

New California Law Requires Pharmaceutical Companies to Adopt Compliance Programs

California recently enacted a law requiring pharmaceutical companies to adopt “Comprehensive Compliance Programs.” The programs must be “in accordance with” the HHS Office of Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers and the PhRMA Code on Interactions with Health Care Professionals. The requirement becomes effective July 1, 2005.

The Comprehensive Compliance Programs must include annual dollar limits on gifts, incentives, and “promotional materials” furnished to healthcare professionals. The law exempts the following items from the limits, provided that they comply with the guidance from OIG and PhRMA:

- Drug samples intended for free distribution to patients
- Financial support for continuing medical education forums and health education scholarships
- Payments to health and medical professionals for their legitimate professional services, as long as the payments do not exceed fair market value.

A pharmaceutical company must certify annually that it is in compliance with its Comprehensive Compliance Program and with this new California law. It must also make available on its website its Program and declaration of compliance, as well as a toll-free telephone number where copies of these documents can be requested. There is no enforcement mechanism on the face of the statute.

The new law includes ambiguous provisions and raises a number of questions about its interpretation and enforcement.

