient into a patient record system shared with the primary care provider (PCP), as permitted by the patient and the primary care provider. In the event there is no primary care provider, or the patient chooses not to give such consent, the pharmacist should provide the patient with written record of the test as well as information to consult an appropriate healthcare provider of the patient's choice. This would be in addition to required reporting by any local health department or the state's Department of Public Health (CDPH).

Additional members also noted agreement with such an approach.

Mark Johnston, CVS Health, noted federal law states the laboratory must immediately release the results to the patient.

Steven Gray, CSHP, agreed with the general comments and suggested if a referral is required, the pharmacist should be able to have access to the patient record noting that most patients may request the results in writing.

Danny Martinez, CPhA, noted that written record should be provided to the patient and that mandatory reporting should be required to local health departments and/or the Department of Public Health.

3. Should we specify either space requirements or specify that a pharmacy must use physical barriers or other safeguards?

Chairperson. Veale indicated that she does not believe the Board needs specify any requirements and that the pharmacists and pharmacies need to operate in a specific manner.

Dr. Oh agreed noting that the Board does not need to overregulate this area while also emphasizing the necessity of patient privacy.

Member Wong commented in support of privacy provisions.

Member Patel indicated the space where the specimen collection is taken needs to be a clean area and be dedicated for this type of testing to protect patient privacy and contamination of other people. He suggested the collection of the specimen as an example should not be taken by reaching across the counter to perform the test.

Member Weisz agreed that safety is important and requested information similar procedures in place that pharmacists are using to provide shots and how are those handled for distance privacy.

Danny Martinez, CPhA, stated at the end of the day pharmacists should be allowed to exercise professional judgement to provide patient care and privacy. He cautioned the Board in defining specific requirements in statute as the settings may change offering drive up testing as an example.

Jignesh Mehta, pharmacist, stated agreement that pharmacists' practice safely and noted a concern was if the Board were to define settings, it could limit drive thru testing which is a great way to ensure safety for all.

Mark Johnston, CVS Health, commented federal law does not have any requirements and to allow the pharmacists to use their professional judgement.

Steven Gray reminded the Board that current privacy rules apply to consultation requirements. Dr. Gray suggested the Board consider the policy issue of contamination and where testing can be performed.

Ms. Veale responded the questions are specific to a pharmacist performing these duties and not a pharmacy technician.

Lori Walmsley, Walgreens, agreed with the comments offered and noted the policy has evolved. She strongly encouraged regulations be limited as it may limit what can be offered to the public.

Jassy Grewal, United Food and Commercial Workers (UFCW), agreed with comments offered by Steven Gray and other members to offer some private space to conduct the test inside a pharmacy. Ms. Grewal commented on the need for this specifically in a retail setting as you potentially have someone who may be COVID-19 positive, walking through the entire store to get pharmacy. Ms. Grewal emphasized a need for a controlled private space that is properly sanitized.

Ms. Sodergren suggested a proposal to develop a statute requiring the pharmacy to establish their own policies and procedures outlining how the pharmacy will take precautions to maintain patient privacy, patient safety, safety of the pharmacy staff, and sanitation of the testing area.

Members spoke in favor of such an approach, noting it would address many of the items being discussed included the use of PPE.

# 4. Is it necessary to detail out PPE requirements?

Danny Martinez, CPhA, expressed his concern if there was to be a shortage of PPE and inquired if the pharmacy would be required to adhere to their policies and procedures if they do not have the PPE. He agreed pharmacists should use their professional judgement and believed the pharmacy can also address this in their policies and procedures.

Mark Johnston, CVS Health, commented federal law requires laboratories to maintain records, equipment and facilities necessary for the proper and effective method of the laboratory. He suggested as part of a policies and procedures rule, this would be enough.

Steven Gray suggested in general it is important that policies and procedures are dated and maintained for a period of three years to ensure there is a record of what policy and procedures were in effect at the time, especially if a compliant is received by the Board. He also stated a pharmacist should not be required to perform these tests if there is not adequate protection for the staff.

Paige Talley, California Council for the Advancement of Pharmacy (CCAP), supported the policy and inquired if the Board would require prior review of the policies and procedures. She also spoke in support of testing complete through a drive thru.

Ms. Veale responded she does not envision the Board would be reviewing and approving the pharmacy's policies and procedures. The Board would need to rely on the professional judgement of the pharmacist and the pharmacy.

Rob Geddes, Albertsons and Safeway, noted support for allowing a pharmacy to adhere to their policies and procedures, indicating such an approach would allow for flexibility for the different types of testing.

Jassy Grewal, UFCW, understood the need for flexibility but believed there needs to be a baseline for consistency in different practice settings to protect the patient and the pharmacists. She encouraged some type of Board oversight of the policies and procedures.

- 5. Should the Board be notified in advance of a pharmacy providing such services?
- 6. Should the Board specify records requirements.

Ms. Veale suggested questions 5 and 6 could be addressed together and indicated she did not believe the Board needs to be notified by the pharmacy as there is a lot of oversight by the CLIA waiver or CDPH. She further agreed with the recommendations received by Danny Martinez, CPhA.

Members noted agreement suggesting it was important to ensure basic requirements are set by the Board and to ensure a plan is in place for treatment and safety.

Mark Johnston stated the majority of the states require a CLIA Waived certificate and suggested this could be used as notification that the CLIA waived laboratory is at a pharmacy address.

7. Should the proposal encompass pharmacists provide patient education as part of the process?

Ms. Veale indicated the proposal did not need to specify any patient education requirements and members noted agreement.

Mark Johnston, CVS Health, commented that generally speaking California is by far the most restrictive state when it comes to CLIA waived testing. He noted the majority of states defer to federal law. He hopes that California will expand to allow for all CLIA waived testing like the other states.

Danny Martinez, CPhA, expressed his appreciation to the members in taking their recommendations into consideration and will look forward to working with the Board in establishing this authority for pharmacist.

**Motion:** To move forward to expand the authority of the pharmacist providing COVID-19 and influenza point-of care testing. To direct staff to work with the Chairperson Veale to put together a proposal to require the pharmacy to have a written policies and procedures that would address privacy and safety precautions, incorporate professional judgment of the pharmacist, safety of the staff, proper safety protection equipment, sanitation requirements as well as taking the CLIA Waiver, CDPH, and CDC policies into consideration. The committee's initial intent is to immediately pursue a policy statement in support to seek a waiver through the proper channels and draft proposed statutory language for a permanent solution to bring forward to the board next week.

Ms. Veale directed staff to bring forward information on the CLIA Federal Law requirements and the examples of FDA manufacture inserts.

M/S Wong/Oh

Support: 5 Oppose: 0 Abstain: 0

V. Discussion and Consideration of Action Taken by the Accreditation Council of Pharmacy Education Related to California Health Sciences University Loss of Accreditation Status

Ms. Veale reported on the action taken by the Accreditation Council for Pharmacist Education (ACPE) to withdraw the pre-accreditation status of California Health Sciences University (CHSU). As indicated in the meeting materials, ACPE determined that CHSU's program was not

sufficiently complaint with three of the 25 ACPE standards and as such, consistent with ACPE policy, more time could not be granted for accreditation. As indicated in the meeting materials and information obtained by ACPE, CHSU is not allowed to admit any new students, however existing students are allowed to continue their education through the school's "Teachout" program.

There were no comments received by committee members or from the public.

# VI. Discussion and Consideration of Development of Mandatory Reporting Requirement for Schools of Pharmacy to Notify the Board of Licensees Engaged in Academic Dishonesty as Part of the Students Academics

Ms. Veale reported this item was agendized to allow for follow up discussion on the published research and presentation the Board considered as part of its July 2020 meeting. Ms. Veale noted that students enrolled in pharmacy school are required to complete introductory and advanced pharmacy practice experience. Such practice experience cannot be earned without an intern license.

Ms. Veale noted that mandatory reporting provisions already exist in Pharmacy Law, for chemical, mental or physical impairment as well as for theft, diversion or self-use of dangerous drugs and that establishing a policy to require such mandatory reporting would allow the Board to determine if the activity is substantially related to the license, and if so, what if any action is appropriate.

Member Oh was in support of some type of action to ensure students' integrity is maintained.

Danny Martinez, CPhA, referenced previously submitted comments to the committee which stated CPhA's newly adopted policy statement related to dishonest conduct. He commented that he understood the Board's desire to address this issue but questioned the authority indicating that while the Board holds jurisdiction over the licensee, Mr. Martinez did not believe the jurisdiction applies to the oversight of the pharmacy school. He added he was not offering a specific solution only that CPhA was happy to work with the Board in developing either statute or regulations.

Ms. Veale appreciated receiving CPhA's adopted policy and believed this is in alignment with the direction of the Board.

Steven Gray agreed with the importance of this topic and reflected on where the profession is going and the importance of maintaining the public's trust. He stated CSHP supports developing a process to help facilitate this type of reporting and stated licensees have a responsibility to report this type of dishonest conduct to the Board. He noted that UCSD has an extensive program that reports academic dishonesty on the student's transcript. He supported statutory or regulatory language to hold the school and licensee responsible.

Daniel Robinson, Dean at Western University of Health Sciences, recognized academic dishonesty is a problem and noted that it can occur in all programs which is why there are various mechanisms to check for plagiarism.

Ms. Sodergren provided the board receives information from the schools of pharmacy, including confirmation when a student is enrolled. Further, Ms. Sodergren advised members when a student's eligibility changes, the school is required to notify the Board the student is no longer enrolled as it impacts their intern pharmacist license.

Dean Robinson suggested schools could include as part of its reporting to the Board, information regarding the reason a student is no longer participating in the program for example if it is as a result of academic dishonesty.

Member Oh stated the focus should be the requirement to notify the Board of academic dishonesty. Additionally, he inquired if there should be a question on the application that requires the applicant to report academic dishonesty.

Members discussed that first steps could be defining academic dishonestly and identifying different ways of reporting to the Board.

The members agreed to continue to work with staff to find solutions to bring forward to the board for consideration.

# VII. Discussion and Consideration of Authorized Duties of a Pharmacy Technician and Possible Expansion to allow for Administration of Influenza Vaccinations by Pharmacy Technicians

As an introduction to this topic, Ms. Veale noted it is important to mention the immunization alert released last week. Included in this alert was an important reminder. Ms. Veale read the alert.

The Board has received information and inappropriate practices have been observed in some California community pharmacies relating to vaccines. Specifically, the Board has received complaints and observed practices where non-pharmacist staff are initiating the immunization process.

The authority to independently initiate and administer a vaccination extends only to pharmacists (BPC 4052.8). The Board strongly encourages pharmacies, designated pharmacists-in-charge, and pharmacists to evaluate their practices of initiating and administering vaccinations and take immediate corrective action to ensure that their practices comply with BPC 4052.8.

Ms. Veale stated the committee cannot discuss the issue in more detail because of pending investigation matters, but believed it was important to note that nothing under existing law allows for a pharmacy technician to initiate or administer a vaccine. Further, Ms. Veale noted

that as agendized, the committee is not considering expansion of authority for a pharmacy technician to initiate a vaccine. Chairperson Veale indicated that individual pharmacies need to evaluate their current practice to ensure pharmacy technicians or other non-pharmacist staff are not initiating vaccinations.

Ms. Veale also noted the actions by HHS to expand access to childhood vaccines during the COVID-19 under the PREP Act to increase access to lifesaving childhood vaccines and decrease the risk of vaccine-preventable disease outbreaks. She further noted that in California, pharmacists already have the authority to provide ACIP recommendations.

As part of its Pandemic Guidance, CDC notes that the COVID-19 pandemic has caused healthcare providers to change how they operate and to continue to provide essential services to patients. Ensuring immunization services are maintained or reinitiated is essential for protecting individuals and communities and reducing the burden of respiratory illness during the upcoming influenza season.

Ms. Veale continued to report some states have either pursued authority or are currently pursuing emergency rules to allow pharmacy technicians to engage in vaccine administration. As an example, it was her understanding that Rhode Island, appears to allow a pharmacy technician to be involved in the administration of adult immunizations in accordance with training requirements promulgated by the department of health. The regulation then provides that a pharmacy technician II who has completed a recognized certificate training course on appropriate immunization administration technique and holds a current basic CPR certification is permitted to administer vaccines under the direct supervision and with the authorization of an immunizing pharmacist. It was also her understanding that a pharmacy technician II license in Rhode Island requires an individual to pass a national certification examination.

Ms. Veale further advised members that Nevada, in response to COVID-19, amended authority to authorize a pharmacy technician with appropriate training to administer immunizations under the direct supervision of a pharmacist. In its notice, the Nevada Board adopted emergency regulations to allow pharmacies to meet the increased demand for vaccine services. Under the Nevada emergency rules, a pharmacy technician can administer immunizations by an intranasal, intramuscular or subcutaneous injection under the direct and immediate supervision of a pharmacist who has subscribed a written protocol established by a physician if the pharmacist has determined, that the patient should be immunized. Under the emergency rule, the pharmacy technician must complete at least one hour of training related to vaccines, immunization and the administration of immunizations. Further, such pharmacy technicians must complete at least one hour of CE on an annual basis.

Ms. Veale stated to aid in the discussion today, several policy questions are provided and suggested the committee start the discussion with the large policy question; "Is there a benefit to patients to expand authority for pharmacy technicians to administer flu vaccines?". She further noted that if the committee does not believe in the larger policy issue, it may not be necessary to further discuss.

Member Patel expressed he believed a pharmacy technician performing this service under the supervision of a pharmacist would benefit the community.

Member Wong believed pharmacy technicians should be allowed to administer the influenza vaccines in California.

Member Oh expressed some concerns, such as, if pharmacy technicians are allowed to administer the influenza vaccine then he believed they should be allowed to administer all vaccines. Member Oh added it was important to ensure pharmacy technicians would be supervised appropriately and that there was a clear understanding of the process. He was inclined to review this issue further but did not want to move too quickly until there is adequate understanding.

Member Wong spoke in support of Dr. Oh's comments and believed there should be some sort of training requirement. He noted the pharmacy profession has worked hard to allow pharmacists to administer the influenza vaccine and did not want to see that be compromised. He added the pharmacy technician would need adequate training.

Member Weisz believed that pursuing the issue is worthwhile and noted he looks forward to future discussions on what qualifies a pharmacy technician to perform this function, especially to educate the consumer.

Chairperson Veale noted support for moving forward with a policy as there are a lot of states that allow pharmacy technicians to administer the flu vaccine. In addition, she emphasized the importance to do what is right for the consumer when placing the right parameters in place.

Lindsey Gullahorn, CRA and NACDS, supported the board exploring this policy and suggested pursuing a waiver as well as statutory change indicating the benefit to patients especially now during this pandemic.

Paige Talley, CCAP, opposed this policy and stated vaccine administration provides an opportunity for the pharmacist to speak to the patient.

Ms. Veale responded the pharmacist would still need to interact with the patient indicating that the proposal was only to allow the nondiscretionary task.

Steven Gray, CSHP, strongly recommended moving forward with both a waiver and permanency regulation, especially due to the pandemic. He noted pharmacists still need to make the decision and the training of the pharmacy technician only needs to perform the physical act of making the injection. He offered his assistance to help in any capacity to move this forward.

Rob Geddes, Albertson and Safeway, also supported moving forward with a waiver and permanency. He mentioned Albertsons participated in a pilot program for pharmacy technicians

administering the flu vaccine in Ohio and there were no problems adding pharmacists are extremely engaged in the process.

Mark Johnston, CVS Health, supported this policy; however, he suggested the Board address the ratio of pharmacy technicians as well when allowing the pharmacy technician to perform this activity otherwise the pharmacy may not be able to implement this change. He suggested the proposal should allow unlicensed personnel in a pharmacy to administer flu vaccine as well indicating that the permit holder would be held responsible for any issues that occurred by the unlicensed individual.

Danny Martinez, CPHA, notes support of the policy stating the importance of including minimal requirements for a pharmacy technician such as CPR. Further he noted, a pharmacist must have the sole authority to allow or disallow a pharmacy technician to perform these tasks.

Lori Walmsley, Walgreens, spoke in support of the policy indicating such a policy supports consumer protection. Further Ms. Walmsley encouraged the Board to incorporate all vaccines rather than limiting the policy to flu vaccines. She noted Walgreens has already initiated these services in other states that have implemented this policy.

Leona Dombroske, pharmacy technician program in Santa Ana, noted opposition the policy; however, indicated she support it if direct supervision and observation is required.

After receiving comments in support of the policy, Ms. Veale solicited comments from the following questions the committee first considered if initial training, ongoing CE, CPR requirements and authority to administer epinephrine were appropriate. Ms. Veale noted the American Pharmacist Association which provides a six-hour pharmacy-based immunization administration program. The course includes a self-study component combined with a live seminar that teaches hands-on immunization techniques. Chairperson Veale spoke in support of requiring training, CE, and CPR, express hesitancy with incorporating provisions for epinephrine administration.

Member Wong also supported inclusion of training and continuing education requirements. He expressed his concerns with duties of a pharmacist being moved to the pharmacy technicians adding that pharmacies need to hire more pharmacists. Member Wong opposed pharmacy technicians administering epinephrine.

Member Weisz agreed hands on training and continuing education as necessary.

Member Patel spoke in support of requiring hands on training to verify technique noting it was critical along, along with a requirement for ongoing, one hour continuing education course. Member Patel noted that if the Board is moving forward with authority for pharmacy technicians to administers vaccines, then it would be appropriate for a pharmacy technician to administer epinephrine if requiring basic life support (BLS).

Member Oh agreed with member comments regarding training but expressed concern with pharmacy technicians administering epinephrine. He inquired if the Board is aware if pharmacy technicians are requesting the ability to do this. He requested feedback from pharmacy technicians on what their understanding is in allowing them to perform these services.

Member Patel provided history of the provisions for pharmacists to provide immunization noting that at that time there were similar concerns, noting that in today's environment, pharmacists administer the vast majority of vaccines. Member Patel encouraged the committee to be forward thinking and to view the future and what can be provided to consumers by empowering pharmacy technicians to take on these tasks.

Danny Martinez, CPhA, supported the training as mentioned but believed epinephrine should be its own discussion.

Steven Gray, CHSP, strongly supported pharmacy technicians administering vaccines and did not believe there needs to be a separate license or training program. He added the pharmacist is required to provide the supervision indicating that administering a shot is all about technique which needs to be verified on a periodic basis.

Paige Talley indicated opposition to a pharmacy technician administering epinephrine and suggested such discussion should be separation. Ms. Talley also noted that if the committee moves forward with the proposal, training and continuing education should be required.

Member Patel responded that epinephrine is administered for all types of allergies, such as peanuts. As a pharmacist, you provide instruction to a parent in five minutes on how to use the epinephrine device to administer it to their child and there is no subsequent oversight of a pharmacist. Member Patel questioned if a pharmacist can train a parent why would the same not be true for a pharmacy technician who is under their direct supervision.

Lori Walmsley, Walgreens, spoke in support of training and CPR and stated in the states where Walgreens have pharmacy technicians are allowed to administer the influenza vaccines, they are not finding pharmacy technicians refusing to provide these services as they are receiving the proper training.

Lindsey Gullahorn, CRA and NACDS, noted support for the provisions.

Jignesh Mehta expressed concern with how the pharmacist would be able to handle pharmacy technicians performing additional tasks.

Mark Johnston, CVS Health, mentioned an independent study that was published that indicated that pharmacy technicians reported feeling empowered and part of the health care practice when being able to perform these functions. Additionally, he added there are several states that allow the dispensing of epinephrine without a license, such as schools, restaurants, etc. to use in

the case of an emergency. He strongly supported if a pharmacy technician receives the proper training, they should be able to administer epinephrine.

Jassy Grewa, UFCW, stated she not only represents pharmacists but represents pharmacy technicians and indicated that pharmacy technicians do not appreciate the additional tasks being imposed on them. She expressed concern that given the power dynamic in a pharmacy, would a pharmacy technician have the right to refuse these duties if they did not feel the space was safe, etc.

Rob Geddes, Albertsons and Safeway, advised the committee that the training provided by APhA is good and his company has not encountered pharmacy technicians refusing to perform these duties.

Member Wong stated in real life there is a man power problem in the pharmacy. He does not believe his pharmacy technician would want to take on additional tasks without additional salary. In most community pharmacies, there is only one pharmacy technician and one pharmacist, and it will be hard for them to take on these extra tasks and responsibilities.

The committee also discussed documentation requirements, if there was a need to limit the routes of administration a pharmacy technician could provide, if age restrictions for patients receiving vaccines what necessary as well as provisions specifying authority for pharmacists to delegate vaccine administration.

Chairperson Veale noted the importance of documenting who administers a vaccine, noted that it is appropriate for a pharmacy technician to perform administration for all routes of administration, suggested that an age restriction is not necessary and indicated that the language should include a provision that a pharmacist can refuse to delegate these functions as well as that a technician can refuse to perform the functions.

Member Oh spoke in support of the benefit to the public but suggested the need to ensure pharmacists and their liability was protected. He commented there must be explicit authority empowering the pharmacist to not delegate this function if they do not feel the pharmacy technician can perform this task safely.

The minutes are to reflect member Seung Oh left the meeting at 12:55 p.m. and the committee still had a quorum.

Member Wong stated he did not believe pharmacist will have the right to refuse, especially in chain stores.

Member Patel commented that all routes of administration should be permitted and supported and that no age restriction are necessary as long as the pharmacy technician was properly trained in how to handle small children. In addition, he stated a pharmacist should have the

authority to delegate or not delegate these tasks to a pharmacy technician as long as there is some reasoning behind it.

Member Weisz requested additional feedback on where the pharmacy technician stands on these issues and agreed in supporting the explicit authority to deny any action they have discomfort.

Steven Gray, CSHP, strongly supported moving forward. He noted there was already an age limitation in California law that states a pharmacist can administer vaccines to a patient three years or older and believed this would be appropriate for a pharmacy technician as well. He agreed with Member Patel on provisions to allow for the administering epinephrine, noting that epinephrine as it needs to be given timely to be effective.

Lindsey Gullahorn, CRA and NACDS, continued to express her support and did not believe age restrictions were necessary.

Mark Johnston stated he has been researching independent pharmacy technician studies on providing vaccinations and he will be sending these all to Ms. Sodergren.

Member Wong stated after hearing all the comments he supports pharmacy technicians administering the epinephrine pen.

Ms. Veale summarized based on the discussion that the path will be to move forward with pursuing a waiver and also a change in statute to move toward permanency to allow a pharmacy technician to administer vaccines. She indicated the Board will continue to sort out the details of the training, continuing education, CPR, and epinephrine. She stated the age has already been determined by law and added that the pharmacist should have the discretion and authority to delegate to the pharmacy technician.

**Motion:** To recommend to the board to move forward immediately with a policy statement to pursue a waiver through DCA due to COVID-19 to allow for pharmacy technicians to administer influenza vaccinations. In addition, to pursue a permanent statutory change by proposing language to allow pharmacy technicians to administer influenza vaccinations. The committee would like to have a future discussion to expand pharmacy technicians administering vaccinations that include the COVID-19 vaccine.

M/S: Patel/Wong

Support: 4 Oppose: 0 Abstain: 0

Mr. Oh was not present for the motion or vote.

Lindsey Gullahorn, CRA and NACDS supported the motion and commented the need to include the COVID-19 vaccine.

Steven Gray, CSHP, agreed with Ms. Gullahorn's statement to include more than the flu vaccine and inquired if the agenda for the Board meeting include the COVID vaccine.

Members of the committee and public were advised that the proposal needed to stay within the agendized item.

# VIII. Discussion and Consideration of Pharmacy Technician Application Requirements and Common Deficiencies

Ms. Veale reported there are various pathways to licensure as a pharmacy technician. In the past the Board has undertaken efforts to reduce the deficiency rate for such applications, including development of a video on the application process.

In last fiscal year 44% of the pharmacy technician applications received were deficient. The most common deficiencies noted are detailed in the chair report and include:

- 1. The application itself is not complete, e.g. the application is not signed and dated, information is not completed on the form, etc.
- 2. The self-query report is not received in a sealed envelope or the personal identifying information is not consistent with information provided on the application.
- 3. The high school transcript does not reflect a graduation date.
- 4. The applicant did not include a copy of the certification earned.
- 5. The technician training program failed to complete the affidavit correctly.

Long term many of these issues can be resolved through the Board's transition to online application submissions that can be programed with business rules to prevent submission of an application without completed information. In the interim, staff will continue to work with technician training programs to address issues. Ms. Veale directed staff to include application information and common deficiencies in a future issue of *The Script*.

There were no comments received by the committee members or the public.

# IX. Licensing Statistics

Ms. Veale directed members to the quarterly licensing statistics for fiscal year 2020/2021 and current application processing times were provided in the meeting materials.

# IX. Future Committee Meeting Dates

- January 27, 2021
- April 21, 2021
- July 14, 2021
- October 27, 2021

## X. Adjournment

The licensing committee meeting adjourned at 1:23 p.m.

# **Attachment 2**

# Draft Statutory Proposal Related to Pharmacist Provided COVID-19 and Influenza Testing

# Proposal to Amend Business and Professions Code section 4052.4.

(a) Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5 or 1206.6. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for himself or herself, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5 or Section 1206.6. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

(b) A pharmacist may perform any aspect of any FDA approved or authorized point-of-care test for the presence of SARS-CoV-2 or influenza that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments as described in (a) under the following conditions:

1.The pharmacist completes the testing in a pharmacy licensed by the Board and that is appropriately licensed in California as a laboratory pursuant to BPC 1265.

2. The pharmacist has completed necessary training as specified in the pharmacy's policies and procedures.

# Add BPC section 4119.10

A pharmacy located in this state, may employ pharmacists to perform FDA approved or authorized point-of-care tests for the presence of SARS-CoV-2 or influenza that are classified as waived pursuant the Federal Clinical Laboratory Improvement Amendments of 1988 under the following conditions:

- 1. The pharmacy is appropriately licensed as a laboratory under BPC section 1265.
- 2. The pharmacy maintains policies and procedures that at minimum describe the following:
  - a. <u>Establish the initial training requirements, including specimen collection techniques relevant to the test(s) being performed at the pharmacy and ongoing training.</u>
  - b. Establish the necessary safety precautions to protect pharmacy staff and consumers to reduce the risk of transmission consistent with CalOSHA and CDC requirements. Such policies should, at a minimum, include provisions for use for personal protective equipment, cleaning and sanitizing procedures, appropriate biohazard waste requirements and space requirements to protect the safety of staff and consumers.
  - c. Ensure dedicated physical or other segregated space that allows for privacy during the testing process, provides for private consultation with the pharmacist and to limit the potential contamination of other consumers in the pharmacy.

- d. Detail requirements for providing test results to the patient in a nonverbal manner, complying with mandatory reporting requirements to local and state reporting systems, and notification to primary care providers if consent is provided.
- e. <u>Ensure documentation of testing equipment maintenance and</u> calibration.
- f. Ensure appropriate storage and handling of specimens, testing reagents, etc.
- 3. The pharmacist-in-charge must review the policies and procedures on an annual basis. As part of this annual review the pharmacist-in-charge must also assess the pharmacy's compliance with its policies and where noncompliance is noted, document corrective actions to be taken. Documentation of the review must be maintained in a readily retrievable format for a period of three years from the date of completion.
- 4. The pharmacy must maintain documentation related to performing these tests that demonstrate compliance with all conditions in this subsection, including, the name of the pharmacist performing the test, the results and communication of results to a patient's primary medical provider. These documents must be maintained for period of three years from the date of making and must be maintained in a readily retrievable format.

#### Amend BPC section 1206.5.

- (a) Notwithstanding subdivision (b) of Section 1206 and except as otherwise provided in Sections 1206.6 and 1241, no person shall perform a clinical laboratory test or examination classified as waived under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:
- (1) A licensed physician and surgeon holding a M.D. or D.O. degree.
- (2) A licensed podiatrist, a licensed dentist, or a licensed naturopathic doctor, if the results of the tests can be lawfully utilized within his or her practice.
- (3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.
- (4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.
- (5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.
- (6) A person licensed under Chapter 6 (commencing with Section 2700).
- (7) A person licensed under Chapter 6.5 (commencing with Section 2840).

- (8) A perfusionist if authorized by and performed in compliance with Section 2590.
- (9) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).
- (10) A medical assistant, as defined in Section 2069, if the waived test is performed pursuant to a specific authorization meeting the requirements of Section 2069.
- (11) A pharmacist, as defined in Section 4036, if ordering drug therapy-related laboratory tests in compliance with paragraph (2) of subdivision (a) of Section 4052.1 or paragraph (2) of subdivision (a) of Section 4052.2, or if performing skin puncture in the course of performing routine patient assessment procedures in compliance with Section 4052.1 or performing testing as authorized in section 4052.4.
- (12) A naturopathic assistant, as defined in Sections 3613 and 3640.2, if the waived test is performed pursuant to a specific authorization meeting the requirements of Sections 3613 and 3640.2.
- (13) A licensed optometrist as authorized under Chapter 7 (commencing with Section 3000).
- (14) Other health care personnel providing direct patient care.
- (15) Any other person performing nondiagnostic testing pursuant to Section 1244.
- (b) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of moderate complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:
- (1) A licensed physician and surgeon holding a M.D. or D.O. degree.
- (2) A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.
- (3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.
- (4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.
- (5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.
- (6) A person licensed under Chapter 6 (commencing with Section 2700).
- (7) A perfusionist if authorized by and performed in compliance with Section 2590.
- (8) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).

- (9) A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section 107150) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.
- (10) Any person if performing blood gas analysis in compliance with Section 1245.
- (11) (A) A person certified or licensed as an "Emergency Medical Technician II" or paramedic pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code while providing prehospital medical care, a person licensed as a psychiatric technician under Chapter 10 (commencing with Section 4500) of Division 2, as a vocational nurse pursuant to Chapter 6.5 (commencing with Section 2840), or as a midwife licensed pursuant to Article 24 (commencing with Section 2505) of Chapter 5, or certified by the department pursuant to Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations as a nurse assistant or a home health aide, who provides direct patient care, if the person is performing the test as an adjunct to the provision of direct patient care by the person, is utilizing a point-of-care laboratory testing device at a site for which a laboratory license or registration has been issued, meets the minimum clinical laboratory education, training, and experience requirements set forth in regulations adopted by the department, and has demonstrated to the satisfaction of the laboratory director that he or she is competent in the operation of the point-of-care laboratory testing device for each analyte to be reported.
- (B) Prior to being authorized by the laboratory director to perform laboratory tests or examinations, testing personnel identified in subparagraph (A) shall participate in a preceptor program until they are able to perform the clinical laboratory tests or examinations authorized in this section with results that are deemed accurate and skills that are deemed competent by the preceptor. For the purposes of this section, a "preceptor program" means an organized system that meets regulatory requirements in which a preceptor provides and documents personal observation and critical evaluation, including review of accuracy, reliability, and validity, of laboratory testing performed.
- (12) Any other person within a physician office laboratory if the test is performed under the supervision of the patient's physician and surgeon or podiatrist who shall be accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed, and shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of the clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.
- (13) A pharmacist, if ordering drug therapy-related laboratory tests in compliance with paragraph (2) of subdivision (a) of Section 4052.1 or paragraph (2) of subdivision (a) of Section 4052.2.
- (c) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of high complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the

adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

- (1) A licensed physician and surgeon holding a M.D. or D.O. degree.
- (2) A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.
- (3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory if the test or examination is within a specialty or subspecialty authorized by the person's licensure.
- (4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code if the test or examination is within a specialty or subspecialty authorized by the person's certification.
- (5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.
- (6) A perfusionist if authorized by and performed in compliance with Section 2590.
- (7) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).
- (8) A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section 107150) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.
- (9) Any person if performing blood gas analysis in compliance with Section 1245.
- (10) Any other person within a physician office laboratory if the test is performed under the onsite supervision of the patient's physician and surgeon or podiatrist who shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.
- (d) Clinical laboratory examinations classified as provider-performed microscopy under CLIA may be personally performed using a brightfield or phase/contrast microscope by one of the following practitioners:
- (1) A licensed physician and surgeon using the microscope during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or employee.
- (2) A nurse midwife holding a certificate as specified by Section 2746.5, a licensed nurse practitioner as specified in Section 2835.5, or a licensed physician assistant acting under the supervision of a physician pursuant to Section 3502 using the microscope during the patient's visit on a specimen obtained from his or her own patient or from the patient of a clinic, group medical practice, or other health care provider of which the certified nurse midwife, licensed nurse practitioner, or licensed physician assistant is an employee.

(3) A licensed dentist using the microscope during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee.

## Amend BPC section 1209.

- (a) As used in this chapter, "laboratory director" means any person who is any of the following:
- (1) A duly licensed physician and surgeon.
- (2) Only for purposes of a clinical laboratory test or examination classified as waived, is any of the following:
- (A) A duly licensed clinical laboratory scientist.
- (B) A duly licensed limited clinical laboratory scientist.
- (C) A duly licensed naturopathic doctor.
- (D) A duly licensed optometrist serving as the director of a laboratory that only performs clinical laboratory tests authorized in paragraph (10) of subdivision (d) of Section 3041.
- (E) A pharmacist-in-charge of a pharmacy serving as the director of a laboratory that only performs CLIA waived tests as authorized in Pharmacy Law.
- (3) Licensed to direct a clinical laboratory under this chapter.
- (b) (1) A person defined in paragraph (1) or (3) of subdivision (a) who is identified as the CLIA laboratory director of a laboratory that performs clinical laboratory tests classified as moderate or high complexity shall also meet the laboratory director qualifications under CLIA for the type and complexity of tests being offered by the laboratory.
- (2) As used in this subdivision, "CLIA laboratory director" means the person identified as the laboratory director on the CLIA certificate issued to the laboratory by the federal Centers for Medicare and Medicaid Services (CMS).
- (c) The laboratory director, if qualified under CLIA, may perform the duties of the technical consultant, technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to persons qualified under CLIA. If the laboratory director reapportions performance of those responsibilities or duties, he or she shall remain responsible for ensuring that all those duties and responsibilities are properly performed.
- (d) (1) The laboratory director is responsible for the overall operation and administration of the clinical laboratory, including administering the technical and scientific operation of a clinical laboratory, the selection and supervision of procedures, the reporting of results, and active participation in its operations to the extent necessary to ensure compliance with this act and CLIA. He or she shall be responsible for the proper performance of all laboratory work of all subordinates and shall employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests, and report test results in

accordance with the personnel qualifications, duties, and responsibilities described in CLIA and this chapter.

- (2) Where a point-of-care laboratory testing device is utilized and provides results for more than one analyte, the testing personnel may perform and report the results of all tests ordered for each analyte for which he or she has been found by the laboratory director to be competent to perform and report.
- (e) As part of the overall operation and administration, the laboratory director of a registered laboratory shall document the adequacy of the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory test procedures and examinations. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for personnel, in addition to any CLIA requirements relative to the education or training of personnel.
- (f) As part of the overall operation and administration, the laboratory director of a licensed laboratory shall do all of the following:
- (1) Ensure that all personnel, prior to testing biological specimens, have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for, and the type of procedures that may be performed by, personnel in addition to any CLIA requirements relative to the education or training of personnel. Any regulations adopted pursuant to this section that specify the type of procedure that may be performed by testing personnel shall be based on the skills, knowledge, and tasks required to perform the type of procedure in question.
- (2) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to ensure that they are competent and maintain their competency to process biological specimens, perform test procedures, and report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills.
- (3) Specify in writing the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases of clinical laboratory tests or examinations, including which clinical laboratory tests or examinations the individual is authorized to perform, whether supervision is required for the individual to perform specimen processing, test performance, or results reporting, and whether consultant, supervisor, or director review is required prior to the individual reporting patient test results.
- (g) The competency and performance of staff of a licensed laboratory shall be evaluated and documented by the laboratory director, or by a person who qualifies as a technical consultant or a technical supervisor under CLIA depending on the type and complexity of tests being offered by the laboratory.

- (1) The procedures for evaluating the competency of the staff shall include, but are not limited to, all of the following:
- (A) Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen handling, processing, and testing.
- (B) Monitoring the recording and reporting of test results.
- (C) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
- (D) Direct observation of performance of instrument maintenance and function checks.
- (E) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.
- (F) Assessment of problem solving skills.
- (2) Evaluation and documentation of staff competency and performance shall occur at least semiannually during the first year an individual tests biological specimens. Thereafter, evaluations shall be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance shall be reevaluated to include the use of the new test methodology or instrumentation.
- (h) The laboratory director of each clinical laboratory of an acute care hospital shall be a physician and surgeon who is a qualified pathologist, except as follows:
- (1) If a qualified pathologist is not available, a physician and surgeon or a clinical laboratory bioanalyst qualified as a laboratory director under subdivision (a) may direct the laboratory. However, a qualified pathologist shall be available for consultation at suitable intervals to ensure high-quality service.
- (2) If there are two or more clinical laboratories of an acute care hospital, those additional clinical laboratories that are limited to the performance of blood gas analysis, blood electrolyte analysis, or both, may be directed by a physician and surgeon qualified as a laboratory director under subdivision (a), irrespective of whether a pathologist is available.

As used in this subdivision, a qualified pathologist is a physician and surgeon certified or eligible for certification in clinical or anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.

- (i) Subdivision (h) does not apply to any director of a clinical laboratory of an acute care hospital acting in that capacity on or before January 1, 1988.
- (j) A laboratory director may serve as the director of up to the maximum number of laboratories stipulated by CLIA, as defined under Section 1202.5.

# **Attachment 3**

# **BUSINESS AND PROFESSIONS CODE - BPC**

# **DIVISION 2. HEALING ARTS [500 - 4999.129]**

(Division 2 enacted by Stats. 1937, Ch. 399.)

# CHAPTER 9. Pharmacy [4000 - 4427.8]

(Chapter 9 repealed and added by Stats. 1996, Ch. 890, Sec. 3.)

# **ARTICLE 7. Pharmacies [4110 - 4126.9]**

(Article 7 added by Stats. 1996, Ch. 890, Sec. 3.)

# 4115.

- (a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.
- (b) This section does not authorize the performance of any tasks specified in subdivision (a) by a pharmacy technician without a pharmacist on duty.
- (c) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.
- (d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.
- (e) A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician.
- (f) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility

- operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs.
- (2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.
- (3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of his or her professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist in charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. An entity employing a pharmacist shall not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.
- (g) Notwithstanding subdivisions (a) and (b), the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. This subdivision shall not be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (f).
- (h) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

- (i) In a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code, a pharmacy technician's duties may include any of the following:
- (1) Packaging emergency supplies for use in the health care facility and the hospital's emergency medical system or as authorized under Section 4119.
- (2) Sealing emergency containers for use in the health care facility.
- (3) Performing monthly checks of the drug supplies stored throughout the health care facility. Irregularities shall be reported within 24 hours to the pharmacist in charge and the director or chief executive officer of the health care facility in accordance with the health care facility's policies and procedures.

(Amended by Stats. 2015, Ch. 303, Sec. 5. (AB 731) Effective January 1, 2016.)

# § 1793.2. Duties of a Pharmacy Technician.

16 CA ADC § 1793.2BARCLAYS OFFICIAL CALIFORNIA CODE OF REGULATIONS

Barclays Official California Code of Regulations

Title 16. Professional and Vocational Regulations

Division 17. California State Board of Pharmacy

Article 11. Ancillary Personnel (Refs & Annos)

# 16 CCR § 1793.2

§ 1793.2. Duties of a Pharmacy Technician.

"Nondiscretionary tasks" as used in Business and Professions Code section 4115, include:

- (a) removing the drug or drugs from stock;
- (b) counting, pouring, or mixing pharmaceuticals;
- (c) placing the product into a container;
- (d) affixing the label or labels to the container;
- (e) packaging and repackaging.

Note: Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

## **HISTORY**

- 1. New section filed 8-12-92; operative 9-11-92 (Register 92, No. 33).
- 2. Change without regulatory effect amending first paragraph and Note filed 9-11-2002 pursuant to section 100, title 1, California Code of Regulations (Register 2002, No. 37).
- 3. Repealer of first paragraph filed 9-22-2004; operative 10-22-2004 (Register 2004, No. 39).

This database is current through 1/8/21 Register 2021, No. 2

16 CCR § 1793.2, 16 CA ADC § 1793.2

# Proposal to Amend Business and Professions Code section 4115.

- (a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.
- (b) This section does not authorize the performance of any tasks specified in subdivision (a) by a pharmacy technician without a pharmacist on duty.
- (c) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.
- (d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.
- (e) A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician.
- (f) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs.
- (2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.
- (3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of his or her professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist in charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. An entity employing a pharmacist shall not discharge, discipline, or otherwise discriminate

against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

- (g) Notwithstanding subdivisions (a) and (b), the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. This subdivision shall not be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (f).
- (h) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.
- (i) In a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code, a pharmacy technician's duties may include any of the following:
- (1) Packaging emergency supplies for use in the health care facility and the hospital's emergency medical system or as authorized under Section 4119.
- (2) Sealing emergency containers for use in the health care facility.
- (3) Performing monthly checks of the drug supplies stored throughout the health care facility. Irregularities shall be reported within 24 hours to the pharmacist in charge and the director or chief executive officer of the health care facility in accordance with the health care facility's policies and procedures.

- (j) A pharmacy technician may administer a COVID-19 or influenza vaccine, if deemed appropriate and delegated by the supervising pharmacist, if the following conditions are met:
  - 1. The pharmacy technician holds a current certification in cardiopulmonary resuscitation (CPR).
  - 2. The pharmacy technician has completed a training consisting of a minimum of 6 hours of training, which includes live training, assessment and evaluation of injection technique assessment, and completing the online assessment and evaluation from an ACPE accredited provider.
  - 3. The pharmacy technician completes 1 hours of immunization related continuing education once every two years.
  - 4. <u>If deemed appropriate by the supervising pharmacist, a pharmacy technician may also administer epinephrine.</u>
  - 5. The pharmacy maintains a record of the identification of the pharmacy technician administering the vaccine and the identification of the supervising pharmacist.

# **Attachment 4**

# Vaccines in the Child and Adolescent Immunization Schedule\*

Vaccines	Abbreviations	Trade names
Diphtheria, tetanus, and acellular pertussis vaccine	DTaP	Daptacel® Infanrix®
Diphtheria, tetanus vaccine	DT	No trade name
Haemophilus influenzae type b vaccine	Hib (PRP-T) Hib (PRP-OMP)	ActHIB® Hiberix® PedvaxHIB®
Hepatitis A vaccine	НерА	Havrix® Vaqta®
Hepatitis B vaccine	НерВ	Engerix-B® Recombivax HB®
Human papillomavirus vaccine	HPV	Gardasil 9®
Influenza vaccine (inactivated)	IIV	Multiple
Influenza vaccine (live, attenuated)	LAIV	FluMist® Quadrivalent
Measles, mumps, and rubella vaccine	MMR	M-M-R <sup>®</sup> II
Meningococcal serogroups A, C, W, Y vaccine	MenACWY-D	Menactra®
	MenACWY-CRM	Menveo®
Meningococcal serogroup B vaccine	MenB-4C	Bexsero®
	MenB-FHbp	Trumenba®
Pneumococcal 13-valent conjugate vaccine	PCV13	Prevnar 13®
Pneumococcal 23-valent polysaccharide vaccine	PPSV23	Pneumovax® 23
Poliovirus vaccine (inactivated)	IPV	IPOL <sup>®</sup>
Rotavirus vaccine	RV1 RV5	Rotarix® RotaTeq®
Tetanus, diphtheria, and acellular pertussis vaccine	Tdap	Adacel® Boostrix®
Tetanus and diphtheria vaccine	Td	Tenivac® Tdvax™
Varicella vaccine	VAR	Varivax®

# Combination vaccines (use combination vaccines instead of separate injections when appropriate)

DTaP, hepatitis B, and inactivated poliovirus vaccine	DTaP-HepB-IPV	Pediarix®
DTaP, inactivated poliovirus, and Haemophilus influenzae type b vaccine	DTaP-IPV/Hib	Pentacel®
DTaP and inactivated poliovirus vaccine	DTaP-IPV	Kinrix® Quadracel®
Measles, mumps, rubella, and varicella vaccine	MMRV	ProQuad®

<sup>\*</sup>Administer recommended vaccines if immunization history is incomplete or unknown. Do not restart or add doses to vaccine series for extended intervals between doses. When a vaccine is not administered at the recommended age, administer at a subsequent visit. The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

# How to use the child/adolescent immunization schedule

Determine recommended vaccine by age (Table 1)

Determine recommended interval for catch-up vaccination (Table 2)

Assess need for additional recommended vaccines by medical condition and other indications situations (Table 3)

Review vaccine types, frequencies, intervals, and considerations for special (Notes)

Recommended by the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/acip) and approved by the Centers for Disease Control and Prevention (www.cdc.gov), American Academy of Pediatrics (www.aap.org), American Academy of Family Physicians (www.aafp.org), American College of Obstetricians and Gynecologists (www.acog.org), and American College of Nurse-Midwives (www.midwife.org).

# Report

- Suspected cases of reportable vaccine-preventable diseases or outbreaks to your state or local health department
- Clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or 800-822-7967



Download the CDC Vaccine Schedules App for providers at www.cdc.gov/vaccines/schedules/hcp/schedule-app.html.

# Helpful information

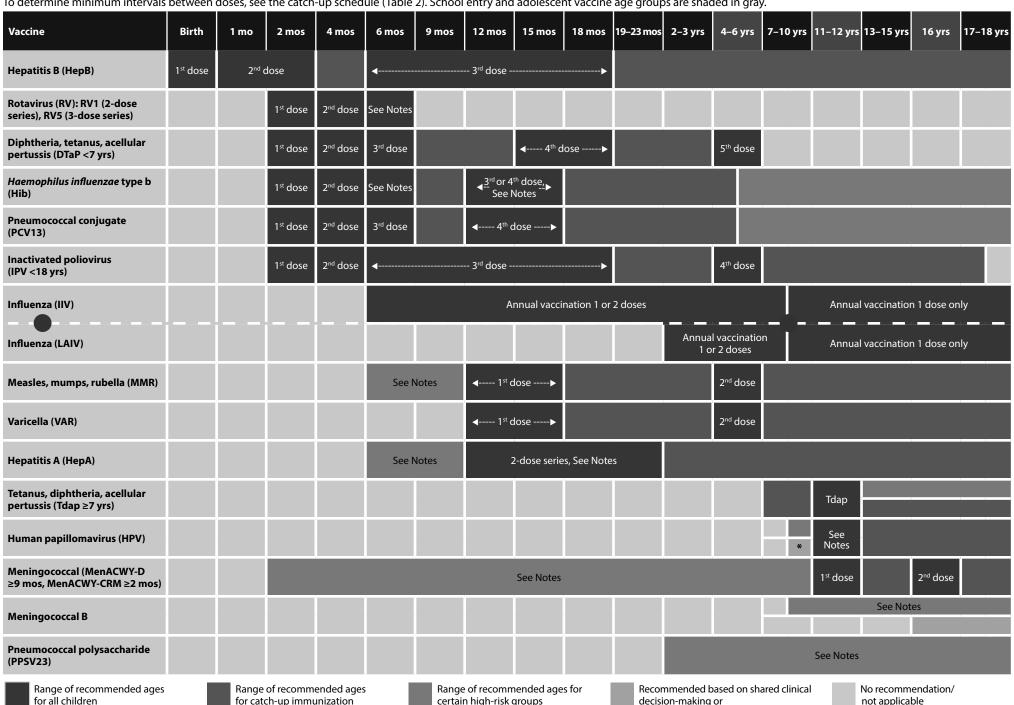
- Complete ACIP recommendations: www.cdc.gov/vaccines/hcp/acip-recs/index.html
- General Best Practice Guidelines for Immunization: www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- Outbreak information (including case identification and outbreak response), see Manual for the Surveillance of Vaccine-Preventable Diseases: www.cdc.gov/vaccines/pubs/surv-manual



U.S. Department of **Health and Human Services** Centers for Disease Control and Prevention



**These recommendations must be read with the notes that follow.** For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars. To determine minimum intervals between doses, see the catch-up schedule (Table 2). School entry and adolescent vaccine age groups are shaded in gray.



\*can be used in this age group



# Recommended Catch-up Immunization Schedule for Children and Adolescents Who Start Late or Who are More

than 1 month Behind, United States, 2020

The table below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. Always use this table in conjunction with Table 1 and the notes that follow.

			Children age 4 months through 6 years		
Vaccine	Minimum Age for		Minimum Interval Between Doses		
	Dose 1	Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Dose 4	Dose 4 to Dos
Hepatitis B	Birth	4 weeks	8 weeks and at least 16 weeks after first dose.  Minimum age for the final dose is 24 weeks.		
Rotavirus	6 weeks Maximum age for first dose is 14 weeks, 6 days	4 weeks	4 weeks Maximum age for final dose is 8 months, 0 days.		
Diphtheria, tetanus, and acellular pertussis	6 weeks	4 weeks	4 weeks	6 months	6 months
Haemophilus influenzae type b	6 weeks	No further doses needed if first dose was administered at age 15 months or older.  4 weeks if first dose was administered before the 1st birthday.  8 weeks (as final dose) if first dose was administered at age 12 through 14 months.	No further doses needed if previous dose was administered at age 15 months or older.  4 weeks if current age is younger than 12 months and first dose was administered at younger than age 7 months and at least 1 previous dose was PRP-T (ActHib, Pentacel, Hiberix) or unknown.  8 weeks and age 12 through 59 months (as final dose) if current age is younger than 12 months and first dose was administered at age 7 through 11 months; OR if current age is 12 through 59 months and first dose was administered before the 1st birthday and second dose administered at younger than 15 months; OR if both doses were PRP-OMP (PedvaxHIB, Comvax) and were administered before the 1st birthday.	8 weeks (as final dose) This dose only necessary for children age 12 through 59 months who received 3 doses before the 1st birthday.	
Pneumococcal conjugate	6 weeks	No further doses needed for healthy children if first dose was administered at age 24 months or older.  4 weeks if first dose was administered before the 1st birthday.  8 weeks (as final dose for healthy children) if first dose was administered at the 1st birthday or after.	ff current age is younger than 12 months and previous dose was administered at <7 months old.  8 weeks (as final dose for healthy children)	8 weeks (as final dose) This dose only necessary for children age 12 through 59 months who received 3 doses before age 12 months or for children at high risk who received 3 doses at any age.	
Inactivated poliovirus	6 weeks	4 weeks	4 weeks if current age is < 4 years. 6 months (as final dose) if current age is 4 years or older.	<b>6 months</b> (minimum age 4 years for final dose).	
Measles, mumps, rubella	12 months	4 weeks	, , , , , , , , , , , , , , , , , , , ,		
Varicella	12 months	3 months			
Hepatitis A	12 months	6 months			
Meningococcal ACWY	2 months MenACWY- CRM 9 months MenACWY-D	8 weeks	See Notes	See Notes	
			Children and adolescents age 7 through 18 years		
Meningococcal ACWY	Not applicable (N/A)	8 weeks			
Tetanus, diphtheria; tetanus, diphtheria, and acellular pertussis	7 years	4 weeks	4 weeks if first dose of DTaP/DT was administered before the 1st birthday. 6 months (as final dose) if first dose of DTaP/DT or Tdap/Td was administered at or after the 1st birthday.	<b>6 months</b> if first dose of DTaP/DT was administered before the 1st birthday.	
Human papillomavirus	9 years	Routine dosing intervals are recomme	nded.		
Hepatitis A	N/A	6 months			
Hepatitis B	N/A	4 weeks	8 weeks and at least 16 weeks after first dose.		
Inactivated poliovirus	N/A	4 weeks	<b>6 months</b> A fourth dose is not necessary if the third dose was administered at age 4 years or older and at least 6 months after the previous dose.	A fourth dose of IPV is indicated if all previous doses were administered at <4 years or if the third dose was administered <6 months after the second dose.	
Measles, mumps, rubella	N/A	4 weeks			
Varicella	N/A	<b>3 months</b> if younger than age 13 years. <b>4 weeks</b> if age 13 years or older.			



# Table 3 Recommended Child and Adolescent Immunization Schedule by Medical Indication, United States, 2020

Always use this table in o	conjunction w	ith Table 1 and the	notes that follo	ow.						
					INI	DICATION				
		Immunocom- promised status (excluding HIV	HIV infection <15% and total CD4 cell count of	CD4+ count <sup>1</sup> ≥15% and total CD4 cell count of	Kidney failure, end-stage renal disease, or on	Heart disease or	CSF leaks or cochlear	Asplenia or persistent complement component	Chronic liver	
VACCINE	Pregnancy	infection)	<200/mm3	≥200/mm3	hemodialysis	chronic lung disease	implants	deficiencies	disease	Diabetes
Hepatitis B										
Rotavirus		SCID <sup>2</sup>								
Diphtheria, tetanus, & acellular pertussis (DTaP)										
Haemophilus influenzae type b										
Pneumococcal conjugate										
Inactivated poliovirus										
Influenza (IIV)							<u> </u>			
Influenza (LAIV)						Asthma, wheezing: 2–4yrs³	4			
Measles, mumps, rubella										
Varicella										
Hepatitis A										
Tetanus, diphtheria, & acellular pertussis (Tdap)										
Human papillomavirus										
Meningococcal ACWY										
Meningococcal B										
Pneumococcal polysaccharide										
Vaccination according to the routine schedule recommended	Recommend persons with additional ri for which th would be in	sk factor r e vaccine c	/accination is recondent additional dos necessary based or condition. See Note	n medical	Not recommende contraindicated— should not be add	-vaccine might be		Delay vaccination until after pregnancy if vaccine indicated		mmendation, applicable

<sup>1</sup> For additional information regarding HIV laboratory parameters and use of live vaccines, see the General Best Practice Guidelines for Immunization, "Altered Immunocompetence," at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html and Table 4-1 (footnote D) at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.

<sup>2</sup> Severe Combined Immunodeficiency

<sup>3</sup> LAIV contraindicated for children 2-4 years of age with asthma or wheezing during the preceding 12 months.



For vaccine recommendations for persons 19 years of age or older, see the Recommended Adult Immunization Schedule.

#### **Additional information**

- Consult relevant ACIP statements for detailed recommendations at www.cdc.gov/vaccines/hcp/acip-recs/index.html.
- For information on contraindications and precautions for the use of a vaccine, consult the General Best Practice Guidelines for Immunization at www.cdc.gov/vaccines/hcp/acip-recs/generalrecs/contraindications.html and relevant ACIP statements at www.cdc.gov/vaccines/hcp/acip-recs/index.html.
- For calculating intervals between doses, 4 weeks = 28 days. Intervals of ≥4 months are determined by calendar months.
- Within a number range (e.g., 12–18), a dash (–) should be read as "through."
- Vaccine doses administered ≤4 days before the minimum age or interval are considered valid. Doses of any vaccine administered ≥5 days earlier than the minimum age or minimum interval should not be counted as valid and should be repeated as ageappropriate. The repeat dose should be spaced after the invalid dose by the recommended minimum interval. For further details, see Table 3-1, Recommended and minimum ages and intervals between vaccine doses, in General Best Practice Guidelines for Immunization at www.cdc.gov/vaccines/hcp/acip-recs/generalrecs/timing.html.
- Information on travel vaccine requirements and recommendations is available at www.cdc.gov/travel/.
- For vaccination of persons with immunodeficiencies, see
   Table 8-1, Vaccination of persons with primary and secondary
   immunodeficiencies, in General Best Practice Guidelines for
   Immunization at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html, and Immunization in Special
   Clinical Circumstances (In: Kimberlin DW, Brady MT, Jackson MA,
   Long SS, eds. Red Book: 2018 Report of the Committee on Infectious
   Diseases. 31st ed. Itasca, IL: American Academy of Pediatrics;
   2018:67–111).
- For information regarding vaccination in the setting of a vaccinepreventable disease outbreak, contact your state or local health department.
- The National Vaccine Injury Compensation Program (VICP) is a no-fault alternative to the traditional legal system for resolving vaccine injury claims. All routine child and adolescent vaccines are covered by VICP except for pneumococcal polysaccharide vaccine (PPSV23). For more information, see www.hrsa.gov/ vaccinecompensation/index.html.

**Diphtheria, tetanus, and pertussis (DTaP) vaccination** (minimum age: 6 weeks [4 years for Kinrix or Ouadracell)

#### **Routine vaccination**

- 5-dose series at 2, 4, 6, 15–18 months, 4–6 years
- **Prospectively:** Dose 4 may be administered as early as age 12 months if at least 6 months have elapsed since dose 3.
- Retrospectively: A 4<sup>th</sup> dose that was inadvertently administered as early as 12 months may be counted if at least 4 months have elapsed since dose 3.

# **Catch-up vaccination**

- Dose 5 is not necessary if dose 4 was administered at age 4 years or older and at least 6 months after dose 3.
- For other catch-up guidance, see Table 2.

# *Haemophilus influenzae* type b vaccination (minimum age: 6 weeks)

#### Routine vaccination

- ActHIB, Hiberix, or Pentacel: 4-dose series at 2, 4, 6, 12– 15 months
- PedvaxHIB: 3-dose series at 2, 4, 12-15 months

# **Catch-up vaccination**

- Dose 1 at 7-11 months: Administer dose 2 at least 4 weeks later and dose 3 (final dose) at 12-15 months or 8 weeks after dose 2 (whichever is later).
- **Dose 1 at 12–14 months:** Administer dose 2 (final dose) at least 8 weeks after dose 1.
- Dose 1 before 12 months and dose 2 before 15 months: Administer dose 3 (final dose) 8 weeks after dose 2.
- 2 doses of PedvaxHIB before 12 months: Administer dose 3 (final dose) at 12–59 months and at least 8 weeks after dose 2.
- Unvaccinated at 15-59 months: 1 dose
- Previously unvaccinated children age 60 months or older who are not considered high risk do not require catch-up vaccination.
- For other catch-up guidance, see Table 2.

## **Special situations**

• Chemotherapy or radiation treatment:

#### 12-59 months

- Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
- 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

Doses administered within 14 days of starting therapy or during therapy should be repeated at least 3 months after therapy completion.

#### • Hematopoietic stem cell transplant (HSCT):

- 3-dose series 4 weeks apart starting 6 to 12 months after successful transplant, regardless of Hib vaccination history
- Anatomic or functional asplenia (including sickle cell disease):

#### 12-59 months

- Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
- 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

## <u>Unvaccinated\* persons age 5 years or older</u>

- 1 dose

#### • Elective splenectomy:

<u>Unvaccinated\* persons age 15 months or older</u>

- 1 dose (preferably at least 14 days before procedure)

#### HIV infection:

#### 12-59 months

- Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
- 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

#### *Unvaccinated\* persons age 5–18 years*

- 1 dose

#### Immunoglobulin deficiency, early component complement deficiency:

#### 12-59 months

- Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
- 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

<sup>\*</sup>Unvaccinated = Less than routine series (through 14 months)
OR no doses (15 months or older)



# **Hepatitis A vaccination** (minimum age: 12 months for routine vaccination)

#### **Routine vaccination**

 2-dose series (minimum interval: 6 months) beginning at age 12 months

### **Catch-up vaccination**

- Unvaccinated persons through 18 years should complete a 2-dose series (minimum interval: 6 months).
- Persons who previously received 1 dose at age 12 months or older should receive dose 2 at least 6 months after dose 1.
- Adolescents 18 years and older may receive the combined HepA and HepB vaccine, **Twinrix**®, as a 3-dose series (0, 1, and 6 months) or 4-dose series (0, 7, and 21–30 days, followed by a dose at 12 months).

#### International travel

- Persons traveling to or working in countries with high or intermediate endemic hepatitis A (www.cdc.gov/travel/):
- Infants age 6-11 months: 1 dose before departure; revaccinate with 2 doses, separated by at least 6 months, between 12 and 23 months of age
- Unvaccinated age 12 months and older: Administer dose 1 as soon as travel is considered.

# Hepatitis B vaccination (minimum age: birth)

# **Birth dose (monovalent HepB vaccine only)**

- Mother is HBsAg-negative: 1 dose within 24 hours of birth for all medically stable infants ≥2,000 grams. Infants <2,000 grams: Administer 1 dose at chronological age 1 month or hospital discharge.
- Mother is HBsAg-positive:
- Administer **HepB vaccine** and **hepatitis B immune globulin (HBIG)** (in separate limbs) within 12 hours of birth, regardless of birth weight. For infants <2,000 grams, administer 3 additional doses of vaccine (total of 4 doses) beginning at age 1 month.
- Test for HBsAg and anti-HBs at age 9–12 months. If HepB series is delayed, test 1–2 months after final dose.
- Mother's HBsAg status is unknown:
- Administer **HepB vaccine** within 12 hours of birth, regardless of birth weight.
- For infants <2,000 grams, administer HBIG in addition to HepB vaccine (in separate limbs) within 12 hours of birth. Administer 3 additional doses of vaccine (total of 4 doses) beginning at age 1 month.</li>
- Determine mother's HBsAg status as soon as possible. If mother is HBsAg-positive, administer **HBIG** to infants ≥2,000 grams as soon as possible, but no later than 7 days of age.

#### Routine series

 3-dose series at 0, 1–2, 6–18 months (use monovalent HepB vaccine for doses administered before age 6 weeks)

- Infants who did not receive a birth dose should begin the series as soon as feasible (see Table 2).
- Administration of 4 doses is permitted when a combination vaccine containing HepB is used after the birth dose.
- Minimum age for the final (3<sup>rd</sup> or 4<sup>th</sup>) dose: 24 weeks
- Minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 8 weeks / dose 1 to dose 3: 16 weeks (when 4 doses are administered, substitute "dose 4" for "dose 3" in these calculations)

## Catch-up vaccination

- Unvaccinated persons should complete a 3-dose series at 0, 1–2, 6 months.
- Adolescents age 11–15 years may use an alternative 2-dose schedule with at least 4 months between doses (adult formulation Recombivax HB only).
- Adolescents 18 years and older may receive a 2-dose series of HepB (Heplisav-B®) at least 4 weeks apart.
- Adolescents 18 years and older may receive the combined HepA and HepB vaccine, **Twinrix**, as a 3-dose series (0, 1, and 6 months) or 4-dose series (0, 7, and 21–30 days, followed by a dose at 12 months).
- For other catch-up guidance, see Table 2.

## **Special situations**

- Revaccination is not generally recommended for persons with a normal immune status who were vaccinated as infants, children, adolescents, or adults.
- Revaccination may be recommended for certain populations, including:
- Infants born to HBsAq-positive mothers
- Hemodialysis patients
- Other immunocompromised persons
- For detailed revaccination recommendations, see www.cdc.gov/ vaccines/hcp/acip-recs/vacc-specific/hepb.html.

# **Human papillomavirus vaccination** (minimum age: 9 years)

# Routine and catch-up vaccination

- HPV vaccination routinely recommended at age 11–12 years (can start at age 9 years) and catch-up HPV vaccination recommended for all persons through age 18 years if not adequately vaccinated
- 2- or 3-dose series depending on age at initial vaccination:
- Age 9 through 14 years at initial vaccination: 2-dose series at 0, 6–12 months (minimum interval: 5 months; repeat dose if administered too soon)
- Age 15 years or older at initial vaccination: 3-dose series at 0,
   1-2 months, 6 months (minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 12 weeks / dose 1 to dose 3: 5 months; repeat dose if administered too soon)
- If completed valid vaccination series with any HPV vaccine, no additional doses needed

### **Special situations**

- Immunocompromising conditions, including HIV infection: 3-dose series as above
- **History of sexual abuse or assault:** Start at age 9 years.
- Pregnancy: HPV vaccination not recommended until after pregnancy; no intervention needed if vaccinated while pregnant; pregnancy testing not needed before vaccination

### Influenza vaccination

(minimum age: 6 months [IIV], 2 years [LAIV], 18 years [recombinant influenza vaccine, RIV])

### **Routine vaccination**

- Use any influenza vaccine appropriate for age and health status annually:
- 2 doses, separated by at least 4 weeks, for children age 6
  months-8 years who have received fewer than 2 influenza
  vaccine doses before July 1, 2019, or whose influenza vaccination
  history is unknown (administer dose 2 even if the child turns 9
  between receipt of dose 1 and dose 2)
- 1 dose for **children age 6 months-8 years** who have received at least 2 influenza vaccine doses before July 1, 2019
- 1 dose for all persons age 9 years and older
- For the 2020–21 season, see the 2020–21 ACIP influenza vaccine recommendations.

#### **Special situations**

- Egg allergy, hives only: Any influenza vaccine appropriate for age and health status annually
- Egg allergy with symptoms other than hives (e.g., angioedema, respiratory distress, need for emergency medical services or epinephrine): Any influenza vaccine appropriate for age and health status annually in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions
- LAIV should not be used in persons with the following conditions or situations:
- History of severe allergic reaction to a previous dose of any influenza vaccine or to any vaccine component (excluding egg, see details above)
- Receiving aspirin or salicylate-containing medications
- Age 2-4 years with history of asthma or wheezing
- Immunocompromised due to any cause (including medications and HIV infection)
- Anatomic or functional asplenia
- Cochlear implant
- Cerebrospinal fluid-oropharyngeal communication
- Close contacts or caregivers of severely immunosuppressed persons who require a protected environment
- Pregnancy
- Received influenza antiviral medications within the previous 48 hours



# Measles, mumps, and rubella vaccination (minimum age: 12 months for routine vaccination)

#### Routine vaccination

- 2-dose series at 12-15 months, 4-6 years
- Dose 2 may be administered as early as 4 weeks after dose 1.

# **Catch-up vaccination**

- Unvaccinated children and adolescents: 2-dose series at least 4 weeks apart
- The maximum age for use of MMRV is 12 years.

# **Special situations**

#### **International travel**

- Infants age 6–11 months: 1 dose before departure; revaccinate with 2-dose series with dose 1 at 12–15 months (12 months for children in high-risk areas) and dose 2 as early as 4 weeks later.
- Unvaccinated children age 12 months and older: 2-dose series at least 4 weeks apart before departure

Meningococcal serogroup A,C,W,Y vaccination (minimum age: 2 months [MenACWY-CRM, Menveo], 9 months [MenACWY-D, Menactra])

#### **Routine vaccination**

• 2-dose series at 11-12 years, 16 years

# **Catch-up vaccination**

- Age 13–15 years: 1 dose now and booster at age 16–18 years (minimum interval: 8 weeks)
- Age 16–18 years: 1 dose

#### **Special situations**

Anatomic or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use:

- Menveo
- Dose 1 at age 8 weeks: 4-dose series at 2, 4, 6, 12 months
- Dose 1 at age 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after age 12 months)
- Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart
- Menactra
- Persistent complement component deficiency or complement inhibitor use:
- · Age 9–23 months: 2-dose series at least 12 weeks apart
- · Age 24 months or older: 2-dose series at least 8 weeks apart
- Anatomic or functional asplenia, sickle cell disease, or HIV infection:
- · Age 9–23 months: Not recommended
- · Age 24 months or older: 2-dose series at least 8 weeks apart
- Menactra must be administered at least 4 weeks after completion of PCV13 series.

Travel in countries with hyperendemic or epidemic meningococcal disease, including countries in the African meningitis belt or during the Hajj (www.cdc.gov/travel/):

- Children less than age 24 months:
- Menveo (age 2-23 months):
- · Dose 1 at 8 weeks: 4-dose series at 2, 4, 6, 12 months
- Dose 1 at 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after age 12 months)
- Menactra (age 9-23 months):
- · 2-dose series (dose 2 at least 12 weeks after dose 1; dose 2 may be administered as early as 8 weeks after dose 1 in travelers)
- Children age 2 years or older: 1 dose Menveo or Menactra

First-year college students who live in residential housing (if not previously vaccinated at age 16 years or older) or military recruits:

• 1 dose Menveo or Menactra

# Adolescent vaccination of children who received MenACWY prior to age 10 years:

- Children for whom boosters are recommended because of an ongoing increased risk of meningococcal disease (e.g., those with complement deficiency, HIV, or asplenia): Follow the booster schedule for persons at increased risk (see below).
- Children for whom boosters are not recommended (e.g., those who received a single dose for travel to a country where meningococcal disease is endemic): Administer MenACWY according to the recommended adolescent schedule with dose 1 at age 11–12 years and dose 2 at age 16 years.

**Note:** Menactra should be administered either before or at the same time as DTaP. For MenACWY **booster dose recommendations** for groups listed under "Special situations" and in an outbreak setting and for additional meningococcal vaccination information, see www.cdc.gov/vaccines/hcp/aciprecs/vacc-specific/mening.html.

Meningococcal serogroup B vaccination (minimum age: 10 years [MenB-4C, Bexsero; MenB-FHbp, Trumenba])

# **Shared clinical decision-making**

- Adolescents not at increased risk age 16–23 years (preferred age 16–18 years) based on shared clinical decision-making:
- **Bexsero:** 2-dose series at least 1 month apart
- **Trumenba:** 2-dose series at least 6 months apart; if dose 2 is administered earlier than 6 months, administer a 3<sup>rd</sup> dose at least 4 months after dose 2.

# **Special situations**

Anatomic or functional asplenia (including sickle cell disease), persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use:

- Bexsero: 2-dose series at least 1 month apart
- Trumenba: 3-dose series at 0, 1-2, 6 months

**Bexsero** and **Trumenba** are not interchangeable; the same product should be used for all doses in a series.

For MenB **booster dose recommendations** for groups listed under "Special situations" and in an outbreak setting and for additional meningococcal vaccination information, see www.cdc.gov/vaccines/acip/recommendations.html and www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/mening.html.

# **Pneumococcal vaccination**

(minimum age: 6 weeks [PCV13], 2 years [PPSV23])

#### Routine vaccination with PCV13

• 4-dose series at 2, 4, 6, 12–15 months

## **Catch-up vaccination with PCV13**

- 1 dose for healthy children age 24–59 months with any incomplete\* PCV13 series
- For other catch-up guidance, see Table 2.

# **Special situations**

High-risk conditions below: When both PCV13 and PPSV23 are indicated, administer PCV13 first. PCV13 and PPSV23 should not be administered during the same visit.

Chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure), chronic lung disease (including asthma treated with high-dose, oral corticosteroids), diabetes mellitus:

Age 2–5 years

- Any incomplete\* series with:
- 3 PCV13 doses: 1 dose PCV13 (at least 8 weeks after any prior PCV13 dose)
- Less than 3 PCV13 doses: 2 doses PCV13 (8 weeks after the most recent dose and administered 8 weeks apart)
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose)

#### Age 6–18 years

 No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose)

#### Cerebrospinal fluid leak, cochlear implant:

Age 2–5 years

- Any incomplete\* series with:
- 3 PCV13 doses: 1 dose PCV13 (at least 8 weeks after any prior PCV13 dose)
- Less than 3 PCV13 doses: 2 doses PCV13 (8 weeks after the most recent dose and administered 8 weeks apart)
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose)

#### Age 6–18 years

- No history of either PCV13 or PPSV23: 1 dose PCV13, 1 dose PPSV23 at least 8 weeks later
- Any PCV13 but no PPSV23: 1 dose PPSV23 at least 8 weeks after the most recent dose of PCV13
- PPSV23 but no PCV13: 1 dose PCV13 at least 8 weeks after the most recent dose of PPSV23



Sickle cell disease and other hemoglobinopathies; anatomic or functional asplenia; congenital or acquired immunodeficiency; HIV infection; chronic renal failure; nephrotic syndrome; malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and other diseases associated with treatment with immunosuppressive drugs or radiation therapy; solid organ transplantation; multiple myeloma:

Age 2–5 years

- Any incomplete\* series with:
- 3 PCV13 doses: 1 dose PCV13 (at least 8 weeks after any prior PCV13 dose)
- Less than 3 PCV13 doses: 2 doses PCV13 (8 weeks after the most recent dose and administered 8 weeks apart)
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose) and a 2<sup>nd</sup> dose of PPSV23 5 years later

#### Age 6–18 years

- No history of either PCV13 or PPSV23: 1 dose PCV13, 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after PCV13 and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)
- Any PCV13 but no PPSV23: 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after the most recent dose of PCV13 and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)
- PPSV23 but no PCV13: 1 dose PCV13 at least 8 weeks after the most recent PPSV23 dose and a 2<sup>nd</sup> dose of PPSV23 administered 5 years after dose 1 of PPSV23 and at least 8 weeks after a dose of PCV13

#### Chronic liver disease, alcoholism:

Age 6-18 years

- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose)
- \*Incomplete series = Not having received all doses in either the recommended series or an age-appropriate catch-up series See Tables 8, 9, and 11 in the ACIP pneumococcal vaccine recommendations at www.cdc.gov/mmwr/pdf/rr/rr5911.pdf for complete schedule details.

# **Poliovirus vaccination** (minimum age: 6 weeks)

#### Routine vaccination

- 4-dose series at ages 2, 4, 6–18 months, 4–6 years; administer the final dose at or after age 4 years and at least 6 months after the previous dose.
- 4 or more doses of IPV can be administered before age 4 years when a combination vaccine containing IPV is used. However, a dose is still recommended at or after age 4 years and at least 6 months after the previous dose.

### **Catch-up vaccination**

- In the first 6 months of life, use minimum ages and intervals only for travel to a polio-endemic region or during an outbreak.
- IPV is not routinely recommended for U.S. residents 18 years and older.

# **Series containing oral polio vaccine (OPV)**, either mixed OPV-IPV or OPV-only series:

- Total number of doses needed to complete the series is the same as that recommended for the U.S. IPV schedule. See www.cdc.gov/mmwr/volumes/66/wr/mm6601a6.htm?s\_ cid=mm6601a6 w.
- Only trivalent OPV (tOPV) counts toward the U.S. vaccination requirements.
- Doses of OPV administered before April 1, 2016, should be counted (unless specifically noted as administered during a campaign).
- Doses of OPV administered on or after April 1, 2016, should not be counted.
- For guidance to assess doses documented as "OPV," see www.cdc.gov/mmwr/volumes/66/wr/mm6606a7.htm?s\_ cid=mm6606a7 w.
- For other catch-up guidance, see Table 2.

# Rotavirus vaccination (minimum age: 6 weeks)

# **Routine vaccination**

- Rotarix: 2-dose series at 2 and 4 months
- RotaTeq: 3-dose series at 2, 4, and 6 months
- If any dose in the series is either RotaTeq or unknown, default to 3-dose series.

# **Catch-up vaccination**

- Do not start the series on or after age 15 weeks, 0 days.
- The maximum age for the final dose is 8 months, 0 days.
- For other catch-up guidance, see Table 2.

# Tetanus, diphtheria, and pertussis (Tdap) vaccination

(minimum age: 11 years for routine vaccination, 7 years for catch-up vaccination)

#### **Routine vaccination**

- Adolescents age 11-12 years: 1 dose Tdap
- **Pregnancy:** 1 dose Tdap during each pregnancy, preferably in early part of gestational weeks 27–36
- Tdap may be administered regardless of the interval since the last tetanus- and diphtheria-toxoid-containing vaccine.

### **Catch-up vaccination**

- Adolescents age 13–18 years who have not received Tdap:
   1 dose Tdap, then Td or Tdap booster every 10 years
- Persons age 7–18 years not fully vaccinated with DTaP:
   1 dose Tdap as part of the catch-up series (preferably the first dose); if additional doses are needed, use Td or Tdap.
- Tdap administered at 7-10 years:
- **Children age 7–9 years** who receive Tdap should receive the routine Tdap dose at age 11–12 years.
- **Children age 10 years** who receive Tdap do not need to receive the routine Tdap dose at age 11–12 years.
- DTaP inadvertently administered at or after age 7 years:
  - Children age 7–9 years: DTaP may count as part of catchup series. Routine Tdap dose at age 11–12 years should be administered.
- **Children age 10–18 years**: Count dose of DTaP as the adolescent Tdap booster.
- For other catch-up guidance, see Table 2.
- For information on use of Tdap or Td as tetanus prophylaxis in wound management, see www.cdc.gov/mmwr/volumes/67/rr/ rr6702a1.htm.
- \*Fully vaccinated = 5 valid doses of DTaP OR 4 valid doses of DTaP if dose 4 was administered at age 4 years or older

# Varicella vaccination (minimum age: 12 months)

#### **Routine vaccination**

- 2-dose series at 12-15 months, 4-6 years
- Dose 2 may be administered as early as 3 months after dose 1 (a dose administered after a 4-week interval may be counted).

# **Catch-up vaccination**

- Ensure persons age 7–18 years without evidence of immunity (see www.cdc.gov/mmwr/pdf/rr/rr5604.pdf) have 2-dose series:
- Age 7-12 years: routine interval: 3 months (a dose administered after a 4-week interval may be counted)
- Age 13 years and older: routine interval: 4–8 weeks (minimum interval: 4 weeks)
- The maximum age for use of MMRV is 12 years.

# Recommended Adult Immunization Schedule for ages 19 years or older

UNITED STATES

2020

# How to use the adult immunization schedule

Determine recommended vaccinations by age (Table 1)

Assess need for additional recommended vaccinations by medical condition and other indications (Table 2)

Review vaccine types, frequencies, and intervals and considerations for special situations (Notes) Recommended by the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/acip) and approved by the Centers for Disease Control and Prevention (www.cdc.gov), American College of Physicians (www.acponline.org), American Academy of Family Physicians (www.aafp.org), American College of Obstetricians and Gynecologists (www.acog.org), and American College of Nurse-Midwives (www.midwife.org).

#### Vaccines in the Adult Immunization Schedule\*

Vaccines	Abbreviations	Trade names
Haemophilus influenzae type b vaccine	Hib	ActHIB® Hiberix® PedvaxHIB®
Hepatitis A vaccine	НерА	Havrix® Vaqta®
Hepatitis A and hepatitis B vaccine	НерА-НерВ	Twinrix®
Hepatitis B vaccine	НерВ	Engerix-B <sup>®</sup> Recombivax HB <sup>®</sup> Heplisav-B <sup>®</sup>
Human papillomavirus vaccine	HPV vaccine	Gardasil 9®
Influenza vaccine (inactivated)	IIV	Many brands
Influenza vaccine (live, attenuated)	LAIV	FluMist® Quadrivalent
Influenza vaccine (recombinant)	RIV	Flublok® Quadrivalent
Measles, mumps, and rubella vaccine	MMR	M-M-R <sup>®</sup> II
Meningococcal serogroups A, C, W, Y vaccine	MenACWY	Menactra® Menveo®
Meningococcal serogroup B vaccine	MenB-4C MenB-FHbp	Bexsero® Trumenba®
Pneumococcal 13-valent conjugate vaccine	PCV13	Prevnar 13®
Pneumococcal 23-valent polysaccharide vaccine	PPSV23	Pneumovax® 23
Tetanus and diphtheria toxoids	Td	Tenivac® Tdvax™
Tetanus and diphtheria toxoids and acellular pertussis vaccine	Tdap	Adacel® Boostrix®
Varicella vaccine	VAR	Varivax®
Zoster vaccine, recombinant	RZV	Shingrix
Zoster vaccine live	ZVL	Zostavax®

<sup>\*</sup>Administer recommended vaccines if vaccination history is incomplete or unknown. Do not restart or add doses to vaccine series if there are extended intervals between doses. The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

# Report

- Suspected cases of reportable vaccine-preventable diseases or outbreaks to the local or state health department
- Clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System at www.vaers.hhs.gov or 800-822-7967

# Injury claims

All vaccines included in the adult immunization schedule except pneumococcal 23-valent polysaccharide (PPSV23) and zoster (RZV, ZVL) vaccines are covered by the Vaccine Injury Compensation Program. Information on how to file a vaccine injury claim is available at www.hrsa.gov/vaccinecompensation.

#### **Questions or comments**

Contact www.cdc.gov/cdc-info or 800-CDC-INFO (800-232-4636), in English or Spanish, 8 a.m.–8 p.m. ET, Monday through Friday, excluding holidays.



Download the CDC Vaccine Schedules App for providers at www.cdc.gov/vaccines/schedules/hcp/schedule-app.html.

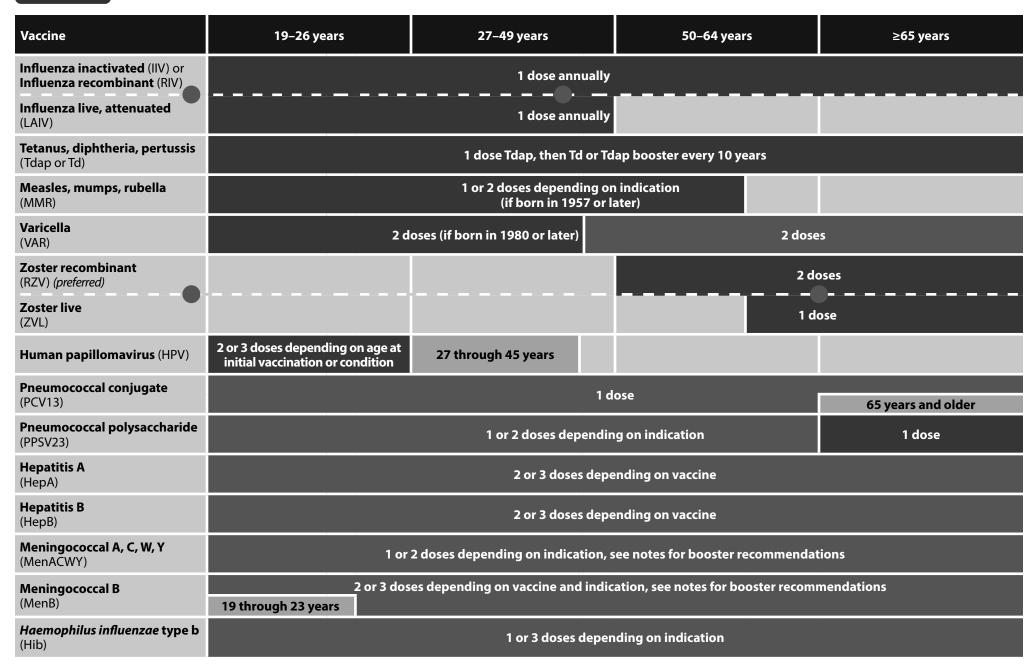
# **Helpful information**

- Complete ACIP recommendations: www.cdc.gov/vaccines/hcp/acip-recs/index.html
- General Best Practice Guidelines for Immunization (including contraindications and precautions): www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/index.html
- Manual for the Surveillance of Vaccine-Preventable Diseases (including case identification and outbreak response): www.cdc.gov/vaccines/pubs/surv-manual
- Travel vaccine recommendations: www.cdc.gov/travel
- Recommended Child and Adolescent Immunization Schedule, United States, 2020: www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html



U.S. Department of Health and Human Services Centers for Disease Control and Prevention

# Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2020



evidence of past infection

# Table 2 Recommended Adult Immunization Schedule by Medical Condition and Other Indications, United States, 2020

Vaccine	Pregnancy	Immuno- compromised	HIV inf	ection count	Asplenia, complement	End-stage renal	Heart or lung disease,	Chronic liver	Diabetes	Health care	Men who have
Vaccine	regulaticy	(excluding HIV infection)	<200	≥200	deficiencies	disease; or on hemodialysis	alcoholism <sup>1</sup>	disease	Diabetes	personnel <sup>2</sup>	sex with men
IIV or RIV						1 dose a	nnually				
LAIV		NOT RECO	MMEND	ED			PRECA	UTION		1 dose a	annually
Tdap or Td	1 dose Tdap each pregnancy				1 dos	e Tdap, then Td	or Tdap booster	every 10 years			
MMR	NOT RE	ECOMMENDED					1 or 2 doses de	pending on ind	ication		
VAR	NOT RE	ECOMMENDED						2 doses			
RZV (preferred)	DELAY						2 do	ses at age ≥50 y	ears		
ZVL	NOT RE	ECOMMENDED					1 do	 ose at age ≥60 ye	ears		
HPV	DELAY	3 doses throug	gh age 2	б years		2	or 3 doses thro	ugh age 26 year	s		
PCV13						1 c	lose				
PPSV23							1, 2, or 3 d	oses depending	on age and ind	ication	
НерА							2 o	<sup>,</sup> 3 doses depen	ding on vaccine		
НерВ							2 o	· 3 doses depen	ding on vaccine		
MenACWY		1 or 2 d	oses dep	ending	on indication, s	ee notes for boo	oster recommen	dations			
MenB	PRECAUTION			2 or 3	doses dependii	ig on vaccine an	d indication, se	e notes for boos	ter recommend	ations	
Hib		3 doses HSCT <sup>3</sup> recipients only			1 d	ose					
Recommend for adults we age required documentativaccination,	ment, lack tion of	Recommended for adults with a risk factor or and indication	an addition		Precaution—vaccin might be indicated of protection outwo of adverse reaction	if benefit aff eighs risk in	elay vaccination until ter pregnancy if vacci dicated	ine is contra	commended/ indicated—vaccine I not be administerec	Not appli	nmendation/ cable

<sup>1.</sup> Precaution for LAIV does not apply to alcoholism. 2. See notes for influenza; hepatitis B; measles, mumps, and rubella; and varicella vaccinations. 3. Hematopoietic stem cell transplant.



# Recommended Adult Immunization Schedule, United States, 2020

# Haemophilus influenzae type b vaccination

# **Special situations**

- Anatomical or functional asplenia (including sickle cell disease): 1 dose if previously did not receive Hib; if elective splenectomy, 1 dose, preferably at least 14 days before splenectomy
- Hematopoietic stem cell transplant (HSCT): 3-dose series 4 weeks apart starting 6–12 months after successful transplant, regardless of Hib vaccination history

# **Hepatitis A vaccination**

#### Routine vaccination

• Not at risk but want protection from hepatitis A (identification of risk factor not required): 2-dose series HepA (Havrix 6–12 months apart or Vaqta 6–18 months apart [minimum interval: 6 months]) or 3-dose series HepA-HepB (Twinrix at 0, 1, 6 months [minimum intervals: 4 weeks between doses 1 and 2/5 months between doses 2 and 3])

# **Special situations**

- At risk for hepatitis A virus infection: 2-dose series HepA or 3-dose series HepA-HepB as above
- **Chronic liver disease** (e.g., persons with hepatitis B, hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice the upper limit of normal)
- HIV infection
- Men who have sex with men
- Injection or noninjection drug use
- Persons experiencing homelessness
- Work with hepatitis A virus in research laboratory or with nonhuman primates with hepatitis A virus infection
- Travel in countries with high or intermediate endemic hepatitis A
- Close, personal contact with international adoptee (e.g., household or regular babysitting) in first 60 days after arrival from country with high or intermediate endemic hepatitis A (administer dose 1 as soon as adoption is planned, at least 2 weeks before adoptee's arrival)

- Pregnancy if at risk for infection or severe outcome from infection during pregnancy
- **Settings for exposure, including** health care settings targeting services to injection or noninjection drug users or group homes and nonresidential day care facilities for developmentally disabled persons (individual risk factor screening not required)

# **Hepatitis B vaccination**

#### Routine vaccination

• Not at risk but want protection from hepatitis B (identification of risk factor not required): 2- or 3-dose series (2-dose series Heplisav-B at least 4 weeks apart [2-dose series HepB only applies when 2 doses of Heplisav-B are used at least 4 weeks apart] or 3-dose series Engerix-B or Recombivax HB at 0, 1, 6 months [minimum intervals: 4 weeks between doses 1 and 2/8 weeks between doses 2 and 3/16 weeks between doses 1 and 3]) or 3-dose series HepA-HepB (Twinrix at 0, 1, 6 months [minimum intervals: 4 weeks between doses 1 and 2/5 months between doses 2 and 3])

# Special situations

- At risk for hepatitis B virus infection: 2-dose (Heplisav-B) or 3-dose (Engerix-B, Recombivax HB) series or 3-dose series HepA-HepB (Twinrix) as above
- **Chronic liver disease** (e.g., persons with hepatitis *C*, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice upper limit of normal)
- HIV infection
- **Sexual exposure risk** (e.g., sex partners of hepatitis B surface antigen [HBsAg]-positive persons; sexually active persons not in mutually monogamous relationships; persons seeking evaluation or treatment for a sexually transmitted infection; men who have sex with men)
- Current or recent injection drug use
- Percutaneous or mucosal risk for exposure to blood (e.g., household contacts of HBsAg-positive persons; residents and staff of facilities for developmentally disabled persons; health care and public safety personnel with reasonably anticipated risk for

- exposure to blood or blood-contaminated body fluids; hemodialysis, peritoneal dialysis, home dialysis, and predialysis patients; persons with diabetes mellitus age younger than 60 years and, at discretion of treating clinician, those age 60 years or older)
- Incarcerated persons
- Travel in countries with high or intermediate endemic hepatitis B
- Pregnancy if at risk for infection or severe outcome from infection during pregnancy (Heplisav-B not currently recommended due to lack of safety data in pregnant women)

# **Human papillomavirus vaccination**

## **Routine vaccination**

- HPV vaccination recommended for all adults through age 26 years: 2- or 3-dose series depending on age at initial vaccination or condition:
- **Age 15 years or older at initial vaccination**: 3-dose series at 0, 1–2, 6 months (minimum intervals: 4 weeks between doses 1 and 2/12 weeks between doses 2 and 3/5 months between doses 1 and 3; repeat dose if administered too soon)
- Age 9 through 14 years at initial vaccination and received 1 dose or 2 doses less than 5 months apart: 1 dose
- Age 9 through 14 years at initial vaccination and received 2 doses at least 5 months apart: HPV vaccination complete, no additional dose needed.
- If completed valid vaccination series with any HPV vaccine, no additional doses needed

# **Shared clinical decision-making**

- Age 27 through 45 years based on shared clinical decision-making:
- 2- or 3-dose series as above

## **Special situations**

 Pregnancy through age 26 years: HPV vaccination is not recommended until after pregnancy; no intervention needed if vaccinated while pregnant; pregnancy testing not needed before vaccination



# Recommended Adult Immunization Schedule, United States, 2020

#### Influenza vaccination

#### Routine vaccination

- **Persons age 6 months or older**: 1 dose any influenza vaccine appropriate for age and health status annually
- For additional guidance, see www.cdc.gov/flu/ professionals/index.htm

# **Special situations**

- **Egg allergy, hives only**: 1 dose any influenza vaccine appropriate for age and health status annually
- Egg allergy more severe than hives (e.g., angioedema, respiratory distress): 1 dose any influenza vaccine appropriate for age and health status annually in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions
- LAIV should not be used in persons with the following conditions or situations:
- History of severe allergic reaction to any vaccine component (excluding egg) or to a previous dose of any influenza vaccine
- Immunocompromised due to any cause (including medications and HIV infection)
- Anatomic or functional asplenia
- Cochlear implant
- Cerebrospinal fluid-oropharyngeal communication
- Close contacts or caregivers of severely immunosuppressed persons who require a protected environment
- Pregnancy
- Received influenza antiviral medications within the previous 48 hours
- History of Guillain-Barré syndrome within 6 weeks of previous dose of influenza vaccine: Generally should not be vaccinated unless vaccination benefits outweigh risks for those at higher risk for severe complications from influenza

# Measles, mumps, and rubella vaccination

#### Routine vaccination

- No evidence of immunity to measles, mumps, or rubella: 1 dose
- **Evidence of immunity**: Born before 1957 (health care personnel, see below), documentation of receipt of MMR vaccine, laboratory evidence of immunity or disease (diagnosis of disease without laboratory confirmation is not evidence of immunity)

### **Special situations**

- Pregnancy with no evidence of immunity to rubella: MMR contraindicated during pregnancy; after pregnancy (before discharge from health care facility), 1 dose
- Nonpregnant women of childbearing age with no evidence of immunity to rubella: 1 dose
- HIV infection with CD4 count ≥200 cells/µL for at least 6 months and no evidence of immunity to measles, mumps, or rubella: 2-dose series at least 4 weeks apart; MMR contraindicated in HIV infection with CD4 count <200 cells/µL</li>
- Severe immunocompromising conditions: MMR contraindicated
- Students in postsecondary educational institutions, international travelers, and household or close, personal contacts of immunocompromised persons with no evidence of immunity to measles, mumps, or rubella: 2-dose series at least 4 weeks apart if previously did not receive any doses of MMR or 1 dose if previously received 1 dose MMR
- Health care personnel:
- Born in 1957 or later with no evidence of immunity to measles, mumps, or rubella: 2-dose series at least 4 weeks apart for measles or mumps or at least 1 dose for rubella
- Born before 1957 with no evidence of immunity to measles, mumps, or rubella: Consider 2-dose series at least 4 weeks apart for measles or mumps or 1 dose for rubella

# **Meningococcal vaccination**

# **Special situations for MenACWY**

- Anatomical or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use: 2-dose series MenACWY (Menactra, Menveo) at least 8 weeks apart and revaccinate every 5 years if risk remains
- Travel in countries with hyperendemic or epidemic meningococcal disease, microbiologists routinely exposed to Neisseria meningitidis: 1 dose MenACWY (Menactra, Menveo) and revaccinate every 5 years if risk remains
- First-year college students who live in residential housing (if not previously vaccinated at age 16 years or older) and military recruits: 1 dose MenACWY (Menactra, Menveo)

# **Shared clinical decision-making for MenB**

• Adolescents and young adults age 16 through 23 years (age 16 through 18 years preferred) not at increased risk for meningococcal disease: Based on shared clinical decision-making, 2-dose series MenB-4C at least 1 month apart or 2-dose series MenB-FHbp at 0, 6 months (if dose 2 was administered less than 6 months after dose 1, administer dose 3 at least 4 months after dose 2); MenB-4C and MenB-FHbp are not interchangeable (use same product for all doses in series)

# **Special situations for MenB**

- Anatomical or functional asplenia (including sickle cell disease), persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use, microbiologists routinely exposed to *Neisseria meningitidis*: 2-dose primary series MenB-4C (Bexsero) at least 1 month apart or 3-dose primary series MenB-FHbp (Trumenba) at 0, 1–2, 6 months (if dose 2 was administered at least 6 months after dose 1, dose 3 not needed); MenB-4C and MenB-FHbp are not interchangeable (use same product for all doses in series); 1 dose MenB booster 1 year after primary series and revaccinate every 2–3 years if risk remains
- Pregnancy: Delay MenB until after pregnancy unless at increased risk and vaccination benefits outweigh potential risks



# Recommended Adult Immunization Schedule, United States, 2020

#### **Pneumococcal vaccination**

#### **Routine vaccination**

- Age 65 years or older (immunocompetent–see www. cdc.gov/mmwr/volumes/68/wr/mm6846a5.htm?s\_ cid=mm6846a5\_w): 1 dose PPSV23
- If PPSV23 was administered prior to age 65 years, adminster 1 dose PPSV23 at least 5 years after previous dose

# **Shared clinical decision-making**

- Age 65 years and older (immunocompetent): 1 dose
   PCV13 based on shared clinical decision-making
- If both PCV13 and PPSV23 are to be administered, PCV13 should be administered first
- PCV13 and PPSV23 should be administered at least 1 year apart
- PCV13 and PPSV23 should not be administered during the same visit

# **Special situations**

(see www.cdc.gov/mmwr/volumes/68/wr/mm6846a5. htm?s\_cid=mm6846a5\_w)

- Age 19 through 64 years with chronic medical conditions (chronic heart [excluding hypertension], lung, or liver disease, diabetes), alcoholism, or cigarette smoking: 1 dose PPSV23
- Age 19 years or older with immunocompromising conditions (congenital or acquired immunodeficiency [including B- and T-lymphocyte deficiency, complement deficiencies, phagocytic disorders, HIV infection], chronic renal failure, nephrotic syndrome, leukemia, lymphoma, Hodgkin disease, generalized malignancy, iatrogenic immunosuppression [e.g., drug or radiation therapy], solid organ transplant, multiple myeloma) or anatomical or functional asplenia (including sickle cell disease and other hemoglobinopathies): 1 dose PCV13 followed by 1 dose PPSV23 at least 8 weeks later, then another dose PPSV23 at least 5 years after previous PPSV23; at age 65 years or older, administer 1 dose PPSV23 at least 5 years after most recent PPSV23 (note: only 1 dose PPSV23 recommended at age 65 years or older)

 Age 19 years or older with cerebrospinal fluid leak or cochlear implant: 1 dose PCV13 followed by 1 dose PPSV23 at least 8 weeks later; at age 65 years or older, administer another dose PPSV23 at least 5 years after PPSV23 (note: only 1 dose PPSV23 recommended at age 65 years or older)

# Tetanus, diphtheria, and pertussis vaccination

#### **Routine vaccination**

- Previously did not receive Tdap at or after age 11 years: 1 dose Tdap, then Td or Tdap every 10 years
   Special situations
- Previously did not receive primary vaccination series for tetanus, diphtheria, or pertussis: At least 1 dose Tdap followed by 1 dose Td or Tdap at least 4 weeks after Tdap and another dose Td or Tdap 6–12 months after last Td or Tdap (Tdap can be substituted for any Td dose, but preferred as first dose); Td or Tdap every 10 years thereafter
- **Pregnancy**: 1 dose Tdap during each pregnancy, preferably in early part of gestational weeks 27–36
- For information on use of Td or Tdap as tetanus prophylaxis in wound management, see www.cdc.gov/ mmwr/volumes/67/rr/rr6702a1.htm

#### Varicella vaccination

### **Routine vaccination**

- No evidence of immunity to varicella: 2-dose series 4–8 weeks apart if previously did not receive varicella-containing vaccine (VAR or MMRV [measles-mumps-rubella-varicella vaccine] for children); if previously received 1 dose varicella-containing vaccine, 1 dose at least 4 weeks after first dose
- Evidence of immunity: U.S.-born before 1980 (except for pregnant women and health care personnel [see below]), documentation of 2 doses varicella-containing vaccine at least 4 weeks apart, diagnosis or verification of history of varicella or herpes zoster by a health care provider, laboratory evidence of immunity or disease

#### **Special situations**

- Pregnancy with no evidence of immunity to varicella: VAR contraindicated during pregnancy; after pregnancy (before discharge from health care facility) 1 dose if previously received 1 dose varicella-containing vaccine or dose 1 of 2-dose series (dose 2: 4–8 weeks later) if previously did not receive any varicella-containing vaccine, regardless of whether U.S.-born before 1980
- Health care personnel with no evidence of immunity to varicella: 1 dose if previously received 1 dose varicella-containing vaccine; 2-dose series 4–8 weeks apart if previously did not receive any varicellacontaining vaccine, regardless of whether U.S.-born before 1980
- HIV infection with CD4 count ≥200 cells/µL with no evidence of immunity: Vaccination may be considered (2 doses, administered 3 months apart); VAR contraindicated in HIV infection with CD4 count <200 cells/µL
- Severe immunocompromising conditions: VAR contraindicated

### **Zoster vaccination**

#### **Routine vaccination**

- **Age 50 years or older**: 2-dose series RZV (Shingrix) 2–6 months apart (minimum interval: 4 weeks; repeat dose if administered too soon), regardless of previous herpes zoster or history of ZVL (Zostavax) vaccination (administer RZV at least 2 months after ZVL)
- Age 60 years or older: 2-dose series RZV 2-6 months apart (minimum interval: 4 weeks; repeat if administered too soon) or 1 dose ZVL if not previously vaccinated.
   RZV preferred over ZVL (if previously received ZVL, administer RZV at least 2 months after ZVL)

# **Special situations**

- **Pregnancy**: ZVL contraindicated; consider delaying RZV until after pregnancy if RZV is otherwise indicated
- Severe immunocompromising conditions (including HIV infection with CD4 count <200 cells/μL): ZVL contraindicated; recommended use of RZV under review

# **Attachment 5**

### CALIFORNIA STATE BOARD OF PHARMACY QUARTERLY LICENSING STATISTICS FISCAL YEAR 2020/2021

### APPLICATIONS RECEIVED

Individual Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Designated Representatives (EXC)	92	90	0	0	182
Designated Representatives Vet (EXV)	0	1	0	0	1
Designated Representatives-3PL (DRL)	27	29	0	0	56
Designated Representatives-Reverse Distributor (DRR)	1	1	0	0	2
Designated Paramedic (DPM)	0	0	0	0	0
Intern Pharmacist (INT)	1,237	111	0	0	1,348
Pharmacist Exam Applications	299	152	0	0	451
Pharmacist Retake Exam Applications	585	489	0	0	1,074
Pharmacist Initial License Application (RPH)	935	555	0	0	1,490
Advanced Practice Pharmacist (APH)	60	44	0	0	104
Pharmacy Technician (TCH)	1,182	1,036	0	0	2,218
Total	4,418	2,508	0	0	6,926

Site Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Automated Drug Delivery System (ADD)	50	60	0	0	110
Automated Drug Delivery System EMS (ADE)	0	0	0	0	0
Automated Patient Dispensing System 340B Clinic (ADC)	0	0	0	0	0
Centralized Hospital Packaging Government Owned (CHE)	0	0	0	0	0
Centralized Hospital Packaging (CHP)	1	0	0	0	1
Clinics (CLN)	26	40	0	0	66
Clinics Government Owned (CLE)	19	13	0	0	32
Drug Room (DRM)	0	0	0	0	0
Drug Room Government Owned (DRE)	0	0	0	0	0
Hospitals (HSP)	6	9	0	0	15
Hospitals Government Owned (HPE)	1	0	0	0	1
Hospital Satellite Sterile Compounding (SCP)	0	0	0	0	0
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	0	0	0	0
Hypodermic Needle and Syringes (HYP)	4	5	0	0	9
Correctional Pharmacy (LCF)	0	0	0	0	0
Outsourcing Facility (OSF)	0	0	0	0	0
Outsourcing Facility Nonresident (NSF)	1	4	0	0	5
Pharmacy (PHY)	84	108	0	0	192
Pharmacy (PHY) Chain	5	8	0	0	13
Pharmacy Government Owned (PHE)	4	2	0	0	6
Remote Dispensing Pharmacy (PHR)	2	0	0	0	2
Pharmacy Nonresident (NRP)	30	33	0	0	63
Sterile Compounding (LSC)	23	37	0	0	60
Sterile Compounding Government Owned (LSE)	1	1	0	0	2
Sterile Compounding Nonresident (NSC)	5	2	0	0	7
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0
Third-Party Logistics Providers (TPL)	4	2	0	0	6
Third-Party Logistics Providers Nonresident (NPL)	8	8	0	0	16
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0
Wholesalers (WLS)	20	9	0	0	29
Wholesalers Government Owned (WLE)	0	6	0	0	6
Wholesalers Nonresident (OSD)	30	26	0	0	56
Total	324	373	0	0	697

Applications Received with Temporary License Requests	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Drug Room -Temp (DRM)	0	2	0	0	2
Hospitals - Temp (HSP)	6	10	0	0	16
Hospital Satellite Sterile Compounding - Temp (SCP)	0	0	0	0	0
Outsourcing Facility - Temp (OSF)	0	0	0	0	0
Outsourcing Facility Nonresident - Temp (NSF)	0	0	0	0	0
Pharmacy - Temp (PHY)	58	77	0	0	135
Remote Dispensing Pharmacy - Temp (PHR)	1	0	0	0	1
Pharmacy Nonresident - Temp (NRP)	18	21	0	0	39
Sterile Compounding - Temp (LSC)	17	21	0	0	38
Sterile Compounding Nonresident - Temp (NSC)	1	1	0	0	2
Third-Party Logistics Providers - Temp (TPL)	3	0	0	0	3
Third-Party Logistics Providers Nonresident - Temp (NPL)	7	6	0	0	13
Veterinary Food-Animal Drug Retailer - Temp (VET)	0	0	0	0	0
Wholesalers - Temp (WLS)	6	6	0	0	12
Wholesalers Nonresident - Temp (OSD)	13	1	0	0	14
Total	130	145	0	0	275

# LICENSES ISSUED

Individual Licenses	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Designated Representatives (EXC)	57	63	0	0	120
Designated Representatives Vet (EXV)	2	0	0	0	2
Designated Representatives-3PL (DRL)	18	19	0	0	37
Designated Representatives-Reverse Distributor (DRR)	0	1	0	0	1
Designated Paramedic (DPM)	0	0	0	0	0
Intern Pharmacist (INT)	935	389	0	0	1,324
Pharmacist (RPH)	936	557	0	0	1,493
Advanced Practice Pharmacist (APH)	34	41	0	0	75
Pharmacy Technician (TCH)	711	762	0	0	1,473
Total	2,693	1,832	0	0	4,525

Site Licenses	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Automated Drug Delivery System (ADD)	28	54	0	0	82
Automated Drug Delivery System EMS (ADE)	0	0	0	0	0
Automated Patient Dispensing System 340B Clinic (ADC)	0	0	0	0	0
Centralized Hospital Packaging Government Owned (CHE)	0	0	0	0	0
Centralized Hospital Packaging (CHP)	0	0	0	0	0
Clinics (CLN)	18	7	0	0	25
Clinics Government Owned (CLE)	18	13	0	0	31
Drug Room (DRM)	0	0	0	0	0
Drug Room Government Owned (DRE)	0	0	0	0	0
Hospitals (HSP)	0	0	0	0	0
Hospitals Government Owned (HPE)	0	0	0	0	0
Hospital Satellite Sterile Compounding (SCP)	0	0	0	0	0
Hospital Satellite Sterile Compounding Government Owned (SCE)	1	0	0	0	1
Hypodermic Needle and Syringes (HYP)	1	0	0	0	1
Correctional Pharmacy (LCF)	0	0	0	0	0
Outsourcing Facility (OSF)	0	0	0	0	0
Outsourcing Facility Nonresident (NSF)	1	0	0	0	1
Pharmacy (PHY)	27	15	0	0	42
Pharmacy Government Owned (PHE)	1	1	0	0	2
Remote Dispensing Pharmacy (PHR)	2	0	0	0	1
Pharmacy Nonresident (NRP)	4	0	0	0	4
Sterile Compounding (LSC)	10	7	0	0	17
Sterile Compounding Government Owned (LSE)	1	0	0	0	1
Sterile Compounding Nonresident (NSC)	0	0	0	0	0
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0
Third-Party Logistics Providers (TPL)	0	1	0	0	1
Third-Party Logistics Providers Nonresident (NPL)	1	2	0	0	3
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0
Wholesalers (WLS)	5	5	0	0	10
Wholesalers Government Owned (WLE)	0	0	0	0	0
Wholesalers Nonresident (OSD)	15	4	0	0	19
Total	133	109	0	0	241

Site Temporary Licenses	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Drug Room -Temp (DRM)	0	1	0	0	1
Hospitals - Temp (HSP)	4	6	0	0	10
Hospital Satellite Sterile Compounding - Temp (SCP)	0	0	0	0	0
Outsourcing Facility - Temp (OSF)	1	0	0	0	1
Outsourcing Facility Nonresident - Temp (NSF)	1	0	0	0	1
Pharmacy - Temp (PHY)	49	49	0	0	98
Remote Dispensing Pharmacy - Temp (PHR)	2	0	0	0	2
Pharmacy Nonresident - Temp (NRP)	17	9	0	0	26
Sterile Compounding - Temp (LSC)	11	5	0	0	16
Sterile Compounding Nonresident - Temp (NSC)	1	0	0	0	1
Third-Party Logistics Providers - Temp (TPL)	0	2	0	0	2
Third-Party Logistics Providers Nonresident - Temp (NPL)	1	7	0	0	8
Veterinary Food-Animal Drug Retailer - Temp (VET)	0	0	0	0	0
Wholesalers - Temp (WLS)	4	8	0	0	12
Wholesalers Nonresident - Temp (OSD)	11	4	0	0	15
Total	102	91	0	0	193

# PENDING APPLICATIONS (Data reflects number of pending applications at the end of the quarter)

Individual Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun
Designated Representatives (EXC)	178	206		
Designated Representatives Vet (EXV)	2	3		
Designated Representatives-3PL (DRL)	42	54		
Designated Representatives-Reverse Distributor (DRR)	2	2		
Designated Paramedic (DPM)	0	0		
Intern Pharmacist (INT)	410	125		
Pharmacist (exam not eligible)	1,343	1,351		
Pharmacist (exam eligible)	1,456	941		
Advanced Practice Pharmacist (APH)	85	85		
Pharmacy Technician (TCH)	1,499	1,472		
Total	5,017	4,239	0	0

Site Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun
Automated Drug Delivery System (ADD)	163	179		-
Automated Drug Delivery System EMS (ADE)	0	0		
Automated Patient Dispensing System 340B Clinic (ADC)	0	0		
Centralized Hospital Packaging Government Owned (CHE)	1	1		
Centralized Hospital Packaging (CHP)	5	5		
Clinics (CLN)	95	116		
Clinics Government Owned (CLE)	29	29		
Drug Room (DRM)	1	1		
Drug Room Government Owned (DRE)	0	0		
Hospitals (HSP)	19	16		
Hospitals Government Owned (HPE)	3	2		
Hospital Satellite Sterile Compounding (SCP)	2	2		
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	0		
Hypodermic Needle and Syringes (HYP)	5	10		
Correctional Pharmacy (LCF)	0	0		
Outsourcing Facility (OSF)	0	0		
Outsourcing Facility Nonresident (NSF)	5	9		
Pharmacy (PHY)	150	190		
Pharmacy Government Owned (PHE)	4	5		
Remote Dispensing Pharmacy (PHR)	3	3		
Pharmacy Nonresident (NRP)	132	155		
Sterile Compounding (LSC)	84	106		
Sterile Compounding - Government Owned (LSE)	10	11		
Sterile Compounding Nonresident (NSC)	11	12		
Surplus Medication Collection Distribution Intermediary (SME)	0	0		
Third-Party Logistics Providers (TPL)	4	3		
Third-Party Logistics Providers Nonresident (NPL)	46	46		
Veterinary Food-Animal Drug Retailer (VET)	1	1		
Wholesalers (WLS)	46	50		
Wholesalers Government Owned (WLE)	1	1		
Wholesalers Nonresident (OSD)	91	109		
Total	911	1,062	0	0

Applications Pending with Temporary Licenses Issued - Pending Full License	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun
Drug Room -Temp (DRM)	0	1		
Hospitals - Temp (HSP)	4	15		
Hospital Satellite Sterile Compounding - Temp (SCP)	0	0		
Outsourcing Facility - Temp (OSF)	1	0		
Outsourcing Facility Nonresident - Temp (NSF)	3	3		
Pharmacy - Temp (PHY)	99	91		
Remote Dispensing Pharmacy - Temp (PHR)	2	2		
Pharmacy Nonresident - Temp (NRP)	36	25		
Sterile Compounding - Temp (LSC)	11	13		
Sterile Compounding Nonresident - Temp (NSC)	2	1		
Third-Party Logistics Providers - Temp (TPL)	1	0		
Third-Party Logistics Providers Nonresident - Temp (NPL)	0	1		
Veterinary Food-Animal Drug Retailer - Temp (VET)	0	0		
Wholesalers - Temp (WLS)	4	9		
Wholesalers Nonresident - Temp (OSD)	9	9		
Total	172	170	0	0

# APPLICATIONS WITHDRAWN

Individual Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Designated Representatives (EXC)	233	4	0	0	237
Designated Representatives Vet (EXV)	1	0	0	0	1
Designated Representatives-3PL (DRL)	70	0	0	0	70
Designated Representatives-Reverse Distributor (DRR)	1	0	0	0	1
Designated Paramedic (DPM)	0	0	0	0	0
Intern Pharmacist (INT)	3	5	0	0	8
Pharmacist (exam applications)	239	430	0	0	669
Advanced Practice Pharmacist (APH)	9	4	0	0	13
Pharmacy Technician (TCH)	7	5	0	0	12
Total	563	448	0	0	1,011

Site Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Automated Drug Delivery System (ADD)	3	2	0	0	5
Automated Drug Delivery System EMS (ADE)	0	0	0	0	0
Automated Patient Dispensing System 340B Clinic (ADC)	0	0	0	0	0
Centralized Hospital Packaging Government Owned (CHE)	0	0	0	0	0
Centralized Hospital Packaging (CHP)	0	0	0	0	0
Clinics (CLN)	1	8	0	0	9
Clinics Government Owned (CLE)	0	0	0	0	0
Drug Room (DRM)	0	0	0	0	0
Drug Room Government Owned (DRE)	0	0	0	0	0
Hospitals (HSP)	0	0	0	0	0
Hospitals Government Ownerd (HPE)	0	0	0	0	0
Hospital Satellite Sterile Compounding (SCP)	0	0	0	0	0
Hospital Satellite Sterile Compounding Government Owned (SCE)	1	0	0	0	1
Hypodermic Needle and Syringes (HYP)	0	0	0	0	0
Correctional Pharmacy (LCF)	0	0	0	0	0
Outsourcing Facility (OSF)	0	0	0	0	0
Outsourcing Facility Nonresident (NSF)	0	0	0	0	0
Pharmacy (PHY)	9	7	0	0	16
Pharmacy Government Owned (PHE)	2	0	0	0	2
Remote Dispensing Pharmacy (PHR)	0	0	0	0	0
Pharmacy Nonresident (NRP)	0	1	0	0	1
Sterile Compounding (LSC)	1	1	0	0	2
Sterile Compounding - Government Owned (LSE)	0	0	0	0	0
Sterile Compounding Nonresident (NSC)	0	0	0	0	0
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0
Third-Party Logistics Providers (TPL)	0	0	0	0	0
Third-Party Logistics Providers Nonresident (NPL)	3	0	0	0	3
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0
Wholesalers (WLS)	1	0	0	0	1
Wholesalers Government Owned (WLE)	0	0	0	0	0
Wholesalers Nonresident (OSD)	1	1	0	0	2
Total	22	20	0	0	42

### APPLICATIONS DENIED

Individual Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Designated Representatives (EXC)	0	0	0	0	0
Designated Representatives Vet (EXV)	0	0	0	0	0
Designated Representatives-3PL (DRL)	0	0	0	0	0
Designated Representatives-Reverse Distributor (DRR)	0	0	0	0	0
Designated Paramedic (DPM)	0	0	0	0	0
Intern Pharmacist (INT)	0	0	0	0	0
Pharmacist (exam application)	1	1	0	0	2
Pharmacist (exam eligible)	0	0	0	0	0
Advanced Practice Pharmacist (APH)	0	0	0	0	0
Pharmacy Technician (TCH)	1	2	0	0	3
Total	2	3	0	0	5

Site Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Centralized Hospital Packaging Government Owned (CHE)	0	0	0	0	0
Centralized Hospital Packaging (CHP)	0	0	0	0	0
Clinics (CLN)	0	0	0	0	0
Clinics Government Owned (CLE)	0	0	0	0	0
Drug Room (DRM)	0	0	0	0	0
Drug Room Government Owned (DRE)	0	0	0	0	0
Hospitals (HSP)	0	0	0	0	0
Hospitals Government Owned (HPE)	0	0	0	0	0
Hospital Satellite Sterile Compounding (SCP)	0	0	0	0	0
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	0	0	0	0
Hypodermic Needle and Syringes (HYP)	0	0	0	0	0
Correctional Pharmacy (LCF)	0	0	0	0	0
Outsourcing Facility (OSF)	0	0	0	0	0
Outsourcing Facility Nonresident (NSF)	0	0	0	0	0
Pharmacy (PHY)	2	4	0	0	6
Pharmacy Government Owned (PHE)	0	0	0	0	0
Remote Dispensing Pharmacy (PHR)	0	0	0	0	0
Pharmacy Nonresident (NRP)	3	1	0	0	4
Sterile Compounding (LSC)	0	0	0	0	0
Sterile Compounding Government Owned (LSE)	0	0	0	0	0
Sterile Compounding Nonresident (NSC)	1	1	0	0	2
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0
Third-Party Logistics Providers (TPL)	0	0	0	0	0
Third-Party Logistics Providers Nonresident (NPL)	0	0	0	0	0
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0
Wholesalers (WLS)	0	0	0	0	0
Wholesalers Government Owned (WLE)	0	0	0	0	0
Wholesalers Nonresident (OSD)	0	0	0	0	0
Total	6	6	0	0	12

# RESPOND TO STATUS INQUIRIES

Email Inquiries	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Designated Representative Received	1,123	364	0	0	1,487
Designated Representative Responded	1,018	165	0	0	1,183
Advanced Practice Pharmacist Received	110	203	0	0	313
Advanced Practice Pharmacist Responded	110	217	0	0	327
Pharmacist/Intern Received	2,473	1,876	0	0	4,349
Pharmacist/Intern Responded	1,796	1,773	0	0	3,569
Pharmacy Technician Received	1,215	2,058	0	0	3,273
Pharmacy Technician Responded	1,193	1,325	0	0	2,518
Pharmacy Received	2,013	1,272	0	0	3,285
Pharmacy Responded	1,799	1,561	0	0	3,360
Sterile Compounding/Outsourcing Received	1,196	1,276	0	0	2,472
Sterile Compounding/Outsourcing Responded	630	846	0	0	1,476
Wholesale/Clinic/Hypodermic/3PL Received	1,014	757	0	0	1,771
Wholesale/Clinic/Hypodermic/3PL Responded	803	563	0	0	1,366
Automated Drug Delivery Systems Received	180	252	0	0	432
Automated Drug Delivery Systems Responded	112	197	0	0	309
Pharmacist-in-Charge Received	686	679	0	0	1,365
Pharmacist-in-Charge Responded	542	413	0	0	955
Change of Permit Received	1,285	1,090	0	0	2,375
Change of Permit Responded	891	746	0	0	1,637
Renewals Received	1,986	2,135	0	0	4,121
Renewals Responded	1,727	1,869	0	0	3,596

Telephone Calls Received	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Designated Representative	62	12	0	0	74
Advanced Practice Pharmacist	16	9	0	0	25
Pharmacist/Intern	991	980	0	0	1,971
Pharmacy	480	477	0	0	957
Sterile Compounding/Outsourcing	121	77	0	0	198
Wholesale/Clinic/Hypodermic/3PL	232	166	0	0	398
Automated Drug Delivery Systems	40	103	0	0	143
Pharmacist-in-Charge	117	60	0	0	177
Change of Permit	118	107	0	0	225
Renewals	853	985	0	0	1,838
Reception	17,184	17,940	0	0	35,124

# UPDATE LICENSING RECORDS

Change of Pharmacist-in-Charge	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Received	441	546	0	0	987
Processed	469	489	0	0	958
Approved	457	471	0	0	928
Pending (Data reflects number of pending at the end of the quarter.)	175	250			n/a
Change of Designated Representative-in-Charge	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Received	28	38	0	0	66
Processed	24	31	0	0	55
Approved	23	24	0	0	47
Pending (Data reflects number of pending at the end of the quarter.)	175	67			n/a
Change of Responsible Manager	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Received	6	2	0	0	8
Processed	5	2	0	0	7
Approved	5	2	0	0	7
Pending (Data reflects number of pending at the end of the quarter.)	2	2			n/a
Change of Professional Director	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Received	24	27	0	0	51
Processed	31	19	0	0	50
Approved	17	12	0	0	29
Pending (Data reflects number of pending at the end of the quarter.)	47	61			n/a
Change of Permits	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Received	238	267	0	0	505
Processed	268	332	0	0	600
Approved	178	475	0	0	653
Pending (Data reflects number of pending at the end of the quarter.)	1,799	1,611			n/a
Clinic Co-Location	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Received	0	0	0	0	0
Processed	0	0	0	0	0
Approved	0	0	0	0	0
Pending (Data reflects number of pending at the end of the quarter.)	0	0			n/a
Discontinuance of Business	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Received	92	101	0	0	193
Processed	92	59	0	0	151
Approved	79	38	0	0	117
Pending (Data reflects number of pending at the end of the quarter.)	237	294			n/a
Intern Pharmacist Extensions	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Received	31	37	0	0	68
Processed	25	33	0	0	58
Completed	13	27	0	0	40
Pending (Data reflects number of pending at the end of the quarter.)	28	40			n/a
Requests Approved	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Address/Name Changes	3,351	3,009	0	0	6,360
Off-site Storage	94	14	0	0	108
Transfer of Intern Hours	5	10	0	0	15
License Verification	514	453	0	0	967

# DISCONTINUED OF BUSINESS

discontinued by date of closure

Site Licenses	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Automated Drug Delivery System (ADD)	12	31	0	0	43
Automated Drug Delivery System EMS (ADE)	0	0	0	0	0
Automated Patient Dispensing System 340B Clinic (ADC)	0	1	0	0	1
Centralized Hospital Packaging Government Owned (CHE)	0	0	0	0	0
Centralized Hospital Packaging (CHP)	0	0	0	0	0
Clinics (CLN)	2	3	0	0	5
Clinics Government Owned (CLE)	1	2	0	0	3
Drug Room (DRM)	0	1	0	0	1
Drug Room Government Owned (DRE)	0	0	0	0	0
Hospitals (HSP)	2	1	0	0	3
Hospitals Government Owned (HPE)	1	1	0	0	2
Hospital Satellite Sterile Compounding (SCP)	0	0	0	0	0
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	0	0	0	0
Hypodermic Needle and Syringes (HYP)	2	0	0	0	2
Correctional Pharmacy (LCF)	0	0	0	0	0
Outsourcing Facility (OSF)	0	0	0	0	0
Outsourcing Facility Nonresident (NSF)	0	0	0	0	0
Pharmacy (PHY)	20	30	0	0	50
Pharmacy (PHY) Chain	10	7	0	0	17
Pharmacy Government Owned (PHE)	0	0	0	0	0
Remote Dispensing Pharmacy (PHR)	0	1	0	0	1
Pharmacy Nonresident (NRP)	4	4	0	0	8
Sterile Compounding (LSC)	4	10	0	0	14
Sterile Compounding Government Owned (LSE)	1	0	0	0	1
Sterile Compounding Nonresident (NSC)	0	3	0	0	3
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0
Third-Party Logistics Providers (TPL)	0	2	0	0	2
Third-Party Logistics Providers Nonresident (NPL)	2	0	0	0	2
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0
Wholesalers (WLS)	3	3	0	0	6
Wholesalers Government Owned (WLE)	0	0	0	0	0
Wholesalers Nonresident (OSD)	4	5	0	0	9
Total	68	105	0	0	173

# LICENSES RENEWED

Individual Licenses Renewed	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Designated Representatives (EXC)	495	632	0	0	1,127
Designated Representatives Vet (EXV)	12	7	0	0	19
Designated Representatives-3PL (DRL)	82	62	0	0	144
Designated Representatives-Reverse Distributor (DRR)	0	0	0	0	0
Designated Paramedic (DPM)	0	0	0	0	0
Pharmacist (RPH)	4,846	5,254	0	0	10,100
Advanced Practice Pharmacist (APH)	99	112	0	0	211
Pharmacy Technician (TCH)	6,975	7,640	0	0	14,615
Total	12,509	13,707	0	0	26,216

Site Licenses Renewed	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Automated Drug Delivery System (ADD)	21	645	0	0	666
Automated Drug Delivery System EMS (ADE)	0	0	0	0	0
Automated Patient Dispensing System 340B Clinic (ADC)	0	0	0	0	0
Centralized Hospital Packaging Government Owned (CHE)	2	0	0	0	2
Centralized Hospital Packaging (CHP)	3	1	0	0	4
Clinics (CLN)	400	231	0	0	631
Clinics Government Owned (CLE)	116	800	0	0	916
Drug Room (DRM)	3	4	0	0	7
Drug Room Government Owned (DRE)	5	5	0	0	10
Hospitals (HSP)	53	142	0	0	195
Hospitals Government Owned (HPE)	44	11	0	0	55
Hospital Satellite Sterile Compounding (SCP)	2	1	0	0	3
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	0	0	0	0
Hypodermic Needle and Syringes (HYP)	59	52	0	0	111
Correctional Pharmacy (LCF)	2	57	0	0	59
Outsourcing Facility (OSF)	1	2	0	0	3
Outsourcing Facility Nonresident (NSF)	2	6	0	0	8
Pharmacy (PHY)	1,027	1,994	0	0	3,021
Pharmacy Government Owned (PHE)	59	50	0	0	109
Remote Dispensing Pharmacy (PHR)	1	0	0	0	1
Pharmacy Nonresident (NRP)	69	164	0	0	233
Sterile Compounding (LSC)	139	244	0	0	383
Sterile Compounding Government Owned (LSE)	69	5	0	0	74
Sterile Compounding Nonresident (NSC)	10	18	0	0	28
Surplus Medication Collection Distribution Intermediary (SME)	1	0	0	0	1
Third-Party Logistics Providers (TPL)	4	5	0	0	9
Third-Party Logistics Providers Nonresident (NPL)	20	24	0	0	44
Veterinary Food-Animal Drug Retailer (VET)	3	5	0	0	8
Wholesalers (WLS)	123	100	0	0	223
Wholesalers Government Owned (WLE)	5	5	0	0	10
Wholesalers Nonresident (OSD)	174	173	0	0	347
Total	2,417	4,744	0	0	7,161

CURRENT LICENSES - Data reflects number of licenses at the end of the quarter.

Individual Licenses	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun
Designated Representatives (EXC)	2,849	2,826		
Designated Representatives Vet (EXV)	67	60		
Designated Representatives-3PL (DRL)	351	358		
Designated Representatives-Reverse Distributor (DRR)	4	5		
Designated Paramedic (DPM)	3	3		
Intern Pharmacist (INT)	7,039	6,492		
Pharmacist (RPH)	48,587	48,788		
Advanced Practice Pharmacist (APH)	851	896		
Pharmacy Technician (TCH)	68,637	68,350		
Total	128,388	127,778	0	0

Site Licenses	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun
Automated Drug Delivery System (ADD)	930	942		
Automated Drug Delivery System EMS (ADE)	1	1		
Automated Patient Dispensing System 340B Clinic (ADC)	1	0		
Centralized Hospital Packaging Government Owned (CHE)	2	2		
Centralized Hospital Packaging (CHP)	8	8		
Clinics (CLN)	1,311	1,317		
Clinics Government Owned (CLE)	898	907		
Drug Room (DRM)	22	22		
Drug Room Government Owned (DRE)	10	10		
Hospitals (HSP)	392	401		
Hospitals Government Owned (HPE)	79	79		
Hospital Satellite Sterile Compounding (SCP)	4	4		
Hospital Satellite Sterile Compounding Government Owned (SCE)	2	2		
Hypodermic Needle and Syringes (HYP)	300	300		
Correctional Pharmacy (LCF)	61	61		
Outsourcing Facility (OSF)	4	4		
Outsourcing Facility Nonresident (NSF)	25	25		
Pharmacy (PHY)	6,378	6,387		
Pharmacy Government Owned (PHE)	136	136		
Remote Dispensing Pharmacy (PHR)	3	2		
Pharmacy Nonresident (NRP)	589	583		
Sterile Compounding (LSC)	744	742		
Sterile Compounding Government Owned (LSE)	112	112		
Sterile Compounding Nonresident (NSC)	68	66		
Surplus Medication Collection Distribution Intermediary (SME)	1	1		
Third-Party Logistics Providers (TPL)	32	33		
Third-Party Logistics Providers Nonresident (NPL)	84	92		
Veterinary Food-Animal Drug Retailer (VET)	20	20		
Wholesalers (WLS)	530	530		
Wholesalers Government Owned (WLE)	14	14		
Wholesalers Nonresident (OSD)	807	809		
Total	13,568	13,612	0	0
Total Population of Licenses	141,956	141,390	0	0