

DEPARTMENT OF REGULATORY AGENCIES

Division of Insurance

3 CCR 702-4

LIFE, ACCIDENT AND HEALTH

Proposed Amended Regulation 4-2-9

CONCERNING NON-DISCRIMINATORY TREATMENT OF ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) AND HUMAN IMMUNODEFICIENCY VIRUS (HIV) RELATED ILLNESS BY LIFE AND HEALTH CARRIERS

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Section 1 Authority

This amended regulation is promulgated and adopted by the Commissioner of Insurance under the authority of §§ 10-1-109, 1104.5(3)(d)(II) and 10-3-1110, C.R.S.

Section 2 Scope and Purpose

The purpose of this regulation is to establish standards that will assure nondiscriminatory treatment with respect to AIDS and HIV infection in underwriting practices, policy forms and benefit provisions utilized by entities subject to the provisions of this regulation. It also establishes what HIV/AIDS medical tests, permitted under § 10-3-1104.5, C.R.S., are considered medically reliable for underwriting decisions.

Section 3 ScopeApplicability

This regulation applies to all entities that provide life or health coverage in this state including a franchise insurance plan, a fraternal benefit society, a health maintenance organization, a nonprofit hospital and health service corporation, a sickness and accident company, a life or annuity company, and any other entity providing a plan of life, annuity, health coverage or health benefits subject to the insurance laws and regulations of Colorado.

Section 4 Definitions

- A. "Insurance Coverage" shall mean life insurance policies and health coverage plans.
- B. "Person" shall have the meaning in § 10-3-1104.5(2)(f), C.R.S.

Section 5 StandardsRules

- A. No person, their agent or employee shall make any inquiry or investigation to determine an insurance applicant's sexual orientation.
- B. Sexual orientation may not be used in the underwriting process or in the determination of insurability.
- C. Insurance support organizations shall be directed by insurers to not investigate, directly or indirectly, the sexual orientation of an applicant or a beneficiary. All persons shall give written notice to their agents and employees who conduct investigations of applicants for insurance coverage, that they shall not investigate, either directly or indirectly, the sexual orientation of an applicant or beneficiary.
- D. No question shall be used which is designed to establish the sexual orientation of the applicant.
- E. Questions relating to the applicant having or having been diagnosed as having AIDS or HIV infection are permissible if they are designed solely to establish the existence of the condition. For example, straightforward questions on applications are acceptable, such as, "Have you had or been told by a member of the medical profession that you have AIDS or HIV infection?" or "Have you received treatment from a member of the medical profession for AIDS or HIV infection?" are acceptable.
- F. Questions relating to medical and other factual matters intending to reveal the possible existence of a medical condition are permissible if they are not used as a proxy to establish the sexual orientation of the applicant, and the applicant has been given an opportunity to provide an explanation for any affirmative answers given in the application. For example: "Have you had chronic cough, significant weight loss, chronic fatigue, diarrhea, enlarged glands..." These types of questions should be related to a finite period of time preceding completion of the application and should be specific. Such questions should provide the applicant the opportunity to give a detailed explanation.
- G. Insurers may not use an applicant's marital status, living arrangements, occupation, gender, medical history, beneficiary designation, or zip code or other territorial classification to establish, or aid in establishing, the applicant's sexual orientation.
- H. For the purpose of rating an applicant for health and life insurance, a person may impose territorial rates only if the rates are based on sound actuarial principles or are related to actual or reasonably anticipated experience.
- I. No adverse underwriting decision shall be made because medical records or any investigation or report indicates that the applicant has demonstrated AIDS or HIV infection related concerns by seeking counseling from health care professionals. Neither shall an adverse underwriting decision be made on the basis of such AIDS or HIV infection related concerns unless a medical test which is a reliable predictor of infection, as defined in **Section 5-subsection J, of this section below**, has been administered. This subsection does not apply to an applicant seeking treatment and/or diagnosis.
- J. Reliable predictors of infection are delineated in **Section 10-3-1104.5 (3)(d)(I)**, C.R.S. Pursuant to **Section 10-3-1104.5 (3)(d)(II)**, C.R.S., the commissioner designates the following tests, approved by the Colorado Department of Public Health and Environment, as equally reliable predictors of AIDS OR HIV infection:
 - 1. A positive HIV-1 p24 antigen test, as defined by the U.S. Department of Public Health and Human Services, Center for Disease Control and Prevention (The Morbidity and Mortality Weekly Report, Volume 95, March 1, 1996). A copy of this USDPHHS

publication is on file at the Colorado Division of Insurance. This regulation does not include later editions or amendments to this USDPHHS report.

2. A positive licensed polymerase chain reaction assay for HIV levels in the serum.
3. Two positive or repeatedly reactive commercially licensed serum, oral fluid or urine ELISA or EIA tests and either:
 - a. For serum or oral fluid specimens, a Western Blot test with bands present at any two of p24, gp41 or gp120/gp160; or
 - b. or urine specimens, a Western Blot test with bands present gp160.
- K. To be used for issuing or underwriting a policy, a test described in **Section 5-subsection J of this section** must have been licensed by the U.S. Food and Drug Administration as of the effective date of this regulation. A list of such tests is attached as Exhibit 1.
- L. If a specific test licensed by the U.S. Food and Drug Administration indicates the presence of the HIV infection or medical condition indicative of the HIV infection, the insurer shall, before relying on a single test result to deny or limit coverage or to rate the coverage, follow the U.S. Food and Drug Administration confirmation protocols licensed as of the effective date of this regulation and shall use any applicable confirmatory tests or series of tests licensed as of the effective date of this regulation by the U.S. Food and Drug Administration to confirm the indication. The confirmation protocols and applicable follow-up test regimens are attached as Exhibit 1.
- M. If an applicant is required to take an AIDS or HIV infection test in connection with an application for life or health insurance, the use of such test must be revealed to the applicant and his or her written consent obtained. Test results shall be strictly confidential medical information. However, this regulation is not intended nor should it be interpreted as prohibiting reporting HIV infection to state and local departments of health as provided in **Sections §§ 25-4-1402 and 25-4-1403, C.R.S.**
- N. Persons subject to this regulation may include questions on applications as to whether or not the applicant has tested positive on an AIDS or HIV infection test. However, in the event of an affirmative response, no adverse underwriting decisions shall be made on the basis of such response unless it can be determined that the test protocols in **this Section 5, subsections J, and K, of this section,** above, have been followed.
- O. Insurance coverage which excludes or limits coverages for expenses related to the treatment of AIDS and HIV related illness or complications of AIDS, e.g., opportunistic infection resulting from AIDS, will not be approved for use in Colorado, except to the extent that such exclusions or limitations are consistent with the exclusions or limitations applicable to other covered illnesses or conditions covered by the policy or certificate.

Section 6 Severability

If any provisions of this regulation or the application thereof to any person or circumstance are for any reason held to be invalid, the remainder of the regulation shall not be affected in any way.

Section 67 Enforcement

Noncompliance with this regulation may result, after proper notice and hearing, in the imposition of **all applicable any** of the sanctions made available in the Colorado statutes pertaining to the business of insurance or other laws, which include the imposition of fines, **issuance of cease and desist orders,** and/or

suspension or revocation of license. Amount others, the penalties provided for in § 10-3-1108, C.R.S. may be applied.

Section 7 — Severability

If any provisions of this regulation or the application thereof to any person or circumstance are for any reason held to be invalid, the remainder of the regulation shall not be affected in any way.

Section 8 Effective Date

This regulation as amended is effective April 1, 2000~~May 1, 2010~~.

Section 9 History

Originally issued as Regulation 87-2, effective January 1, 1988.

Renumbered as Regulation 4-2-9, effective June 1, 1992.

Amended Section IV(J), effective February 1, 1995.

Amended Regulation, effective March 2, 1999.

Amended Regulation, effective April 1, 2000~~May 1, 2010~~.

EXHIBIT 4 Appendix A

FDA Licensed/Approved HIV Tests for Colorado Regulation 4-2-9

Published as of 7/16/98

Licensed Tests Antibody to Human Immunodeficiency Virus (HIV-1 Antigen Assay)

Tradename(s)	Format	Sample	Use	Manufacturer	Approval
Abbott HIVAG-1 Monoclonal	EIA	Serum / Plasma	Donor Screen & Neut. Kit	Abbott Laboratories Abbott Park, IL US License 0043	04/23/96
Coulter HIV-1 p24 Ag Assay; HIV-1 p24 Antigen ELISA Test System	EIA	Serum / Plasma	Donor Screen & Neut. Kit	Coulter Corporation Miami, FL US License 1185	03/14/96
Abbott HIVAG-1	EIA	Serum / Plasma	Prognosis & Neut. Kit	Abbott Laboratories	08/03/89
Abbott HIVAG-1 Monoclonal	EIA	Serum / Plasma	Prognosis & Neut. Kit	Abbott Laboratories	04/23/96
Coulter HIV-1 p24 Ag Assay; HIV-1 p24 Antigen ELISA Test System	EIA	Serum / Plasma	Prognosis & Neut. Kit	Coulter Corporation	03/14/96
Coulter HIV-1 p24 Ag Assay	EIA	Viral Culture Supernatant	Prognosis (Quantitative) & Neut. Kit	Coulter Corporation	03/14/96

Human Immunodeficiency Virus Type 1 (Anti-HIV-1 Assay) Human Immunodeficiency Virus Types 1 & 2 (Anti-HIV-1/2 Assay)

Tradename(s)	Format	Sample	Use	Manufacturer	Approval
HIVAB HIV-1 EIA	EIA	Serum / Plasma	Donor Screen	Abbott Laboratories Abbott Park, IL US License 0043	03/01/85
Recombigen (env & gag) HIV-1 EIA	EIA	Serum / Plasma	Donor Screen	Cambridge Biotech Corp. Rockville, MD US License 1063	05/01/90

Microtrak HIV-1 EIA (env & gag)	EIA	Serum / Plasma	Donor Screen	Cambridge Biotech Corp.	05/30/90
RLAV EIA	EIA	Serum / Plasma	Donor Screen	Genetic Systems Corp. Redmond, WA US License 0978	06/29/98

Tradename(s)	Format	Sample	Use	Manufacturer	Approval
Murex SUDS HIV-1 Test	Rapid EIA	Serum / Plasma	Donor Screen	Murex Diagnostics, Inc. Norcross, GA US License 1152	05/22/92
Vironostika HIV-1 Microelisa System	EIA	Serum / Plasma	Donor Screen	Organon Teknika Corp. Durham, NC US License 0956	12/18/87
UBI-OLYMPUS HIV-1 EIA	EIA	Serum / Plasma	Donor Screen	United Biomedical, Inc. Hauppauge, NY US License 1079	05/31/89
Novapath HIV-1 Immunoblot	WB	Serum / Plasma	Donor Supplemental	Bio-Rad Laboratories Hercules, CA US License 1109	06/15/90
HIV-1 Western Blot Kit	WB	Serum / Plasma	Donor Supplemental	Cambridge Biotech Corp.	01/03/91
EPIblot HIV-1	WB	Serum / Plasma	Donor Supplemental	Epitope, Inc. Beaverton, OR US License 1133	03/20/91
Fluorognost HIV 1 IFA	IFA	Serum / Plasma	Donor Supplemental	Waldheim Pharmazeutika G.m.b.H. Vienna, Austria US License 1150	02/05/92
HIVAB HIV-1 EIA	EIA	Dried Blood Spot	Non-Donor Screen	Abbott Laboratories	04/22/92
HIV-1 Urine EIA; Seradyn Sentinel HIV-1 Urine EIA	EIA	Urine Screen	Non-Donor Screen	Calypte Biomedical Corp. Berkeley, CA US License 1207	08/06/96
RLAV EIA	EIA	Dried Blood Spot	Non-Donor Screen	Genetic Systems Corp.	06/29/98
Vironostika HIV-1	EIA	Dried Blood	Non-Donor Screen	Organon Teknika Corp.	04/11/90

Microelisa System		Spot			
Oral Fluid Vironostika HIV-1 Microelisa System	EIA	Oral Fluid	Non-Donor Screen	Organon Teknika Corp.	12/23/94
HIV-1 Western Blot Kit	WB	Dried Blood Spot	Non-Donor Supplemental	Cambridge Biotech Corp.	01/03/91
HIV-1 Western Blot Kit	WB	Urine	Non-Donor Supplemental	Cambridge Biotech Corp.	5/28/98
OraSure HIV-1 Western Blot Kit	WB	Oral Fluid	Non-Donor Supplemental	Epitope, Inc.	06/03/96
Fluorognost HIV 1 IFA	IFA	Dried Blood Spot	Non-Donor Supplemental	Waldheim Pharmazeutika G.m.b.H.	05/14/96

Tradename(s)	Format	Sample	Use	Manufacturer	Approval
Abbott HIVAB HIV-1/HIV-2 (rDNA) EIA	EIA	Serum / Plasma	Donor Screen	Abbott Laboratories Abbott Park, IL US License 0043	02/14/92
Genetic Systems HIV-1/HIV-2 Peptide EIA	EIA	Serum / Plasma	Donor Screen	Genetic Systems Corp. Redmond, WA US License 0978	08/22/97
UBI HIV-1/2 EIA	EIA	Serum / Plasma	Donor Screen	United Biomedical, Inc. Hauppauge, NY U.S. License 1079	12/20/96

Human Immunodeficiency Virus Type 2 (Anti-HIV-2 Assay)

Tradename(s)	Format	Sample	Use	Manufacturer	Approval
Genetic Systems HIV-2 EIA	EIA	Serum / Plasma	Donor Screen	Genetic Systems Corp. Redmond, WA US License 0978	04/25/90

Premarket Approvals -Anti-HIV-1 Testing Service

Tradename(s)	Format	Sample	Use	Manufacturer	Approval
Home Access HIV-1 Test	Dried Blood Spot	Dried Blood	Non-Donor Screen	Home Access Health Corp. Hoffman Estates, IL	07/22/96

	Collection			
System	Device	Spot		

Anti-HIV-1 Oral Specimen Collection Device

Tradename(s)	Format	Sample	Use	Manufacturer	Approval
Epitope OraSure HIV-1 Oral Specimen Collection Device	Oral Specimen Collection Device	Oral Fluid	For Use in Designated Non- Donor Screen and Non-Donor Supplemental Assays	Epitope, Inc. Beaverton, OR	05/09/91

HIV-1 Viral Load Assay

Tradename(s)	Format	Sample	Use	Manufacturer	Approval
Roche Amplicor HIV-1 Monitor Test	PCR	Serum / Plasma	Prognosis	Roche Molecular Systems, Inc. Branchburg Township, NJ	06/03/96