

California Health & Safety Code § 119402 Annual Declaration

The California Health & Safety Code, §§ 119400 – 119402, requires pharmaceutical companies to adopt a compliance program in accordance with the Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers (“OIG Pharmaceutical Guidance”). The California Code states that the compliance program must include policies for compliance with the Pharmaceutical Research and Manufacturers of America Code on Interactions with Health Care Professionals (“PhRMA Code”). The California law defines pharmaceutical companies as entities who produce, prepare, propagate, compound, convert, or process any drug or device that may be dispensed only by prescription to adopt a compliance program.

I-Flow Corporation does not produce prescription drugs. It does, however, produce medical devices that may be dispensed with a prescription. Thus, I-Flow Corporation has made reasonable good faith efforts to comply with the California Health & Safety Code as it applies to medical device manufacturers.

I-Flow Corporation has adopted a Healthcare Compliance Program based upon the relevant portions of the OIG Pharmaceutical Guidance as well as the OIG Guidance for the Durable Medical Equipment Prosthetics, Orthotics and Supply Industry (“OIG DMEPOS Guidance”). The I-Flow Corporation Healthcare Compliance Program includes policies designed in consideration of the Code of Ethics on Interactions with Health Care Professionals published by the Advanced Medical Technology Association (“AdvaMed Code”) as well as the relevant portions of the PhRMA Code. The Healthcare Compliance Program document is available for review on-line by clicking on the Healthcare Compliance Program link on the Home page.

Copies of the Healthcare Compliance Program and this Annual Declaration are also available by contacting I-Flow Corporation’s Compliance Officer at 1 800 448-3569.

Declaration

I-Flow Corporation is committed to compliance with the applicable healthcare laws and third party payor requirements. To that end, I-Flow has adopted a HealthCare Compliance Program. I-Flow fully intends for its employees to use this Program as a guide in furtherance of its continuing good faith efforts to comply with applicable laws. I-Flow recognizes that, in practice, complete perfection in the area of compliance may not be truly attainable; however, it is I-Flow's goal to strive for excellence and use good faith efforts in its compliance activities. To the best of its knowledge and based upon a good faith understanding of the applicable statutory requirements, I-Flow is in substantial compliance with its HealthCare Compliance Program and the requirements of the California Health & Safety Code §§ 119400 – 119402 as it applies to medical device manufacturers.

As acknowledged by the Office of Inspector General in the OIG Pharmaceutical Guidance and in the OIG DMEPOS Guidance, implementation of compliance programs cannot eliminate the possibility of inappropriate conduct. As a result, this declaration is not intended and should not be construed as an assertion that I-Flow has not identified any individual instances in which an employee may have violated a provision of the HealthCare Compliance Program. When and if issues with respect to compliance are discovered, the issues are investigated and responses are taken in accordance with the HealthCare Compliance Program.