~~(E)~~ (I) THIS SECTION MAY NOT BE CONSTRUED TO AFFECT COMPLIANCE WITH § 15–804 OF THIS SUBTITLE REGARDING COVERAGE FOR OFF–LABEL USE OF DRUGS.

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19–706.

(Y) THE PROVISIONS OF § 15–826 OF THE INSURANCE ARTICLE SHALL APPLY TO HEALTH MAINTENANCE ORGANIZATIONS.

~~SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 1998.~~

SECTION 2. AND BE IT FURTHER ENACTED, That:

(a) On or before June 1 of each year, each insurer, nonprofit health service plan, and health maintenance organization subject to the requirements of this Act shall submit to the Insurance Commissioner, on the form the Insurance Commissioner requires, a report that describes the clinical trials covered during the previous year.

(b) The Insurance Commissioner shall compile an annual summary report based on the information provided under subsection (a) of this section and provide copies of the summary report to the Senate Finance Committee and the House Economic Matters Committee in accordance with § 2–1246 of the State Government Article.

SECTION 3. AND BE IT FURTHER ENACTED, That:

(a) The Insurance Commissioner shall create a Workgroup on Insurance Coverage for Patient Care Cost in Clinical Trials.

(b) The purpose of the Workgroup is to assess the costs and benefits of insurance coverage for patient care cost incurred in clinical trials.

(c) At a minimum, the Workgroup shall:

(1) Develop a methodology for assessing the economic and clinical impact of the health insurance coverage required by this Act for patient care cost in clinical trials;

(2) Request and collect from health care providers and payers pertinent aggregate clinical and financial data on patient treatment to assess differences in patient care costs and clinical outcomes between patients treated in clinical trials and patients treated outside of clinical trials; and

(3) Review any other issues the Workgroup considers appropriate to assess and on which to make recommendations pertaining to coverage for patient care cost in clinical trials.

(d) The Workgroup shall be comprised of 11 members, appointed by the Commissioner: