

Healthcare Compliance Program

Comprehensive Compliance Program

I. Compliance Program

1. Compliance Officer and Compliance Committee

Grifols' Compliance Officer is a member of senior management who oversees all compliance activities. The Compliance Officer is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with federal health care programs. The Compliance Officer makes periodic reports regarding compliance activities to the Compliance Committee.

2. Written Standards of Conduct

Grifols has established written standards of conduct, including the Code of Conduct (PDF) posted on this Web site, that are designed to ensure compliance with the requirements associated with federal healthcare programs. The Code of Conduct is updated as necessary. Relevant employees are required to certify on an annual basis that they have read and understand Grifols' written standards.

3. Confidential Disclosure Program

Grifols maintains a confidential disclosure program, which includes a toll-free telephone line or online reporting platform, that allows employees to report to the Compliance Officer suspected violations of federal or state health care program requirements or of the company's policies and procedures. Reports may be made anonymously. Grifols thoroughly investigates all reports it receives and no employee will be subjected to retaliation or any other adverse action for making a report in good faith. Grifols has adopted a non-retaliation policy.

4. Compliance Training

Relevant employees receive annual training that covers healthcare compliance policies and procedures and the pertinent legal requirements. Employees must certify completion of all training.

5. Ineligible Persons

Prior to hiring any individual for a position involving marketing, selling, contracting for or reporting prices for Grifols products, Grifols ascertains that the job candidate is not an Ineligible Person — i.e., an individual who is excluded, suspended, debarred or otherwise ineligible to participate in Government reimbursement programs or who has been convicted of a criminal offense related to federal health care programs. If Grifols becomes aware of a current employee who becomes excluded from participation in a Government reimbursed program the company will, at minimum, remove the employee from work involving Government reimbursed products.

6. Monitoring and Auditing

Grifols routinely self-assesses and audits Grifols' compliance with applicable laws and regulations, industry guidelines, and company policies. Grifols uses audit tools to assess and monitor compliance with its written standards, to identify areas of potential concern and to correct and prevent the recurrence of problems identified.

II. Government Price Reporting

7. Promotion and Government Reimbursement

Grifols employees must comply with all applicable laws and federal health care program requirements in marketing and promoting the company's products. Grifols expressly prohibits any promotion of product based on the "spread" — or the difference between what a customer pays for a product and the amount the customer receives in government reimbursement.

8. Reporting Product Prices to the Government

It is Grifols' policy to comply with all applicable laws and regulations pertaining to product pricing and the reporting of those prices to Government agencies. Everything that may affect the net pricing of Grifols products, including discounts, rebates, and all other price concessions, is taken into account in reporting prices to the Government in accordance with the laws and regulations of Medicare, Medicaid and other Government reimbursement programs.

III. Interactions with Healthcare Professionals

9. No Incentives to Prescribe or Use Grifols Products

No Grifols employee may offer any remuneration — that is, anything of value — to induce or encourage prescriptions or purchases of Grifols products. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's prescribing practices in accordance with the PhRMA code. Certain discounts and other price concessions may be provided in conformance with the Discount Safe Harbor to the Anti-Kickback Statute.

10. Educational Grants

Grifols provides grants to fund educational activities that foster increased understanding of scientific, clinical, or health care issues that contribute to the improvement of patient care. Grants may not be solicited or provided to encourage recipients to prescribe, purchase, order, or recommend Grifols products or provided in place of a product discount.

Grifols provides financial support for educational programs in accordance with the U.S. Food and Drug Administration and industry guidelines.

11. Research and Clinical Study Support

Grifols only supports research and clinical studies that promote legitimate research goals and are conducted pursuant to a written agreement. Support for such studies cannot be provided with the intent to induce or encourage the entity receiving the support to prescribe, purchase or order Grifols products.

12. Interactions with Healthcare Professionals

Grifols complies with the PhRMA Code on interactions with Healthcare Professionals. Grifols may engage healthcare professionals as consultants or advisors to furnish important and needed information to Grifols, provided that it selects such consultants based on their relevant qualifications, experience, and expertise and pay them fair market value for their legitimate services, pursuant to written contracts.

Grifols has a \$1,500 annual dollar limit on promotional materials, business meals and items or activities that it may provide to an individual healthcare professional practicing in the State of California.

13. Discipline

Violations of Grifols' healthcare compliance policies and procedures subject employees to disciplinary action. Employees who fail to comply with these policies, or who negligently or willfully fail to detect and report violations of these policies, will be subject to a variety of sanctions, up to and including termination.