

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 2.1-20.1, as it is currently effective and as it may become effective, and 38.2-3407.5 of the Code of Virginia, relating to off-label drug use.

[S 1164]

Approved

Be it enacted by the General Assembly of Virginia:

1. That §§ 2.1-20.1, as it is currently effective and as it may become effective, and 38.2-3407.5 of the Code of Virginia are amended and reenacted as follows:

§ 2.1-20.1. Health and related insurance for state employees.

A. 1. The Governor shall establish a plan for providing health insurance coverage, including chiropractic treatment, hospitalization, medical, surgical and major medical coverage, for state employees and retired state employees with the Commonwealth paying the cost thereof to the extent of the coverage included in such plan. The Department of Personnel and Training shall administer this section. The plan chosen shall provide means whereby coverage for the families or dependents of state employees may be purchased. The Commonwealth may pay all or a portion of the cost thereof, and for such portion as the Commonwealth does not pay, the employee may purchase the coverage by paying the additional cost over the cost of coverage for an employee.

2. Such contribution shall be financed through appropriations provided by law.

B. ~~4.~~ The plan shall:

1. Include coverage for low-dose screening mammograms for determining the presence of occult breast cancer. Such coverage shall make available one screening mammogram to persons age thirty-five through thirty-nine, one such mammogram biennially to persons age forty through forty-nine, one such mammogram annually to persons age fifty and over and may be limited to a benefit of fifty dollars per mammogram subject to such dollar limits, deductibles, and coinsurance factors as are no less favorable than for physical illness generally. The term "mammogram" shall mean an X-ray examination of the breast using equipment dedicated specifically for mammography, including but not limited to the X-ray tube, filter, compression device, screens, film, and cassettes, with an average radiation exposure of less than one rad mid-breast, two views of each breast.

2. ~~The plan shall~~ Include coverage for the treatment of breast cancer by dose-intensive chemotherapy with autologous bone marrow transplants or stem cell support when performed at a clinical program authorized to provide such therapies as a part of clinical trials sponsored by the National Cancer Institute. For persons previously covered under the plan, there shall be no denial of coverage due to the existence of a preexisting condition.

3. ~~The plan shall~~ Include coverage for postpartum services providing inpatient care and a home visit or visits which shall be in accordance with the medical criteria, outlined in the most current version of or an official update to the "Guidelines for Perinatal Care" prepared by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists or the "Standards for Obstetric-Gynecologic Services" prepared by the American College of Obstetricians and Gynecologists. Such coverage shall be provided incorporating any changes in such Guidelines or Standards within six months of the publication of such Guidelines or Standards or any official amendment thereto.

4. *Not deny coverage for any drug approved by the United States Food and Drug Administration for use in the treatment of cancer on the basis that the drug has not been approved by the United States Food and Drug Administration for the treatment of the specific type of cancer for which the drug has been prescribed, if the drug has been recognized as safe and effective for treatment of that specific type of cancer in any of the standard reference compendia.*

5. *Not deny coverage for any drug prescribed to treat a covered indication so long as the drug has been approved by the United States Food and Drug Administration for at least one indication and the drug is recognized for treatment of the covered indication in one of the standard reference compendia or in substantially accepted peer-reviewed medical literature.*

C. Claims incurred during a fiscal year but not reported during that fiscal year shall be paid from such funds as shall be appropriated by law. Appropriations, premiums and other payments shall be deposited in the employee health insurance fund, from which payments for claims, premiums, cost containment programs and administrative expenses shall be withdrawn from time to time. The assets of the fund shall be held for the sole benefit of the employee health insurance program. The fund shall be held in the state treasury. Any interest on unused balances in the fund shall revert back to the credit of the fund.

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D. For the purposes of this section, ~~the term:~~

"Peer-reviewed medical literature" means a scientific study published only after having been critically reviewed for scientific accuracy, validity, and reliability by unbiased independent experts in a journal that has been determined by the International Committee of Medical Journal Editors to have met the Uniform Requirements for Manuscripts submitted to biomedical journals. Peer-reviewed medical literature does not include publications or supplements to publications that are sponsored to a significant extent by a pharmaceutical manufacturing company or health carrier.

"Standard reference compendia" means the American Medical Association Drug Evaluations, the American Hospital Formulary Service Drug Information, or the United States Pharmacopoeia Dispensing Information.

"State employee" means state employee as defined in § 51.1-124.3, employee as defined in § 51.1-201, the Governor, Lieutenant Governor and Attorney General, judge as defined in § 51.1-301 and judges, clerks and deputy clerks of regional juvenile and domestic relations, county juvenile and domestic relations, and district courts of the Commonwealth, interns and residents employed by the School of Medicine and Hospital of the University of Virginia, and interns, residents, and employees of the Medical College of Virginia Hospitals Authority as provided in § 23-50.16:24.

E. Provisions shall be made for retired employees to obtain coverage under the above plan. The Commonwealth may, but shall not be obligated to, pay all or any portion of the cost thereof.

F. Any self-insured group health insurance plan established by the Department of Personnel and Training which utilizes a network of preferred providers shall not exclude any physician solely on the basis of a reprimand or censure from the Board of Medicine, so long as the physician otherwise meets the plan criteria established by the Department.

§ 2.1-20.1. (Delayed effective date) Health and related insurance for state employees.

A. 1. The Governor shall establish a plan for providing health insurance coverage, including chiropractic treatment, hospitalization, medical, surgical and major medical coverage, for state employees and retired state employees with the Commonwealth paying the cost thereof to the extent of the coverage included in such plan. The Department of Personnel and Training shall administer this section. The plan chosen shall provide means whereby coverage for the families or dependents of state employees may be purchased. The Commonwealth may pay all or a portion of the cost thereof, and for such portion as the Commonwealth does not pay, the employee may purchase the coverage by paying the additional cost over the cost of coverage for an employee.

2. Such contribution shall be financed through appropriations provided by law.

B. 4. The plan shall:

1. Include coverage for low-dose screening mammograms for determining the presence of occult breast cancer. Such coverage shall make available one screening mammogram to persons age thirty-five through thirty-nine, one such mammogram biennially to persons age forty through forty-nine, one such mammogram annually to persons age fifty and over and may be limited to a benefit of fifty dollars per mammogram subject to such dollar limits, deductibles, and coinsurance factors as are no less favorable than for physical illness generally. The term "mammogram" shall mean an X-ray examination of the breast using equipment dedicated specifically for mammography, including but not limited to the X-ray tube, filter, compression device, screens, film, and cassettes, with an average radiation exposure of less than one rad mid-breast, two views of each breast.

2. ~~The plan shall~~ Include coverage for the treatment of breast cancer by dose-intensive chemotherapy with autologous bone marrow transplants or stem cell support when performed at a clinical program authorized to provide such therapies as a part of clinical trials sponsored by the National Cancer Institute. For persons previously covered under the plan, there shall be no denial of coverage due to the existence of a preexisting condition.

3. ~~The plan shall~~ Include coverage for postpartum services providing inpatient care and a home visit or visits which shall be in accordance with the medical criteria, outlined in the most current version of or an official update to the "Guidelines for Perinatal Care" prepared by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists or the "Standards for Obstetric-Gynecologic Services" prepared by the American College of Obstetricians and Gynecologists. Such coverage shall be provided incorporating any changes in such Guidelines or Standards within six months of the publication of such Guidelines or Standards or any official amendment thereto.

4. *Not deny coverage for any drug approved by the United States Food and Drug Administration for use in the treatment of cancer on the basis that the drug has not been approved by the United States Food and Drug Administration for the treatment of the specific type of cancer for which the drug has been prescribed, if the drug has been recognized as safe and effective for treatment of that specific type of cancer in any of the standard reference compendia.*

5. *Not deny coverage for any drug prescribed to treat a covered indication so long as the drug has been approved by the United States Food and Drug Administration for at least one indication and the*

drug is recognized for treatment of the covered indication in one of the standard reference compendia or in substantially accepted peer-reviewed medical literature.

C. Claims incurred during a fiscal year but not reported during that fiscal year shall be paid from such funds as shall be appropriated by law. Appropriations, premiums and other payments shall be deposited in the employee health insurance fund, from which payments for claims, premiums, cost containment programs and administrative expenses shall be withdrawn from time to time. The assets of the fund shall be held for the sole benefit of the employee health insurance program. The fund shall be held in the state treasury. Any interest on unused balances in the fund shall revert back to the credit of the fund.

D. For the purposes of this section, ~~the term:~~

"Peer-reviewed medical literature" means a scientific study published only after having been critically reviewed for scientific accuracy, validity, and reliability by unbiased independent experts in a journal that has been determined by the International Committee of Medical Journal Editors to have met the Uniform Requirements for Manuscripts submitted to biomedical journals. Peer-reviewed medical literature does not include publications or supplements to publications that are sponsored to a significant extent by a pharmaceutical manufacturing company or health carrier.

"Standard reference compendia" means the American Medical Association Drug Evaluations, the American Hospital Formulary Service Drug Information, or the United States Pharmacopoeia Dispensing Information.

"State employee" means state employee as defined in § 51.1-124.3, employee as defined in § 51.1-201, the Governor, Lieutenant Governor and Attorney General, judge as defined in § 51.1-301 and judges, clerks and deputy clerks of district courts of the Commonwealth, interns and residents employed by the School of Medicine and Hospital of the University of Virginia, and interns, residents, and employees of the Medical College of Virginia Hospitals Authority as provided in § 23-50.15:25.

E. Provisions shall be made for retired employees to obtain coverage under the above plan. The Commonwealth may, but shall not be obligated to, pay all or any portion of the cost thereof.

F. Any self-insured group health insurance plan established by the Department of Personnel and Training which utilizes a network of preferred providers shall not exclude any physician solely on the basis of a reprimand or censure from the Board of Medicine, so long as the physician otherwise meets the plan criteria established by the Department.

§ 38.2-3407.5. Denial of benefits for certain prescription drugs prohibited.

A. Each (i) insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical or major medical coverage on an expense incurred basis, (ii) corporation providing individual or group accident and sickness subscription contracts, and (iii) health maintenance organization providing a health care plan for health care services, whose policy, contract or plan, including any certificate or evidence of coverage issued in connection with such policy, contract or plan, includes coverage for prescription drugs, whether on an inpatient basis, outpatient basis, or both, shall provide in each such policy, contract, plan, certificate, and evidence of coverage that such benefits will not be denied for any drug approved by the United States Food and Drug Administration for use in the treatment of cancer on the basis that the drug has not been approved by the United States Food and Drug Administration for the treatment of the specific type of cancer for which the drug has been prescribed, provided the drug has been recognized as safe and effective for treatment of that specific type of cancer in any of the following standard reference compendia:

1. The American Medical Association Drug Evaluations;
2. The American Hospital Formulary Service Drug Information; or
3. The United States Pharmacopoeia Dispensing Information.

B. Each (i) insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical or major medical coverage on an expense-incurred basis, (ii) corporation providing individual or group accident and sickness subscription contracts, and (iii) health maintenance organization providing a health care plan for health care services, whose policy, contract or plan, including any certificate or evidence of coverage issued in connection with such policy, contract or plan, includes coverage for prescription drugs, whether on an inpatient basis, outpatient basis, or both, shall provide in each such policy, contract, plan, certificate, and evidence of coverage that such benefits will not be denied for any drug prescribed to treat a covered indication so long as the drug has been approved by the United States Food and Drug Administration for at least one indication and the drug is recognized for treatment of the covered indication in one of the standard reference compendia or in substantially accepted peer-reviewed medical literature.

C. For the purposes of subsections A and B:

"Peer-reviewed medical literature" means a scientific study published only after having been critically reviewed for scientific accuracy, validity, and reliability by unbiased independent experts in a journal that has been determined by the International Committee of Medical Journal Editors to have

179 met the Uniform Requirements for Manuscripts submitted to biomedical journals. Peer-reviewed medical
 180 literature does not include publications or supplements to publications that are sponsored to a
 181 significant extent by a pharmaceutical manufacturing company or health carrier.

182 "Standard reference compendia" means the American Medical Association Drug Evaluations, the
 183 American Hospital Formulary Service Drug Information, or the United States Pharmacopoeia
 184 Dispensing Information.

185 D. Coverage, as described in ~~subsection~~ subsections A and B, includes medically necessary services
 186 associated with the administration of the drug.

187 C. E. ~~Subsection~~ Subsections A and B shall not be construed to do any of the following:

188 1. Require coverage for any drug if the United States Food and Drug Administration has determined
 189 its use to be contraindicated for the treatment of the specific type of cancer *or indication* for which the
 190 drug has been prescribed;

191 2. Require coverage for experimental drugs not otherwise approved for any indication by the United
 192 States Food and Drug Administration;

193 3. Alter any law with regard to provisions limiting the coverage of drugs that have not been
 194 approved by the United States Food and Drug Administration;

195 4. Create, impair, alter, limit, modify, enlarge, abrogate, or prohibit reimbursement for drugs used in
 196 the treatment of any other disease or condition; or

197 5. Require coverage for prescription drugs in any contract, policy or plan that does not otherwise
 198 provide such coverage.

199 D. F. The provisions of this section shall not apply to short-term travel, or accident-only policies, or
 200 to short-term nonrenewable policies of not more than six months' duration.

201 E. G. The provisions of ~~this section~~ subsection A are applicable to contracts, policies or plans
 202 delivered, issued for delivery or renewed in this Commonwealth on and after July 1, 1994, and the
 203 provisions of subsection B are applicable to contracts, policies or plans delivered, issued for delivery or
 204 renewed in this Commonwealth on and after July 1, 1997.