

REPORT ON PHYSICIAN COMPENSATION ARRANGEMENTS

EXECUTIVE SUMMARY

The Division of Consumer Affairs presents this Report on Physician Compensation to the Attorney General. In 2007, the Division of Consumer Affairs was tasked with identifying ways in which the potential for conflicts of interest between doctors and pharmaceutical companies and medical device manufacturers could be minimized to ensure that patient care is always guided by the unbiased, best judgments of the treating doctor. As part of that initiative, the Division has engaged in a dialogue with physicians, pharmacists, hospital executives, and pharmaceutical industry and insurance company representatives, who provided insight on current developments in industry, academia, the medical community and state and federal initiatives. Through that dialogue, as well as the substantial, independent research undertaken, the Division of Consumer Affairs devised the policy recommendations contained in this report.

The report offers complementary reforms — for consideration by the Board of Medical Examiners (“BME”), the Board of Pharmacy, the Department of Health and Senior Services (“DHSS”) and academic medical centers — that would regulate New Jersey physicians’ financial relationships with industry. While several states have imposed disclosure obligations and other conflict of interest limitations on industry, no state has imposed such requirements on physicians. The imposition of such obligations on physicians is a critical element of the initiative to impose principled standards on the relationships between doctors and industry. These standards will benefit New Jersey’s patients and health care consumers.

The following is a summary of the key recommendations contained in the report.

GIFTS: For years, pharmaceutical companies and medical device manufacturers have given physicians expensive gifts, free vacations, and lavish meals. Recent studies show that even small gifts, including food, affect physician prescribing practices, by creating a feeling of obligation in the receiver to reciprocate. The report recommends that BME regulations be amended to prohibit a licensee from accepting from any pharmaceutical or medical device manufacturer any of the following: (1) payments, including tuition, fees, travel, lodging or other incidental expenses, to support attendance as a participant at an accredited continuing medical education (“CME”) program; (2) fees, travel, or lodging reimbursement for non-faculty or non-consultant attendees at company-sponsored meetings; (3) items intended for the personal benefit of a licensee (such as floral arrangements, artwork, CDs, DVDs or tickets to a sporting event), or items that may have utility in both the professional and non-professional setting (such as a DVD or a CD player); (4) payments in cash or a cash equivalent (such as a gift certificate) unless it is compensation for bona fide services such as serving as a consultant or participating in research or publication activities; and (5) company-funded entertainment or recreational items, unless the licensee is a salaried employee of the manufacturer.

Doctors, however, should receive items that provide a direct benefit to patients — such as, samples or anatomical models for use in examination rooms — and things of value that indirectly benefit patients by advancing physician learning or legitimate research goals — such as remuneration for service as a speaker or faculty organizer for CME events.

MEALS: Providing free food to physicians and staff in an office setting or at an educational/promotional dinner has no benefit to patients or to the broader public, and would appear to have no other purpose than to gain access and favor with the physician. The report recommends that BME regulations be amended to: (1) prohibit physicians and physician in-office staff from accepting food from manufacturers, whether in-office, at health care facilities or in commercial venues; (2) require physicians attending unaccredited educational or promotional sessions organized by manufacturers at which meals are served to pay the fair market value for the meals served in connection with those sessions; and (3) allow the receipt of modest meals at continuing medical education seminars, third-party conferences and professional meetings accredited by the Accreditation Council for Continuing Medical Education, where the provision of meals facilitates the scheduling of the educational program to maximize physician learning, and where such meals are provided at the discretion of the CME provider, and are not paid for directly by manufacturers.

FREE SAMPLES: The provision of samples for newer, more expensive brand-name medications is a key component of pharmaceutical company marketing. The availability of samples affects physician prescribing, and may lead to the increased prescription of those marketed drugs. Still, there is a consensus among physicians that the provision of sample medications benefits patients and should be continued. Moreover, providing samples is perceived by patients as convenient and economical. The report recommends that BME regulations permit continued receipt of sample medications by physicians for the exclusive benefit of patients.

DISCLOSURE: While physicians should not be permitted to accept gifts from industry, physicians do enter into other types of permissible financial arrangements with pharmaceutical or device companies that should be known to patients, including serving as consultants, participating in the development of new treatments and therapies, and providing training on behalf of the companies, all of which are necessary activities. These financial arrangements may play a role in influencing physician behavior and can create excessive or inappropriate loyalties and entanglements. Greater transparency of these arrangements will serve to deter the most flagrant abuses. Many states have instituted disclosure requirements and similar disclosures are being considered on the federal level. The report recommends that the BME mandate, as part of its biennial renewal process, that physicians disclose whether they accepted more than \$200 during the preceding two years from manufacturers, whether in cash, food, travel, consulting fees, research funding, or any other economic benefit. The value of samples would not count towards the disclosure threshold. The required disclosure should include the name of the company, the value, date and nature of the payment, and if applicable, the name of the product, and whether the

payment is related to marketing, education or research pertaining to a specific drug, device, biological or medical supply.

The report recommends the creation of a searchable, user-friendly database to make physician-disclosed information available to the public. The report also recommends that the State enact legislation requiring manufacturers to disclose payments and other things of value made to physicians, physician practices and physician groups.

CONTINUING MEDICAL EDUCATION: Physicians must participate in CME as a condition of licensure renewal. The FDA requires that industry limit its CME involvement to financial support — otherwise it might cross the line into advertising or product labeling, both of which are subject to agency oversight. Still, even though CME providers maintain control of program planning, many believe that industry-funded courses are promotional in nature, focusing on the newest available treatments and off-label uses that lack evidence of safety or efficacy. The report recommends that BME regulations be amended to: (1) provide credit only for those CME courses that meet Accreditation Council for Continuing Medical Education or American Osteopathic Association standards that specifically bar the CME provider from obtaining advice from a subsidizing company as to faculty or content; (2) impose an obligation on physicians who are engaged as CME speakers to directly disclose to physician-learners, at the beginning of the presentation, the receipt of reportable compensation from manufacturers; and (3) direct that a phase-in begin to require 25% of CME to be obtained in evidence-based educational programs or through academic detailing.

DATA MINING: Healthcare Information Organizations (“HIOs”) are companies that acquire, compile and analyze prescription data and other medical information for resale, a practice known as “data mining.” Industry purchases this information from HIOs to tailor their marketing to each physician’s prescribing habits. The American Medical Association has created an “opt-out” mechanism that physicians may use to stop the release or sale of their prescriber-identified information, although many physicians remain unaware of its existence. Some states have adopted legislative restrictions on the sharing of prescriber identified data. Though early legislative efforts were challenged in court, recent decisions have affirmed the states ability to regulate data mining. The report recommends that: (1) the BME use its biennial renewal process and website to acquaint physicians with the AMA’s data mining opt-out program; (2) Board of Pharmacy regulations be amended to require pharmacies to maintain documentation confirming that prescribers have consented to the sale of their prescribing information; and (3) the State enact legislation to restrict the transfer, use or sale of prescriber-identifiable prescription information for commercial purposes.

PHYSICIANS-IN-TRAINING: Industry funding for medical education and the operation of academic medical centers has significantly increased, and financial relationships among industry and academic medical institutions, departments, and faculty are common. The medical-education community therefore has a heightened responsibility to develop and maintain robust conflict of interest standards. The medical-education community must provide appropriate educational opportunities to physicians-in-training,

free from commercial bias. The report recommends that BME regulations be amended to: (1) hold physicians, who are serving as faculty and preceptors, accountable to adhere to Association of American Medical Colleges conflict guidelines, both on and off campus; and (2) add a requirement that Medical Education Directors incorporate, as part of residency training, curriculum designed to teach residents to identify evidence-based data and conflicts of interest, which will permit residents to better assess the impact that the source of research funding may have on the values of the information presented.

PHYSICIAN ACCOUNTABILITY: Physicians bear a responsibility to provide accurate and truthful information in promotional or educational settings, including in medical school and residency training, as well as in professional publications. Physicians should provide information about their financial interests so that the public, their colleagues and regulators can evaluate whether their interest should be considered in evaluating their statements. The report recommends that BME regulations be amended to prohibit physicians from: (1) recklessly providing inaccurate and misleading information in educational or promotional venues; (2) claiming authorship of any article or study unless they, in fact, authored the work in question; and (3) misrepresenting financial interests in any required disclosure form, including through the omission of required information.

HEALTH CARE FACILITIES: The mixture of industry, physician and health care institutions brings about additional conflicts that create impediments to unbiased medical decision-making. The DHSS, which licenses certain health care institutions in the State, can play a key role in monitoring the activities of individuals working within these institutions to assess possible conflicts of interest with industry. The report encourages the DHSS to (1) create a standardized conflict of interest form for use by all New Jersey licensed health care facilities; (2) consider whether physicians with financial interests should serve on advisory bodies, such as formulary committees, purchasing committees or groups established to develop practice guidelines, or should conduct clinical trials or participate in IRB research; (3) consider whether disclosures of interests should be mandated in in-hospital educational venues before presentations begin; (4) create programs allowing community hospitals to ensure that the acceptance of industry funding for CME does not skew the message of educational sessions; and (5) create a system to manage conflicts to avoid potential detriment to the safety of clinical trial participants or to the integrity of the research.

ACADEMIC DETAILING: Academic detailing is a method of outreach education that combines the interactive, one-on-one communication approach of industry detailers with the evidence-based, noncommercial information of academia. These programs work by sending a pharmacist, nurse or doctor (known as a “detailer”) to visit a physician’s office, just as industry would. However, the academic detailer is not sent to promote a certain product to the exclusion of all others, as is the case with an industry detailer. Instead, academic detailers discuss general medical issues with physicians. Disseminating evidence-based information has the potential of not only containing costs, but improving the quality of health care. The report recommends encouraging academic detailing programs by amending BME regulations to require that physicians obtain a certain percentage of required CME credits from courses un-subsidized by industry. The

report also recommends that the State pursue grants that could be used to introduce academic detailing programs in some DHSS regulated venues.