

In the Matter of:
Express Scripts, Inc.

ASSURANCE OF VOLUNTARY COMPLIANCE AND DISCONTINUANCE

This Assurance of Voluntary Compliance and Discontinuance ("AVC" or "Assurance") is entered into by the Attorneys General of Arizona, Arkansas, California, Connecticut, Delaware, Florida, Illinois, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nevada, New Mexico, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington and the District of Columbia (referred to collectively as the "Participating States"), acting pursuant to their respective consumer protection statutes,¹ and Express Scripts, Inc., a Delaware corporation, its subsidiaries, successors and assigns, as those terms are defined

¹ ARIZONA – Arizona Consumer Fraud Act, A.R.S. §44-1521 et seq.; ARKANSAS – Deceptive Trade Practices, Ark. Code Ann. § 4-88-101, et seq.; CALIFORNIA – Bus. & Prof Code §§ 17200 et seq. and 17500 et seq.; CONNECTICUT – Unfair "Trade Practices Act, Conn. Gen. Stat. §§ 42-110a et seq.; DELAWARE – Delaware Consumer Fraud Act, Del. CODE ANN. tit. 6, §§ 2511 to 2527; DISTRICT OF COLUMBIA, Consumer Protection Procedures Act, D.C. Code §§ 28-3901 et seq.; - FLORIDA – Florida Deceptive and Unfair Trade Practices Act, Part II, Chapter 501, Florida Statutes, 501.001-501.164, 501.207; ILLINOIS – Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/2 et seq.; IOWA – Consumer Fraud Act, Iowa Code § 714.16; LOUISIANA – Unfair Trade-Practices and Consumer Protection Law, LSA-R.S. 51:1401, et seq.; MARYLAND – Maryland Consumer Protection Act, Md. Code Ann., Com. Law § 13-101, et seq.; MASSACHUSETTS – Mass. Gen. Laws c. 93A, §§ 2 and 4; MICHIGAN – Michigan Consumer Protection Act, MCL §445.901 et seq.; MISSISSIPPI – Mississippi Consumer Protection Act, Miss. Code Ann. § 75-24-1 et seq. (1972 as amended); MISSOURI – MOST § 407.010 to 407.130; MONTANA – Montana Code Annotated 30-14-101 et. al.; NEVADA – Nevada Deceptive Trade Practices Act, Nevada Revised Statutes 598.0903 to 598.0999; NEW MEXICO – NMSA 1978, § 57-12-1 et seq.; NORTH CAROLINA – North Carolina Unfair and Deceptive Trade Practices Act, N.C.G.S. 75-1,1, et seq.; OHIO – Ohio Consumer Sales Practices Act, R.C. 1345.01, et seq.; OREGON – Oregon Unlawful Trade Practices Act, ORS 646.605 et seq.; PENNSYLVANIA – Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. 201-1 et seq.; SOUTH CAROLINA – South Carolina Unfair Trade Practices Act, sections 39-5-10 et seq.; SOUTH DAKOTA – South Dakota Deceptive Trade Practices and Consumer Protection, SD ST 37-24-1, 37-24-6, 37-24-23, 37-24-31, 22-41-10; TENNESSEE – Tennessee Consumer Protection Act, Tenn. Code Ann. 47-18-101 et seq.; TEXAS – Texas Deceptive Trade Practices and Consumer Protection Act, Tex. Bus. And Conn. Code 17.47, et seq.; VERMONT – Consumer Fraud Act, 9 V.S.A. §§ 2451 et seq.; WASHINGTON – Washington Consumer Protection Act, RCW §§ 19.86 et seq.; With regard to Virginia, the document shall be titled "Agreement."

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herein (collectively, "ESI"). This AVC constitutes the documentation effectuating this settlement and is intended to and shall be binding upon the Participating States and ESI (the "Parties") in accordance with the terms hereof.

ESI is a pharmacy benefit manager ("PBM") which administers pharmacy benefit programs for, among other entities, employers and health plans which contract with employers ("Clients"). In order to provide those benefits, ESI contracts with pharmaceutical manufacturers to receive rebates or other payments tied to the utilization of brand drugs. ESI contracts with pharmacies to dispense drugs to the individual members of client plans for whom ESI is providing a drug benefit. ESI also operates its own mail order pharmacies which dispense drugs.

Beginning in March 2003, ESI stated in its "Client Pledge" that it will:

- Always align its interests with those of its clients and members
- Develop clinically sound formularies based on evaluations of independent physicians
- Aggressively promote the use of generic drugs
- Support the use of clinically appropriate, lower-cost brand-name drugs
- Never recommend switching a member to a higher-cost drug
- Provide its clients with a detailed disclosure of its sources of revenue and financial relationships with drug manufacturers
- Always respect the physician's prescribing authority

The Attorneys General contend that not all of ESI's activities in the past have been consistent with its representations to consumers and Client Plans. The Attorneys General contend that ESI may have engaged in or promoted some drug switches which may have resulted in additional medical costs to consumers or ESI's

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Client Plans, and that ESI did not reimburse consumers or Client Plans for these medical costs. The Attorneys General further contend that ESI engaged in drug switches on the grounds that such switches would result in cost savings to Client Plans and consumers when these switches may have actually involved little or no cost savings, before consideration of any rebates to the Client Plans. The Attorneys General contend that in certain instances switches were made to a more expensive drug on an Average Wholesale Price basis. The Attorneys General contend that ESI may have distributed literature and promotional materials which did not adequately disclose the extent to which the literature or promotional materials were funded by drug manufacturers. The Attorneys General also contend that ESI did not adequately define pricing terms used in its Client contracts, such as “rebate” and “MAC.” The Attorneys General also contend that ESI failed to adequately disclose that Phoenix Marketing Group, a subsidiary of ESI since 2002, provided sample fulfillment services to manufacturers for brand drugs which were not always on ESI’s national formularies.

ESI denies that it has engaged in any wrongful or unlawful conduct. ESI does not admit any of the allegations in this AVC. ESI contends that it voluntarily developed and enacted its Client Pledge in 2003 and has made good faith efforts to comply with its terms. ESI contends that it has implemented and continually refined its procedures to ensure that any drug switches were safe and appropriate, and ESI disputes allegations that switches resulted in additional medical costs to consumers or in higher net costs to Clients or consumers. ESI further contends that its

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disclosures to Clients were forthright and disputes that such disclosures were at any point inadequate.

The parties agree as follows:

I. DEFINITIONS

Defined terms include:

“Actual Cost Savings” means, with respect to a proposed Drug Interchange, the actual amount in dollars a Client Plan and Patient, respectively, shall save in Net Drug Costs annually if a Drug Interchange occurs at the expected dosage, assuming the Patient shall use the drug for twelve months.

“AVC” and “Assurance” mean the Assurance of Voluntary Compliance and Discontinuance entered into between ESI and the Participating States.

“Beneficiaries” mean the persons on whose behalf a Client Plan provides pharmacy benefits.

“Clear & Conspicuous” / “Clearly & Conspicuously” mean a disclosure in such size, color, contrast and location, that it is readily noticeable, readable and understandable; is presented in proximity to all information necessary to prevent it from being misleading or deceptive, in a manner that such information is readily noticeable, readable and understandable and not obscured in any manner; and if a print disclosure, it appears in a type size, contrast and location sufficient for a Patient or Prescriber to read and comprehend it. A statement may not contradict or be inconsistent with any other information with which it is presented. If a statement modifies or is necessary to prevent other information from being misleading or

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deceptive, then the statement must be presented in proximity to that information, in a manner that is readily noticeable, readable, and understandable, and is not obscured in any manner. For purposes of this AVC, nothing in this definition shall prevent ESI from disclosing prescription, health and safety information first.

“Client Plan” means any governmental entity, employer, insurer, union or other entity that contracts directly with ESI to provide or administer a pharmacy benefit for such plan and its Beneficiaries.

“Covered Conduct” means the specific conduct covered by this Assurance during the period January 1, 1997 through the Effective Date of this Assurance and includes disclosures related to:

- a) Pricing and cost effectiveness of ESI products;
- b) Rebates and any other remuneration ESI received from pharmaceutical manufacturers for any services provided;
- c) Drug Interchanges;
- d) ESI pharmaceutical and therapeutics committee and formulary development process;
- e) Pharmaceutical ethics breaches, to the extent those breaches violate consumer protection statutes, and compliance by ESI pharmacists with pharmaceutical ethics, to the extent failure to comply would violate consumer protection statutes; and
- f) ESI mail order pharmacy practices involving returned drugs, short-filling, prescription turn-around time, repackaging,

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restocking, chart tagging, and shipment of temperature sensitive drugs.

“Currently Prescribed Drug” means a drug prescribed for a Patient that is the subject of an ESI Drug Interchange Solicitation.

“Drug Interchange” means any change from one branded prescription drug to another branded prescription drug, requested by ESI. “Drug Interchange,” however, shall not include those Drug Interchanges:

- a) initiated pursuant to a Drug Utilization Review;
- b) initiated for Patient safety reasons;
- c) required due to market unavailability of the Currently Prescribed Drug;
- d) from a brand drug to its Generic Equivalent, to any chemical equivalent or to a multi-source brand equivalent; or
- e) required for coverage reasons, that is, where the Currently Prescribed Drug is not covered by the formulary or plan applicable to the Patient.

“Drug Interchange-Related Health Care Costs” mean a Patient’s co-pays for tests, doctor visits, and other health care services that are incurred in accordance with a treating physician’s instructions, and either a) are incurred as a result of a Drug Interchange, for the purpose of assessing the continuum of the previous therapy, for up to six months following a Drug Interchange; or b) are incurred as a result of a Drug Interchange Solicitation, for the purpose of assessing whether to undertake a

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proposed Drug Interchange. With respect to co-pays that may be incurred for purposes of assessing whether to undertake a proposed Drug Interchange (within clause (b) above), if, following a Drug Interchange Solicitation, a Prescriber or Patient indicates that a proposed Drug Interchange shall result in such costs being incurred, ESI in its discretion may cease to seek the proposed Drug Interchange. If a Patient, because of a deductible or cap requirement, pays actual costs of tests or doctor visits instead of co-pays, then that Patient's Drug Interchange-Related Health Care Costs shall be based on the co-pay (if any) that would apply upon satisfaction of the deductible or the co-pay applicable prior to the cap being met.

"Drug Interchange Solicitation" means any communication by, on behalf of, or at the request of ESI for the purpose of requesting a Drug Interchange.

"Drug Utilization Review" means the process used to assess the appropriateness of drug therapy by engaging in the evaluation of data on drug use in a given health care environment against predetermined criteria and standards.

"ESI" means Express Scripts, Inc., its subsidiaries including all state licensed pharmacy subsidiaries and affiliated companies, their assigns, and their corporate predecessors and successors, and employees of any such entity solely in their capacity as employees acting within the scope of their employment and not in any individual or personal capacity.

"ESI Total Product Revenue" means ESI's net revenue which consists principally of sales of prescription drugs to Clients, either through ESI's network of independently contracted retail pharmacies or through ESI's mail order pharmacies.

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Where ESI acts as a principal in accordance with generally accepted accounting principles, which is the case in the majority of ESI's Client contracts, revenues are recognized at the prescription price negotiated with Clients, as well as the associated administrative fees.

"Generic Equivalent" means a drug or biologic product that has been approved by the Food and Drug Administration ("FDA") under the Federal Food Drug and Cosmetic Act or the Public Health Service Act on the basis, in whole or in part, of studies, data or other information submitted to FDA in connection with the application for a previously-approved product or that has been otherwise deemed chemically equivalent to a branded drug or biologic product as signified by: an A rating by the FDA; approval by the FDA as a biogeneric product, biosimilar product, or follow-on biologic product; approval for substitution on any state formulary; or approval for substitution by the ESI P&T Committee.

"Manufacturer Additional Payments" mean all Manufacturer Payments other than Manufacturer Formulary Payments. These payments are not provided by ESI to those Client Plans that have contracted to receive a certain share of "formulary" rebates or payments, although certain Client Plans may contract to receive a certain share of all Manufacturer Payments, including both "Formulary" and "Additional" Payments.

"Manufacturer Formulary Payments" mean payments that ESI receives from a manufacturer in return for or as part of formulary placement and/or access, and/or payments that are characterized as "formulary" or "base" rebates or payments

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pursuant to ESI's agreements with pharmaceutical manufacturers, including discounts set forth in any Preferred Savings Grid ® based contract.

"Manufacturer Payments" mean any or all compensation or remuneration ESI receives from or on behalf of a pharmaceutical manufacturer in connection with ESI's administration of pharmacy benefit services, including but not limited to, rebates, regardless of how categorized, Preferred Savings Grid ® discounts, market share incentives, commissions, fee for service programs, and administrative or management fees. It also includes any fees received for sales of utilization data to a pharmaceutical manufacturer. It does not include purchase discounts based upon invoiced purchase terms. For purposes of ESI's "Manufacturer Payment Reports" provided to Client Plans hereunder, all "Manufacturer Payments" received by ESI fit into one of two categories defined herein, namely, "Manufacturer Formulary Payments" or "Manufacturer Additional Payments." Manufacturer Payments does not include revenue received by Phoenix Marketing Group for services provided to a manufacturer that are not related to ESI's administration of pharmacy benefits for Client Plans.

"Minimum Cost Savings" mean the minimum amount in dollars a Client Plan and Patient, respectively, shall save in their costs annually if a Drug Interchange occurred at the expected dosage.

"Net Drug Cost" means the price ESI charges a Client Plan and/or Patient for a prescription drug whether that drug is delivered through a retail pharmacy or mail order. The Net Drug Cost may take into account all discounts, rebates, credits or

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other payments that lower the cost of the drug, to the extent such payments are provided to the Client Plan. Net Drug Cost may be reduced by Manufacturer Payments to the extent those payments are provided to the Client Plan, but shall not be reduced by Manufacturer Payments that are paid to and retained by ESI.

“P&T Committee” means the Pharmacy & Therapeutics Committee maintained by ESI, comprised of at least seven members, all of whom shall be physicians, pharmacists or other health care professionals, and a majority of whom are actively practicing and who are not employed by ESI, responsible for playing a role in developing ESI’s standard formularies, the clinical appropriateness for ESI’s Drug Interchange programs, developing and maintaining clinical criteria used as a basis for ESI’s standard coverage management program, and other responsibilities pertaining to the clinical components of programs and services designed to effect drug utilization.

“Patient” means a person whose prescription drug benefit is administered by ESI.

“Prescriber” means a physician, dentist, physician’s assistant, optometrist or other health care professional authorized by law to write prescriptions for prescription drugs.

“Proposed Drug” means the drug or drugs that ESI, in its Drug Interchange Solicitation, proposes to substitute for a Currently Prescribed Drug.

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“State Proprietary Health Plan” means a health plan of a state, state agency, state subdivision, state college or university system, any state public or quasi-public entity, municipality or locality that contracted with ESI for PBM services.

II. INJUNCTIONS

A. General Restrictions on Drug Interchanges

1. Unless otherwise specifically directed by a Client Plan with respect to a proposed Drug Interchange, ESI shall not do any of the following:

- a) Make or cause to be made any Drug Interchange Solicitation where the Net Drug Cost of the Proposed Drug exceeds that of the Currently Prescribed Drug.
- b) Make or cause to be made any Drug Interchange Solicitation where the Currently Prescribed Drug has Generic Equivalents, and the Proposed Drug has no Generic Equivalents, unless the Proposed Drug has a lower Net Drug Cost than all Generic Equivalents of the Currently Prescribed Drug.
- c) Make or cause to be made any Drug Interchange Solicitation where the patent protection for the Currently Prescribed Drug is scheduled to expire within six months of the Drug Interchange Solicitation, or where the effect of the proposed Drug Interchange reasonably is to avoid substitution for, or generic competition against, the Currently Prescribed Drug,

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excepting Drug Interchanges with the effect of decreasing Net Drug Costs.

- d) Make or cause to be made any Drug Interchange Solicitation that fails to disclose to Client Plans, Prescribers and Patients, Clearly and Conspicuously, Minimum Cost Savings or Actual Cost Savings, as well as the difference, if any, in co-payments to be made by the Patient (or absence of effect on co-payments, if such is the case). When making these disclosures, ESI may reasonably rely on information provided by the Client Plan with respect to eligibility and co-payments, irrespective of deductibles and caps.
- e) Make or cause to be made any Drug Interchange Solicitation where the Minimum Cost Savings fails to meet ESI's current standards for implementation of Drug Interchange Solicitations, including but not limited to the standards relating to de minimus cost savings as such standards may be supplemented in connection with biogeneric products, biosimilar products, or follow-on biologic products.
- f) Make or cause to be made any Drug Interchange Solicitation to a Patient who, within two years preceding the solicitation, and with respect to the same therapeutic class involved in the proposed Drug Interchange, has either: a) interchanged his or

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her drug following a Drug Interchange Solicitation from or on behalf of ESI or b) interchanged his or her drug following a Drug Interchange Solicitation by or on behalf of ESI but had the Drug Interchange reversed, unless all of the Proposed Drugs in the current Drug Interchange Solicitation were not among the Proposed Drugs in the prior Drug Interchange.

2. ESI shall ensure that a Patient does not pay out-of-pocket costs for Drug Interchange-Related Health Care Costs incurred by a Patient by reimbursing the Patient for such costs, within thirty days of receipt of a claims form for such costs, or ensuring that the Client Plan reimburses the Patient for such costs.

3. ESI shall enact and follow a procedure for reimbursing Patients such out-of-pocket costs, by which ESI shall, without limitation, (a) permit Patients, Prescribers or treating physicians to request such reimbursement, by phone or in writing, and (b) upon such request, provide a single-page claim form (with instructions) to request reimbursement. For reimbursement requests initiated by Patients (not Prescribers or treating physicians), ESI may (but need not) require that the Patient's reimbursement claim provide information showing that Drug Interchange-Related Health Care Costs were incurred, which requirement may be satisfied by a physician or Prescriber's notation at a designated place on the claim form, or by providing a Prescriber's or physician's written order, or other evidence showing payment of costs (e.g., co-pays for tests or doctor visits) incurred as a result

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of a Drug Interchange. ESI shall not directly or indirectly prevent or discourage Patients, Prescribers, or treating physicians from requesting or receiving reimbursement for Drug Interchange-Related Health Care Costs.

4. ESI's written communications to both Prescribers and Patients concerning Drug Interchanges, as set forth below, shall Clearly and Conspicuously disclose ESI's policy, consistent with this section, with respect to Drug Interchange-Related Health Care Costs. ESI's telephone communications with Prescribers and Patients concerning Drug Interchanges, as set forth below, shall communicate the existence of ESI's policies with respect to Drug Interchange-Related Health Care Costs. In its communications with Prescribers, Patients and Client Plans, ESI shall not misrepresent, directly or indirectly, its policy with respect to Drug Interchange-Related Health Care Costs.

5. Should Drug Interchange-Related Health Care Costs paid to a Patient with respect to any particular Drug Interchange exceed \$200.00, ESI, while complying with the timely reimbursement requirement set forth in II.A.2 . above, may, in its sole discretion, choose to have a third party chosen by ESI review the costs paid. If a determination is made that the costs were not related to a Drug Interchange, nothing herein shall prevent ESI from pursuing remedies to recoup those costs against the Patient and any other party involved.

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B. The Drug Interchange Solicitation Process and Prescribers

1. With respect to each Drug Interchange, ESI shall first obtain express verifiable authorization from the Prescriber of the Currently Prescribed Drug. All ESI Drug Interchange Solicitations to a Prescriber shall:

- a) identify the name and title of the person making the Drug Interchange Solicitation;
- b) state that ESI is soliciting a Drug Interchange;
- c) identify the Minimum Cost Savings or Actual Cost Savings to be achieved by interchanging to the Proposed Drug from the Currently Prescribed Drug;
- d) describe under what circumstances the Currently Prescribed Drug shall continue to be covered by the Client Plan, if such is the case;
- e) describe the difference in co-pay, if any, or the absence of effect on co-pay, if such is the case;
- f) if ESI receives Manufacturer Payments from a drug manufacturer as a result of the proposed Drug Interchange or the Drug Interchange Solicitation that is not reflected in the Net Drug Cost because it is compensation that does not inure to the Client Plan, ESI shall disclose that it receives such compensation or potential compensation;

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- g) disclose the existence of ESI's policy with respect to Drug Interchange-Related Health Care Costs outlined in Section II.A.2. If the Drug Interchange Solicitation is written, this disclosure shall be Clear and Conspicuous and direct the Prescriber to the written communication (Section II. B.4 below) for details. If the Drug Interchange Solicitation is by telephone, ESI may disclose its policy by directing the Prescriber to the written communication for details;
- h) if ESI uses the term "preferred" drug or similar words, then it shall provide a clear explanation of what that term means in the context in which it is used.

2. With respect to each Drug Interchange, ESI shall first obtain express verifiable authorization from the Prescriber, as communicated directly by the Prescriber (in writing or verbally) or by a person who affirms (in writing or verbally) that the Drug Interchange has been authorized by the Prescriber. If such authorization is by a person other than the Prescriber and is verbal, ESI shall document that person's first and last name and title or position.

3. With respect to each Drug Interchange, ESI shall maintain records for 5 years memorializing how express verifiable authorization was obtained, including the name of the person providing express verifiable authorization of the Drug Interchange; whether the authorization was written or verbal; and, if verbal and by a person other than the Prescriber, that person's title or position, if provided.

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4. Upon express verifiable authorization of a Drug Interchange, ESI shall send a written communication to the Prescriber confirming the Drug Interchange. If the Drug Interchange Solicitation (containing the requirements above) was verbal, then the written confirmation shall include the information required in Section II.B.1. Regardless of whether the Drug Interchange Solicitation was in writing, the written confirmation shall:

- a) identify the Minimum Cost Savings or Actual Cost Savings resulting from the Drug Interchange;
- b) Clearly and Conspicuously disclose ESI's policy with respect to Drug Interchange-Related Health Care Costs, in accordance with Section II.A.2.; and
- c) provide a toll free telephone number for the Prescriber.

C. Drug Interchange Solicitation and Patients

1. With respect to ESI home delivery prescriptions, within 24 hours of express verifiable authorization of a branded Drug Interchange by the Prescriber, ESI shall send to the Patient a written communication ("Written Patient Drug Interchange Notice,") and make a telephonic communication ("Telephonic Patient Drug Interchange Notice") advising the Patient of the Prescriber's approval of the Drug Interchange.

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2. Following express verifiable authorization of a Prescriber's approval of a Drug Interchange for a non-home delivery prescription, ESI shall send the Patient a Written Patient Drug Interchange Notice.

3. The Written Patient Drug Interchange Notice shall Clearly and Conspicuously:

- a) state that ESI requested a Drug Interchange by contacting the Patient's Prescriber;
- b) state that, following ESI's Drug Interchange Solicitation, the Prescriber approved the Drug Interchange;
- c) identify the Proposed Drug and the Currently Prescribed Drug;
- d) identify the Minimum Cost Savings or Actual Cost Savings;
- e) describe under what circumstances the Currently Prescribed Drug shall continue to be covered by the Client Plan, if such is the case;
- f) describe the difference in co-pay, if any, or the absence of effect on co-pay, if such is the case;
- g) disclose the fact of compensation or potential compensation if ESI receives compensation from a drug manufacturer as a result of the proposed Drug Interchange or the Drug Interchange Solicitation that is not reflected in the Net Drug Cost because it is compensation that does not inure to the Client Plans;

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- h) disclose ESI's policy with respect to Drug Interchange-Related Health Care Costs, in accordance with Section II.A.2;
- i) advise the Patient that he or she may decline the Drug Interchange in which case the Patient shall receive the Currently Prescribed Drug, if the Currently Prescribed Drug remains on the Client Plan's formulary and the Patient is willing to pay any difference in co-pay;
- j) advise the patient of a toll-free number where he or she may call with questions; and
- k) disclose any material differences in efficacy and side effects as determined by the ESI P&T Committee between the Currently Prescribed Drug and the Proposed Drug.

4. The Telephonic Patient Interchange Notice made for ESI home delivery Drug Interchanges shall:

- a) state that ESI requested a Drug Interchange by contacting the Patient's Prescriber;
- b) state that, following ESI's Drug Interchange Solicitation, the Prescriber approved the Drug Interchange;
- c) not represent that the Prescriber initiated the Drug Interchange;
- d) identify the Proposed Drug and the Currently Prescribed Drug;
and

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- e) advise the Patient that further written information about the Drug Interchange shall arrive in the mail and give a toll-free telephone number so that the Patient may speak to a customer service representative about the Drug Interchange.

5. ESI shall not represent in any of its written or telephone communications that the Prescriber initiated the Drug Interchange.

D. Rejected Drug Interchanges.

1. Unless a Currently Prescribed Drug is no longer on the Client Plan's formulary or the Patient is unwilling to pay any higher applicable co-pay or other costs associated with the Currently Prescribed Drug, ESI shall cancel and reverse the Drug Interchange upon written or verbal instructions from a Prescriber or Patient.

2. ESI shall maintain a toll free telephone number(s) during business hours to field telephone calls from Patients and Prescribers in response to ESI's Drug Interchange confirmations, and the customer service standards (e.g., waiting time) for those telephone number(s) shall be equivalent to ESI's other customer service standards.

3. Upon cancellation, if ESI has not yet dispensed the Proposed Drug, ESI, upon approval of the Prescriber, shall dispense the Currently Prescribed Drug.

4. If ESI has already dispensed the Proposed Drug, ESI shall obtain a prescription for and dispense the Currently Prescribed Drug, and ESI shall charge the Patient only one co-pay and shipping and handling fee (so that a proposed but

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reversed Drug Interchange shall not increase Patient costs beyond the costs had ESI dispensed the Currently Prescribed Drug).

5. Unless otherwise provided by contract with a Client Plan, ESI shall also bear the expense of shipping the Proposed Drug back to ESI (either by offset or by reversing and crediting the initial co-pay).

6. ESI shall provide notice to Client Plans that Client Plans may request information regarding the costs to it resulting from a Patient's rejection of a proposed Drug Interchange.

7. ESI shall offer to provide Client Plans with rejection rates for proposed Drug Interchanges upon request.

8. In the event a Patient will exhaust his or her supply of the Currently Prescribed Drug before a replacement shipment shall arrive to the Patient, ESI shall arrange for dispensing of an appropriate quantity of replacement medications at a participating ESI network pharmacy at no additional cost to the Patient.

9. In the event that a Patient reverses a Drug Interchange and ESI is unable to obtain approval from the Prescriber (or a physician covering for Prescriber) for the Currently Prescribed Drug, ESI shall take reasonable steps to provide either the Currently Prescribed Drug or the Proposed Drug before the Patient exhausts his or her existing supply.

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E. Drug Interchange Communications Regarding the P&T Committee

1. With respect to all Drug Interchange Solicitations and communications related to Drug Interchanges, ESI shall not misrepresent the role of ESI's P&T Committee in initiating, reviewing, approving or endorsing a proposed Drug Interchange or Drug Interchange Solicitation.

2. If ESI mentions the P&T Committee in any Drug Interchange Solicitation or communication related to Drug Interchanges, ESI shall Clearly and Conspicuously disclose:

- a) the role of ESI's P&T Committee in ESI's Drug Interchange proposal process;
- b) that the Drug Interchange being proposed by ESI was not initiated by the P&T Committee and not initiated due to medical care considerations;
- c) that the P&T Committee did not consider cost issues, if such is the case.

F. Other P&T Committee Matters

1. With respect to the operation of the P&T Committee, ESI shall provide to Client Plans (at the Client Plan's expense, unless the Client Plan contract otherwise provides), upon request, copies of all information provided to the P&T Committee. Nothing in this provision shall be read to require ESI to provide Client Plans with any documents that identify the P&T Committee members.

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2. In the event that ESI's P&T Committee places any conditions on a Drug Interchange, ESI shall provide a complete description of such conditions to the Prescriber at the time of the Drug Interchange Solicitation.

G. Monitoring of Drug Interchange Health Effects

1. ESI shall monitor any Beneficiary comments, complaints, or inquiries relating to the effects of Drug Interchanges requested by ESI upon the health of Patients, and shall report to ESI's P&T Committee, not less than quarterly, the results of such monitoring. Such monitoring shall include, without limitation, a system designed to a) identify Patient and Prescriber communications with ESI that concern the efficacy or health effects of a Drug Interchange, and b) capture information from such communications in a manner that ESI can collect, and generate reports on, Patient and Prescriber communications concerning Drug Interchanges. The P&T Committee shall reasonably consider the results of ESI's monitoring.

H. ESI's General Disclosures to Client Plans

1. In a new Client Plan contract or renewal of a Client Plan contract upon the expiration of the negotiated term of that contract, ESI shall from the date this AVC is entered:

- a) Clearly and Conspicuously disclose that it may receive Manufacturer Additional Payments from manufacturers participating in rebate programs that are calculated on the basis of the price of the dispensed prescription drugs which

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are eligible for Manufacturer Formulary Payments (“Rebated Product”) and disclose the maximum fee that ESI may receive as a percentage of the Average Wholesale Price of Rebated Product (currently 3.5%) and as a percentage of the Wholesale Acquisition Cost of the Rebated Product (currently 4.375%).

If ESI uses an alternative benchmark in the future to calculate Manufacturer Additional Payments, ESI will Clearly and Conspicuously disclose to Client Plans how Manufacturer Additional Payments are calculated under the new benchmark.

- b) if ESI uses a maximum allowable cost (“MAC”) or a maximum reimbursement amount (“MRA”) list of prices for any generic drug, advise Client Plans of the definition of the client MAC or MRA list, and, upon request, provide the terms of operation of the client MAC or MRA list, including the characteristics and factors used to develop client MAC or MRA pricing and monthly access to the client MAC or MRA list containing the prices the Client Plan is paying for various drugs under the Client Plan’s contract.
- c) disclose the terms by which ESI’s shared savings programs operate and how shared savings are calculated.

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- d) Clearly and Conspicuously disclose when a manufacturer pays, even in part, for any educational or informational communication to a Prescriber or Patient.
- e) not, through its Phoenix Marketing Group, Inc. subsidiary or any other division or subsidiary, participate in the sampling of drugs that are not on all of ESI's national formularies without first Clearly and Conspicuously disclosing to Client Plans both the fact of the sampling and that not all of the sampled drugs are on all of ESI's national formularies.

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I. Disclosures to Client Plans Regarding Compensation From Drug Manufacturers

1. Quarterly and Annual Disclosures. With respect to each Client Plan that has contracted to receive (directly or by credit) any Manufacturer Payments from ESI, for each ESI fiscal year during which the Client Plan receives any such Manufacturer Payments, ESI shall provide those Client Plans, for each ESI fiscal quarter and year, a Manufacturer Payments Report. ESI's Manufacturer Payment Reports shall identify, for the reported fiscal quarter or year (the "Reporting Period"), the information set forth below in (a) through (e). If the precise reported figure is not known by ESI at the time of its report, ESI shall provide its current best estimate of the reported information, provided that, with respect to each report, should the reported information subsequently need revision in accordance with generally accepted accounting principles, ESI shall provide an update to the reported information to reflect that revision. Manufacturer Payment Reports shall include:

- a) the dollar amount of ESI Total Product Revenue (as defined) for the Reporting Period, with respect to ESI's entire client base, together with;
- b) the dollar amount of total drug expenditures for each Client Plan;
- c) the dollar amount of all Manufacturer Payments earned by ESI for a Reporting Period;

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- d) the percentage of all Manufacturer Payments earned by ESI for the Reporting Period that were Manufacturer Formulary Payments; and
- e) the percentage of all Manufacturer Payments received by ESI during the Reporting Period that were Manufacturer Additional Payments.

2. ESI's Manufacturer Payment Reports shall present the information listed in II.I.1.(a) - (e) Clearly and Conspicuously and in a manner that serves to inform Client Plans, including, by way of illustration only and not as an exclusive list, those Client Plans that share only in Manufacturer Formulary Payments but not Manufacturer Additional Payments, of all Manufacturer Payments earned by ESI.

3. Disclosure at Contracting Stage. In advance of executing a contract (whether an initial contract or renewal contract) with a Client Plan, ESI shall:

- a) disclose to such Client Plan that ESI will solicit and receive Manufacturer Payments and that ESI may pass through those payments to Client Plans or may retain those payments for itself, depending on contract terms.
- b) inform Client Plans and prospective Client Plans, upon request, about the form of Manufacturer Payments it receives.
- c) inform Client Plans and prospective Client Plans whether it earns revenue from a spread between the cost of drugs

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dispensed through retail pharmacies and the amounts it

charges Client Plans; and

- d) inform Client Plans and prospective Client Plans whether it earns revenue from a spread between the cost incurred by ESI Mail Order Pharmacies in acquiring drugs and the amount ESI Mail Order Pharmacies charge for such products.

J. Pharmaceutical Care Ethics

1. ESI shall adopt the Code of Ethics of the American Pharmacists Association or similar code of ethics for its employed pharmacists. ESI's current Code of Ethics for Patient Services Pharmacy Practice satisfies this requirement.

2. ESI shall make available to its employed pharmacists, Client Plans, and Patients copies (which may be in electronic form or available on a website) of such codes of ethics or professional standards.

3. ESI shall require its pharmacists to comply with all state law requirements governing pharmacists.

4. ESI shall permit its pharmacists to give good faith, professional opinions.

5. No ESI pharmacist shall be required to fill a prescription if the pharmacist believes that such prescription is not in the best interest of the Patient.

6. When a Patient asks to speak with a pharmacist about a matter relating to the practice of pharmacy, or when the nature of a Patient's question

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implicates the practice of pharmacy, ESI shall promptly make a pharmacist available to the Patient.

7. ESI shall continue to investigate and implement appropriate solutions to mail shipment of temperature sensitive drugs. ESI shall comply with all relevant laws regarding the shipment of temperature sensitive drugs.

III. REIMBURSEMENT AND CY PRES PAYMENT

A. Reimbursement to Consumers

1. ESI shall pay up to \$200,000 to reimburse "Affected Consumers," as defined below, up to \$25.00 each for out-of-pocket expenses incurred as a result of a "Statin Drug Interchange," using the notification and claims process described in Section III.A.1 & 2. For purposes of this Section, a "Statin Drug Interchange" means a Patient's Drug Interchange, from one already dispensed branded drug to another branded drug within the HMG-CoA Reductase Inhibitors therapeutic class, from January 1, 2002 through the Effective Date. "Affected Consumers" means those persons who (i) following a Statin Drug Interchange, paid co-pays for tests, doctor visits or other health care services incurred as a result of the Statin Drug Interchange, (ii) have not received reimbursement from ESI for those out-of-pocket expenses, and (iii) currently reside in a Participating State or resided in a Participating State at the time of the Statin Drug Interchange at issue.

2. ESI, or its designee, shall identify and pay Affected Consumers using the following notification and claims process, the costs of which shall be borne by ESI:

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- a) Using its Patient records and records related to Drug Interchanges, ESI shall identify all Patients who had a Statin Drug Interchange, including statin prescriptions filled by a ESI home delivery (mail order) pharmacy or at retail (collectively, “Potential Affected Consumers”). ESI shall make reasonable efforts to identify the current address for each Potential Affected Consumer, using its current Patient records and other reasonable methods.
- b) ESI shall mail to each Potential Affected Consumer a “Reimbursement Notice and Claim Form,” in a form (or forms) approved by the participating Attorneys General. The Reimbursement Notice shall, Clearly and Conspicuously, (i) advise Potential Affected Consumers that ESI reached a settlement with the participating Attorneys General, and that ESI shall reimburse Affected Consumers up to \$25.00 for Statin Drug Interchange related expenses, (ii) explain how Affected Consumers may obtain reimbursement, and (iii) explain that Affected Consumers must submit all claims to ESI within six months of the Affected Consumer’s receipt of the Reimbursement Notice and Claim Form.
- c) The Claim Form, which shall be coupled with the Reimbursement Notice, may request that the Potential

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Affected Consumer: (i) generally describe any costs incurred as a result of a Statin Drug Interchange; and (ii) attest, under penalty of perjury, that the information provided on the Claim Form is true and accurate. The Claim Form also shall advise the Potential Affected Consumer that acceptance of reimbursement pursuant to the claims process shall reduce, by the reimbursement amount, any recovery by any other means, of out-of-pocket costs attributable to co-pays for tests, doctor visits or other health care services incurred as a result of the Statin Drug Interchange. A pre-paid envelope shall accompany the Reimbursement Notice and Claim Form. The Claim Form also shall provide a toll-free number for Potential Affected Consumers to call should they have questions.

- d) ESI shall mail all Reimbursement Notice and Claim Forms as soon as practicable following the Effective Date, but in any event within four months of the Effective Date. ESI then shall accept claims for seven months after the last mailing of Reimbursement Notice and Claim Forms (the "Time Period"). After expiration of the Time Period, ESI shall make reimbursement of \$25.00 to each Affected Consumer who submits a completed Claim Form and attests that he or she incurred out-of-pocket expenses following a Statin Drug

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Interchange (a "Qualified Claim"). In the event that, after expiration of the Time Period, ESI has received Qualified Claims in an amount that exceeds \$200,000 based upon a \$25.00 payment (i.e., more than 8,000 Qualified Claims), then payments to Affected Consumers shall be prorated by dividing the \$200,000 by the number of Qualified Claims received.

- e) Following completion of the above notification and claims process, and in any event not more than 12 months after the Effective Date, ESI shall certify to the participating Attorneys General that it has complied with this reimbursement Section and provide a report identifying, without limitation: (i) the number of Reimbursement Notice and Claims Forms mailed to Potentially Affected Consumers, (ii) the number of phone calls received concerning the notice and claims process, (iii) the number of Claims Forms submitted, (iv) the number of Qualified Claims submitted, (v) the total amount in reimbursement paid by ESI to Affected Consumers, and vi) the estimated costs of administration of this reimbursement program.

B. Cy Pres Payment

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1. Within five (5) business days of the Effective Date, ESI shall pay the Participating States \$7,000,000, to be apportioned among the Participating States proportionally based upon population, with a minimum per state distribution, as agreed by the Participating States. Each Participating State's proportional share of the \$7.0 million shall be reflected in a schedule provided to ESI in advance of the Effective Date (the "State Schedule").

2. Participating States that receive a monetary payment shall make a *cy pres* distribution of these funds, pursuant to a state-specific Cy Pres Distribution Plan, to a political subdivision(s) thereof or to a state agency or program, a non-profit corporation(s) and/or a charitable organization(s), at the sole discretion of the Attorney General of each Participating State, with the express condition that the funds be used to benefit low income, disabled, or elderly consumers of prescription medications, to promote lower drug costs for residents of that Participating State, to educate consumers concerning the cost differences among medications, or to fund other programs reasonably targeted to benefit a substantial number of persons affected by the Covered Conduct addressed in this AVC.²

3. Each Participating State shall direct that its share of the distribution funds shall only be utilized to fund activities which have not been funded and which, but for the receipt of money from the Distribution fund, would not be fully funded. If a Participating State uses its distribution to fund an activity which has previously

² For Washington State, in lieu of direct restitution, the funds may be used for recovery of

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been partially funded, it will direct that the distributed funds do not supplant existing funding and are only used to fund shortfalls in existing funding.

4. Each Participating State may present its Cy Pres Distribution Plan to a court of competent jurisdiction for approval, if that State's laws or practices so require.

IV. PAYMENT OF FEES AND COSTS TO THE STATES

A. Fees and Costs to the States

1. Within five (5) business days of the Effective Date, ESI shall pay \$2.3 million to the Participating States, to be distributed among those Participating States as agreed by the Attorneys General, for attorneys' fees and investigative costs, consumer education, litigation, public protection, consumer protection purposes or local consumer aid funds or any other purpose permitted by state law at the sole discretion of each State's Attorney General.³ ESI shall pay this total amount by check to the Office of the Pennsylvania Attorney General. The Pennsylvania Attorney General shall hold that payment in trust and, as soon as practicable but not later than six months after receipt, shall distribute the payment among the Participating States pursuant to the Participating States' agreement, provided, however, that prior to receiving its allotted distribution hereunder, a Participating

costs and fees and consumer education cy pres.

³ With respect to the Commonwealth of Pennsylvania, such amounts may be used for costs, attorneys' fees and future public protection and consumer protection purposes. With respect to the State of Montana, such amounts may be used for attorney's fees and investigative costs, consumer education, consumer reimbursement, litigation, public protection, consumer protection purposes or local

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State has entered in its State an AVC in substantively the same form as this AVC. A Participating State may not receive its distribution or share of money held in trust for it by Pennsylvania, whether that money be cy pres or for costs and attorneys' fees, until it has signed the Assurance and completed the necessary procedures, if any, for entering or recording it in court.

V. GENERAL PROVISIONS

1. Scope of AVC. The injunctive provisions of this AVC are applicable to ESI, its officers, agents, employees, and attorneys, and all those persons or entities in active concert or participation with them who receive actual notice of this AVC by personal service or otherwise, whether acting directly or through any entity, corporation, subsidiary, division, or other device.

2. Release of Claims. By its execution hereof, each Participating State releases ESI and all of its past and present subsidiaries, affiliates, predecessors and successors and each of the past and present officers, directors, attorneys, insurers and assigns of any of the foregoing and employees of any such entity solely in their capacity as employees acting within the scope of their employment and not in any individual or personal capacity (collectively, the "Releasees") from all civil claims or causes of action for all damages, restitution, fines, costs and penalties on behalf of the Participating State arising under the consumer protection statutes listed in footnote one of this AVC and any claims under antitrust, unfair business practice,

consumer aid funds, or any other purpose permitted by state law at the sole discretion of the Attorney General.

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unfair competition statutes and regulations, or claims of unjust enrichment or misrepresentation related to said consumer protection statutes, all arising from the Covered Conduct which is the subject of this AVC, which the Participating State asserted or could have asserted from January 1, 1997, through the Effective Date of this AVC.

3. The Participating States agree that they shall not proceed with or institute any civil action or proceeding, either individually or collectively, based upon the Covered Conduct, under the consumer protection statutes listed in footnote one of this AVC and any claims under antitrust, unfair business practice, or unfair competition-statutes and regulations, or claims of unjust enrichment or misrepresentation related to said consumer protection statutes against the Releasees, including but not limited to an action or proceeding seeking damages, restitution, injunctive relief, fines, penalties, attorneys fees or costs for any conduct undertaken or omissions prior to the Effective Date of this AVC arising from the Covered Conduct. No Participating State shall initiate any claim in the nature of a class action arising from the Covered Conduct from January 1, 1997, through the Effective Date. ESI may plead this Assurance as a full and complete defense to any claim, whether class, individual or otherwise in nature, released hereunder that may be instituted, prosecuted, or attempted by any Participating State with respect to the Covered Conduct.

4. Notwithstanding the foregoing, no Participating State releases any claim arising under statutes, laws or regulations other than those set forth in

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paragraph V.2. above and arising from the Covered Conduct that is the subject matter of this Assurance. Claims excluded from each Participating State's release include, but are not limited to, claims arising from Best Price, Average Wholesale Price or Wholesale Acquisition Cost reporting practices or price manipulation claims, or Medicaid fraud or abuse. Each Participating State is also expressly not releasing any State Proprietary Health Plan claim, any claim under its state false claims act, or any regulatory action under the jurisdiction of its state pharmacy board or, for any Participating State that does not have a state pharmacy board, the equivalent state entity or entities that regulate(s) compliance with such state's pharmacy laws and regulations, any claim of a state regulatory body regarding drug safety, and any claim that has been, could have been, or may be brought on behalf of or in connection with a state Medicaid program. The Participating States expressly are not releasing any State Proprietary Health Plan claims. Any State Proprietary Health Plan claim is unaffected by this Assurance.

5. In addition, each Participating State does not release any personal claim, right or cause of action that a consumer or other person or entity other than the Participating State may have against ESI. Moreover, a Participating State may institute an action or proceeding to enforce the terms and provisions of this Assurance or take action based on future conduct by the Releasees.

6. Preservation of Law Enforcement Action. Nothing herein precludes a Participating State from enforcing the provisions of this AVC, or from pursuing any law enforcement action with respect to the acts or practices of ESI not covered by

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this AVC or any acts or practices of ESI conducted after the Effective Date of this AVC.

7. Compliance with and Application of State Law. Nothing herein relieves ESI of its duty to comply with applicable laws of the Participating States nor constitutes authorization by the Participating States for ESI to engage in acts and practices prohibited by such laws. This AVC shall be governed by the laws of each of the respective Participating States, with respect to ESI's conduct in each of the Participating States.

8. Non-Approval of Conduct. Nothing herein constitutes approval by the Participating States of ESI's therapeutic interchange program or other business practices. ESI shall not make any representation contrary to this paragraph.

9. Effective Date. The "Effective Date" shall be the date that this AVC is executed by ESI and by each one of the Participating States.

10. Effective Date of Section II. Notwithstanding that ESI shall endeavor to comply with all injunctive terms in Section II as promptly as practicable, Sections A, B, C, D, E, F and I shall be implemented on or before 120 days after the Effective Date.

VI. COMPLIANCE PROVISIONS

1. Within 30 days after the Effective Date, ESI shall provide a copy of this AVC and obtain a signed and dated acknowledgment of receipt or electronic verification of receipt from:

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- a) Each officer and director;
- b) ESI senior management, namely, the top 200 leadership positions at ESI, which shall include the Chief Executive Officer, each position that reports to the CEO (excluding Administrative Assistants); each position that reports to a position that reports to the CEO (excluding Administrative Assistants);
- c) Each manager of ESI pharmacies, manager of managed care operations, and pharmacist involved in Drug Interchange communications with Patients or Prescribers; and
- d) Each customer service representative to whom a telephone call concerning Drug Interchanges may be directed in the routine routing of calls concerning Drug Interchanges.

2. For five years from the Effective Date, ESI shall provide a copy of this AVC to and obtain a signed and dated acknowledgment of receipt or electronic verification of receipt from future personnel described in 1 (a) through (d) of this Section within 30 days after the person assumes such position or responsibilities.

3. ESI shall make this AVC accessible to Client Plans and Patients through its website.

4. ESI shall maintain an executive review panel to assess, on a quarterly basis, ESI's compliance with this AVC. As warranted, the panel shall review and/or

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recommend initiatives to ensure that ESI's Drug Interchange practices and disclosures to Prescribers, Patients and Client Plans comply with this AVC.

5. ESI shall maintain and distribute methods and procedures ("M&Ps") establishing a code of conduct for all ESI employees engaged in the Drug Interchange program. The M&Ps must be designed to establish quality standards for the manner in which information is disseminated to Prescribers and Patients by ESI employees regarding Drug Interchanges. ESI shall review the M&Ps annually with their pharmacists and other personnel involved with the Drug Interchange program.

6. ESI shall create and retain for a period of five (5) years following the Effective Date, books and records that in reasonable detail accurately reflect ESI's compliance with this AVC. These records shall include, but are not limited to, the following:

- a) Documents reflecting the current addresses, telephone numbers, and fax numbers for ESI and its subsidiaries;
- b) The original signed and dated acknowledgments of the receipt or the electronic verification of receipt of the AVC described in paragraph 1 of this Section;
- c) Documents provided to or received from Client Plans concerning any Client Plans' instructions, if any, concerning opting out of any provisions of this AVC;
- d) An exemplar of each written notice sent to Prescribers regarding Drug Interchanges;

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- e) An exemplar of each written notice sent to Patients regarding Drug Interchanges;
- f) A copy of each script used in telephonic communications with Prescribers and Patients relating to Drug Interchanges;
- g) A copy of all training materials used to inform employees of the requirements of this AVC;
- h) A copy of all M&Ps developed by the executive review panel;
- i) The P&T Committee information described in Section II.G.1;
- j) Documents concerning the drug pairs subject to Drug Interchanges;
- k) Documents reflecting Patient rejections of Drug Interchanges; and
- l) Exemplars of ESI's quarterly and annual disclosures to Client Plans required by section II.I. of this AVC.

7. One year after the Effective Date, and then annually for five years from the Effective Date, ESI shall provide to the Attorney General of each Participating State a certification, signed by an ESI senior officer, certifying ESI's compliance with this AVC. ESI's annual certification may be accompanied by a report showing the manner in which ESI has complied with the AVC.

8. For a period of five years beginning on the Effective Date, and within thirty (30) days of a written request by an Attorney General of a Participating State, ESI shall provide to that Attorney General:

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- a) Copies of the documents described in paragraph VI.6; and
- b) Such other records and documents as the Attorney General determines reasonably bear on compliance with this AVC.

9. Nothing in this AVC limits the Attorneys' General lawful use of compulsory process to investigate whether ESI has violated any provision of law enforced by the Attorneys General.

VII. ADMINISTRATIVE PROVISIONS

1. Jurisdiction is retained of this matter for all purposes by each Participating State, including but not limited to, the purpose of enabling any of the parties to this AVC to apply to a court at any time for such further orders or directives as may be necessary or appropriate for the interpretation or modification of this AVC, or for the enforcement of compliance therewith. Any party to this AVC may seek modification of the AVC if it believes the facts and circumstances underlying the AVC have changed in any material respect. The Participating States who have served on the Executive Committee for purposes of this AVC (Vermont, Pennsylvania, Texas and Washington) agree to coordinate discussions with ESI regarding any such modification and to make recommendations to the Participating States. The parties may jointly agree to modification only by a written instrument signed by or on behalf of both ESI and the Participating States and, where required, by court order.

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2. A Participating State shall give ESI 30 days' notice before filing a motion or other pleading seeking sanctions or other relief for violation of this AVC. The giving of such notice shall not prevent the Participating State from beginning such proceeding following the expiration of the 30 day period.

3. If, after the date of entry of this AVC, a Participating State, its Attorney General, or any agency of a Participating State enacts or promulgates legislation, rules or regulations with respect to matters governed by this AVC that conflict with any provision of this AVC, or if the applicable law of the Participating State shall otherwise change so as to conflict with any provision of this AVC, the Attorney General shall not unreasonably withhold his or her consent to the modification of such provision to the extent necessary to eliminate such conflict. Laws, rules, or regulations, or other changes in Participating State law, with respect to the matters governed by this AVC, shall not be deemed to conflict with a provision of this AVC unless ESI cannot reasonably comply with both such law, rule, or regulation and the applicable provision of this AVC.

4. The parties certify that their undersigned representative is fully authorized to enter into the terms and conditions of this AVC and to legally bind the party represented.