
Clinical Pharmacology and Biopharmaceutics

**Alternative Work Schedules for OCPB
(AWS)**

CONTENTS

**PURPOSE
BACKGROUND
REFERENCES
DEFINITIONS
POLICY
RESPONSIBILITIES
PROCEDURES
REDELEGATION
EFFECTIVE DATE**

PURPOSE This MAPP describes policies and procedures governing the alternative work schedule (AWS) program for all components of the Office of Clinical Pharmacology and Biopharmaceutics.

BACKGROUND

- The AWS program provides individuals with the flexibility to schedule their work time to accommodate their needs so long as it does not materially disrupt the conduct of the Center's business.
- FDA has revised its policies regarding core hours and flexible bands. CDER's AWS program is described under MAPP 4657.1. This MAPP provides the policies and procedures for implementing AWS within all components of the Office of Clinical Pharmacology and Biopharmaceutics (OCPB), as required under MAPP 4657.1.
- Implementing AWS within OCPB acknowledges the partnership and team work that occurs among reviewers in the Offices of Review Management (ORM), New Drug Chemistry (ONDC), and Clinical Pharmacology and Biopharmaceutics. As such, this plan is patterned after and follows most of the provisions set forth in the ORM plan.

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- The review work of OCPB is highly demanding, requiring multiple applications to be reviewed concurrently under tight deadlines. To meet these deadlines, the individual reviewers must work well with the ORM team, with opportunities for frequent and direct (often face-to-face) communication. For this reason, CDER has located all members of the review team together in contiguous space. The implementation of AWS must not undermine the effectiveness and efficiency of this team effort. At the same time, we want to allow employees and supervisors to use the AWS program to accommodate the employee's needs as much as possible without compromising our work and mission. OCPB's AWS plan represents an effort to achieve a balance.
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REFERENCES

FDA's Master Plan - Flexible Workplace Arrangements Program (1994)
MAPP 4657.1, CDER Plan for Alternative Work Schedules
MAPP 4657.3, CDER Policy on Overtime Approval
MAPP 5000.1, OPS Alternate Work Schedules (AWS)
MAPP 5100.2. OCPB Flexible Workplace Arrangements Program (FWAP)

DEFINITIONS

- **Alternative Work Schedules:** Any work schedule other than a designated fixed work schedule.
- **Basic Work Requirement:** The number of hours an employee is regularly scheduled to work. Full-time employees: 8 ½ hours a day, 40 hours in a week or 80 hours in a biweekly pay period; part-time employees: fewer than 40 hours (but not fewer than 16 hours or more than 32 hours) in a week or fewer than 80 hours in a biweekly pay period.
- **Core Hours:** The time during the workday during which an employee covered by a flexible (not compressed) work schedule must be present for work. (Note: Official business hours for OCPB and CDER are 8:00 a.m. to 4:30 p.m., Monday through Friday. Core hours for OCPB are from 9:30 a.m. to 3:30 p.m.)
- **Compressed Work Schedule:** Employees fulfill the requirement of working 80 hours in a biweekly pay period over a span of eight or nine work days: 5-4/9 (work 9 hours for 5 days of the first week and 4 days the next week with 1 day off) or 4/10 (work 4 days for 10 hours each week with 1 day off a week). This is a fixed schedule with a predetermined starting and ending time for each workday in the pay period and the same day off each pay period. No credit hours may be earned by employees on a compressed work schedule. (Note: OCPB employees are not permitted to work a compressed work schedule.)

- **Credit Hours:** Hours worked in a day in excess of the basic work requirement.
- **Flexible Bands:** The time band during the workday during which an employee may choose to vary the times of arrival to and departure from the work site. These time frames also provide the time bands in which credit hours may be earned. Flexible bands also define the times on weekends during which credit hours can be earned.
- **Maxiflex:** Work is performed within the designated flexible band of hours and employees must be present for work or on approved leave during core hours. Employees are allowed, with supervisory approval, to earn credit hours during the flexible bands.
- **Overtime and Compensatory Time Work:** Work that is officially ordered and *approved in advance* for a specifically defined project and performed outside the employee's official work schedule.

POLICY

The maximum flexible bands that can be permitted in OCPB are as follows:
Maxiflex Schedule:

MONDAY THRU FRIDAY

	Core Hours	Workable Hours	Required Approval Level for Earning Credit	Required Approval Level for Earning OT/Comp
On Site	9:30am-3:30pm	5:00am-12:30am	None (up to 4 hours)	Office
Off Site (FWAP)	9:30am-3:30pm	7:00am-6:00pm	Office	Office

SATURDAY & SUNDAY

	Core Hours	Workable Hours	Required Approval Level for Earning Credit	Required Approval Level for Earning OT/Comp
On Site	N/A	5:00am-6:00pm	Supervisory	Office
Off Site (FWAP)	N/A	7:00am-6:00pm	Office	Office

1. Routine working hours (i.e., “business hours”) for OCPB are from 8:00 a.m. until 4:30 p.m., Monday through Friday (and these are also the official business hours for FDA). At a minimum, live phone coverage is to be provided during these hours. Any absence during established core hours (9:30 a.m. - 3:30 p.m.) or working fewer than 8 hours on any normal business day, must be approved in advance through the normal process for requesting the use of annual leave, sick leave, station leave, compensatory time, leave without pay, or credit hours.
2. Employees are expected to be available for meetings during business hours even if their attendance would interfere with their normal work schedule. Meeting times and training times are not defined by the core hours, but can be scheduled to accommodate Center/Office or Division needs. Center/Office/Division management are required to ensure adequate staffing of all Center functions during official business hours.
3. Most full-time and part-time employees are eligible to participate in a maxiflex work schedule. In all cases, the maxiflex schedule options available to employees will depend on coordinating employee schedules so that adequate office coverage is maintained and work operations are not hindered. An employee’s participation in AWS may temporarily be withdrawn or modified by a supervisor for a specified period of time based on anticipated or emergency workloads. Advance notice of at least one week should be given to the employees if circumstances permit. Requests to participate in a maxiflex work schedule must be approved by the *employee's supervisor*. For part-time employees, time worked in excess of the scheduled tour may be recorded as credit time.
4. A full-time employee working under a FWAP agreement is permitted with supervisory approval to vary the beginning of the workday between the hours of 7:00 a.m. to 9:30 a.m. on those days that the employee is scheduled to work offsite. A part-time employee working offsite under a FWAP agreement must report to work at the time designated in his/her FWAP agreement.
5. Under certain circumstances such as a user fee deadline, eligible employees may substitute a Saturday and/or Sunday for a regular workday(s) by earning up to 8 hours a day of credit time, and up to 16 hours for both Saturday and Sunday. This request must be approved in advance by the employee’s Office Director. For those who would perform this work away from their official duty station, a flexible workplace agreement must be approved in advance in writing, and employees must account for the time claimed as work. NOTE: Flexible bands do not permit earning credit time after 6:00 p.m. on Saturday or Sunday.
6. Employees in OCPB are not permitted to work a compressed work schedule.
7. Credit hours may not be earned by Commissioned Corps Officers, SES employees, or Title 38 employees. However, employees in these categories are permitted with supervisory approval to adjust their core hours within the limits defined by MAPP 4657.1 to receive credit for an 8 and ½ hour workday, or for portions thereof.
8. For eligible full-time employees, up to 4 hours of credit time may be earned in a normal workday (Monday through Friday) without prior supervisory approval. For eligible part-time employees, up to 2 hours of credit time may be earned in a normal workday without prior supervisory approval. Credit time earned in excess of these amounts must be approved in advance by the

employee's supervisor. Any credit time earned on weekends must be approved in advance by the employee's supervisor, or, if earned offsite, by the Office Director.

A maximum of 24 credit hours may be accumulated and carried forward from one pay period to the next for *full-time employees only*. Part-time employees may carry forward credit hours up to ¼ of their official tour of duty hours as recorded on their SF-50. Any credit hours in excess of the amount allowed to be carried forward to the next pay period are lost. Credit hours must be earned in advance and may be used just like annual leave, with the advance approval of the supervisor. Credit hours do not convert to pay.

9. Attendance at professional meetings during the evenings (after 5 p.m.) and weekends may not substitute for a normal workday, and cannot be claimed as credit time, compensatory time, or overtime. This includes the time spent traveling to and from the meeting site. This policy does not apply to *nonexempt* employees who are covered by the Fair Labor Standards Act (FLSA), who include secretaries and all employees Grade GS-7 and below.
10. Time off during an employee's basic work requirement must be charged to the appropriate leave category. The minimum charge for leave is ¼ hour and additional charges are in multiples thereof. All employees will be required to account for their time through use of a designated time and attendance accounting system.
11. Overtime and Compensatory Time work must be approved in advance, and must be in excess of the employee's scheduled tour of duty. SES, Commissioned Corps, and Title 38 employees are not eligible to earn overtime.

RESPONSIBILITIES

- **The Director, OCPB:**
 1. Review the OCPB AWS plan at least annually and decide whether to continue, modify, or terminate it. Any changes should be filed with the Director, OM.
 2. Approve/disapprove employee requests for exceptions to OCPB core hours.
 3. For employees in the immediate office, consider each employee's preference and determine the appropriate schedule for each employee, based on the needs of the work unit, workload requirements, and the requests of other employees.
 4. Approve/disapprove the division's methods and procedures for accounting for time and attendance.

- **Division Directors:**
 1. Adopt OCPB's plan and distribute to all employees in the division.
 2. Determine on a continuing basis when the work requirements of certain positions preclude employees in those positions from participating in the maxiflex work schedules.
 3. Consider each employee's preference and determine the appropriate schedule for each employee, based on the needs of the work unit, workload requirements, and the requests of other employees.
 4. Review and, if concur, forward employee requests for exceptions to OCPB core hours to the Director, OCPB.

 - **Employees:**
 1. Request advance permission from their Division Director to participate in a maxiflex work schedule.
 2. Account for their time through use of a division designated time and attendance accounting system.
 3. Submit to their Division Director written requests for ongoing exceptions to OCPB core hours for approval/disapproval by the Director, OCPB. Employees may not participate in maxiflex work schedules that contain exceptions to OCPB's core hours until they have received approval from the Director, OCPB.

 - **Division of Management Services, Office of Management:**
 1. Provide information and guidance to Center employees on AWS policies and procedures.
 2. Review Office supplemental plans for adherence to Center policies before submitting to Director, OM for clearance.
 3. Maintain a record of all Office supplemental plans.
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REDELEGATION

The Center Director has redelegated authority to approve AWS requests to Office Directors with no further redelegation authorized.

EFFECTIVE DATE

This guide is effective upon date of publication.