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April 20, 2019

The Honorable Andrea Salinas
Chair, House Committee on Health Care ***via email***
State Capitol
900 Court Street NE, Room 453
Salem, OR 97301

RE: Senate Bill 9A: Expanded and annotated version of public comment delivered before the House Committee on Health Care, April 16, 2019

Dear Senator Courtney and members of the Committee:

My name is Charles Fournier. I represent the Type 1 Diabetes Defense Foundation (T1DF). On behalf of T1DF and Oregonians with type 1 diabetes, I want to thank you for the opportunity to state our support for Senate Bill 9A—and I would like to suggest two critical improvements to this stopgap emergency refill bill.[1]

First, we should make emergency refills available for a broader range of life-saving medicines —not just insulin. At a minimum, the bill should include glucagon kits, the emergency injection kits used to treat life-threatening insulin-induced severe hypoglycemia.[2] But patients with

[1] Any state located in the vicinity of the Cascadia Subduction Zone needs a more comprehensive approach to emergency access to life-saving pharmaceuticals. The written comment of Ms. Lorentz submitted to this committee regarding SB 9 also illustrates the many inadequacies of our pharmaceutical dispensing and disaster planning regulatory frameworks. Individuals with life-threatening medical conditions such as type 1 diabetes can die in a matter of days if they don't have access to their life-saving pharmaceuticals. The 2013 Resilience Plan documented that it would take at least 18 months to restore critical healthcare infrastructure—far longer than the target state of recovery. The Plan does not address non-structural disruptions to the pharmaceutical supply chain. However, the Transportation section clearly indicates that the highway's 60% operational milestone would not be reached in the Willamette Valley until at least 6 months after event. It would take more than a month to restore the Eugene airport to working condition—assuming construction equipment and crews can reach it. Without access to emergency supplies, all Lane County residents with type 1 diabetes would be condemned to certain death.

[2] Glucagon is not covered by this bill, as it is neither a device nor a supply. It is also not an insulin but a different legend drug, also an essential life-saving medication, not available over the counter.

asthma and severe food allergies, people with opioid-use disorder, and other individuals with severe chronic conditions also need emergency access to life-saving pharmaceuticals. No Oregonians' lives should be jeopardized for merely administrative reasons. An emergency refill bill should embrace as many acute medical needs and treatments as possible.

Second, the bill completely sidesteps the current primary barrier to insulin access, which is cost. The measure requires health benefit plans and medical assistance programs to provide payment for emergency refills of insulin and associated insulin-related devices and supplies—but does not specify the basis of these reimbursements nor address the impact on uninsured and underinsured Oregonians of inflated list prices now driven by deep discounts negotiated by payers. As acknowledged by Sen. Linthicum in this committee and vividly described by countless Oregonians,[3] there are far more people in Oregon every year who don't fill an insulin prescription because they can't afford to do so than people who have the money to pay but don't have a current prescription.

We can easily fix this.

For example, a true emergency refill bill could require that the fill be made available to uninsured and underinsured Oregonians at a low price pegged to the average net price

[3] Every person speaking before this committee in an individual capacity regarding SB 9 raised the issue of insulin cost in no uncertain terms.

negotiated by the Oregon Prescription Drug Program (OPDP) for PEBB plans.[4] Uninsured and underinsured Oregonians would be automatically enrolled in OPDP's Discount Card Program, and the difference between the pharmacy acquisition cost and the drug's low net price would be charged back by the pharmacy to OPDP. (300,000 "lives" in the OPDP discount card

[4] OPDP and the Northwest Drug Pricing Consortium negotiate manufacturers' rebates on behalf of all OPDP members. The OPDP administrator's responsibilities include: "[n]egotiate price discounts **and rebates** on prescription drugs with prescription drug manufacturers" ORS 414.312(3)(a)(Emphasis added); "[a]dopt and implement a preferred drug list for the program" ORS 414.312(3)(e); and "[d]evelop a system for allocating and distributing the operational costs of the program and **any rebates obtained** to participants of the program." ORS 414.312(3)(f)(Emphasis added). OHA interpreted this requirement under Rule 431-121-2000(17) to mean that drug prices offered to OPDP members, individuals and groups, must be net of all applicable manufacturers discounts and rebates. Accordingly, Moda's 5th Restated Contract (OHA #133419) appointed Moda as the Discount Card's agent "for the purpose of negotiating and arranging, either directly or indirectly, pharmaceutical manufacturer Rebates and other incentives in connection with prescription drugs dispensed to Members under the Participating Program Agreement." (Attachment 1, Section 15(E) on p. 22.) Under Moda's contract, "rebates" means "retrospective payments or discounts, including promotional or volume-related refunds, incentives or other credits however characterized, pre-arranged with pharmaceutical companies on certain Prescription Drugs, which are paid to or on behalf of Contractor, and are directly attributable to the utilization of certain drugs by Members… 'Rebate' includes all rebates, discounts, payments or benefits (however characterized) generated by Participating Program's Prescription Drug Claims, or derived from any other payment or benefit for the dispensing of Prescription Drugs or classes or brands of drugs within Participating Program or arising out of any relationships Contractor has with pharmaceutical companies." (Attachment 6, p.131) Participating programs include the Discount Card Program (Attachment 6, p. 128). Every two weeks, Moda Health invoices each participating program "based on the Contractor's **actual net cost** of the specific Covered Drug." (Attachment 5, Contract Costs and Financial Guarantees, Section 4(G) p. 110 – emphasis added.) Rebate Program Management is addressed in Section 2 of Moda Health's Statement of Work (Attachment 3). The Contract also provides for an audit of the rebate program for each participating program, including the audit of all manufacturer rebate contracts. (Attachment 1, Section 13(D)(iv) on p. 20.) If performing any or all of these statutory, regulatory and contractual requirements is the only way to achieve the program's stated purpose, i.e. to "[m]ake prescription drugs available at the lowest possible cost to participants in the program as a means to promote health," (ORS 414.312(2)(b)), then OHA and Moda Health must explain why OPDP's TPA Moda Health has failed to perform those tasks. With manufacturer rebates on analog insulins now reported at 70% of list price and greater, an unrebated per-vial price of $270 is manifestly not "lowest possible cost."

program are part of OPDP's negotiations with manufacturers.)[5] The same low net prices would be offered to uninsured out-of-state residents and the cost offset by the large manufacturer rebates OPDP already negotiates with insulin manufacturers.

For the insured, cost sharing would be based on net price actually paid by insurers (less than $65 per 10ml vial of analog insulin)[6] when taking into consideration all discounts and rebates paid by manufacturers to any plan, subsidiary or holding company controlled by the carrier. OPDP would act as the payer of last resort and coordination of benefits would be handled as on the Medicaid model.[7] OPDP would actively pursue COB collection activities, i.e. collect and retain all monies available from all available resources for the full amount of OPDP liabilities, after deduction of all manufacturer discount and rebate entitlement under OPDP/ Northwest Prescription Drug Consortium (NPDC) rebate contracts – but only if the transaction volume justifies the fixed COB collection costs.[8]

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[5] The Competitive Marketplace Assessment ("2016 Market Check") performed by The Burchfield Group for Northwest Prescription Drug Consortium/Moda Health assessed the performance of OPDP/WPDP based on its overall adjusted lives (discount card and groups). As of June 2017, discount card lives were 'normalized' based on utilization (14 discount card lives assumed to equal 1 non-discount card life), for an adjusted lives total of 462,811.

[6] Peter Loftus, "As Political Scrutiny Mounts, Eli Lilly Divulges New Insulin Pricing Data," *The Wall Street Journal,* March 24, 2019. Available at: https://www.wsj.com/articles/as-political-scrutiny-mounts-eli-lilly-divulges-new-insulin-pricing-data-11553436000?fbclid=IwAR22zRWZpLuo7jICFJ4sQRCJVWViV0WPX2FPAVIFr03YGcNq_ngpocX14JM.

[7] Net cost accounting in state plans is required by Oregon insurance regulations for the purpose of ranking pharmaceuticals. OAR836-053-0473(2)(l)(B). See the final rule establishing the Oregon Prescription Drug Price Transparency Program, available at: https://dfr.oregon.gov/laws-rules/Documents/id02-2019_rule-order.pdf. Price offset accounting on the GAAP model in Medicare Part D should be effective in January 2020. Net cost accounting is already required in the Federal Employees Health Benefits Program in order to comply with the statutory mandate that all rates "reasonably and equitably reflect the cost of the benefits provided." Public Employees Health Benefits Program Act of 1959, Public Law 86-382, Section 6(h). Price offset accounting will likely also be required in subsidized ACA plans after January 2020, under new safe harbor jurisprudence governing manufacturer rebates.

[8] The volume of transactions under the proposed emergency refill bill is likely to be extremely low and may not justify the cost of awarding COB collection contracts. Similarly, the additional cost incurred from out-of-state uninsured is likely to be de minimis. Rebated brand drugs such as analog insulins have very low net prices. It may be more cost-effective for the state to provide emergency insulin fills at a figure pegged to OPDP's negotiated net cost and then write off the expense, rather than seeking reimbursement from out-of-state entities or third-party payers.

This innovative use of OPDP would require that Moda Health, OPDP's third party administrator (TPA), end the practice of swapping manufacturer rebates between its Discount Card Program and the other government and union plans serviced by OPDP. The Discount Card Program is OPDP's largest program, but all manufacturer rebates earned by discount card transactions are currently diverted to subsidize other programs. This practice must end.[9]

Rebate pass-through in OPDP is the only hurdle. OPDP's third party administrator contract already needs to be renegotiated to implement the June 2017 recommendations of the Burchfield Group.[10] Chargeback transactions between pharmacies and OPDP[11] and rebate pass-through in Oregon State plans could be implemented tomorrow. In fact, these could have been implemented ten years ago.

How do I know this?

[9] Throughout 2018, T1DF communicated with the Office of Governor Brown and the HB 4005 Task Force regarding OPDP's failure to deliver on its legislative mandate. See, e.g., https://www.t1df.org/news/2018/6/7/t1df-asks-oregon-gov-kate-brown-to-deliver-lowest-possible-cost-to-opdp-discount-card-holders and https://www.t1df.org/news/2018/5/21/t1df-statement-to-oregons-joint-interim-task-force-on-fair-pricing-of-prescription-drugs. Oregon Health Authority responded that OPDP discount card program does not earn any manufacturer rebates. OHA has provided no evidence in support of its public acknowledgement that OPDP is in breach of both the letter and intent of its statute and, to our knowledge, no audit of OPDP has been initiated. OHA has not officially performed any meaningful audit of the OPDP rebate program since 2006. The unsigned OHA response (posted in meeting documents for the HB 4005 Task Force) has been attributed to Dana Hargunani, MD, Chief Medical Officer and Director of the Office of Delivery Systems Innovation.

[10] OPDP is still using an antiquated rebate negotiation framework that incentivizes spread pricing. To reduce OPDP's net costs for brand drugs, the Burchfield Group recommended in their June 2017 report "eliminating the effective rate guarantee over all specialty drugs and obtaining drug-by-drug pricing," with reimbursement to pharmacy networks based on acquisition cost plus fee.

[11] OPDP would be de facto acting as a manufacturer switch/clearinghouse or third-party chargeback administrator, on the model of the Medicare Part D Transaction Facilitator function currently contracted to Relay Health/Change Healthcare, a McKesson company.

As a member of Work Groups 7 (manufacturer rebates) and 9 (government programs) of the National Council for Prescription Drug Programs (NCPDP),[12] I joined the small task force that for several weeks assessed the technical implementation of the chargeback scheme proposed by HHS Secretary Azar for Medicare Part D, and I participated in drafting NCPDP's comments on the proposed rule.[13] That process required evaluating the feasibility of point-of-sale net pricing within NCPDP's Telecommunication Standard (Rev. D.0). It is also common industry knowledge that NCPDP telecommunication standards for POS transactions have supported rebate pass-through in government programs and private plans since at least Rev D.0 issued in 2007 (but only fully implemented in January 2012) and possibly since Rev 5.1 issued in 1999[14] and named by CMS for ePrescribing in its Part D Final Rule issued in 2005.

Please do not hesitate to contact T1DF if your committee needs further assistance with these matters.

Thank you.

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[12] The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit, multi-stakeholder, ANSI-accredited standards development organization providing healthcare solutions. NCPDP standards are named in federal legislation, including HIPAA, MMA, HITECH and Meaningful Use (MU). CMS mandated NCPDP D.0 as standard for point-of-service pharmacy benefits management (X12 835 applied to related payment and remittance advice transactions between trading partners). The deadline for industry-wide transition to full use of NCPDP Telecommunication Standard vD.0 was delayed to 2012. NCPDP also maintains a voluntary Manufacturer Rebate Standard for rebate payment transactions, audit and reconciliation between Medicaid programs, manufacturers and private payers. The current version of the Manufacturer Rebate Standard is 7.02. Rev. 3.02 was issued in November 2003. NCPDP Manufacturer Rebate Standard v1.0 was first issued in February 1995.

[13] Comment from NCPDP in response to Proposed Rule OIG-0936-P: "Fraud and Abuse: Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees." NCPDP's comments are available at: https://www.regulations.gov/document?D=HHSIG-2019-0001-19807.

[14] The Manufacturer Rebate Standard v3.01 and its associated Utilization, Plan, Formulary, and Market Basket Flat File Standard were approved in January 2002 to support NCPDP Telecommunication Standard v5.0. These EDI standards provided the technical certainty regarding the feasibility of point-of-sale pharmacy claims adjudication based on net prices required to support the Medicare Part D negotiated price scheme in the MMA of 2003. Part D's effective date of 2006 provided sufficient time to trading partners for coding, business case testing and implementation – about 3 years.

Attachment:

A. NCPDP Letter to HHS Office of Inspector General Re: Proposed Rule (file code OIG–0936–P) entitled "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees".

About T1DF. The Type 1 Diabetes Defense Foundation is a nonpartisan Oregon-based nonprofit 501(c)(3) dedicated to advancing equal rights and opportunities for all people with type 1 and other forms of insulin-dependent diabetes. We focus on the significant social impact of living with a condition that requires patients to make constant dosing decisions with a drug that, without careful management and constant monitoring, can kill them. T1DF strives to improve the regulatory, legal and social ecosystem essential to development and adoption of new technologies and therapies, with an explicit commitment to inclusive policies that will deliver for all Americans with diabetes, insured and uninsured, equal access to standard-of-care pharmaceuticals and equipment. T1DF accepts no funding from the pharmaceutical, pharmacy benefit management, or insurance industries.