Second Regular Session
Sixty-seventh General Assembly
STATE OF COLORADO

PREAMENDED

This Unofficial Version Includes Committee Amendments Not Yet Adopted on Second Reading

LLS NO. 10-0027.01 Christy Chase **SENATE BILL 10-126**

SENATE SPONSORSHIP

Carroll M.,

HOUSE SPONSORSHIP

Tyler,

Senate Committees
Health and Human Services
Appropriations

House Committees

A BILL FOR AN ACT

CONCERNING INCREASED TRANSPARENCY REPORTING REQUIREMENTS FOR CERTAIN PHARMACEUTICAL MANUFACTURERS.

Bill Summary

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at http://www.leg.state.co.us/billsummaries.)

The bill enacts the "Pharmaceutical Transparency Act" (act), to be administered by the secretary of state (secretary). The act, which is modeled on the federal "Physician Payments Sunshine Act of 2009" pending in the United States congress, requires manufacturers of a drug, medical device, biological product, or medical supply for which payment

is available under the state medicaid program or the children's basic health plan to submit an annual transparency report to the secretary. The transparency report, due March 31, 2011, and each March 31 thereafter, is to detail information regarding payments or other transfers of value made by the manufacturer to a health care practitioner during the immediately preceding calendar year. Specifically, the bill requires information as to the name, address, and other identifying information of the health care practitioner, and the value, dates, and description of the form and nature of the payment or transfer of value.

Like the pending federal legislation, the bill would also require manufacturers to disclose information pertaining to ownership or investment interests held by a health care practitioner in the manufacturer, detailing the dollar amount invested, the value and terms of the interest, and payments or other transfers of value provided to the health care practitioner.

The bill imposes an additional transparency requirement, not contained in the federal proposal, obligating a manufacturer to disclose whether or not it has adopted procedures to assure adherence to the code of interactions with healthcare professionals (code) adopted by the pharmaceuticals trade group known as "pharmaceutical research and manufacturers of America" (PhRMA). A manufacturer would also have to disclose whether it: Has publicly announced its commitment to abide by the code; completes an annual certification of its policies to ensure compliance; and is identified by PhRMA on a public web site as a manufacturer that has committed to abide by the code.

The bill authorizes the secretary to impose fines on a manufacturer for failure to comply with the reporting requirements of the act. The fines may be between $1,000 and $10,000 for each payment or transfer of value not reported, not to exceed an aggregate fine of $150,000 per calendar year, and in the case of knowing violations, between $10,000 and $100,000 for each payment or transfer of value not reported, not to exceed an aggregate fine of $1,000,000 in any calendar year.

The bill requires the secretary to adopt rules to establish reporting procedures and a method for making the reported information available to the public through a searchable web site. The secretary is also required, by rule, to establish fees to be imposed on reporting manufacturers to cover the secretary's direct and indirect costs to administer the act. The fees and any fines imposed on manufacturers are to be deposited in the department of state cash fund and are to be available, subject to appropriation by the general assembly, to the secretary for use in administering the act.

Finally, the act obligates the secretary to submit an annual report to the governor and the general assembly by May 1, 2011, and each May 1 thereafter, analyzing the data submitted by manufacturers that year.

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. Article 21 of title 24, Colorado Revised Statutes, is amended BY THE ADDITION OF A NEW PART to read:

PART 4

PHARMACEUTICAL TRANSPARENCY

24-21-401. Short title. THIS PART 4 SHALL BE KNOWN AND MAY BE CITED AS THE "PHARMACEUTICAL TRANSPARENCY ACT".

24-21-402. Definitions. AS USED IN THIS PART 4, UNLESS THE CONTEXT OTHERWISE REQUIRES:

(1) "CLINICAL INVESTIGATION" MEANS ANY EXPERIMENT INVOLVING ONE OR MORE HUMAN SUBJECTS, OR MATERIALS DERIVED FROM HUMAN SUBJECTS, IN WHICH A DRUG OR DEVICE IS ADMINISTERED, DISPENSED, OR USED.

(2) "COVERED DRUG, MEDICAL DEVICE, BIOLOGICAL PRODUCT, OR MEDICAL SUPPLY" MEANS ANY DRUG, AS DEFINED IN SECTION 12-22-102, C.R.S., MEDICAL DEVICE, BIOLOGICAL PRODUCT, OR MEDICAL SUPPLY FOR WHICH PAYMENT IS AVAILABLE UNDER A STATE HEALTH PROGRAM.

(3) (a) "GROUP PURCHASING ORGANIZATION" MEANS AN ORGANIZATION THAT PURCHASES, ARRANGES FOR, OR NEGOTIATES THE PURCHASE OF A COVERED DRUG, MEDICAL DEVICE, BIOLOGICAL PRODUCT, OR MEDICAL SUPPLY THAT HAS BEEN APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

(b) "GROUP PURCHASING ORGANIZATION" MEANS AN ORGANIZATION THAT ENGAGES IN THE ACTIVITIES DESCRIBED IN PARAGRAPH (a) OF THIS SUBSECTION (3) IN CONNECTION WITH A COVERED DRUG, MEDICAL DEVICE, BIOLOGICAL PRODUCT, OR MEDICAL SUPPLY THAT

IS APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION ON OR AFTER THE EFFECTIVE DATE OF THIS PART 4, AND SUCH GROUP PURCHASING ORGANIZATION SHALL BE SUBJECT TO THE REPORTING REQUIREMENTS OF THIS PART 4 ONE YEAR AFTER THE YEAR IN WHICH APPROVAL FROM THE UNITED STATES FOOD AND DRUG ADMINISTRATION IS OBTAINED.

(4) (a) "HEALTH CARE PRACTITIONER" MEANS A PERSON WHO IS AUTHORIZED BY LAW TO PRESCRIBE A COVERED DRUG, MEDICAL DEVICE, BIOLOGICAL PRODUCT, OR MEDICAL SUPPLY FOR AN INDIVIDUAL AND WHO IS LICENSED IN COLORADO TO PROVIDE, OR IS OTHERWISE LAWFULLY PROVIDING, HEALTH CARE TO INDIVIDUALS IN THIS STATE.

(b) "HEALTH CARE PRACTITIONER" INCLUDES A PARTNERSHIP OR CORPORATION MADE UP OF THE PRESCRIBING HEALTH CARE PRACTITIONER AND AN OFFICER, EMPLOYEE, AGENT, OR CONTRACTOR OF THE PRESCRIBING HEALTH CARE PRACTITIONER ACTING IN THE COURSE AND SCOPE OF EMPLOYMENT, AGENCY, OR CONTRACT RELATED TO OR SUPPORTIVE OF THE PROVISION OF HEALTH CARE TO INDIVIDUALS.

(5) "IMMEDIATE FAMILY MEMBER" MEANS, WITH RESPECT TO A PERSON:

(a) A SPOUSE, PARENT, BROTHER, SISTER, OR CHILD OF THE PERSON, OR AN INDIVIDUAL TO WHOM THAT PERSON STANDS IN LOCO PARENTIS; OR

(b) ANY OTHER PERSON LIVING IN THE HOUSEHOLD OF THAT PERSON AND RELATED TO THAT PERSON BY BLOOD OR MARRIAGE.

(6) (a) "MANUFACTURER" MEANS A PERSON WHO ENGAGES IN THE PRODUCTION, PREPARATION, PROPAGATION, COMPOUNDING, CONVERSION, PROCESSING, MARKETING, OR DISTRIBUTION OF A COVERED DRUG,

MEDICAL DEVICE, BIOLOGICAL PRODUCT, OR MEDICAL SUPPLY THAT HAS BEEN APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

(b) "MANUFACTURER" INCLUDES A PERSON WHO ENGAGES IN THE ACTIVITIES DESCRIBED IN PARAGRAPH (a) OF THIS SUBSECTION (6) IN CONNECTION WITH A COVERED DRUG, MEDICAL DEVICE, BIOLOGICAL PRODUCT, OR MEDICAL SUPPLY THAT IS APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION ON OR AFTER THE EFFECTIVE DATE OF THIS PART 4, AND SUCH MANUFACTURER SHALL BE SUBJECT TO THE REPORTING REQUIREMENTS OF THIS PART 4 ONE YEAR AFTER THE YEAR IN WHICH APPROVAL FROM THE UNITED STATES FOOD AND DRUG ADMINISTRATION IS OBTAINED.

(c) "MANUFACTURER" DOES NOT MEAN A PERSON WHO ENGAGES IN THE ACTIVITIES DESCRIBED IN PARAGRAPH (a) OF THIS SUBSECTION (6) FOR THE USE, DISTRIBUTION, OR RESALE OF A COVERED DRUG, MEDICAL DEVICE, BIOLOGICAL PRODUCT, OR MEDICAL SUPPLY WITHIN ITS OWN PHARMACIES OR HEALTH CARE FACILITIES OR PRESCRIPTION DRUG OUTLETS AS DEFINED IN SECTION 12-22-102, C.R.S.

(7) "MEDICAL DEVICE" MEANS AN INSTRUMENT, APPARATUS, IMPLEMENT, MACHINE, CONTRIVANCE, IMPLANT, IN VITRO REAGENT, OR OTHER SIMILAR OR RELATED ARTICLE, INCLUDING ANY COMPONENT, PART, OR ACCESSORY, THAT IS ELIGIBLE FOR PAYMENT OR REIMBURSEMENT UNDER A STATE HEALTH PROGRAM.

(8) (a) (I) "PAYMENT OR OTHER TRANSFER OF VALUE" MEANS A TRANSFER OF ANYTHING OF VALUE AND INCLUDES, WITHOUT LIMITATION, ANY COMPENSATION, GIFT, HONORARIUM, SPEAKING FEE, CONSULTING FEE, TRAVEL, SERVICE, DIVIDEND, PROFIT DISTRIBUTION, STOCK OR STOCK

OPTION GRANT, OR OWNERSHIP OR INVESTMENT INTEREST.

(II) "PAYMENT OR OTHER TRANSFER OF VALUE" DOES NOT INCLUDE A TRANSFER OF ANYTHING OF VALUE THAT IS MADE INDIRECTLY TO A HEALTH CARE PRACTITIONER THROUGH A THIRD PARTY, OTHER THAN THE APPLICABLE MANUFACTURER, IN CONNECTION WITH AN ACTIVITY OR SERVICE IN THE CASE WHERE THE APPLICABLE MANUFACTURER IS UNAWARE OF THE IDENTITY OF THE HEALTH CARE PRACTITIONER.

(b) "PAYMENT OR OTHER TRANSFER OF VALUE" DOES NOT INCLUDE THE FOLLOWING:

(I) A PAYMENT OR OTHER TRANSFER OF VALUE PROVIDED BY A MANUFACTURER TO A HEALTH CARE PRACTITIONER WHERE THE AGGREGATE AMOUNT TRANSFERRED TO, REQUESTED BY, OR DESIGNATED ON BEHALF OF THE HEALTH CARE PRACTITIONER DOES NOT EXCEED ONE HUNDRED DOLLARS DURING A SINGLE CALENDAR YEAR, EXCLUDING THOSE PAYMENTS OF OTHER TRANSFERS OF VALUE DESCRIBED IN SUBPARAGRAPHS (II) TO (IX) OF THIS PARAGRAPH (b);

(II) PRODUCT SAMPLES THAT ARE NOT INTENDED TO BE SOLD AND ARE INTENDED FOR PATIENT USE;

(III) EDUCATIONAL MATERIALS THAT DIRECTLY BENEFIT PATIENTS OR ARE INTENDED FOR PATIENT USE;

(IV) THE LOAN OF A COVERED MEDICAL DEVICE FOR A SHORT-TERM TRIAL PERIOD, NOT TO EXCEED NINETY DAYS, TO PERMIT EVALUATION OF THE COVERED DEVICE BY THE HEALTH CARE PRACTITIONER;

(V) ITEMS OR SERVICES PROVIDED UNDER A CONTRACTUAL WARRANTY, INCLUDING THE REPLACEMENT OF A COVERED MEDICAL DEVICE, WHERE THE TERMS OF THE WARRANTY ARE SET FORTH IN THE

PURCHASE OR LEASE AGREEMENT FOR THE COVERED MEDICAL DEVICE;

(VI) A TRANSFER OF ANYTHING OF VALUE TO A HEALTH CARE PRACTITIONER WHEN THE HEALTH CARE PRACTITIONER IS A PATIENT AND IS NOT ACTING IN A PROFESSIONAL CAPACITY AS A HEALTH CARE PRACTITIONER;

(VII) DISCOUNTS, INCLUDING REBATES;

(VIII) IN-KIND ITEMS USED FOR THE PROVISION OF CHARITY CARE; OR

(IX) A DIVIDEND OR OTHER PROFIT DISTRIBUTION FROM, OR OWNERSHIP OR INVESTMENT INTEREST IN, A PUBLICLY TRADED SECURITY AND MUTUAL FUND, AS DESCRIBED IN 42 U.S.C. SEC. 1395nn (c).

(9) "PERSON" MEANS AN INDIVIDUAL, BUSINESS, CORPORATION, UNION, ASSOCIATION, FIRM, PARTNERSHIP, COMMITTEE, OR OTHER ORGANIZATION OR GROUP OF PERSONS.

(10) "SECRETARY" MEANS THE COLORADO SECRETARY OF STATE.

(11) "STATE HEALTH PROGRAM" MEANS A PROGRAM IN WHICH THE STATE REIMBURSES FOR DRUGS, AS DEFINED IN SECTION 12-22-102, C.R.S., MEDICAL DEVICES, BIOLOGICAL PRODUCTS, OR MEDICAL SUPPLIES. "STATE HEALTH PROGRAM" INCLUDES A PROGRAM OF MEDICAL ASSISTANCE UNDER THE "COLORADO MEDICAL ASSISTANCE ACT", ARTICLES 4 TO 6 OF TITLE 25.5, C.R.S., AND THE CHILDREN'S BASIC HEALTH PLAN, AS DEFINED IN ARTICLE 8 OF TITLE 25.5, C.R.S.

24-21-403. Transparency reports - payments or other transfers of value - adherence to code - delayed reporting for product development or clinical investigation payments. (1) EXCEPT AS PROVIDED IN SUBSECTION (5) OF THIS SECTION, ON MARCH 31, 2011, AND ON EACH MARCH 31 THEREAFTER, A MANUFACTURER THAT PROVIDES A

PAYMENT OR OTHER TRANSFER OF VALUE TO A HEALTH CARE PRACTITIONER, OR TO AN ENTITY OR INDIVIDUAL AT THE REQUEST OF OR DESIGNATED ON BEHALF OF A HEALTH CARE PRACTITIONER, SHALL SUBMIT TO THE SECRETARY, IN A FORM AS PRESCRIBED BY THE SECRETARY, THE FOLLOWING INFORMATION REGARDING SUCH PAYMENTS OR OTHER TRANSFERS OF VALUE PROVIDED DURING THE PRIOR CALENDAR YEAR:

(a) THE NAME OF THE HEALTH CARE PRACTITIONER;

(b) THE BUSINESS ADDRESS OF THE HEALTH CARE PRACTITIONER AND, IN THE CASE OF A HEALTH CARE PRACTITIONER WHO IS AN INDIVIDUAL, THE HEALTH CARE PRACTITIONER'S AREA OF PRACTICE, SPECIALTY, IF ANY, AND STATE LICENSE NUMBER;

(c) THE VALUE OF THE PAYMENT OR OTHER TRANSFER OF VALUE;

(d) THE DATE ON WHICH THE PAYMENT OR OTHER TRANSFER OF VALUE WAS PROVIDED TO THE HEALTH CARE PRACTITIONER;

(e) A DESCRIPTION OF THE FORM OF THE PAYMENT OR OTHER TRANSFER OF VALUE, INDICATED, AS APPROPRIATE FOR ALL THAT APPLY, AS:

(I) CASH OR A CASH EQUIVALENT;

(II) IN-KIND ITEMS OR SERVICES;

(III) STOCK, A STOCK OPTION, OR ANY OTHER OWNERSHIP INTEREST, DIVIDEND, PROFIT, OR OTHER RETURN ON INVESTMENT; OR

(IV) ANY OTHER FORM OF PAYMENT OR OTHER TRANSFER OF VALUE, AS DEFINED BY THE SECRETARY;

(f) A DESCRIPTION OF THE NATURE OF THE PAYMENT OR OTHER TRANSFER OF VALUE, INDICATED, AS APPROPRIATE FOR ALL THAT APPLY, AS:

(I) CONSULTING FEES;

(II) COMPENSATION FOR SERVICES OTHER THAN CONSULTING;

(III) HONORARIA;

(IV) GIFTS;

(V) ENTERTAINMENT;

(VI) FOOD;

(VII) TRAVEL;

(VIII) EDUCATION;

(IX) RESEARCH;

(X) CHARITABLE CONTRIBUTIONS;

(XI) ROYALTIES OR LICENSES;

(XII) CURRENT OR PROSPECTIVE OWNERSHIP OR INVESTMENT INTERESTS;

(XIII) COMPENSATION FOR SERVING AS FACULTY OR AS A SPEAKER FOR A CONTINUING MEDICAL EDUCATION PROGRAM;

(XIV) GRANTS; OR

(XV) ANY OTHER NATURE OF PAYMENT OR OTHER TRANSFER OF VALUE, AS DEFINED BY THE SECRETARY;

(g) IF THE PAYMENT OR OTHER TRANSFER OF VALUE IS RELATED TO MARKETING, EDUCATION, OR RESEARCH SPECIFIC TO A COVERED DRUG, MEDICAL DEVICE, BIOLOGICAL PRODUCT, OR MEDICAL SUPPLY, THE NAME OF THAT COVERED DRUG, MEDICAL DEVICE, BIOLOGICAL PRODUCT, OR MEDICAL SUPPLY; AND

(h) ANY OTHER CATEGORIES OF INFORMATION REGARDING THE PAYMENT OR OTHER TRANSFER OF VALUE THE SECRETARY DETERMINES APPROPRIATE.

(2) A MANUFACTURER REPORTING INFORMATION PURSUANT TO SUBSECTION (1) OF THIS SECTION SHALL INCLUDE THE AGGREGATE

AMOUNT OF ALL PAYMENTS OR OTHER TRANSFERS OF VALUE THAT THE MANUFACTURER PROVIDED DURING THE PRIOR CALENDAR YEAR TO HEALTH CARE PRACTITIONERS AND TO ENTITIES OR INDIVIDUALS AT THE REQUEST OF OR DESIGNATED ON BEHALF OF A HEALTH CARE PRACTITIONER.

(3) WHEN A MANUFACTURER PROVIDES A PAYMENT OR OTHER TRANSFER OF VALUE TO AN ENTITY OR INDIVIDUAL AT THE REQUEST OF OR DESIGNATED ON BEHALF OF A HEALTH CARE PRACTITIONER, THE MANUFACTURER SHALL DISCLOSE THE PAYMENT OR OTHER TRANSFER OF VALUE UNDER THE NAME OF THE HEALTH CARE PRACTITIONER REQUESTING OR DESIGNATING THE ENTITY OR INDIVIDUAL.

(4) IN ADDITION TO THE INFORMATION REQUIRED TO BE REPORTED UNDER SUBSECTION (1) OF THIS SECTION, A MANUFACTURER SHALL DISCLOSE WHETHER THE MANUFACTURER:

(a) HAS ADOPTED PROCEDURES TO ASSURE ADHERENCE TO OR COMPLIANCE WITH ONE OF THE FOLLOWING CODES, AS APPLICABLE:

(I) THE CODE OF INTERACTIONS WITH HEALTHCARE PROFESSIONALS, EFFECTIVE JANUARY 2009, OR ITS SUCCESSOR CODE (CODE), ADOPTED BY THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA), OR ITS SUCCESSOR ORGANIZATION, INCLUDING PROCEDURES TO ENSURE ADHERENCE WITH THE PROHIBITION AGAINST PROVIDING GIFTS OR OTHER ITEMS FOR HEALTH CARE PRACTITIONERS' USE THAT DO NOT ADVANCE DISEASE OR TREATMENT EDUCATION;

(II) THE CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS, REVISED AND RESTATED, EFFECTIVE JULY 1, 2009, OR ITS SUCCESSOR CODE, ADOPTED BY THE ADVANCED MEDICAL TECHNOLOGY

ASSOCIATION (ADVAMED), OR ITS SUCCESSOR ASSOCIATION, INCLUDING PROCEDURES TO ENSURE EFFECTIVE COMPLIANCE WITH THE CODE; OR

(III) THE REVISED CODE OF CONDUCT ON INTERACTIONS WITH HEALTH CARE PROVIDERS, ADOPTED JULY 1, 2009, OR ITS SUCCESSOR CODE, ADOPTED BY THE MEDICAL DEVICE MANUFACTURERS ASSOCIATION (MDMA), OR ITS SUCCESSOR ASSOCIATION, INCLUDING IMPLEMENTATION OF AN EFFECTIVE COMPLIANCE PROGRAM.

(b) HAS PUBLICLY ANNOUNCED ITS COMMITMENT TO ABIDE BY THE APPLICABLE CODE AND COMPLETES AN ANNUAL CERTIFICATION OF ITS POLICIES TO ENSURE SUCH COMPLIANCE; AND

(c) IS IDENTIFIED BY PHRMA, ADVAMED, OR MDMA, ON A PUBLIC WEB SITE, OR IS SELF-IDENTIFIED ON ITS OWN WEB SITE, AS A MANUFACTURER THAT HAS COMMITTED TO ABIDE BY THE APPLICABLE CODE.

(5) IN THE CASE OF A PAYMENT OR OTHER TRANSFER OF VALUE MADE TO A HEALTH CARE PRACTITIONER BY A MANUFACTURER PURSUANT TO A PRODUCT DEVELOPMENT AGREEMENT FOR SERVICES FURNISHED IN CONNECTION WITH THE DEVELOPMENT OF A NEW DRUG, MEDICAL DEVICE, BIOLOGICAL PRODUCT, OR MEDICAL SUPPLY, OR BY A MANUFACTURER IN CONNECTION WITH A CLINICAL INVESTIGATION, THE MANUFACTURER MAY REPORT THE VALUE OF SUCH PAYMENT OR OTHER TRANSFER OF VALUE IN THE FIRST REPORTING PERIOD UNDER SUBSECTION (1) OF THIS SECTION AFTER THE EARLIER OF THE FOLLOWING:

(a) THE DATE OF APPROVAL OR CLEARANCE OF THE COVERED DRUG, MEDICAL DEVICE, BIOLOGICAL PRODUCT, OR MEDICAL SUPPLY BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION; OR

(b) TWO CALENDAR YEARS AFTER THE DATE THE PAYMENT OR

OTHER TRANSFER OF VALUE WAS MADE.

(6) A MANUFACTURER THAT DISCLOSES THE INFORMATION REQUIRED BY THIS SECTION, OR SUBSTANTIALLY SIMILAR INFORMATION, ON ITS WEB SITE COMPLIES WITH THIS SECTION IF THE MANUFACTURER PROVIDES TO THE SECRETARY, BY MARCH 31, 2011, AND BY EACH MARCH 31 THEREAFTER, A CURRENT, FUNCTIONING LINK TO THE INFORMATION ON ITS WEB SITE.

24-21-404. Reporting ownership interests. (1) IN ADDITION TO THE REPORTING REQUIREMENTS UNDER SECTION 24-21-403, ON MARCH 31, 2011, AND ON EACH MARCH 31 THEREAFTER, A MANUFACTURER OR GROUP PURCHASING ORGANIZATION SHALL SUBMIT TO THE SECRETARY, IN THE FORM DETERMINED BY THE SECRETARY, THE FOLLOWING INFORMATION REGARDING ANY OWNERSHIP OR INVESTMENT INTEREST HELD BY A HEALTH CARE PRACTITIONER, OR IMMEDIATE FAMILY MEMBER OF A HEALTH CARE PRACTITIONER, IN THE MANUFACTURER OR GROUP PURCHASING ORGANIZATION DURING THE PRIOR CALENDAR YEAR:

(a) THE DOLLAR AMOUNT INVESTED BY EACH HEALTH CARE PRACTITIONER HOLDING AN OWNERSHIP OR INVESTMENT INTEREST;

(b) THE VALUE AND TERMS OF EACH OWNERSHIP OR INVESTMENT INTEREST;

(c) ANY PAYMENT OR OTHER TRANSFER OF VALUE PROVIDED TO A HEALTH CARE PRACTITIONER HOLDING AN OWNERSHIP OR INVESTMENT INTEREST, OR PROVIDED TO AN ENTITY OR INDIVIDUAL AT THE REQUEST OF OR DESIGNATED ON BEHALF OF A HEALTH CARE PRACTITIONER HOLDING THE OWNERSHIP OR INVESTMENT INTEREST, INCLUDING THE INFORMATION DESCRIBED IN SECTION 24-21-403 (1) (a) TO (1) (h); AND

(d) ANY OTHER INFORMATION REGARDING THE OWNERSHIP OR

INVESTMENT INTEREST THE SECRETARY DETERMINES APPROPRIATE.

(2) A MANUFACTURER IS NOT REQUIRED TO SUBMIT THE INFORMATION REQUIRED IN SUBSECTION (1) OF THIS SECTION IF THE OWNERSHIP OR INVESTMENT INTEREST IS IN A PUBLICLY TRADED SECURITY AND MUTUAL FUND, AS DESCRIBED IN 42 U.S.C. SEC. 1395nn (c).

(3) A MANUFACTURER OR GROUP PURCHASING ORGANIZATION THAT DISCLOSES THE INFORMATION REQUIRED BY THIS SECTION, OR SUBSTANTIALLY SIMILAR INFORMATION, ON ITS WEB SITE COMPLIES WITH THIS SECTION IF THE MANUFACTURER OR GROUP PURCHASING ORGANIZATION PROVIDES TO THE SECRETARY, BY MARCH 31, 2011, AND BY EACH MARCH 31 THEREAFTER, A CURRENT, FUNCTIONING LINK TO THE INFORMATION ON ITS WEB SITE.

24-21-405. Penalties for noncompliance. (1) EXCEPT AS PROVIDED IN SUBSECTION (2) OF THIS SECTION, ANY MANUFACTURER OR GROUP PURCHASING ORGANIZATION THAT FAILS TO SUBMIT INFORMATION AS REQUIRED UNDER SECTIONS 24-21-403 AND 24-21-404 IN A TIMELY MANNER SHALL BE SUBJECT TO A FINE OF NOT LESS THAN ONE THOUSAND DOLLARS, BUT NOT MORE THAN TEN THOUSAND DOLLARS, FOR EACH PAYMENT OR OTHER TRANSFER OF VALUE OR OWNERSHIP OR INVESTMENT INTEREST NOT REPORTED. THE TOTAL AMOUNT OF ANY FINE IMPOSED AGAINST A MANUFACTURER OR GROUP PURCHASING ORGANIZATION PURSUANT TO THIS SUBSECTION (1) WITH RESPECT TO EACH ANNUAL SUBMISSION OF INFORMATION REQUIRED BY SECTIONS 24-21-403 AND 24-21-404 SHALL NOT EXCEED ONE HUNDRED FIFTY THOUSAND DOLLARS IN ANY ONE CALENDAR YEAR.

(2) ANY MANUFACTURER OR GROUP PURCHASING ORGANIZATION THAT KNOWINGLY FAILS TO SUBMIT INFORMATION AS REQUIRED UNDER

SECTIONS 24-21-403 AND 24-21-404 IN A TIMELY MANNER SHALL BE SUBJECT TO A FINE OF NOT LESS THAN TEN THOUSAND DOLLARS, BUT NOT MORE THAN ONE HUNDRED THOUSAND DOLLARS, FOR EACH PAYMENT OR OTHER TRANSFER OF VALUE OR OWNERSHIP OR INVESTMENT INTEREST NOT REPORTED. THE TOTAL AMOUNT OF ANY FINE IMPOSED AGAINST A MANUFACTURER OR GROUP PURCHASING ORGANIZATION PURSUANT TO THIS SUBSECTION (2) WITH RESPECT TO EACH ANNUAL SUBMISSION OF INFORMATION REQUIRED BY SECTIONS 24-21-403 AND 24-21-404 SHALL NOT EXCEED ONE MILLION DOLLARS IN ANY ONE CALENDAR YEAR.

(3) IF A MANUFACTURER OR GROUP PURCHASING ORGANIZATION DISPUTES A FINE IMPOSED PURSUANT TO SUBSECTION (1) OR (2) OF THIS SECTION, THE SECRETARY OF STATE SHALL CONDUCT A HEARING IN ACCORDANCE WITH SECTION 24-4-105, AND THE FINAL DECISION SHALL BE SUBJECT TO JUDICIAL REVIEW IN ACCORDANCE WITH SECTION 24-4-106.

(4) FINES IMPOSED AND COLLECTED PURSUANT TO THIS SECTION SHALL BE DEPOSITED IN THE DEPARTMENT OF STATE CASH FUND CREATED IN SECTION 24-21-104 (3) (b) AND SHALL BE AVAILABLE FOR APPROPRIATION BY THE GENERAL ASSEMBLY TO THE DEPARTMENT OF STATE FOR THE PURPOSE OF CARRYING OUT THE SECRETARY'S RESPONSIBILITIES UNDER THIS PART 4.

24-21-406. Rules - procedures to submit information - public access to information. (1) AS SOON AS PRACTICABLE, THE SECRETARY SHALL ADOPT RULES THAT:

(a) ESTABLISH PROCEDURES FOR MANUFACTURERS AND GROUP PURCHASING ORGANIZATIONS TO SUBMIT INFORMATION TO THE SECRETARY AS REQUIRED BY SECTIONS 24-21-403 AND 24-21-404 IN AN ELECTRONIC FORMAT IN ACCORDANCE WITH SECTION 24-21-111.

(b) (I) ESTABLISH PROCEDURES FOR THE SECRETARY TO MAKE THE INFORMATION FILED BY MANUFACTURERS AND GROUP PURCHASING ORGANIZATIONS AVAILABLE TO THE PUBLIC. THESE PROCEDURES SHALL ENSURE THAT, BY A DATE DETERMINED BY THE SECRETARY, THE INFORMATION SUBMITTED PURSUANT TO SECTIONS 24-21-403 AND 24-21-404 REGARDING THE PRIOR CALENDAR YEAR IS MADE AVAILABLE THROUGH A WEB SITE THAT:

(A) IS SEARCHABLE AND IS IN A FORMAT THAT IS CLEAR AND UNDERSTANDABLE;

(B) ALLOWS INFORMATION TO BE ACCESSED AND SEARCHED ACCORDING TO THE VALUE OF THE PAYMENT OR OTHER TRANSFER OF VALUE; THE DATE ON WHICH THE PAYMENT OR OTHER TRANSFER OF VALUE WAS PROVIDED TO THE HEALTH CARE PRACTITIONER; THE FORM OF THE PAYMENT OR OTHER TRANSFER OF VALUE; THE NATURE OF THE PAYMENT OR OTHER TRANSFER OF VALUE; AND THE NAME OF THE COVERED DRUG, MEDICAL DEVICE, BIOLOGICAL PRODUCT, OR MEDICAL SUPPLY;

(C) ALLOWS INFORMATION TO BE EASILY AGGREGATED AND DOWNLOADED;

(D) CONTAINS A DESCRIPTION OF ANY ACTIONS TAKEN TO ENFORCE THE REQUIREMENTS OF THIS PART 4, INCLUDING ANY PENALTIES IMPOSED PURSUANT TO SECTION 24-21-405, DURING THE PRIOR CALENDAR YEAR;

(E) CONTAINS BACKGROUND INFORMATION ON INDUSTRY-HEALTH CARE PRACTITIONER RELATIONSHIPS;

(F) IN THE CASE OF INFORMATION SUBMITTED WITH RESPECT TO A PAYMENT OR OTHER TRANSFER OF VALUE DESCRIBED IN SECTION 24-21-403 (1), LISTS SUCH INFORMATION SEPARATELY FROM THE OTHER

INFORMATION SUBMITTED PURSUANT TO SECTIONS 24-21-403 AND 24-21-404 AND DESIGNATES SUCH SEPARATELY LISTED INFORMATION AS FUNDING FOR CLINICAL RESEARCH;

(G) CONTAINS ANY OTHER INFORMATION THE SECRETARY DETERMINES WOULD BE HELPFUL TO CONSUMERS; AND

(H) PROVIDES A HEALTH CARE PRACTITIONER AN OPPORTUNITY TO SUBMIT CORRECTIONS TO THE INFORMATION MADE AVAILABLE TO THE PUBLIC REGARDING THAT HEALTH CARE PRACTITIONER.

(II) IF THE SECRETARY DETERMINES THAT PROVIDING THE INFORMATION SUBMITTED PURSUANT TO SECTIONS 24-21-403 AND 24-21-404 ON A WEB SITE IN THE MANNER DESCRIBED IN SUB-SUBPARAGRAPHS (B), (C), AND (F) OF SUBPARAGRAPH (I) OF THIS PARAGRAPH (b) IS COST PROHIBITIVE, THE SECRETARY'S PROCEDURES MAY REQUIRE MANUFACTURERS AND GROUP PURCHASING ORGANIZATIONS TO SUBMIT THE REQUIRED INFORMATION IN AN ELECTRONIC, DOWNLOADABLE DOCUMENT THAT THE SECRETARY CAN POST ON THE WEB SITE.

(c) ESTABLISH FEES THAT THE SECRETARY MAY IMPOSE ON MANUFACTURERS AND GROUP PURCHASING ORGANIZATIONS IN CONNECTION WITH FILING REPORTS AS REQUIRED BY THIS PART 4. THE FEES SHALL BE SET AT A LEVEL TO DEFRAY THE DIRECT AND INDIRECT COSTS INCURRED BY THE SECRETARY TO ADMINISTER THIS PART 4. ANY FEES COLLECTED BY THE SECRETARY SHALL BE DEPOSITED IN THE DEPARTMENT OF STATE CASH FUND CREATED IN SECTION 24-21-104 (3) (b) AND SHALL BE AVAILABLE FOR APPROPRIATION BY THE GENERAL ASSEMBLY TO THE DEPARTMENT OF STATE FOR THE PURPOSE OF CARRYING OUT THE SECRETARY'S RESPONSIBILITIES UNDER THIS PART 4.

(d) ADDRESS ANY OTHER MATTERS NECESSARY TO IMPLEMENT,

AND THAT ARE CONSISTENT WITH THE INTENT OF, THIS PART 4.

(2) IN DEVELOPING THE RULES REQUIRED BY THIS SECTION, THE SECRETARY SHALL CONSULT WITH REPRESENTATIVES OF ANY AFFECTED INDUSTRY, HEALTH CARE PRACTITIONERS, CONSUMERS, CONSUMER ADVOCATES, AND OTHER INTERESTED PARTIES AND DEPARTMENTS OR AGENCIES OF GOVERNMENT IN ORDER TO ENSURE THAT THE INFORMATION MADE AVAILABLE TO THE PUBLIC IS PRESENTED IN THE APPROPRIATE OVERALL CONTEXT.

24-21-407. Effect of federal legislation - compliance with part. IF THE UNITED STATES CONGRESS ENACTS AND THE PRESIDENT SIGNS LEGISLATION KNOWN AS THE "PHYSICIAN PAYMENTS SUNSHINE ACT OF 2009" OR SIMILAR LEGISLATION THAT REQUIRES MANUFACTURERS AND GROUP PURCHASING ORGANIZATIONS TO DISCLOSE INFORMATION CONSISTENT WITH OR SIMILAR TO THE INFORMATION REQUIRED BY SECTIONS 24-21-403 AND 24-21-404, A MANUFACTURER OR GROUP PURCHASING ORGANIZATION MAY COMPLY WITH THIS PART 4 BY PROVIDING TO THE SECRETARY BY MARCH 31 OF THE YEAR IN WHICH THE MANUFACTURER OR GROUP PURCHASING ORGANIZATION IS REQUIRED BY THE FEDERAL LEGISLATION TO SUBMIT INFORMATION, AND BY EACH MARCH 31 THEREAFTER, A LINK TO THE WEB SITE ON WHICH THE MANUFACTURER'S OR GROUP PURCHASING ORGANIZATION'S DISCLOSURES ARE AVAILABLE.

24-21-408. Annual report to governor and general assembly. ON OR BEFORE MAY 1, 2011, AND ON OR BEFORE EACH MAY 1 THEREAFTER, THE SECRETARY SHALL REPORT TO THE GOVERNOR AND THE HEALTH AND HUMAN SERVICES COMMITTEES OF THE SENATE AND HOUSE OF REPRESENTATIVES, OR THEIR SUCCESSOR COMMITTEES, AN ANALYSIS

OF THE DATA SUBMITTED TO THE SECRETARY PURSUANT TO THIS PART 4. THE ANALYSIS SHALL INCLUDE INFORMATION ON PAYMENTS OR OTHER TRANSFERS OF VALUE REQUIRED TO BE DISCLOSED PURSUANT TO SECTION 24-21-403, INFORMATION ON OWNERSHIP OR INVESTMENT INTERESTS REPORTED PURSUANT TO SECTION 24-21-404, AND INFORMATION ON ALL VIOLATIONS AND ENFORCEMENT ACTIONS BROUGHT PURSUANT TO THIS PART 4.

SECTION 2. Act subject to petition - effective date. This act shall take effect at 12:01 a.m. on the day following the expiration of the ninety-day period after final adjournment of the general assembly (August 11, 2010, if adjournment sine die is on May 12, 2010); except that, if a referendum petition is filed pursuant to section 1 (3) of article V of the state constitution against this act or an item, section, or part of this act within such period, then the act, item, section, or part shall not take effect unless approved by the people at the general election to be held in November 2010 and shall take effect on the date of the official declaration of the vote thereon by the governor.