Hoerner Law Offices, PC
1410 Grant Street, Suite B202
Denver, CO 80203
(303)870-0302
jahoerner@comcast.net

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Delivered electronically

Michael Conway
Insurance Commissioner
Colorado Division of Insurance
1560 Broadway, Ste. 850
Denver, CO 80202

Re: Comments on proposed draft regulation 4-2-6X, Concerning prescription insulin drug cost sharing and limitations

Dear Commissioner Conway:

I am submitting comments on behalf of the Colorado Association of Health Plans (CAHP). CAHP is a state association of health insurers that are offering coverage to Coloradans in the individual, small group, large group, Medicaid, and Medicare markets. CAHP's membership includes Colorado specific carriers as well as national carriers. CAHP's mission is promoting high quality, affordable, evidence-based health care in Colorado.

The enabling statute for promulgation of this proposed regulation is Colo. Rev. Stat. Ann. § 10-16-151(5), states that the commissioner may promulgate rules necessary to implement and administer Colo. Rev. Stat. Ann. § 10-16-151. Notably, Colo. Rev. Stat. Ann. § 10-16-151 provides the following:

> 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.*

Colo. Rev. Stat. Ann. § 10-16-151(2) (emphasis added). This provision is clear and unambiguous. A health coverage plan must 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. This cap applies regardless of the amount

or type of insulin needed to fill the covered person's prescription. Put simply, the statute places a $100 cap for each covered prescription of an insulin drug.

Despite the plain language of Colo. Rev. Stat. Ann. § 10-16-151, the Division's new proposed regulation 4-2-6X provides the following:

> Carriers that provide coverage for prescription insulin drugs shall cap the cost-sharing charged to the covered person to $100 per thirty (30) day supply regardless of the number of prescriptions and different types of insulin drugs prescribed and filled in that thirty (30) day period.

This proposed regulation is at odds with the plain language of the enabling statute and seeks to accomplish something that the plain language of the statute simply cannot.

In adopting proposed regulation 4-2-6X, the Division is not promulgating a rule *necessary to implement and administer* Colo. Rev. Stat. Ann. § 10-16-151 as required by the enabling statute. In addition, the Division does not have the authority to promulgate rules that conflict with statutory provisions. *See, e.g.,* Colo. Rev. Stat. Ann. § 24-4-103(4)(b)(IV) ("No rule shall be adopted unless . . . [t]he regulation does not conflict with other provisions of law."). Indeed, a rule that conflicts with a statute is void. *Id.* at (8)(a). Regrettably, the Division's proposed rule conflicts with and expressly modifies the existing statute. *Id.*at (4)(b)(IV).

The Division is effectively adding language to the statute that the General Assembly did not include. A cursory review of the bill's legislative history reveals that the bill required various amendments to successfully pass through the General Assembly. Tellingly, 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.

In any event, the Division is presumably taking steps to promulgate this regulation in an attempt to effectuate the *alleged* intent of the General Assembly. This, too, is improper if the plain language of the statute is clear, as it is here. *See Scoggins v. Unigard Ins. Co.*, 869 P.2d 202, 205 (Colo. 1994); *People v. Tafoya*, 434 P.3d 1193, 1196 (Colo. 2019). "To discern the intent of the legislature, we must look at the plain language of the

statute, and if the statute is clear and the intent of the General Assembly may be discerned with certainty, it is not necessary to resort to other rules of statutory interpretation." *Id.* In fact, "[e]ven if the intent of the General Assembly can be disputed, if the plain language of the statute is clear, it is controlling." *Id.* Again, if the Division promulgates a rule modifying an existing statute (even if done so in an attempt to effectuate the *alleged* intent of the General Assembly), it runs the risk of a court finding that the rule is void. *See Colo. Consumer Health Initiative v. Colo. Bd. of Health*, 240 P.3d 525, 528 (Colo. App. 2010) ("A rule may not modify or contravene an existing statute, and any rule that is inconsistent with or contrary to a statute is void.").

While recognizing that it is not necessary to refer to the rules of statutory construction because the statutory language is clear and unambiguous, the rules of statutory construction nevertheless support the interpretation that the statute places a $100 cap for each covered prescription of an insulin drug and not a $100 cap regardless of the number of prescriptions. Significantly, the first rule of statutory construction states:

> Words and phrases shall be read in context and construed according to the rules of grammar and common usage. *Words and phrases that have acquired a technical or particular meaning, whether by legislative definition or otherwise, shall be construed accordingly.*

Colo. Rev. Stat. Ann § 2-4-101 (emphasis added). This rule of statutory construction is important because the legislation at issue contains words and phrases that have acquired a technical meaning. Therefore, it is necessary to read the statute in context as a whole and give consistent and sensible effect to all parts of the statute. *Tafoya*, 434 P.3d at 1196.

Colo. Rev. Stat. Ann. § 10-16-151(1) defines "Prescription insulin drug" as "a prescription drug, as defined in § 12-42.5-102 (34), that contains insulin and is used to treat diabetes." In turn, Colo. Rev. Stat. Ann. § 12-42.5-102 (34) defines "prescription drug" as:

> 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."

Colo. Rev. Stat. Ann. § 12-42.5-102 (34). "Prescription" is defined as "the finished product of the dispensing of a prescription order in an appropriately labeled and suitable container." Colo. Rev. Stat. Ann. § 12-42.5-102 (33).

In light of the aforementioned definitions, when Colo. Rev. Stat. Ann. § 10-16-151(2) provides, "regardless of the amount or type of insulin needed to fill the covered person's prescription," this means that cap applies regardless of the amount (i.e., the number of units of a prescription insulin drug, which may vary depending on body weight and severity of condition) or type of insulin (i.e., rapid-acting, short-acting, intermediate-acting, mixed or long-acting) *needed* to fill a *single* prescription. The phrase "regardless of the amount or type of insulin needed" addresses the fact that the quantity and type of insulin product prescribed may vary depending on the form (vials, pens, or cartridges), dosing (based on body weight and severity of condition), and the insulin product itself (rapid-acting, short-acting, intermediate-acting, mixed, or long-acting). So, the $100 cap applies regardless of the amount or type of insulin needed to fill the covered person's prescription.

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. *Tafoya*, 434 P.3d at 1196 (in applying a statute's plain and ordinary meaning, "we give consistent, harmonious, and sensible effect to all of its parts, 'and we interpret every word, rendering no words or phrases superfluous and construing undefined words and phrases according to their common usage.'").

Reading the phrase at issue as a whole, it is clear that the cap applies when filling a *single* prescription. As mentioned above, the term "prescription" means "the finished product of the dispensing of a prescription order . . . ." As you know, a prescription necessarily requires a prescription order. If this statute were to apply to prescriptions for multiple drugs (as suggested in the proposed regulation), that would require separate prescription orders for each of the drugs. Further, the Division's proposed regulation inadvertently concedes that the term "prescription" as used in the statute has acquired a technical meaning of a *single* prescription dispensed pursuant to a *single* prescription order. If this were not the case, then the proposed regulation would not need to specify that the cap applies regardless of the "number of prescriptions."

In addition, the term "day supply," as used in the statute, has an accepted technical meaning pursuant to the National Council for Prescription Drug Programs[1] claims transactions standards. That is, a 30-day supply is the intended number of days-supply for a *single* prescription in an NCPDP claim submission. Further, the proposed regulation uses the terms "thirty (30) day supply" and "thirty (30) day period" interchangeably. Significantly, these terms are not synonymous, and a "thirty (30) day supply" does not always equate to a "thirty (30) day period." In fact, it is not uncommon for a pharmacist to provide a patient with a "thirty (30) day supply" of drugs more than once during a "thirty (30) day period." The General Assembly did not take the liberty of using the terms interchangeably when drafting the statute, which further lends support to the fact that General Assembly intended for the statute to place a $100 cap for each *single* prescription of an insulin drug for a "thirty (30) day supply."

On a similar note, the proposed regulation provides the following provision: "[c]arriers shall not charge any additional copayments, deductibles or coinsurance for any additional covered insulin prescriptions filled in that ninety (90) day period." First, this provision is problematic because the Division appears to be modifying the existing statute in that this provision reaches much further than the statute itself. Second, this provision also does not consider the fact that a "ninety (90) day supply" is not always equivalent to a "ninety (90) day period."

Not only is the plain language of the statute clear and unambiguous, the rules of statutory construction also support the interpretation that the statute places a $100 cap for each covered prescription of an insulin drug. In promulgating a regulation that not only modifies, but also contradicts, an existing statute, the Division risks promulgating a regulation that will ultimately be deemed void. *See Colo. Consumer Health Initiative*, 240 P.3d at 528.

In addition, adopting the proposed regulation may lead to many practical issues that have not been taken into consideration. To illustrate, a non-exhaustive list of practical issues follows:

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

[1] The National Council for Prescription Drug Programs ("NCPDP") creates standards for the electronic exchange of healthcare information in the pharmacy services sector. Specifically, the NCPDP develops industry standards related to electronic transactions for prescribing, dispensing, monitoring, managing, billing, and claims. *See* https://www.ncpdp.org/home.

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?

   Specifically:

   a. Fill on 9/1/2020 30 DS with $100 cost share; next refill is available 9/25 (within the 30 day window); Fill price on 9/25 would be $0 cost share because we are in the 30 day window of the 9/1/ fill. Next refill opportunity after 9/25 fill would be 10/20 (within the 30 day window); this fill price on 10/20 would be $0 cost share because we are in the 30 day window of the 9/25 fill. Is that the DOI's intent? Or can we charge the 9/25 fill at a new $100 because it is the same prescription, meant for after the previous 30 DS was complete?

   b. Fill on 9/1/2020 30 DS with $99 cost share; next refill is available 9/25 (within the 30 day window); When member fills same drug again on 9/25 is the cost share $1 since it's within the 30 day widow –OR-- is it $99 again? Next refill opportunity after 9/25 would be 10/20 (within the 30 day window).

   c. Fill on 9/1/2020 90 DS with $300 cost share; next refill is available 11/25 (within the 90 day window); Fill price on 11/25 would be $0 because we are in the 90 day window of the 9/1 fill. Shouldn't they

pay $300 again when they fill on 11/25 since they are filling for their next 90 DS?

d. The DOI should clarify that if an individual ***refills*** a 30-day insulin before the 30-day period is over (e.g., on the 29th day) so that he/she has a sufficient supply on hand to not miss a day, we can still charge them the $100 cap because it is for a new 30-day supply. Section 5(A) explicitly prohibits us from charging beyond the $100 for any fill provided within the 30-day period, even if it is a refill. It seems more appropriate that the 30-day period would be based on supply, not on when the drug is prescribed or filled, so that we could charge a new $100 for an additional 30-day supply.

e. Similarly, if an individual fills a 90-day supply and pays $300, then fills a different 90-day supply 60 days later, do we charge that person $200 for the remaining 60 days that aren't covered by the $300 for the first 90-day fill? Section 5(C) explicitly prohibits any additional cost-sharing for additional insulin prescriptions filled in that 90-day period. Again, this is the problem with using the prescription or fill date, rather than the date the supply should begin.

f. We assume that a 60-day supply can be charged up to $200 but the regulation only addresses 30- and 90-day supplies.

CAHP would like the Division to clarify that the proposed regulation does not apply to health savings account (HSA) qualified health coverage plans. Also, CAHP would like clarification for dental health maintenance organization coverage or any health coverage plans that have a medical or pharmacy deductible and the whether the covered person needs to meet the requirements of his or her deductible before the cap is implemented.

While CAHP members understand the desire to assist patients who require insulin therapy, the proposed regulation would modify the plain language of the statute. By adopting the proposed regulation, the Division is effectively adding language to the statute that the General Assembly did not deem proper. As such, CAHP urges the Division to

reconsider its proposed regulation as the statute is already clear and unambiguous. CAHP members would be happy to discuss this matter further with you and answer any questions.

Best regards,

Julie Hoerner Mowry
Retained Counsel

Cc. CAHP Regulatory Committee
Matt Mortier