



**Built**  
on  
**Integrity**

# COMPREHENSIVE COMPLIANCE PROGRAM

*Compliance is Every Employee's Business*

(Amended and Restated January 1, 2020)



ETHICS & COMPLIANCE

# Compliance is Every Employee's Business

# I. Introduction

As part of its ongoing efforts in the area of compliance, AMAG Pharmaceuticals, Inc. (“AMAG” or the “Company”) has developed a Comprehensive Compliance Program that is designed to comply with applicable federal and state laws that govern the marketing and promotion of our products, as well as the United States Department of Health and Human Services, Office of Inspector General (“OIG”) “Compliance Program Guidance for Pharmaceutical Manufacturers” (“OIG Guidance”) and the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, as amended (“PhRMA Code”).

As recommended in the OIG Guidance, AMAG’s Comprehensive Compliance Program has been designed to fit the specific compliance needs of the Company. AMAG will continue to regularly review the effectiveness of its Comprehensive Compliance Program and refine it to meet the Company’s on-going compliance needs, as well as any changes in applicable federal or state laws to ensure that it is responsive to the Company’s evolving business and associated compliance risks.



## II. Overview of Comprehensive Compliance Program

### Chief Compliance Officer and Compliance Committee

The Company's Board of Directors has designated the Company's General Counsel with responsibility for developing and overseeing AMAG's Comprehensive Compliance Program, including identifying and designating an individual to act as AMAG's Chief Compliance Officer. In the event that an individual has not been so designated or in the event that there is a vacancy for the Chief Compliance Officer position, the General Counsel will act as AMAG's Chief Compliance Officer until one is designated.

The Chief Compliance Officer is charged with the responsibility of developing, maintaining, operating, and monitoring AMAG's Comprehensive Compliance Program. The Chief Compliance Officer has the authority to effectuate change and exercise independent judgment within the Company. Additionally, the Chief Compliance Officer has the authority to report directly to the President and Chief Executive Officer of the Company and is empowered to report compliance matters directly to the Company's Board of Directors. The Chief Compliance Officer interacts routinely with members of the Company's management team.

The Company has established a Compliance Committee, comprised of leaders from key functions in the Company, and that is chaired by the Chief Compliance Officer. The Compliance Committee meets to assist the Chief Compliance Officer with (i) implementation of the Comprehensive Compliance Program, (ii) identification and management of areas of risk and areas of critical focus for AMAG, (iii) discussion of best practices, and (iv) coordination of advice-seeking. The membership of the Compliance Committee may be modified from time to time in the discretion of the Compliance Committee.

## Written Policies and Procedures

As part of its Comprehensive Compliance Program, AMAG has established a Code of Ethics (“**Code**”) consistent with the OIG Guidance, which provides instruction on the principles to which all AMAG directors, officers, employees, independent contractors, and agents must adhere. This Code seeks to foster a culture of compliance across the Company. To view the Code, please see **Exhibit A** attached hereto.

In addition to the Code, AMAG has established the AMAG Compliance Manual (**the “Compliance Manual”**) to govern day-to-day operations. The Compliance Manual covers the key issues identified by the OIG as being potential areas for fraud and abuse, such as: promotional activities; discounts, pricing, and reporting to federal healthcare programs; prescription product sampling; consulting and advisory arrangements with healthcare professionals; and various sales and marketing courtesies including gifts and meals to healthcare professionals. Our Compliance Manual is consistent with the PhRMA Code. In addition, our Compliance Manual expressly prohibits kickbacks and other forms of illegal remuneration between AMAG and persons or entities in a position to generate federal healthcare business for the company, either directly or indirectly. AMAG reviews its policies and procedures on a routine basis and revises them as necessary to meet the changing requirements imposed by law.

## Effective Training and Education

Training and education are critical components of AMAG’s Comprehensive Compliance Program. All employees, officers, and directors receive training on the Code. Additionally, AMAG requires those employees whose job responsibilities involve interactions with healthcare professionals and/or organizations, including, but not limited to, applicable directors, officers, employees, independent contractors, and agents to receive training on the Compliance Manual. The Company may require additional compliance training as it deems necessary. In addition, the Company regularly reviews and updates its training program to ensure the program reflects the most current and meaningful education on Company policies and procedures and applicable federal and state laws.

## II. Overview of Comprehensive Compliance Program *(continued)*

### California Health & Safety Code Sections 119400-119402

AMAG has established a Comprehensive Compliance Program in compliance with California Health & Safety Code Sections 119400-119402 ("California Law"). Accordingly, AMAG has established an annual dollar limit of \$2,000 per individual on gifts, promotional materials or items or activities to medical or healthcare professionals, as defined under the California Law. This limit does not include prescription product samples intended for free distribution to patients, financial support for independent education, including continuing medical education, financial support for health education scholarships, and fair market value payments for legitimate professional services.

### Effective Lines of Communication

AMAG actively fosters dialogue between management and employees. Our goal is that all employees should know whom to turn to when seeking answers to questions or reporting possible compliance violations, and should be able to do so without fear of retaliation. AMAG maintains an open-door policy to encourage open dialogue about compliance questions and concerns. A Company employee is required to report any suspected violation of, or questions regarding, AMAG's Comprehensive Compliance Program, the Code and the Compliance Manual to his or her supervisor, the Chief Compliance Officer or the General Counsel. Alternatively, employees may anonymously report violations or suspected violations either online at [www.amagpharma.alertline.com](http://www.amagpharma.alertline.com) or by telephone at (877) 874-8416. Such reports will be investigated by the Chief Compliance Officer, the General Counsel or their designee.

All employee communications regarding any suspected violation will be handled in strict confidence within the boundaries of the law. No employee who in good faith reports suspected wrongdoing will be subject to discipline, discharge, demotion, suspension, threatening, or harassment for having done so, even if the information incriminates management, supervisors or employees of the Company, or even if the report ultimately is established to be erroneous, unless it is determined that the employee made the report in bad faith or with knowledge that it was false. Such discipline, retaliation or harassment by a manager, supervisor, or any other employee will be grounds for disciplinary action, up to and including termination. Failure to report wrongdoing of which an employee has knowledge may be, in itself, a basis for disciplinary action.

## Monitoring and Auditing

Internal monitoring and auditing techniques are vital parts of AMAG's Comprehensive Compliance Program. Effective monitoring can provide AMAG with the ability to detect and prevent deviations that can potentially affect Company compliance goals. Accordingly, AMAG routinely monitors its Code and Compliance Manual to evaluate whether they adequately address risk areas and personnel compliance with Company policies and procedures and federal and state law. Additionally, "for cause" audits and reviews are undertaken as appropriate. AMAG personnel, at all levels, are responsible for reporting potential compliance issues of which they become aware.

## Disciplinary Guidelines

AMAG's Comprehensive Compliance Program supports prompt response and appropriate corrective action for any detected compliance violations. It is expected that any compliance concerns received by the Chief Compliance Officer or AMAG management will be reviewed carefully, investigated in a timely manner, and result in appropriate corrective action and preventive measures to ensure the integrity of the Comprehensive Compliance Program. In addition, when appropriate, a compliance report may be provided to the relevant authorities.

AMAG personnel who violate AMAG's policies and procedures, applicable state and federal laws, or both, may be subject to disciplinary action, up to and including termination, as determined on a case-by-case basis.

## III. Declaration

AMAG's Declaration of Compliance with California Law, in which AMAG certifies it is in material compliance with this Comprehensive Compliance Program and the requirements of the California Health and Safety Code §§ 119400-119402, can be found at [www.amagpharma.com](http://www.amagpharma.com). Hard copies of AMAG's Comprehensive Compliance Program and Declaration of Compliance with California Law may be obtained by calling (877) 411-2510 or by email at [compliance@amagpharma.com](mailto:compliance@amagpharma.com).



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