

Massachusetts College of Pharmacy and Health Sciences Compliance Manual

Introduction

Massachusetts College of Pharmacy and Health Sciences (MCPHS or the University) is a premier global institution for health profession education, and adherence to the highest standards of professional and institutional ethics is expected of all members of the MCPHS community. Post-secondary education is a highly regulated industry. We all have a responsibility to monitor compliance with a wide variety of complex rules that affect the University's day-to-day operations, authorizations and accreditation status. A strong compliance program ensures that the University continues to deliver quality educational programs and services to our students and carry out its purpose, mission, and values as outlined in the MCPHS Strategic Plan.

This Compliance Manual articulates the University's commitment to compliance and describes the fundamental principles, values, and operational framework for compliance within MCPHS. This manual is designed to supplement MCPHS's written policies that detail expected behavior, objectives, and goals for specific areas of institutional compliance.

Please carefully read this Manual and understand the compliance concepts outlined herein. Cooperation from all employees is necessary for an effective and successful compliance program; every employee is responsible for being aware of University, school, and department policies and procedures that apply to their work, as well as keeping informed about federal, state, and local laws and regulations that impact their scope of duties.

What is Institutional Compliance?

The University and its students, employees, contractors, volunteers, and members of governance are responsible for complying with federal, state, and local law requirements, professional and accreditation standards, and MCPHS policies and procedures.

Compliance Standards

Eight Core Elements of an Effective Compliance Program

The U.S. Sentencing Commission Guidelines set forth eight basic elements that effective compliance programs should have:

1. High-level personnel who exercise effective oversight and have direct reporting authority to the governing body or the appropriate subgroup.
2. Written policies and procedures.
3. Effective training and education.
4. Effective lines of communication.
5. Standards enforced through well-publicized disciplinary guidelines.
6. Internal compliance monitoring.
7. Response to reported or detected offenses and corrective action plans.
8. Periodic risk assessments.

Evidence of Effective Compliance Programs

Under federal law, an effective compliance program is one that well designed, is adequately resourced and empowered to function effectively, and works in practice. To meet these federal standards and be effective, compliance programs must have key elements that include a structure that ensures proper coordination, oversight, and individual accountability; a high level of enterprise-wide compliance awareness and commitment, achieved through well-maintained policies and clear communication and training; regular, periodic assessment of compliance risks; adequate resources; distributed responsibilities; ongoing compliance monitoring; and, when necessary, the development and implementation of corrective action plans.

Overview of the MCPHS Compliance Program

Purpose of the MCPHS Compliance Program

The purpose of the MCPHS Compliance Program is to promote and ensure proactive compliance with all applicable laws, regulations, policies, accreditation requirements, and ethical conduct standards in order to support the University's mission and values. This is achieved through regular identification of high-risk compliance matters; education, training, and guidance provided to members of the MCPHS community, including faculty, staff, Trustees, and all other responsible constituencies; and monitoring the effectiveness of compliance activity.

The MCPHS Compliance Team and the Compliance Committee of the Board of Trustees (the "BOT Compliance Committee") have been established for the purpose of assisting in the oversight of the University's compliance and ethics functions.

Goals of the MCPHS Compliance Program

The goals of the MCPHS Compliance Program include the:

- Establishment and dissemination of formal compliance standards, policies, and procedures to all responsible members of the MCPHS community;
- Implementation of specific policies and procedures to ensure that the University exercises due care not to hire, continue to employ, or contract with individuals who have a demonstrated propensity to engage in unlawful, unethical or unprofessional activity;
- Promotion of compliance awareness through ongoing communication, education, and training;
- Prevention and/or detection of non-compliance through (i) ongoing identification of high-risk activities through assessments and the implementation of appropriate internal controls and monitoring processes; and (ii) the maintenance of a well-publicized reporting mechanism by which compliance concerns or questions may be reported in good faith by MCPHS employees and others without intimidation or fear of retribution or retaliation;
- Identification and resolution of instances of non-compliance through timely investigation of possible non-compliance, including implementation of appropriate corrective action to prevent recurrence of such non-compliance in the future; and
- Assurance of consistent enforcement of compliance standards, including fair, equitable, and consistent disciplinary treatment of individuals responsible for non-compliance.

MCPHS Compliance Team

In order to promote the effectiveness of the MCPHS Compliance Program and to create a culture that promotes understanding of and adherence to applicable policies, laws, and regulations, the University has established the Compliance Team. The Compliance Team is composed of internal University department leaders who are charged with promoting the effectiveness of the MCPHS Compliance Program by doing the following:

- Understanding the University's compliance requirements in order to identify and assess risks, for the purpose of prioritizing Compliance Program initiatives.
- Recommending, developing, and assisting in the implementation of policies, procedures, and controls that reflect best practices to address identified risks.
- Identifying and promoting training relevant to general compliance as well as training responsive to specific risk areas.
- Evaluating the performance of the Compliance Program, including the systems for communicating, evaluating, and responding to complaints and other compliance matters.
- Helping to identify potential instances of non-compliance, waste, fraud, and abuse at MCPHS.
- Assisting in resolving identified compliance issues and implementing corrective action plans.
- Ensuring the ongoing enforcement of compliance policies and procedures and, if required, providing direction regarding disciplinary actions for repeated instances of non-compliance.
- Encouraging a culture of compliance throughout the University.
- Reporting periodically to the BOT Compliance Committee regarding the overall MCPHS compliance program.

The Compliance Team includes the following positions or their designee:

- Chief Financial Officer
- Chief Human Resources Officer
- Chief Inclusion Officer
- University Counsel
- Associate Provost

MCPHS Compliance Workgroup

To enhance communication of and adherence to applicable legal and institutional requirements, certain departments within the institution shall designate a representative to serve as a Departmental Compliance Liaison to the Compliance Workgroup. These appointments shall be made by the Compliance Team in consultation with each department head.

The Departmental Compliance Liaisons provide compliance related communications within specific departments. The goal is for each Liaison, to work closely with the Compliance Team and other members of their department, to achieve consistent implementation of all applicable compliance policies and procedures. Individuals identified as liaisons should have good verbal and written communication skills and be familiar with the day-to-day operations of their respective departments.

The Departmental Compliance Liaison may assume the following responsibilities:

- Collaborating with the Compliance Team and attending periodic meetings of the Compliance Workgroup.
- Assisting in identifying and resolving compliance risks within their department.
- Raising and maintaining compliance awareness.
- Addressing compliance issues and bringing them to the attention of the Compliance Team as appropriate and necessary.
- Communicating Compliance Program updates to their department.
- Participating in planning education and training sessions for their department and facilitating their department's completion of training.

Responsibility for Monitoring Laws and Setting Institutional Policy, and Communicating Procedures and Policies to Faculty and Staff

In order to create a culture supportive of compliance and ethics, department heads and managers in all departments shall be responsible for:

- Participating in the identification of risks in their department.
- Developing and maintaining departmental compliance policies and procedures in consultation with the Compliance Team.
- Providing or arranging for training for all departmental employees to implement policies and procedures in consultation with the Compliance Team.
- Ensuring all employees within the department complete required training.
- Taking all measures reasonably necessary to ensure compliance with the University's policies and procedures, as well as applicable laws and regulations, by:
 - Monitoring employee adherence to established policies and procedures.
 - Reporting and encouraging departmental staff to report potential lapses to the Compliance Team or via the Compliance Hotline.
 - Reviewing suspected instances of non-compliance in conjunction with University Counsel and the Compliance Team.
 - Coordinating with Human Resources regarding any appropriate disciplinary action.
 - Implementing corrective action plans.

Compliance Awareness, Education and Training

A culture of compliance can only be built and maintained in an organization through clear and ongoing communications, education, and training. Proper and continuing training and education of employees at all levels is, therefore, a significant element of the University's Compliance Program.

Each department head should regularly evaluate the training and education programs offered to the employees of their department to determine, and if necessary improve, the value, effectiveness, and appropriateness of any such program. All employees need not have the identical amount of training and

education, nor should the focus of training and educational efforts be the same for all members. The actual amount of training should reflect necessity, an analysis of risk areas, and specific areas of concern identified by MCPHS or a regulatory oversight body, the University's compliance experience, and the results of periodic monitoring. Each department head should also, as part of an annual compliance review, consult with the Compliance Team to identify additional or replacement training and education necessary or advisable for any employees of their respective department.

Adherence to and promotion of the Compliance Program shall be a factor in evaluating employee performance (including supervisory, managerial, and administrative personnel). Employees should be trained and, as necessary, retrained in the specific federal and other laws and regulations that relate to their particular job functions. Failure to comply with training requirements or to attend scheduled training sessions of MCPHS or such MCPHS department may result in corrective or disciplinary action

Reporting of Compliance Concerns

MCPHS is committed to operating ethically and lawfully and expects all members of the University community to conduct their activities in compliance with the University Code of Ethical Conduct, policies and procedures, and applicable law. Members of the University community have an affirmative duty to disclose and seek guidance if they have compliance concerns or believe that another member of the University community or other person associated with or doing business with MCPHS is engaging in unethical or other wrongful conduct. When possible, employees should first contact their supervisor or unit manager. Supervisors and unit managers need to know about issues that arise in the area under their management, and they are often in the best position to answer questions and take action.

If an employee does not feel comfortable raising a concern with their supervisor or manager (or if the concern relates to the supervisor or manager, or if the supervisor or manager has been previously informed but the concern has not been remedied), there are several additional ways to report a concern:

- Report the issue through the Compliance Hotline as outlined below.
- Report the issue to a member of the Compliance Team.

Compliance Hotline

The Compliance Hotline is an anonymous, toll-free, 24-hours-a-day, 7 days-a-week resource for reporting compliance concerns. Once a compliance concern is raised via the Hotline, a detailed report is forwarded to the Office of Legal Affairs and, where necessary and appropriate, shared with the Compliance Team. The Compliance Hotline is staffed and managed by an external company, Lighthouse Services, Inc., that is not affiliated with MCPHS and provides this service under contract. No call tracing or recording devices are ever used on phone calls, and the complainant's contact information will be removed before being transmitted to MCPHS.

Additional information about the Hotline can be found at: <https://www.mcphs.edu/about-mcphs/legal>

To use the Compliance Hotline, you may submit a report using one of the methods set forth below:

Online: <https://www.lighthouse-services.com/MCPHS>
Telephone: 877.472.2110
Email: reports@lighthouse-services.com (Indicate that your report concerns MCPHS)

If you are faced with an emergency or are concerned for the immediate safety of yourself or others, dial 911. MCPHS policy prohibits any retaliation against individuals who report compliance issues in good faith.

Response and Corrective Action

When an instance of non-compliance has been confirmed by the Compliance Team through periodic monitoring, a report on non-compliance, or through an investigation, the Compliance Team, in coordination with appropriate responsible MCPHS officials, will facilitate the implementation of a corrective action plan with the affected departments, faculty, and/or staff. The corrective action plan may include any or all of the following elements: identification of specific areas requiring compliance correction; additional training; change in policies and procedures; further investigation; or disciplinary action.

Disciplinary action may be imposed as part of a corrective action plan for any employee or member of the MCPHS community. Disciplinary actions may include, but are not limited to, spoken and written counseling, spoken or written warnings, demotion, suspension, and any other action deemed appropriate to the particular situation, up to and including termination of employment. The University in its sole discretion, would determine the appropriate disciplinary or corrective action based on an evaluation of the specific circumstances surrounding the non-compliance. Nothing in this Manual gives an employee the right to receive any particular type of discipline nor limits the University's right to terminate the employment relationship at any time, with or without cause or notice.

Retaliation

MCPHS encourages all employees and students to make good-faith disclosures of University-related misconduct. The University will not tolerate retaliation or threat of retaliation of any kind against those who make disclosures of actual or perceived misconduct. Acts or threats of retaliation in response to such disclosures may subject the person threatening or retaliating to disciplinary action, up to and including termination or dismissal.

Conclusion

Complying with the policies and principles outlined in this Manual is of the utmost importance to ensure that MCPHS operates ethically as an organization and avoids significant legal issues. If you have any questions about the application of this Manual, please contact the Office of Legal Affairs at (617) 735-1083 to be connected with a member of the MCPHS Compliance Team.

Please remember that the ultimate responsibility for adhering to compliance standards and ethical behavior ultimately rests with you. Please use your best judgment.

Issuing Authority: The BOT Compliance Committee
Responsible Officers: The MCPHS Compliance Team
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