
POLICY AND PROCEDURES

Office of Communications**FDA Pharmacy Student Experiential Program**

Table of Contents

PURPOSE.....	1
BACKGROUND	1
POLICY	2
RESPONSIBILITIES	3
PROCEDURES.....	4
REFERENCES.....	7
DEFINITIONS	8
EFFECTIVE DATE.....	8
CHANGE CONTROL TABLE.....	8
ATTACHMENT 1: Commitment to Protect Confidential and Privileged Information	9

PURPOSE

This Manual of Policies and Procedures (MAPP) describes the policies and procedures established in the Center for Drug Evaluation and Research (CDER) for receiving and processing applications, and the selection, placement, and onboarding of pharmacy students for advanced pharmacy practice experiences (APPEs) with the U.S. Food and Drug Administration (FDA) Pharmacy Student Experiential Program (hereafter referred to as “PSEP”).

BACKGROUND

- PSEP offers unpaid training opportunities to eligible pharmacy students (individuals enrolled in the study of pharmacy at a school, university, or other accredited educational institution). This experience is part of the pharmacy students’ academic curriculum to develop their professional skills. PSEP provides an opportunity to learn about the FDA’s multidisciplinary processes for addressing public health issues involving drugs, biologics, and medical devices.
- The Accreditation Council for Pharmacy Education sets the national standards for schools of pharmacy in the United States (U.S.), including the key elements for an

APPE curriculum appropriately designed to prepare practice-ready graduates.

- PSEP responds to external and internal inquiries at Pharmacy.Student@fda.hhs.gov.

POLICY

- Students must be U.S. citizens.
- Pharmacy students are considered employees of the Federal Government for the purposes of the benefits provided by U.S.C. 8101 for work-related injuries or diseases. In case of injury sustained by a pharmacy student while in the performance of duty, the procedures applicable to federal government employees should be followed.
- Like Federal employees, pharmacy students are covered by the tort claims provisions of Title 28, U.S. Code.
- Students do not need a Maryland state pharmacy intern license for FDA APPEs.
- Pharmacy students will not receive Federal appointments. Their service is not reported to the Central Personnel Data File (CPDF). The Office of Talent Solutions (OTS) cannot use an Official Personnel Folder for documenting pharmacy student service.
- Pharmacy students may be provided protective clothing and equipment under 5 U.S.C. 7903, to prevent work-related injuries.
- FDA does not provide assistance with housing or a stipend to students.
- Pharmacy students will receive emergency outpatient treatment for injuries sustained while performing assigned PSEP duties. Pharmacy students may also be provided temporary care and treatment in Agency facilities under the same circumstances and to the same extent such care and treatment are available to paid employees as covered by 213-1 Student Educational Employment Program and Student Volunteer Employment Program Handbook.
- Pharmacy students may be subject to the investigative requirements of Executive Order 13467 – Reforming Processes Related to Suitability for Government Employment, Fitness for Contractor Employees, and Eligibility for Access to Classified National Security Information.
- PSEP will not accept applications after the closing date of the annual application period, as announced on FDA's website.
- An APPE may be terminated by a student, Experiential Coordinator, preceptor, or PSEP at any time.
- Pharmacy students must be with FDA 31 calendar days or longer to be eligible for security processing and Personal Identity Verification (PIV) badge issuance.

RESPONSIBILITIES

The PSEP Lead:

- Prepares and promotes an annual application period for pharmacy students and Experiential Coordinators.
- Prepares an internal selection process, maintains documents necessary for preceptors, and provides forms and other resources helpful to preceptors through a SharePoint site.

The preceptor:

- Selects student(s) from eligible applicants.
- Offers APPEs in any of the following formats: on-site, hybrid, or remote.
- Provides learning objectives to the student.
- Is responsible for teaching, guiding, and supervising a pharmacy student during an APPE.
- Secures and provides all necessary equipment needed for the APPE.
- Works with the Administrative Officer/Management Officer (AO/MO) to initiate and ensure all forms, trainings, and tasks required for the APPE such as access to FDA facilities are complete and approved prior to the start date.
- Ensures the pharmacy student adheres to all policies and procedures regarding the use of FDA equipment and access to FDA facilities.
- Serves as the point of contact for the pharmacy school for pre-requisites and affiliation agreements. Preceptors individually affiliate with a pharmacy school with the knowledge of their supervisor. By selecting a pharmacy student for an APPE, preceptors are agreeing to meet any pre-requisites and requirements set forth by the student's pharmacy school prior to precepting the student.
- Designs APPEs to meet the objectives of FDA, the school, and the pharmacy student.
- Agrees not to bring pharmacy students on-site to FDA facilities as a visitor for extended periods of time (i.e., beyond the purposes of an appointment, meeting, or lecture).
- Agrees not to invite pharmacy students to internal FDA meetings intended only for FDA employees.
- Ensures the presence of a pharmacy student is known to others in meetings.
- Ensures PSEP students are not exposed to confidential or privileged information in a manner that presents unnecessary risk.

- Ensures PSEP students consult with the preceptor before accepting any internal FDA meeting invitations.
- Ensures PSEP students consult with their preceptor prior to requesting meetings with other FDA employees.
- Ensures PSEP students understand and sign the *Commitment to Protect Confidential and Privileged Information* (Attachment 1) at the start of the APPE.
- Notifies PSEP if they are no longer able to fulfill an APPE commitment.
- Notifies PSEP of any requests by a pharmacy student or Experiential Coordinator to terminate an APPE.
- Retains records, including copies of completed forms, in an Electronic Record Keeping System (ERKS).
- Agrees to never accept honoraria or compensation.

The Administrative Officer or Management Officer (AO/MO):

- Provides information from FDA security, information technology, and other parties involved in the onboarding and departure of pharmacy students for APPES.
- Communicates deadlines and timelines to preceptors.
- Initiates and manages all network, access, security, equipment, and facility related requests.

PROCEDURES**1. Application and Selection Process:**

- A. PSEP communicates eligibility requirements and other considerations to Experiential Coordinators.
- B. During the annual selection period, preceptors review applications and select pharmacy students. Preceptors inform PSEP of their interest in selecting a pharmacy student and directly contact the pharmacy student and their Experiential Coordinator to offer an APPE. Preceptors communicate directly with pharmacy students and their Experiential Coordinator to confirm a decision to accept an APPE. Students must send requests for absences to their preceptors as soon as they are aware of potential absences.
- C. Preceptors notify PSEP of accepted and declined APPES. Once preceptors confirm an APPE with a pharmacy student and their Experiential Coordinator and share that confirmation with PSEP, pharmacy students are considered placed.

- D. PSEP sends an automated acceptance email to the pharmacy student and Experiential Coordinator within two weeks of selection. PSEP notifies Experiential Coordinators the names of pharmacy students who applied but were not placed after the annual selection period closes. Preceptors will ask pharmacy students to share as early as possible any information that may impact the APPE. (Issues may include ethical conflicts of interest, or issues that may interfere with attendance, such as conferences, ongoing projects, or medical appointments.)
- E. The acceptance email confirms, at a minimum, the APPE format (on-site, hybrid, or remote) and dates. Pharmacy students and their Experiential Coordinator are asked to confirm the information by signing and returning the *FDA Pharmacy Student Experiential Program Student Volunteer Service Agreement*.

Upon receipt of the signed *FDA Pharmacy Student Experiential Program Student Volunteer Service Agreement* from the pharmacy student or their Experiential Coordinator, the form is sent to the Authorizing Official, which is the Operating Division (OPDIV) Director, or designee, for signature. The completed form is then sent to the AO/MO, who submits it to the Student Volunteer Service Program (SVSP). The completed request should be submitted through the Administrative Operations Information System (AOIS) for review, or in accordance with the process of their respective Center.

1. Onboarding process for APPES:

- A. Pharmacy students placed with APPES that require access to FDA facilities or equipment need to successfully complete the onboarding process and receive a PIV card prior to the start of the APPE (or on the first day). Onboarding includes the steps necessary to pass security and background checks and clearances required by FDA and steps required by their pharmacy school.
- B. The preceptor follows the instructions available on the PSEP intranet site to work with the AO/MO to initiate the security and onboarding process within their OPDIV. Preceptors notify PSEP of any pharmacy student scheduled for an APPE who is denied access to FDA facilities or a PIV card. Pharmacy students who fail to meet the requirements for their APPE may have their APPE delayed, rescheduled, or terminated at the discretion of the preceptor or PSEP.

2. During all APPES:

- A. The preceptor makes every effort to safeguard all confidential and privileged information from intentional or inadvertent release.

- B. On the first day, preceptors discuss the definition of confidential and privileged information and expectations for the pharmacy student during the APPE, review pharmacy student responsibilities to protect this information, and have the student sign the *Commitment to Protect Confidential and Privileged Information* (Attachment 1) to accept this commitment, and act as a witness to the pharmacy student signature.
- C. The preceptor teaches, mentors, supervises, guides, and evaluates the pharmacy student throughout the APPE. The preceptor, with the knowledge of their supervisor, ensures pharmacy students complete all required trainings during the APPE, as appropriate. The preceptor oversees the pharmacy student's APPE to ensure the school's objectives and the FDA learning objectives are met. Questions that arise during a pharmacy student's APPE are discussed with the preceptor's supervisor and may be shared with PSEP, as appropriate.
- D. The preceptor provides regular feedback to the pharmacy student regarding the learning objectives, professional behavior, adherence to preceptor instruction, ability to communicate through preferred channels, and any other requirements of the APPE or their pharmacy school. The preceptor provides an evaluation of the pharmacy student's performance as required by the pharmacy school and any other required elements (e.g., tracking days and hours of service, professionalism, etc.) Pharmacy students ensure preceptors are aware of the requirements from their pharmacy schools.
- E. PSEP provides a rotating calendar of lectures, known as the PSEP lecture series, and ad hoc projects and opportunities for students. The preceptor provides resources, instruction, and learning opportunities, appropriate for the pharmacy student to meet the FDA learning objectives and any requirements from their pharmacy school.
- F. Preceptors will inform PSEP as soon as possible when:
 - Any question or concerns arises about a pharmacy students' ethical or professional behavior.
 - A pharmacy student is terminated early or fails to complete or pass an APPE.

3. On or before the day of termination:

- A. Preceptors will:
 1. Complete all evaluations of the pharmacy student's performance, as required by the pharmacy school,

2. Retain records in an ERKS. Records should include copies of completed forms:
 - a. Documentation of the APPE, including evaluation
 - b. Completed *Student Volunteer Service Agreement*
 - c. Completed *Commitment to Protect Confidential and Privileged Information* (Attachment 1)
3. Remind pharmacy students of their requirement to continue to protect any confidential and privileged information indefinitely.
4. Inform students of the requirement to notify their preceptor immediately and to obtain advance clearance before publishing any information related to the APPE, in accordance with CDER MAPP 4510.2, *CDER Clearance of FDA Related Articles, Speeches, and Other Publications*.
5. Make the AO/MO aware of the pharmacy student's departure date at least a week in advance, and if any changes have occurred.

B. The AO/MO makes preceptors aware of any issues or incomplete tasks and initiate the departure procedures, as needed.

C. For APPEs with access to FDA facilities or equipment, preceptors work with the AO/MO to:

1. Collect and return the pharmacy student's PIV card, all internal documents and records, and any FDA equipment to the AO or MO, or as directed.
2. In conjunction with the AO/MO, ensure the eDepart procedures are complete prior to close of business on the day of departure.

REFERENCES

1. Accreditation Council for Pharmacy Education standards, updated 2016. .
2. Executive Order 13467: Reforming Processes Related to Suitability for Government Employment, Fitness for Contractor Employees, and Eligibility for Access to Classified National Security Information. June, 2008.
3. 5 U.S.C. Subpart 3111, Acceptance of Volunteer Service. January, 2011.
4. FDA, 2020, Center for Drug Evaluation and Research, MAPP 4510.2. CDER Clearance of FDA-Related Articles, Speeches, and Other Publications.
5. FDA, 2023, Center for Drug Evaluation and Research, MAPP 4642.3. Student Volunteer Service Program (SVSP).
6. CFR 21 Part 20, Public Information.

DEFINITIONS

Experiential Coordinator: An individual who manages advanced pharmacy practice experiences (APPEs), also known as experiential education, at a pharmacy school.

FDA Pharmacy Student Experiential Program (PSEP): An FDA program designed to provide pharmacy students the opportunity to become acquainted with the workings of FDA, government regulations, rule-making, and government administration. PSEP facilitates matching of pharmacy students with preceptors.

Preceptor: FDA employee who is responsible for teaching, guiding, and supervising a pharmacy student during an APPE at FDA. Preceptors select pharmacy students with the knowledge of their supervisors.

Pharmacy student: An individual who is enrolled in the study of pharmacy at a school, university, or other accredited educational institution. The pharmacy students apply for an APPE at FDA with the knowledge or assistance of their Experiential Coordinator.

Supervisor: First-line supervisor typically responsible for employees' performance appraisals and leave approval.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
12/21/15	N/A	Initial
8/28/19	1	Limit eligibility to U.S. citizens
7/28/25	2	Eliminate duplicative text

ATTACHMENT 1: Commitment to Protect Confidential and Privileged Information

I understand that as a participant in FDA's volunteer Pharmacy Student Experiential Program in _____(office or division) I may be provided with, have access to, or become knowledgeable of, confidential and/or privileged information while attending or participating in meetings at the FDA or working on assigned projects. This confidential and/or privileged information may come from a number of sources, including FDA, other governmental instrumentalities, regulated industry and/or private citizens and organizations. I understand that I am given access to such information for official use only, to be used exclusively for FDA official business.

I understand that use of confidential and/or privileged information for any use other than work related to FDA official business is expressly prohibited. "FDA official business" means work or other activity that is directly related to the authorized mission and functions of FDA or any of its component centers or offices.

For purposes of this agreement, I understand "confidential information" to mean any information that is described or referenced in 21 USC 331(j) or 18 USC 1905, or any other predecisional or nonpublic information related to FDA work or activities and includes, but is not limited to, the following: proprietary data (including information or data that would be considered trade secrets within the meaning of 18 USC 1839 or 21 CFR 20.61), confidential commercial information (including the existence of an application that has not previously been publicly disclosed or acknowledged), information derived from and communicated during Agency deliberative processes, information relating to enforcement actions, and information relating to the development of regulations, guidance documents, citizen petition responses or responses to regulatory consults. I further understand "privileged information" includes, but is not limited to, all information that would fall under the scope of Article V of the Federal Rules of Evidence.

Therefore, I, _____, agree that I shall use confidential and/or privileged information for FDA official business only and will not disclose or reproduce any confidential and/or privileged information without express written authorization. I further agree that I shall not use confidential and/or privileged information except for the limited purpose of participation in meetings and completing work assignments for FDA. I understand that I have an affirmative duty to protect this information from intentional or inadvertent unauthorized disclosure. I will take reasonable precautions to prevent access by any unauthorized personnel to any

confidential and/or privileged information obtained during my Advanced Pharmacy Practice Experience (APPE) at FDA.

I will ask my PSEP preceptor or supervisor for guidance and direction should I have any questions regarding the above rules or if I am at any time not certain as to the confidentiality of any type of information. If I believe there may have been an unauthorized release of confidential and/or privileged information, I will report such breach immediately to my preceptor.

I have read and understand the content of this document and accept the responsibilities as outlined above. I understand that any unauthorized disclosure (whether intentional or inadvertent) of confidential and/or privileged information may lead to civil or criminal action. Further, I understand that FDA may report any such unauthorized disclosure of confidential and/or privileged information to my pharmacy school and state licensing authority.

I also understand that my obligations under this agreement do not end with the termination of my APPE.

I enter into this agreement willingly and with full knowledge of its scope and application.

Signed: _____

Date: _____

Name: _____

Witnessed by: _____

Date: _____

(PSEP Preceptor)