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Kate Harris
Chief Deputy of Health and Life Policy
Colorado Division of Insurance
1560 Broadway, Ste. 850
Denver, CO 80202

Matt Mortier
Director of Compliance
Colorado Division of Insurance
1560 Broadway, Ste. 850
Denver, CO 80202

Comments Submitted via email to: DORA_Ins_RulesandRecords@state.co.us

RE: Implementation of HB 19-1216, Concerning measures to reduce a patient's costs of prescription insulin drugs, and, in connection therewith, making an appropriation.

Dear Ms. Harris and Mr. Mortier

On behalf of the Pharmaceutical Care Management Association (PCMA) we respectfully submit the following comments the proposed new regulation 4-2-6X, Concerning Prescription Insulin Drug Cost Sharing and Limitations. PCMA is the national trade association for PBMs, which administer prescription drug plans for more than 266 million Americans with health coverage provided by large and small employers, health insurers, labor unions, and federal and state-sponsored health programs.

PCMA believes the legislative language creates a $100 cap for a 30-day supply of "a covered prescription" as stated in the law. It is important that a PBM, operating on behalf of the health plan, can administer this benefit consistently and fairly for all beneficiaries. In many cases, the beneficiary will only have one prescription in a month and the cost will be capped at $100 as required by the law, however, the regulation appears to expand and exceed the scope of the statute.

PCMA is concerned that regulation 4-2-6X has added additional language that could change the legislative meaning and intent of HB19-1216. PCMA relies on the statement provided in the request for public comment that specifically states: *Regulations (also called "rules") interpret, but do not exceed the scope of the more general statutes passed by the Colorado General Assembly (also called the Legislature).*

HB19-1216 language specifically states: A CARRIER THAT PROVIDES COVERAGE FOR PRESCRIPTION INSULIN DRUGS PURSUANT TO THE TERMS OF A HEALTH COVERAGE PLAN THE CARRIER OFFERS SHALL CAP THE TOTAL AMOUNT THAT A COVERED PERSON IS REQUIRED TO PAY FOR A COVERED PRESCRIPTION INSULIN DRUG AT AN AMOUNT NOT TO EXCEED ONE HUNDRED DOLLARS PER THIRTY-DAY SUPPLY OF INSULIN, REGARDLESS OF THE AMOUNT OR TYPE OF INSULIN NEEDED TO FILL THE COVERED PERSON'S PRESCRIPTION.

However, the regulation goes beyond the legislative language and adds additional language in Section 5(a) that appears to exceed and expand the scope of HB19-1216 by adding **"regardless of the number of prescriptions"** to the language that otherwise nearly mirrors the language of the legislation. The Division is effectively adding language to the statute that the General Assembly did not deem proper.

The initial version of the bill included cost-sharing calculations for single prescriptions, subject to a $100 cap that applied to prescription insulin drugs overall. As the bill went through the legislative

process, however, the single prescription cost-sharing calculations were removed and language was added to make clear that the $100 cap is for "a prescription insulin drug" and applies regardless of the amount or type of insulin "needed to fill the covered person's prescription." The amendments to the bill clearly demonstrate that a narrowing of the original bill's scope was necessary to obtain passage in the General Assembly.

PCMA strongly believes under the plain meaning of the law that a single prescription is the legislative intent.

"Prescription insulin drug" is defined in the statute as "a prescription drug, as defined in § 12-42.5-102 (34), that contains insulin and is used to treat diabetes." Section 12-42.5-102 (34), C.R.S., defines prescription drug as:

> (34) "Prescription drug" means a drug that:
> (a) Is required by any applicable federal or state law or rule to be dispensed only pursuant to an order;
> (b) Is restricted by any applicable federal or state law or rule to use by practitioners only; or
> (c) Prior to being dispensed or delivered, is required under federal law to be labeled with one of the following statements:
> (I) "Rx only"; or
> (II) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

"Prescription" as defined in § 12-42.5-102 (33), states:

> (33) "Prescription" means the finished product of the dispensing of a prescription order in an appropriately labeled and suitable container.

The statute says, "needed to fill the covered person's prescription" and should be interpreted to mean "the dispensing of a [singular] prescription order." If this were to apply to prescriptions for multiple drugs, that would require separate prescription orders. In addition, according to established industry standards, a 30-day supply is the intended number of days-supply for a single prescription.

In addition, the term "amount or type of insulin" is commonly understood to mean the quantity of insulin required for a 30 day supply of a particular insulin product, which varies depending on the form (vials, pens or cartridges), dosing (based on body weight) and type of insulin (rapid-acting, short-acting, intermediate-acting, mixed or long-acting). So, the singular/plural distinction and the legislative intent only come into play if the statute cannot be construed according to its plain meaning. However, reading the statute as a whole, the plain meaning of a single prescription is clear.

The Division appears to interpret "regardless of the amount or type of insulin" as "regardless of the number of prescriptions and different types of insulin drugs prescribed." Accepting the Division's interpretation would essentially discount and render superfluous the remaining portion of the phrase in the statute that states, "needed to fill the covered person's prescription." *Unquestionably, the statute must be read and considered as a whole, and it is necessary to give consistent and sensible effect to all parts of the statute rendering no words or phrases superfluous*

PCMA also respectfully requests specific guidance and clarification for the following issues:

1. This regulation will lead to uncertainty as to which prescriptions must be aggregated. If the first prescription is for a 10-day supply, the second prescription for a 15-day supply, and the third prescription for a 15-day supply, must the carrier aggregate prescriptions 1 and 2, prescriptions 2 and 3, or prescriptions 1, 2 and 3?

2. Do all prescriptions have to be filled on same day? If not, how does a carrier determine what constitutes a "30 day supply"? What happens when a prescription for a 30-day supply of insulin is filled on January 1, 2020, another prescription for a 30-day supply is filled on January 17, 2020, and another prescription for a 30-day supply is filled on February 2, 2020?

3. How should refills be handled? Generally, a refill threshold is set for less than one hundred percent of the days supply filled. So, for a 30-day supply, the prescription may be refilled after ninety percent of the days supply dispensed has been consumed or 27 days after the dispensing date. If multiple prescriptions are filled on the same day (not uncommon for Colorado patients, as Colorado permits medication synchronization) and the prescriptions are refilled 27 days after the initial dispensing date for additional 30-day supplies, may a cost-sharing amount of up to $100 be charged at the time of refill? Does the same hold true if a 90-day supply is dispensed and refilled 81 days after the initial dispensing date?

Finally, during the legislative session, the Department discussed including an exception to the $100 cap for HSA HDHPs in order to be compliant with IRS regulations. PCMA respectfully requests an explicit exclusion for HSA HDHPs and that individuals with those plans would need to pay full cost (up to their deductible) for the plan to be compliant.

If you should have any questions, please feel free to contact me at 270-454-1773.

Sincerely,

Assistant Vice President – State Affairs
Melodie Shrader

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org