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STATE OF COLORADO

PREAMENDED

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

LLS NO. 21-0462.02 Christy Chase x2008 **HOUSE BILL 21-1297**

HOUSE SPONSORSHIP

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A BILL FOR AN ACT

CONCERNING REQUIREMENTS REGARDING THE ADMINISTRATION OF PRESCRIPTION DRUG BENEFITS UNDER HEALTH BENEFIT PLANS.

Bill Summary

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

The bill precludes a health insurer, a pharmacy benefit manager (PBM), or an entity acting for a health insurer or PBM to conduct on-site audits of pharmacies within 12 months after a prior on-site audit except in specified circumstances.

Additionally, the bill enacts the "Pharmacy Fairness Act" (act), which imposes requirements regarding contracts between PBMs and

pharmacies as follows:

- Requires a health insurer to submit to the commissioner of insurance (commissioner) a list of PBMs the health insurer uses to manage or administer prescription drug benefits under its health benefit plans offered in this state;
- Prohibits PBMs from:
  - Restricting a covered person's access to prescription drug benefits at an in-network retail pharmacy, except as permitted in limited circumstances;
  - Charging a pharmacy or pharmacist a fee for adjudicating a claim, other than a one-time fee of not more than the lesser of 25% of the pharmacy dispensing fee or 25 cents for receipt and processing of the same pharmacy claim;
  - Requiring stricter pharmacy accreditation standards or certification requirements than the standards or requirements that are applicable to similarly situated PBM-affiliated pharmacies within the same PBM network; or
  - Refusing to designate a pharmacy located in a county with a population of 20,000 or fewer as a preferred pharmacy under the health benefit plan.

A PBM that administers the drug assistance program operated by the department of public health and environment is exempt from the requirements and prohibitions of the act with regard to the PBM's administration of that program only.

The bill also:

- Requires a health insurer or PBM to respond in real time to a request from an insured, the insured's health care provider, or a third party acting on behalf of the insured or provider for data regarding the cost, benefits, and coverage under the insured's health benefit plan for a particular drug; and
- Requires a health insurer or PBM that removes a prescription drug from the prescription drug formulary or moves a prescription drug to a higher cost tier on the formulary during the benefit year to notify a covered person that is prescribed that drug at least 30 days before the action and allow the covered person to continue using the drug without prior authorization and at the same coverage level for the remainder of the benefit year, except in specified circumstances.

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

SECTION 1. Legislative declaration. (1) The general assembly finds that:

(a) Pharmacies are vital community resources, with local pharmacies often serving as the only source of health information and care for many patients;

(b) Pharmacies and pharmacists are particularly important in rural communities, where residents may lack access to other regular health care;

(c) Moreover, many pharmacists are authorized to dispense and administer routine vaccinations and will play a critical role in distributing the COVID-19 vaccine;

(d) Pharmacy benefit managers (PBMs) function as claims-processing intermediaries between health insurers or plans and pharmacies, and as administrators of the financial and logistical aspects of claims processing, PBMs can serve a valuable purpose;

(e) By establishing infrastructure and centralizing processing, PBMs can streamline services, realize efficiencies, and potentially reduce system costs across the board, and by amassing large patient networks, PBMs can gain leverage to negotiate discounts for the ultimate benefit of the patient;

(f) When patients are left without a trusted pharmacy, they are alone to navigate a confusing and unpredictable prescription drug benefits system that includes barriers to medication access from diagnosis to prescription pickup, such as impersonal technology and benefit complications; and

(g) Access to prescription drugs needs to be fair, predictable, easy, and empowered by technologies that break down barriers to medication

access and improve the lives of patients.

(2) The general assembly declares that the intent of this act is to:

(a) Ensure that all Colorado pharmacies and their patients are treated fairly and equitably;

(b) Preserve patient access to pharmacy services; and

(c) Ensure that:

(I) Pharmacists are fairly compensated for their services;

(II) Patients have access to affordable, life-saving medications; and

(III) Transactions between PBMs, patients, and pharmacies are transparent.

SECTION 2. In Colorado Revised Statutes, 10-16-102, **amend** (49) as follows:

10-16-102. Definitions. As used in this article 16, unless the context otherwise requires:

(49) (a) "Pharmacy benefit management firm", "PHARMACY BENEFIT MANAGER", OR "PBM" means any entity doing business in this state that ~~contracts to administer or manage~~ ADMINISTERS OR MANAGES prescription drug benefits, INCLUDING CLAIMS PROCESSING SERVICES AND OTHER PRESCRIPTION DRUG OR DEVICE SERVICES AS DEFINED IN SECTION 10-16-122.1, on behalf of any carrier that provides prescription drug benefits to residents of this state, EITHER PURSUANT TO A CONTRACT WITH THE CARRIER OR AS AN ENTITY THAT IS RELATED TO, ASSOCIATED BY COMMON OR OTHER OWNERSHIP WITH, OR OTHERWISE ASSOCIATED WITH THE CARRIER.

(b) "PHARMACY BENEFIT MANAGEMENT FIRM", "PHARMACY BENEFIT MANAGER", OR "PBM" DOES NOT INCLUDE:

(I) A HEALTH CARE FACILITY LICENSED OR CERTIFIED BY THE DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT PURSUANT TO SECTION 25-1.5-103 (1)(a);

(II) A PROVIDER;

(III) A CONSULTANT WHO ONLY PROVIDES ADVICE AS TO THE SELECTION OR PERFORMANCE OF A PHARMACY BENEFIT MANAGEMENT FIRM; OR

(IV) A NONPROFIT HEALTH MAINTENANCE ORGANIZATION THAT OFFERS MANAGED CARE PLANS THAT PROVIDE A MAJORITY OF COVERED PROFESSIONAL SERVICES THROUGH A SINGLE, CONTRACTED MEDICAL GROUP AND THAT OPERATES ITS OWN PHARMACIES.

SECTION 3. In Colorado Revised Statutes, **add** 10-16-122.1 as follows:

10-16-122.1. Contracts between PBMs and pharmacies - carrier submit list of PBMs - prohibited practices - exception - short title - definitions. (1) THE SHORT TITLE OF THIS SECTION IS THE "PHARMACY FAIRNESS ACT".

(2) (a) STARTING IN 2022, EACH CARRIER SHALL SUBMIT TO THE COMMISSIONER, CONTEMPORANEOUSLY WITH ITS RATE FILING PURSUANT TO SECTION 10-16-107 AND IN A FORM AND MANNER SPECIFIED BY THE COMMISSIONER BY RULE, A LIST OF ALL PHARMACY BENEFIT MANAGERS THE CARRIER CONTRACTS WITH OR OTHERWISE USES FOR CLAIMS PROCESSING SERVICES OR OTHER PRESCRIPTION DRUG OR DEVICE SERVICES UNDER HEALTH COVERAGE PLANS THE CARRIER OFFERS.

(b) THE LIST OF PBMS SUBMITTED TO THE COMMISSIONER PURSUANT TO THIS SUBSECTION (2) IS CONSIDERED PROPRIETARY AND CONFIDENTIAL INFORMATION AND IS NOT SUBJECT TO DISCLOSURE UNDER

THE "COLORADO OPEN RECORDS ACT", PART 2 OF ARTICLE 72 OF TITLE 24.

(3) STARTING IN 2022, A PBM OR THE REPRESENTATIVE OF A PBM SHALL NOT:

(a) (I) WITH REGARD TO INDIVIDUAL AND GROUP HEALTH BENEFIT PLANS, PRECLUDE COVERED PERSONS FROM ACCESSING PRESCRIPTION DRUG BENEFITS UNDER THE HEALTH BENEFIT PLAN AT AN IN-NETWORK RETAIL PHARMACY UNLESS:

(A) THE FDA HAS RESTRICTED DISTRIBUTION OF THE PRESCRIPTION DRUG; OR

(B) THE PRESCRIPTION DRUG REQUIRES SPECIAL HANDLING, PROVIDER COORDINATION, OR PATIENT EDUCATION THAT CANNOT BE PROVIDED BY A RETAIL PHARMACY.

(II) A HEALTH BENEFIT PLAN MAY IMPOSE A DIFFERENT COST-SHARING AMOUNT FOR OBTAINING A COVERED PRESCRIPTION DRUG AT A RETAIL PHARMACY, BUT ALL COST SHARING MUST COUNT TOWARDS THE PLAN'S ANNUAL LIMITATION ON COST SHARING SPECIFIED IN 45 CFR 156.130 AND MUST BE ACCOUNTED FOR IN THE PLAN'S ACTUARIAL VALUE CALCULATED UNDER 45 CFR 156.135.

(b) CHARGE A PHARMACY OR PHARMACIST A FEE RELATED TO THE ADJUDICATION OF A PHARMACIST SERVICES CLAIM, OTHER THAN A ONE-TIME, REASONABLE FEE, NOT TO EXCEED THE LESSER OF TWENTY-FIVE PERCENT OF THE PHARMACY DISPENSING FEE OR TWENTY-FIVE CENTS, FOR RECEIPT AND PROCESSING OF THE SAME PHARMACIST SERVICES CLAIM; OR

(c) REQUIRE PHARMACY ACCREDITATION STANDARDS OR CERTIFICATION REQUIREMENTS INCONSISTENT WITH, MORE STRINGENT THAN, OR IN ADDITION TO REQUIREMENTS APPLICABLE TO SIMILARLY

SITUATED PBM-AFFILIATED PHARMACIES WITHIN THE SAME PBM NETWORK.

(4) THIS SECTION DOES NOT APPLY TO THE ADMINISTRATION OR MANAGEMENT OF THE DRUG ASSISTANCE PROGRAM AUTHORIZED PURSUANT TO SECTION 25-4-1401.

(5) AS USED IN THIS SECTION AND SECTION 10-16-122.9, UNLESS THE CONTEXT OTHERWISE REQUIRES:

(a) "CLAIMS PROCESSING SERVICES" MEANS THE ADMINISTRATIVE SERVICES PERFORMED IN CONNECTION WITH PROCESSING AND ADJUDICATING CLAIMS RELATED TO PHARMACIST SERVICES, WHICH SERVICES INCLUDE:

(I) RECEIVING PAYMENTS FOR PHARMACIST SERVICES; OR

(II) MAKING PAYMENTS TO PHARMACIES OR PHARMACISTS FOR PHARMACIST SERVICES.

(b) "OTHER PRESCRIPTION DRUG OR DEVICE SERVICES" MEANS SERVICES, OTHER THAN CLAIMS PROCESSING SERVICES, PROVIDED DIRECTLY OR INDIRECTLY AND EITHER IN CONNECTION WITH OR SEPARATE FROM CLAIMS PROCESSING SERVICES. THE TERM INCLUDES:

(I) MANAGING OR PARTICIPATING IN INCENTIVE PROGRAMS OR ARRANGEMENTS FOR PHARMACIST SERVICES;

(II) NEGOTIATING OR ENTERING INTO CONTRACTUAL ARRANGEMENTS WITH PHARMACIES OR PHARMACISTS;

(III) DEVELOPING FORMULARIES;

(IV) DESIGNING PRESCRIPTION DRUG BENEFITS PROGRAMS; AND

(V) ADVERTISING OR PROMOTING SERVICES.

(c) "PBM-AFFILIATED PHARMACY" MEANS A PHARMACY OR PHARMACIST THAT, EITHER DIRECTLY OR INDIRECTLY THROUGH ONE OR

MORE INTERMEDIARIES, OWNS OR CONTROLS OR IS OWNED OR CONTROLLED BY A PBM.

(d) "PBM NETWORK" MEANS A NETWORK OF PHARMACIES OR PHARMACISTS THAT ARE OFFERED AN AGREEMENT OR CONTRACT TO PROVIDE PHARMACIST SERVICES FOR A HEALTH BENEFIT PLAN.

(e) "PHARMACIST" HAS THE SAME MEANING AS SET FORTH IN SECTION 12-280-103 (35).

(f) "PHARMACIST SERVICES" MEANS PRODUCTS, GOODS, AND SERVICES PROVIDED AS A PART OF THE PRACTICE OF PHARMACY, AS DEFINED IN SECTION 12-280-103 (39).

(g) "PHARMACY" HAS THE SAME MEANING AS SET FORTH IN SECTION 12-280-103 (43).

SECTION 4. In Colorado Revised Statutes, 10-16-122.5, **add** (5.5) as follows:

10-16-122.5. Pharmacy benefit manager - audit of pharmacies - time limits on on-site audits. (5.5) EXCEPT UNDER CIRCUMSTANCES SPECIFIED IN SUBSECTION (5) OF THIS SECTION, ON OR AFTER THE EFFECTIVE DATE OF THIS SUBSECTION (5.5), A PHARMACY BENEFIT MANAGER, A CARRIER, OR AN ENTITY ACTING ON BEHALF OF A PBM OR A CARRIER SHALL NOT CONDUCT AN ON-SITE AUDIT OF A PHARMACY FOR WHICH THE PBM, CARRIER, OR ENTITY ACTING ON BEHALF OF A PBM OR A CARRIER HAS CONDUCTED AN ON-SITE AUDIT WITHIN THE IMMEDIATELY PRECEDING TWELVE MONTHS.

SECTION 5. In Colorado Revised Statutes, **add** 10-16-122.9 as follows:

10-16-122.9. Prescription drug benefits - real-time access to benefit information - definitions. (1) (a) UPON REQUEST OF A COVERED

PERSON, THE COVERED PERSON'S PROVIDER, OR A THIRD PARTY ON BEHALF OF THE COVERED PERSON OR PROVIDER, A CARRIER OR, IF A CARRIER USES A PHARMACY BENEFIT MANAGER FOR CLAIMS PROCESSING SERVICES OR OTHER PRESCRIPTION DRUG OR DEVICE SERVICES UNDER A HEALTH BENEFIT PLAN OFFERED BY THE CARRIER, THE PBM SHALL FURNISH THE COST, BENEFIT, AND COVERAGE DATA SET FORTH IN SUBSECTION (1)(c) OF THIS SECTION TO THE COVERED PERSON, THE COVERED PERSON'S PROVIDER, OR THE THIRD PARTY ACTING ON BEHALF OF THE COVERED PERSON OR PROVIDER AND SHALL ENSURE THAT THE DATA IS:

(I) CURRENT AND UPDATED NO LATER THAN ONE BUSINESS DAY AFTER ANY CHANGE IS MADE;

(II) PROVIDED IN REAL TIME; AND

(III) PROVIDED IN THE SAME FORMAT THAT THE REQUEST IS MADE BY THE COVERED PERSON, PROVIDER, OR THIRD PARTY THAT MADE THE REQUEST.

(b) (I) A COVERED PERSON, THE COVERED PERSON'S PROVIDER, OR A THIRD PARTY ACTING ON BEHALF OF THE COVERED PERSON OR PROVIDER SHALL SUBMIT THE REQUEST FOR COST, BENEFIT, AND COVERAGE DATA AND THE CARRIER OR PBM SHALL RESPOND TO THE REQUEST USING ESTABLISHED INDUSTRY CONTENT AND TRANSPORT STANDARDS PUBLISHED BY:

(A) A STANDARDS-DEVELOPING ORGANIZATION ACCREDITED BY THE AMERICAN NATIONAL STANDARDS INSTITUTE OR ITS SUCCESSOR ENTITY, INCLUDING THE NATIONAL COUNCIL FOR PRESCRIPTION DRUG PROGRAMS, THE ACCREDITED STANDARDS COMMITTEE, OR HEALTH LEVEL SEVEN INTERNATIONAL, OR THEIR SUCCESSOR ENTITIES; OR

(B) A RELEVANT FEDERAL OR STATE GOVERNING BODY, INCLUDING

THE CMS OR THE OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY IN THE FEDERAL DEPARTMENT OF HEALTH AND HUMAN SERVICES.

(II) A FACSIMILE, PROPRIETARY PAYER OR PATIENT PORTAL, OR OTHER ELECTRONIC FORM IS NOT AN ACCEPTABLE ELECTRONIC FORMAT PURSUANT TO THIS SECTION.

(c) (I) UPON RECEIPT OF A REQUEST FOR COST, BENEFIT, AND COVERAGE DATA PURSUANT TO THIS SUBSECTION (1), THE CARRIER OR PBM, AS APPLICABLE, SHALL PROVIDE THE FOLLOWING DATA FOR ANY DRUG COVERED UNDER THE COVERED PERSON'S HEALTH BENEFIT PLAN:

(A) THE COVERED PERSON'S ELIGIBILITY INFORMATION FOR THE DRUG;

(B) A LIST OF ANY CLINICALLY APPROPRIATE ALTERNATIVES TO THE DRUG THAT ARE COVERED UNDER THE COVERED PERSON'S HEALTH BENEFIT PLAN;

(C) COST-SHARING INFORMATION FOR THE DRUG AND FOR CLINICALLY APPROPRIATE ALTERNATIVES, INCLUDING A DESCRIPTION OF ANY VARIANCE IN COST-SHARING BASED ON A PHARMACY, WHETHER RETAIL OR MAIL ORDER, OR PROVIDER DISPENSING OR ADMINISTERING THE DRUG OR ALTERNATIVES; AND

(D) ANY APPLICABLE UTILIZATION MANAGEMENT REQUIREMENTS FOR THE DRUG OR CLINICALLY APPROPRIATE ALTERNATIVES, INCLUDING PRIOR AUTHORIZATION, STEP THERAPY, QUANTITY LIMITS, AND SITE-OF-SERVICE RESTRICTIONS.

(II) THE CARRIER OR PBM SHALL FURNISH THE DATA SPECIFIED IN SUBSECTION (1)(c)(I) OF THIS SECTION, WHETHER THE REQUEST IS MADE USING THE DRUG'S UNIQUE BILLING CODE, SUCH AS A NATIONAL DRUG

CODE OR HEALTHCARE COMMON PROCEDURE CODING SYSTEM CODE, OR A DESCRIPTIVE TERM, SUCH AS THE BRAND OR GENERIC NAME OF THE DRUG. A CARRIER OR PBM SHALL NOT DENY OR DELAY A REQUEST FOR COST, BENEFIT, AND COVERAGE DATA AS A METHOD OF BLOCKING THE DATA FROM BEING SHARED BASED ON HOW THE DRUG WAS REQUESTED.

(d) A CARRIER OR PBM FURNISHING THE DATA REQUESTED PURSUANT TO THIS SUBSECTION (1) SHALL NOT:

(I) RESTRICT, PROHIBIT, OR OTHERWISE HINDER A PROVIDER FROM COMMUNICATING OR SHARING WITH THE COVERED PERSON:

(A) ANY OF THE DATA SET FORTH IN SUBSECTION (1)(c)(I) OF THIS SECTION;

(B) ADDITIONAL INFORMATION ON ANY LOWER-COST OR CLINICALLY APPROPRIATE ALTERNATIVES, WHETHER OR NOT THE ALTERNATIVES ARE COVERED UNDER THE COVERED PERSON'S PLAN; OR

(C) ADDITIONAL PAYMENT OR COST-SHARING INFORMATION THAT MAY REDUCE THE COVERED PERSON'S OUT-OF-POCKET COSTS, SUCH AS CASH PRICE OR PATIENT ASSISTANCE AND SUPPORT PROGRAMS, WHETHER SPONSORED BY A MANUFACTURER, FOUNDATION, OR OTHER ENTITY;

(II) EXCEPT AS MAY BE REQUIRED BY LAW, INTERFERE WITH, PREVENT, OR MATERIALLY DISCOURAGE ACCESS, EXCHANGE, OR USE OF THE DATA SET FORTH IN SUBSECTION (1)(c)(I) OF THIS SECTION, WHICH MAY INCLUDE:

(A) CHARGING FEES;

(B) FAILING TO RESPOND TO A REQUEST, AT THE TIME THE REQUEST IS MADE, WHEN A RESPONSE IS REASONABLY POSSIBLE;

(C) IMPLEMENTING TECHNOLOGY IN NONSTANDARD WAYS OR INSTITUTING COVERED PERSON CONSENT REQUIREMENTS, PROCESSES,

POLICIES, PROCEDURES, OR RENEWALS THAT ARE LIKELY TO SUBSTANTIALLY INCREASE THE COMPLEXITY OR BURDEN OF ACCESSING, EXCHANGING, OR USING THE DATA; OR

(III) PENALIZE A PROVIDER FOR DISCLOSING THE INFORMATION TO A COVERED PERSON OR PRESCRIBING, ADMINISTERING, OR ORDERING A CLINICALLY APPROPRIATE OR LOWER-COST ALTERNATIVE.

(e) A CARRIER OR PBM SHALL TREAT A PERSONAL REPRESENTATIVE OF A COVERED PERSON AS THE COVERED PERSON FOR PURPOSES OF THIS SECTION. IF, UNDER APPLICABLE LAW, A PERSON HAS AUTHORITY TO ACT ON BEHALF OF A COVERED PERSON IN MAKING DECISIONS RELATED TO HEALTH CARE, A CARRIER OR PBM, OR AFFILIATES OR ENTITIES ACTING ON BEHALF OF THE CARRIER OR PBM, MUST TREAT THE PERSON AS A PERSONAL REPRESENTATIVE OF THE COVERED PERSON FOR PURPOSES OF THIS SECTION.

(2) AS USED IN THIS SECTION, UNLESS THE CONTEXT OTHERWISE REQUIRES:

(a) "CMS" MEANS THE FEDERAL CENTERS FOR MEDICARE AND MEDICAID SERVICES IN THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES.

(b) "COST-SHARING INFORMATION" MEANS THE AMOUNT A COVERED PERSON IS REQUIRED TO PAY FOR A DRUG THAT IS COVERED UNDER THE COVERED PERSON'S HEALTH BENEFIT PLAN.

(c) "COVERED" OR "COVERAGE" MEANS THOSE HEALTH CARE SERVICES TO WHICH A COVERED PERSON IS ENTITLED UNDER THE TERMS OF THE COVERED PERSON'S HEALTH BENEFIT PLAN.

(d) "DRUG" MEANS ANY PRESCRIPTION DRUG OR MEDICATION

COVERED UNDER A HEALTH BENEFIT PLAN, WHETHER ORDERED, PRESCRIBED, OR ADMINISTERED.

(e) "HEALTHCARE COMMON PROCEDURE CODING SYSTEM" MEANS THE SYSTEM DEVELOPED BY THE CMS FOR IDENTIFYING HEALTH CARE SERVICES IN A CONSISTENT AND STANDARDIZED MANNER.

(f) "NATIONAL DRUG CODE" MEANS THE UNIQUE, THREE-SEGMENT IDENTIFIER NUMBER USED BY THE FDA TO IDENTIFY DRUGS THAT ARE MANUFACTURED, PREPARED, PROPAGATED, COMPOUNDED, OR PROCESSED FOR SALE IN THE UNITED STATES.

(g) "THIRD PARTY" MEANS A PERSON, OTHER THAN A PBM, THAT IS NOT AN ENROLLEE IN OR A COVERED PERSON UNDER A HEALTH BENEFIT PLAN.

SECTION 6. Severability. If any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity does not affect other provisions or applications of the act that can be given effect without the invalid provision or application, and to this end the provisions of this act are declared to be severable.

SECTION 7. Safety clause. The general assembly hereby finds, determines, and declares that this act is necessary for the immediate preservation of the public peace, health, or safety.