S T A T E O F N E W Y O R K

3156

2009-2010 Regular Sessions

I N S E N A T E

March 12, 2009

Introduced by Sen. MONSERRATE -- read twice and ordered printed, and when printed to be committed to the Committee on Consumer Protection

AN ACT to amend the general business law, in relation to disclosure of certain gifts provided by pharmaceutical manufacturers or medical device manufacturers to health care providers

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. The general business law is amended by adding a new article 38-B to read as follows:

ARTICLE 38-B

PHARMACEUTICAL MANUFACTURERS AND MEDICAL DEVICE MANUFACTURERS; DISCLOSURE

SECTION 825. DEFINITIONS.
826. DISCLOSURE REQUIREMENTS.
827. PENALTIES.
828. RULES AND REGULATIONS.

S 825. DEFINITIONS. AS USED IN THIS ARTICLE, THE FOLLOWING TERMS SHALL HAVE THE FOLLOWING MEANINGS:

1. "PHARMACEUTICAL MANUFACTURER" SHALL MEAN A PERSON WHO COMPOUNDS, MIXES, PREPARES, PRODUCES AND BOTTLES OR PACKS DRUGS FOR THE PURPOSE OF DISTRIBUTING OR SELLING TO PHARMACIES OR TO OTHER CHANNELS OF DISTRIBUTION.

2. "MEDICAL DEVICE MANUFACTURER" SHALL MEAN A PERSON WHO MANUFACTURERS AND PACKS, FOR THE PURPOSE OF DISTRIBUTING OR SELLING TO HEALTH CARE PROVIDERS OR TO OTHER CHANNELS OF DISTRIBUTION:

(A) ANY INSTRUMENT, APPARATUS, IMPLEMENT, MACHINE, CONTRIVANCE, IMPLANT, IN VITRO REAGENT, OR OTHER SIMILAR OR RELATED ARTICLE, INCLUDING A COMPONENT PART, OR ACCESSORY WHICH IS INTENDED FOR USE IN THE DIAGNOSIS OF DISEASE OR OTHER CONDITIONS, OR IN THE CURE, MITIGATION, TREATMENT, OR PREVENTION OF DISEASE; OR

EXPLANATION--Matter in ITALICS (underscored) is new; matter in brackets [ ] is old law to be omitted.

LBD10135-02-9

(B) INTENDED TO AFFECT THE STRUCTURE OR ANY FUNCTION OF THE BODY, AND WHICH DOES NOT ACHIEVE ANY OF ITS PRIMARY INTENDED PURPOSES THROUGH CHEMICAL ACTION WITHIN OR ON THE BODY OF A PERSON AND WHICH IS NOT DEPENDENT UPON BEING METABOLIZED FOR THE ACHIEVEMENT OF ANY OF ITS PRIMARY INTENDED PURPOSES.

S 826. DISCLOSURE REQUIREMENTS. 1. ANY PHARMACEUTICAL MANUFACTURER OR MEDICAL DEVICE MANUFACTURER, INCLUDING ANY EMPLOYEE OR AGENT OF SUCH MANUFACTURER, THAT MAKES ANY GIFT, WHETHER IN THE FORM OF MONEY, SERVICE, LOAN, TRAVEL, ENTERTAINMENT, HOSPITALITY, THING OR PROMISE, OR IN ANY OTHER FORM, TO A HEALTH CARE PROVIDER SHALL REPORT THE GIFT TO THE COMMISSIONER OF HEALTH IN THE MANNER SET FORTH IN SUBDIVISION TWO OF THIS SECTION.

2. ANY PHARMACEUTICAL MANUFACTURER OR MEDICAL DEVICE MANUFACTURER WHO MAKES AT LEAST ONE GIFT UNDER SUBDIVISION ONE OF THIS SECTION SHALL, ON OR BEFORE JUNE FIRST, FILE WITH THE COMMISSIONER OF HEALTH AN ANNUAL REPORT, OF ALL GIFTS MADE BY SUCH MANUFACTURER TO SUCH HEALTH CARE PROVIDER.

3. SUCH ANNUAL REPORT SHALL CONTAIN:

(A) THE NAME, ADDRESS AND TELEPHONE NUMBER OF THE PHARMACEUTICAL MANUFACTURER OR MEDICAL DEVICE MANUFACTURER;

(B) AN ITEMIZED LIST CONTAINING A DESCRIPTION OF EACH GIFT SUBJECT TO THE PROVISIONS OF SUBDIVISION ONE OF THIS SECTION;

(C) THE NAME, ADDRESS AND TELEPHONE NUMBER OF THE HEALTH CARE PROVIDER WHO RECEIVED EACH GIFT;

(D) THE MONETARY VALUE OF EACH GIFT; AND

(E) SUCH OTHER INFORMATION AS IS DEEMED NECESSARY BY THE COMMISSIONER OF HEALTH FOR COMPLIANCE WITH THIS ARTICLE.

4. THE FOLLOWING SHALL BE EXEMPT FROM DISCLOSURE:

(A) THE PAYMENT OF REASONABLE COMPENSATION AND REIMBURSEMENT OF EXPENSES IN CONNECTION WITH BONA FIDE CLINICAL TRIALS;

(B) ANY GIFT THE VALUE OF WHICH IS LESS THAN SEVENTY-FIVE DOLLARS;

(C) SCHOLARSHIP OR OTHER SUPPORT FOR MEDICAL STUDENTS, RESIDENTS AND FELLOWS TO ATTEND A SIGNIFICANT EDUCATIONAL, SCIENTIFIC, OR POLICY-MAKING CONFERENCE OF A NATIONAL, REGIONAL, OR SPECIALITY MEDICAL OR OTHER PROFESSIONAL ASSOCIATION IF THE RECIPIENT OF THE SCHOLARSHIP OR OTHER SUPPORT IS SELECTED BY THE ASSOCIATION;

(D) UNRESTRICTED GRANTS FOR CONTINUING MEDICAL EDUCATION PROGRAM;S

(E) PRESCRIPTION DRUG REBATES AND DISCOUNTS; AND

(F) FREE SAMPLES OF DRUGS.

S 827. PENALTIES. 1. THE COMMISSIONER OF HEALTH MAY IMPOSE A CIVIL PENALTY FOR FAILURE TO FILE A TIMELY REPORT AS REQUIRED BY THIS ARTICLE IN AN AMOUNT UP TO FIFTY DOLLARS A DAY UNTIL SUCH REPORT IS FILED OR THREE THOUSAND DOLLARS, WHICHEVER IS LESS.

2. ANY PERSON WHO VIOLATES ANY OTHER PROVISION OF THIS ARTICLE SHALL BE SUBJECT TO A CIVIL PENALTY IN AN AMOUNT NOT TO EXCEED THREE THOUSAND DOLLARS FOR EACH VIOLATION.

S 828. RULES AND REGULATIONS. THE COMMISSIONER OF HEALTH IS AUTHORIZED TO PROMULGATE RULES AND REGULATIONS AS DEEMED NECESSARY TO CARRY OUT AND ENFORCE THE PROVISIONS OF THIS ARTICLE.

S 2. This act shall take effect on the first of January next succeeding the date on which it shall have become a law.