

January 16, 2017

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-4182-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850  
Submitted electronically via [www.regulations.gov](http://www.regulations.gov)

**RE: CMS-4182-P: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, Section 17, "Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale," on pp. 56419 and following.**

The Type 1 Diabetes Defense Foundation (T1DF) is pleased to submit comments to the Centers for Medicare & Medicaid Services (CMS) regarding the proposed rule entitled "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program," published in Federal Register on November 28, 2017 (file code CMS-4182-P).<sup>1</sup>

## T1DF

The Type 1 Diabetes Defense Foundation is a nonpartisan Oregon-based 501(c)(3) nonprofit dedicated to advancing equal rights and opportunities for Americans with type 1 and other forms of insulin dependent diabetes. T1DF accepts no funding from the pharmaceutical, medical device, pharmacy benefit management, or insurance industries or from any organization they fund. We support regulatory frameworks in which manufacturers compete directly on innovation and price to consumers

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<sup>1</sup> CMS-4182-P, RIN 0938-AT08, "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program," Federal Register, Vol. 82, No. 227, November 28, 2017, Proposed Rules, pp. 56336-56527.

and where drug channel actors can engage in open and efficient price arbitraging, without price discrimination and asymmetries of information.

## General Comments

T1DF broadly supports JRDF's comments submitted on January 10, 2018. We share a similar understanding of the current market dynamics that "strongly incentivize manufacturers to increase their list prices solely for the purpose of being able to pay larger rebates to insurers/PBMs."<sup>2</sup> T1DF also endorses JRDF's position that rebates should be directly passed on to those who actually use the medications, thus reducing their out-of-pocket costs.<sup>3</sup>

Rebating on a shrinking class of 'deep discount' rebatable specialty/brand drugs is now out of control.<sup>4</sup> According to the 2017 QuintilesIMS report, the total value of pharmaceutical manufacturers' rebates, and other price concessions, has now more than doubled, from \$59 billion in 2012 to \$127 billion in 2016.<sup>5</sup> Under Medicare Part D, 79% of aggregate drug spending (about \$137.4 billion) and about 100% of associated rebates are generated by 13% of the dispensed drugs—highly rebatable specialty/brand drugs such as analog insulin.<sup>6</sup>

Rebates paid by manufacturers on analog insulin brands such as Lantus now amount to about 75% of list prices. This trend is unsustainable, as it is pricing a large section of the U.S. population out of the current standard of care. This is especially true for the fastest growing segments of the population: the uninsured and the insured on high-deductible employer or ACA plans.

We do not, however, agree with JRDF's recommendation that "the largest share possible of rebates be passed on to beneficiaries at the point of sale." Any mechanism that does not pass the totality of manufacturers' rebates and price concessions (actual or estimated, with true-up reconciliation), will only incentivize insurers and their PBM agents to demand even larger rebates to compensate, via cost-sharing overpayment, for their smaller retention rate.

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<sup>2</sup> JRDF Comment Letter, January 10, 2018.

<sup>3</sup> See also T1DF's statement to the U.S. Senate Help Committee at <https://www.t1df.org/news/2017/12/15/t1df-letter-to-us-senate-cost-sharing-crisis>

<sup>4</sup> <http://nu-retail.com/three-phases-pbm-business-model/>

<sup>5</sup> <http://www.drugchannels.net/2017/06/new-data-show-gross-to-net-rebate.html>

<sup>6</sup> 2017 Annual Report of the Medicare Board of Trustees.

Furthermore, CMS and other institutional actors must recognize that the impact of the rebating scheme and associated inflated list prices is also intrinsically discriminatory. High list prices for insulin have also been used to publicly stigmatize people with diabetes.<sup>7</sup> This must stop.

## Specific Comments

T1DF's comment is narrowly focused on one topic addressed in the proposed rule: its proposed rule-making on the Prescription Drug Benefit program (Part D), specifically Section 17, "Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale," on pp. 56419 and following. We will address the impact of the current dual-pricing system on people with insulin-dependent diabetes. People with other medical conditions treated primarily or exclusively with deep-discount rebated drugs may be experiencing similar discriminatory impact.

**People who use insulin are facing a cost-sharing crisis created by private insurers'/Part D sponsors' benefit design and amplified by CMS's failure to fully implement the Medicare Prescription Drug, Improvement, and Modernization Act's<sup>8</sup> mandate to based Part D plan design on net drug prices.**

The cost-sharing crisis may not be the only drug pricing crisis Americans are facing, but the cost-sharing crisis remained the elephant in the room throughout 2017's drug-pricing hearings in the Senate H.E.L.P. Committee, which focused anywhere and everywhere but on the problem that is most readily within the federal government's power to solve. Fixing Medicare Part D's cost sharing crisis, and its perverse influence on U.S. drug prices more broadly, does not require a new law; CMS can and should immediately mandate that drugs' estimated net prices<sup>9</sup> be used to assess patient cost-sharing payments as required under the MMA.

Over the past year, Congress held several hearings on drug pricing, and drug pricing was also a focus of questioning during the hearings for Alex Azar's nomination to lead the Department of Health and Human Services. These hearings have taken place at a time when senators' constituents (and the general public as protected by HHS) have been crying out under the burden of paying skyrocketing

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<sup>7</sup> See letter to Senator Hassan regarding the discriminatory implication of the dual pricing system at <https://www.t1df.org/news/2017/11/15/robbing-peter-to-pay-pauls-premium>

<sup>8</sup> Public Law 108-173 108th Congress [H.R. 1] (Dec. 8, 2003), codified under 42 USC 1305.

<sup>9</sup> Manufacturers' rebates can be based on sales volume, outcome/value or other metrics that are not always known at the time of the point-of-sale transaction. This situation is quite common in the insurance industry. Plan sponsors in Medicare Part D use estimated rebates, based on historical trends, to bid.

out-of-pocket costs for prescription drugs they need to manage medical conditions—and in the case of people with type 1 diabetes, whom T1DF specifically represents, paying just to stay alive. The result in Congress, to date, has been a bipartisan agreement that the drug pricing system is ‘very complicated’ and that additional hearings might be required to understand why list prices for rebatable brand name and specialty drugs are ever-increasing.

T1DF begs to disagree.

- CMS and Congress know exactly what amount of the large manufacturer rebates currently received by plan sponsors is being passed through to plan members and beneficiaries under Medicare Part D via reduction of the drug price at the point of sale (short answer: none).<sup>10</sup>
- CMS and Congress know that third-party payers and insurers are receiving, as general revenues, the vast majority of the manufacturer rebates negotiated by PBMs (about 90% on average, about 99% under Medicare Part D, up to 100% under pass-through contracts with large employer plans).<sup>11</sup>
- CMS and Congress know that for many medical conditions such as cancer (oncology class), therapies are in fact extremely expensive. These patients are not facing a cost-sharing crisis.<sup>12</sup>
- CMS and Congress know that the current cost-sharing crisis burdens a specific group of patients with certain chronic medical conditions that require the continuous use of relatively cheap to manufacture but heavily discounted rebatable specialty/brand drugs such as analog insulin (10ml vial: less than \$5 to produce; supra-competitive U.S. net price averaging around \$55—about twice as expensive as European cash prices; U.S. list price over \$280).

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<sup>10</sup> <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-11-16.html>

<sup>11</sup> 42 U.S.C. 1320b-23 requires that PBMs disclose rebates received from manufacturers to both insurers/Part D plan sponsors and the U.S. government. Reporting inaccurate or misleading rebate information to the U. S. government could subject a PBM to criminal liabilities under the False Claim Act. Manufacturers are also required to pay 50% of the list price of certain brand drugs under the ACA Part D Coverage Gap Discount Program. This additional discount amounted to \$5.4 billion in 2015.

<sup>12</sup> As testified by David Mitchell during the Senate H.E.L.P. Committee hearings, cancer treatment may cost over \$250,000 annually. A cancer patient on such therapy will exhaust their deductible and out-of-pocket maximum in the first month of therapy, irrespective of whether the insurer bases cost-sharing on the drugs’ list price or net cost to plan.

- CMS and Congress know that people with diabetes have been unfairly singled out and shamed by commercial insurers<sup>13</sup> and others for the cost of insulin and other drugs whose list prices these commercial insurers are in fact cooperating with manufacturers to artificially inflate<sup>14</sup> in order to extract from those people with diabetes larger cost-sharing amounts, far in excess of the actual net cost, to insurance plans and Part D plan sponsors, for their treatment.
- CMS and Congress know that commercial insurers have been robbing Peter to pay Paul<sup>15</sup>—making people with diabetes subsidize premiums for people who do not need heavily rebated specialty drugs, as well as using rebates insurers receive for the ostensible purpose of offsetting list prices for insulin toward other corporate purposes, including executive bonuses and cash distribution to their shareholders.
- CMS and Congress know that the technology required for delivering point-of-sale net prices under both private insurance and Medicare Part D has existed since at least 2010 and has since been commercially implemented for the delivery of the Medicare Coverage Gap Discount Program established by section 3301 of the Patient Protection and Affordable Care Act, as amended by section 1101 of the Health Care and Education Reconciliation Act of 2010.
- CMS and Congress know that CMS’s refusal, at the urging of insurer lobbyists, to implement the MMA’s mandate to base beneficiary cost-sharing on net drug prices has created the perverse financial incentives that fuel the current gross-to-net drug pricing bubble, driving up list prices. Many insured Americans on high-deductible ACA and employer plans, as well as uninsured Americans, pay these list prices or the even higher U&C prices in full, no matter what level of cost-sharing or rebating arrangement CMS introduces for Medicare Part D beneficiaries.

In the 13 years since CMS’s final rule for Medicare Prescription Drug, Improvement, and Modernization Act was issued in 2005, insurers have continued to base patient cost-sharing on unrebated list prices

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<sup>13</sup> See, e.g., Estay Greene, “Why Does Insulin Cost So Much after 95 Years?” Blue Cross Blue Shield of North Carolina, Nov.11, 2016 <http://blog.bcbsnc.com/2016/11/why-insulin-cost-so-high/>). Accessed Dec. 15, 2017.

<sup>14</sup> Manufacturers and insurers may also negotiate net prices, as suggested by PhRMA representative Lori Reilly during the December 13, 2017, hearing of the Health Subcommittee of the House Energy and Commerce Committee. Such negotiation would explain how even net prices have remained supra-competitive, when compared to launch prices, production costs, and cash prices in international markets.

<sup>15</sup> Insurers’ practice of not sharing rebates with patients under Medicare Part D is believed to have caused insurers to mirror this practice in the private sector, possibly to normalize basing plan member cost-sharing on list price. See, e.g. Written testimony of Patricia M. Manzon, Ph.D., on PBM Compensation and Fee Disclosure for the 2014 ERISA Advisory Council, p. 6.

rather than net prices—and have blamed the resulting inflated drug prices at the point of sale on people with diabetes and, paradoxically, on Medicare Part D itself.<sup>16</sup>

Industry insiders have been quick to point out, when CMS issued its request for comment, that “... the high-list-price/high-rebate system [also called gross-to-net bubble, a term coined by Dr. Fein] [is] a fundamental source of warped incentives and cascading problems ... Medicare Part D, like commercial pharmacy benefit plans, now operates like reverse insurance. The sickest seniors taking medicines for chronic, complex illnesses generate the majority of manufacturer rebate payments. These funds are then used to subsidize the premiums for healthier seniors. To me, this structure is the opposite of how insurance is supposed to function.”<sup>17</sup>

**The current crisis, as experienced by patients, is a cost-sharing crisis: drug costs are being disproportionately borne by patients at the end of the complete drug-pricing channel that begins with manufacturers and ends at the insurers and CMS who create benefit designs that determine patient payment.**

Insurers/Part D sponsors have refused to pass market access and formulary rebates, negotiated and passed through by PBMs to insurers/Part D sponsors, on to the individual plan beneficiaries who actually use the rebated drugs. This failure has continued even through the nomination hearings for Mr. Azar, who has explicitly and publicly described the injury to patients. Mr. Azar has publicly admitted that at the other end of Lilly’s reimbursement contracts, “a significant number of people who already paid premiums for their health insurance then end up paying more than their insurer does for a medicine.”<sup>18</sup> As of January 2018, Congress and CMS have yet to acknowledge this fact.

Since the FTC investigation of Medco in 2003 and the subsequent 2003 class action filed by Hagens Berman on behalf of Community Catalyst’s Prescription Access Litigation fund and third-party payers, the range of PBMs’ retained rebates has been broadly known. The percentage of rebates retained by PBMs peaked at about 40 to 60% in 2002 and then dropped to about 18% in 2008, when Hagens Berman withdrew its California rebate pass-through lawsuit. It is public knowledge that CVS and

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<sup>16</sup> Medicare Part D was conceived as a public-private partnership for the very purpose of preventing the U.S. government from having a direct role in price setting. The price negotiation role was to be fulfilled by commercial insurers and their PBM contractors, and the benefits passed to individual beneficiaries in the form of a lower negotiated price. As early as 2004, ‘patient’ organizations allied to or supported by commercial insurers initiated a blame-shifting campaign to cover for expected insurer-manufacturer price gouging resulting from CMS’s 2005 rule.

<sup>17</sup> Adam Fein, “Will CMS Pop the Gross-to-Net Bubble in Medicare Part D with Point-of-Sale Rebates?” *Drug Channels*, 21 November 2017, <http://www.drugchannels.net/2017/11/will-cms-pop-gross-to-net-bubble-in.html>

<sup>18</sup> Alex Azar, “Prescription for Value,” Manhattan Institute, November 3, 2016.

Express Scripts currently keep, on average, about 10% of the price concessions paid by manufacturers, as confirmed by Credit Suisse, U.S. government agencies (e.g. CMS/OIG) and other experts. As to Medicare Part D, a recent investigation by the Office of the Inspector General concluded that PBMs retain only 1% of negotiated rebates and thus pass over 99% of their value to plan sponsors.<sup>19</sup>

We can thus trace these rebates to the doors of commercial insurers and Part D plan sponsors, and we believe commercial insurers are accounting for these payments as general revenues. AHIP alleges—and CMS states in its current request for comment—that these rebate payments are being used to lower premiums. We don't know. The only other certainty we have regarding the cost-sharing crisis is that commercial insurers are unfairly blaming people with insulin dependent diabetes for the unintended consequences and perverse incentives of a dual-pricing system that commercial insurers have been working to their own corporate advantage under private plans, ACA plans, and Medicare Part D.

**Clarifying what happens to the remaining 99% of the rebates reportedly passed through to Part D plan sponsors under Medicare Part D, enforcing the mandate to pass net prices through to individual beneficiaries (MMA's full "access to negotiated prices")—and countering the insurance industry's public messaging against the very class the pricing scheme has injured—should thus have been the primary focus of CMS. Instead, CMS has made a mockery of the MMA's mandate to pass the full benefit of manufacturer rebates in the form of 'negotiated prices' upon which Part D premium rates and cost sharing payments should have been based.**

The federal government has neglected its oversight responsibilities toward patients for more than a decade. The growing number of ERISA-based class action lawsuits may address insurers' breaches of fiduciary duties towards people with insulin-dependent diabetes and other chronic medical conditions. These lawsuits, which concern the possible misallocation by private insurers of part of the \$127 billion in rebates that manufacturers pay annually to gain formulary placement, should ultimately engage the federal government in acknowledging the injury caused by its breach of oversight and thus in compensating those people whom CMS's failure to implement MMA's negotiated price scheme in 2005 has disproportionately injured—people with chronic medical conditions that require the use of 'deep discount' rebatable specialty/brand name drugs such as analog insulin and glucagon.

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<sup>19</sup> Written testimony of Patricia M. Manzon, Ph.D., on PBM Compensation and Fee Disclosure for the 2014 ERISA Advisory Council, p. 6.

After decades of denial and active attempts to camouflage the patently discriminatory effect of its refusal to implement MMA's negotiated price scheme,<sup>20</sup> CMS finally acknowledged the impact of the gross-to-net pricing bubble it has helped create on November 16, 2017:

"The proposed rule includes a Request for Information soliciting comment on potential policy approaches for applying some manufacturer rebates and all pharmacy price concessions to the price of a drug at the point of sale. We would use ideas and comments provided in response to the Request for Information to evaluate and consider proposals for rulemaking."

While the Senate H.E.L.P. and Finance Committees carefully avoided any meaningful investigation of insurers' (and, by association, the federal government's) role in the current cost-sharing crisis during the several-month-long time span in which Congressional drug-pricing hearings and the hearings on Mr. Azar's nomination have occurred, CMS has been working on a proposed rule that finally acknowledges the need to close the cost-sharing loophole it allowed insurers to carve out for themselves in 2005, despite explicit legislative mandate that Medicare Part D beneficiary cost-sharing be based on "access to negotiated price" as defined by MMA (the price of the drug, net all manufacturers' rebates and other price concessions).

As stated in CMS proposed rule CMS-4182-P, the the key issue to address, going forward, is insurers' failure to apply **"some [or all] manufacturer rebates and all pharmacy price concessions to the price of a drug at the point of sale"** and to pass the full value of those rebates (negotiated price, as defined under the MMA) to the individual plan member who actually purchases the rebated drugs. CMS's rule making should also address the impact that its flawed implementation of the MMA has had on those insured on high-deductible plans and on the uninsured, whose numbers are likely to increase as the result of legislative and policy changes driven by the current Congress. They deserve equal protection, under the law, from the predictable effects of the current dual pricing reimbursement regime that commercial insurers, and their lobbyists, have so deftly taken advantage of.

The MMA does not provide any ground for only passing 'some manufacturer rebates' in the form of negotiated price. Any partial implementation of the MMA mandate to base benefit designs on net drug prices would reinforce the warped incentives that fuel the current net-to-gross pricing bubble.

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<sup>20</sup> Although CMS's regulations use the term "negotiated price," CMS redefined this term to mean actual acquisition cost – a price broadly similar to the pharmacies' "pass-through" price used by insurers and PBMs to internally manage manufacturer rebate transactions. CMS's regulatory "negotiated price" is now roughly equivalent to National Average Drug Acquisition Cost or NADAC, plus dispensing fees.



The MMA creates only two pathways for Part D plan design– the “standard prescription drug **with access to negotiated prices**”<sup>21</sup> and the “alternative prescription drug coverage with at least actuarially equivalent benefits and **access to negotiated prices**.”<sup>22</sup> Access to negotiated prices was thus the key benefit plan sponsors were to convey to Part D beneficiaries in the form of “lower subsidies, lower monthly beneficiary prescription drug premium and lower [drug] prices” at the pharmacy point of sale.<sup>23</sup> Negotiated price is also the only mechanism provided by the MMA to incorporate manufacturers’ rebates in Part D plan design. Instead, the plan design implemented by CMS would be based on pharmacy “pass-through” prices (i.e. list prices). CMS’s definition of ‘negotiated prices’ as a pharmacy’s actual pass-through price makes a mockery of the MMA’s letter and intent.

Under the MMA, statutory direction for managing manufacturer rebates broadly aligned the interests of individual beneficiaries under Medicare Part D with the interests of Part D plan sponsors and the Medicare program by stating that sponsors “shall provide enrollees with access to negotiated prices ... regardless of the fact that no benefits may be payable under the coverage with respect to such drugs because of the application of a deductible or other cost-sharing or an initial coverage limit”<sup>24</sup> and by defining negotiated prices as follows: “negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs.”<sup>25</sup> A negotiated price is thus a net cost-to-plan or net price.

The MMA uses the exact same definition of ‘negotiated price’ in Section 1860D-31, Medicare Prescription Drug Discount Card and Transitional Assistance Program.<sup>26</sup> Under this Section, Congress also mandated disclosure of ‘negotiated prices’ to plan beneficiaries.<sup>27</sup> Under Part D, negotiated prices are not confidential information. Disclosure of the negotiated prices under Section 1860D-31 would also disclose the negotiated prices relied upon by standard plan design under Section 1860D-2. Under Part D, negotiated prices are thus public information—and we believe this is one of the reasons CMS, on behalf of plan sponsors, refused to implement Part D plan design as intended by PL 108-173. CMS’s regulatory overreach undermined the cost control mechanism upon which the Medicare Part D public-private partnership was predicated.

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<sup>21</sup> Part 1860D-2. (a)(1)(A)

<sup>22</sup> Part 1860D-2. (a)(1)(B)

<sup>23</sup> Part 1860D-2. (d)(2)

<sup>24</sup> Part 1860D-2(d)(1)(A)

<sup>25</sup> Part 1860D-2(d)(1)(B)

<sup>26</sup> See 1860D-31(e)(1)(A)(ii)

<sup>27</sup> Part 1860D-31(d)(2)(B)

CMS implemented the Part D discount card program based on the statutory definition of ‘negotiated price’ but, as stated above, engineered a different definition of ‘negotiated prices’ for the implementation of Part D standard prescription drug benefit. As applied to plan design, ‘negotiated price’ now means the pharmacy’s actual pass-through price.<sup>28</sup> Neither the letter of the MMA nor its legislative history supports CMS’s bifurcated approach. The opposite is true—access to lower net prices negotiated by plan sponsors via their PBMs was the central benefit and cost-control measure upon which Part D’s public-private partnership was predicated. CMS’s single-handed rewriting of the MMA partially explains the ongoing public confusion regarding Part D’s ban on direct government price negotiations<sup>29</sup> and the critical role of net price competition in the original intent of Congress and the architecture of the MMA. Beneficiary access to and knowledge of negotiated prices were to encourage competition between plan sponsors and thus drive drug prices and plan costs down—without the need for CMS’s direct intervention. But while CMS strictly implemented the MMA noninterference clause, it liberally modified the definition of negotiated (net) price to mean the opposite of the MMA’s letter and intent, thus undermining the only protection the MMA substituted for direct government intervention: competition between plan sponsors based on beneficiaries’ access to negotiated net prices.

Congress and oversight bodies such as the Office of the Inspector General have subsequently avoided confronting CMS’s unconstitutional grab of legislative power.<sup>30</sup> While the OIG acknowledged that “the MMA requires sponsors to provide their enrollees access to negotiated prices,”<sup>31</sup> the Office of the Inspector General quotes CMS’s regulation, 42 CFR 423.100, which, at the time OIG wrote its report, made use of negotiated price (as defined by the MMA) at the point of sale discretionary, substituting CMS’s own reduced regulatory definition of negotiated price,<sup>32</sup> thus perpetuating CMS’s

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<sup>28</sup> 42 CFR 423.100 (Actual cost) and 79 FR 29844 through 29968

<sup>29</sup> Section 1860D-11(i)—the “noninterference clause” (“In order to promote competition under this part and in carrying out this part, the Secretary (1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP [prescription drug plan] sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.”).

<sup>30</sup> We note here that Hagens Berman’s consolidated manufacturer-only putative class action filed on December 26, 2017 (In Re Insulin Litigation, 3:17-cv-00699-BRM-LHG) was narrowly crafted to avoid challenging CMS’s breach of the MMA and resulting plan design based on list prices instead of negotiated net prices. In essence, it asks the court to extend the Part D Coverage Gap Discount Program to ACA and other private insurance plans—in addition to the rebates and other discounts directly paid by manufacturers to insurers.

<sup>31</sup> Department of Health and Human Services, Office of Inspector General, “Accuracy of Part D Plans’ Drug Prices on the Medicare Prescription Drug Plan Finder,” July 2009, p. 2.

<sup>32</sup> In May 2014, CMS completed the transformation of MMA’s negotiated (net) price into pharmacies’ ‘pass-through’ acquisition costs: it removed the reference to manufacturer rebates from the definition of negotiated price. CMS justified the change as a way to prevent plan sponsors from manipulating rebates, shifting cost-sharing subsidy and reinsurance costs to the government, thus reducing its bid and achieving a competitive advantage solely based on cost allocation.

misrepresentation regarding Part D members' actual entitlement to negotiated price as defined by the MMA, i.e. net all rebates and price concessions.

In 2004, CMS provided no documentary support for its assertion that Congress intended rebate pass-through to be elective, even in the original donut hole when "no benefits may be payable under the coverage with respect to such drugs because of the application of a deductible or other cost-sharing or an initial coverage limit."<sup>33</sup> CMS, nevertheless, implemented a dual pricing system in which Plan D beneficiary cost-sharing payments would be based on pharmacy prices at the POS (under CMS's new definition of "negotiated price," which then included and now typically includes no manufacturer rebates (the CMS final rule defined this POS price as "actual cost")<sup>34</sup> and accounting between Part D sponsors and the Medicare program would be based on costs separately defined as "actually paid," net all manufacturer rebates and other price concessions.<sup>35</sup> For any drug on which significant manufacturer rebates are received but not included in the POS price—which, in practice since 2006 and as specifically directed by CMS since 2014, has meant all manufacturer rebates—"actual cost" as defined by CMS's implementing regulations is likely to be much higher than the cost those regulations define as "actually paid," net of manufacturer rebates and other price concessions.

In the years since 2006, CMS's regulation has exclusively aligned Part D plan sponsor and beneficiary interests for those beneficiaries who have medical conditions treatable with drugs for which no manufacturer rebates are offered: typically, for beneficiaries who use generic drugs, "actual cost" and "actually paid"—under CMS's two separate definitions for these ostensibly synonymous terms—remain closely aligned, albeit subject to small fluctuations in the highly competitive generic market. CMS's regulation created, however, adverse interests between—on the one hand—plan sponsors, the Medicare Part D program, and beneficiaries who do not use rebated drugs and—on the other hand—a significant minority of beneficiaries with specific disease conditions treated with rebated drugs or biologics. This second group includes all people with type 1 diabetes and many people with other forms of insulin-

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<sup>33</sup> Part 1860D-2. (d)(1)(A)

<sup>34</sup> Subpart C—Benefits and Beneficiary Protections. § 423.100 Definitions: CMS defines "actual cost" solely in relationship to beneficiaries, relying on its own limited pharmacy POS definition of "negotiated price." "Actual cost means the negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of-network pharmacy consistent with § 423.124(a)."

<sup>35</sup> In Subpart G—Payments to Part D Plan Sponsors For Qualified Prescription Drug Coverage, § 423.308 (p. 4547), "Actually paid means that the costs must be actually incurred by the Part D sponsor and must be net of any director indirect remuneration (including discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred by the Part D sponsor for the drug."

dependent diabetes, as all insulins available under Part D via prescription are rebated, and analog insulins—the standard of care for all type 1 and most type 2 diabetes—are among the most heavily rebated of all prescription pharmaceuticals.

The interests of the former corporate, government, and majority plan beneficiary entities are served—if, for some members of this group, only within the narrow confines of Part D—by refusing to deliver MMA’s mandated “access to negotiated prices” to the individual beneficiaries who use rebated drugs. The interests of Part D beneficiaries who actually use rebated drugs (who under CMS’s current regulations are now overpaying via “cost-sharing” based on “actual costs”/pharmacy POS prices higher than costs “actually paid” net all rebates) would be served by true individual “access to negotiated prices,” with their payments calculated according to the costs actually paid for their drugs, net all manufacturer rebates and other price concessions. As addressed below, is likely that the greater government and public interest would likely also be served by this direct solution to benefit the individual beneficiaries who use rebated drugs, via lower overall health care costs under the Medicare program as a whole—and, more broadly, by ending Part D’s perverse incentives that have contributed to the increase in U.S. list prices for essential drugs and biologics, including insulin.

While the Part D Coverage Gap Discount Program created by ACA provides some relief, it in fact perpetuates the discriminatory inference that diabetes drugs are expensive—a common misrepresentation directly enabled by CMS’s re-definition of ‘negotiated price’ to mean pharmacy ‘pass-through’ costs, i.e. list price.

Since 2005, CMS has thus allowed the interests of the majority to prevail over the minority’s statutory entitlement to know and access the true cost of their drugs net of rebates and price concessions, despite evidence of increasing financial injury and medical harm to people with specific disease conditions treated with rebated drugs or biologics, including insulin. CMS has tolerated this discriminatory pricing even in as the list prices for life-saving medications—on which CMS has allowed patient cost-sharing to be based—have skyrocketed, potentially (at least in part) as the direct result of CMS’s sanction of the dual-pricing system. Drug channel observers currently report that the most heavily rebated analog insulins—e.g. Lantus and Humalog—are now rebated by as much as 75% off their list prices. This means Part D beneficiary cost-sharing for people with type 1 or other insulin-dependent diabetes is now based on a CMS-defined “actual cost” that is significantly higher than the CMS-defined cost “actually paid,” net all rebates and price concessions, actually paid. As a result, a Part D beneficiary with type 1 diabetes is reaching the uncapped catastrophic phase of the Part D plan substantially faster than his peers who use generics with identical net prices, while making payments misleadingly characterized as “cost-sharing.”

T1DF believes that any amount paid for rebated drugs beyond cost-sharing based on the net cost of drugs is not a payment of costs but is more accurately considered an additional, condition-specific premium, in violation of the uniform premium requirement of the MMA. Even if the MMA did not explicitly require that 100% of manufacturer rebates be passed through in the form of direct beneficiary access to negotiated price (and T1DF believes the MMA did make this explicit direction), such supra-cost payments—payments calculated on a basis other than net cost to plan—may well constitute excess condition-specific premium payments and would thus violate the MMA’s explicit requirement for uniform premiums.

CMS’s current proposed rule-making (CMS-4182-P) entices its readers to tolerate this ongoing abuse by stressing the “benefits” it delivers (flat/slightly declining Part D monthly premiums; Part D government program costs decreasing at about 8% annually; ongoing voluntary participation from private Part D sponsors) while failing to report hard numbers on the percentage of rebates that Part D sponsors are now transferring into general revenue and/or taking as profit, and while failing to acknowledge that it may be unlawful—under the MMA, anti-discrimination, or consumer protection laws—to generate these “benefits” at the direct expense of people with specific medical conditions treated by rebated drugs, whose cost-sharing payments are being inflated far beyond stated statutory limits. CMS also mentions, but fails to quantify, the potentially much larger cost to other parts of the Medicare system, and hence to taxpayers, that may be accumulating as the result of its short-sighted decision to tolerate cost-shifting in Part D onto patients who need rebated drugs (i.e. the increased health care costs, for hospitalizations, surgical procedures, dialysis, and so on, to treat short-term and long-term complications that result from medical non-adherence as a result of discriminatory cost-shifting to beneficiaries for costs of rebated prescription drugs—but not for unrebated drugs, where cost-sharing is based on numbers approximately equal to true net cost). At present, the same people being denied access to true negotiated prices net all rebates and price concessions are also being blamed for the higher medical costs that derive from cost-induced non-adherence.

CMS now states that it is seeking comment on partial pass through of rebates (CMS says “It is important to note that we are not considering requiring that 100 percent of rebates be applied at the point of sale.” (CMS-4182-P, p. 56421).

T1DF opposes any partial pass through. Complete pass-through of manufacturer rebates in the form of negotiated prices, as required under the MMA, is the only approach that correctly aligns the negotiating power of Part D sponsors with, rather than against, the interest of individual beneficiaries. T1DF urges CMS to amend its proposed rule to direct that Part D sponsors pass through 100% of negotiated rebates to beneficiaries. Rebate pass-through can take place exclusively at the point of sale (for volume rebates) or partly at the point of sale based on estimated rebates and partly via some other

true-up mechanism for more complex rebate agreements (e.g. a quarterly true-up payment to beneficiaries).

CMS's own reporting on Part D for the years 2011-2017 confirms that partial pass-through of rebates (the "minimum percentage of rebates" standard suggested in CMS's new proposed rule)<sup>36</sup> is likely to cause ongoing upward pressure on list prices, so that plan sponsors can derive comparable benefit, including profit, from a smaller share of rebates.<sup>37</sup> Since 2011, as CMS has implemented gradually decreasing percentage cost-sharing on brand-name drugs in the donut hole and imposed on manufacturers an additional 50% discount under the Medicare Coverage Gap Discount Program, the scale of rebates (DIR) (and, to a lesser extent, the underlying net effective prices) have increased dramatically, with DIR increasing much faster than total gross drug costs.<sup>38</sup>

Part D plan beneficiaries with medical conditions requiring the use of rebated prescription drugs have not benefited from any of these price and discount manipulations. For a person who buys insulin, actual out-of-pocket "cost-sharing" has been nearly flat in the donut hole, even as the stated cost-sharing percentage has dropped from 100% in 2010 to 35% in 2018. In 2010, paying 100% in the donut hole, at a time when list price (POS pharmacy price defined by CMS regulation as the basis for cost-sharing) for analog insulin was about \$100, a beneficiary paid about \$100 per vial of insulin when in the donut hole. In the 2017 donut hole, a beneficiary paying 40% "cost-sharing" based on the approximate current 2017 list price/POS pharmacy price, approximately \$270, still paid \$100 out of pocket to obtain the same vial of insulin under Part D. The net cost to plan (CMS's costs "actually paid" net all manufacturer rebates and price concessions), meanwhile remained relatively flat, likely around \$65-70 according to current estimates from drug channel observers. Note that this net cost to plan was in 2010, and remains in 2018, significantly *below* the approximately \$100 out of pocket cost to the Part D beneficiary in the donut hole.

Only strict compliance with MMA's original requirement to deliver to beneficiaries "access to negotiated prices"—including all manufacturer rebates—at the point of sale will align plan sponsors' negotiating power with the interests of the beneficiaries who actually use rebated drugs. Based on a decade's evidence that its dual-pricing regulation has created intra-plan discrimination, concentrating significant financial hardship and medical harm on people with specific medical conditions treated with

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<sup>36</sup> "We aim to set the minimum percentage of rebates that must be applied at the point of sale at a point that allows an appropriate balance" between outcomes benefiting individual beneficiaries versus outcomes benefiting other actors." (p. 56421)

<sup>37</sup> See, e.g., <http://nu-retail.com/three-phases-pbm-business-model/>

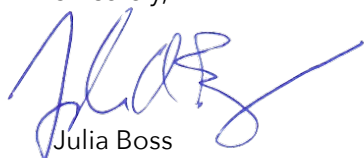
<sup>38</sup> See CMS fact sheet "Medicare Part D – Direct and Indirect Remuneration (DIR), January 19, 2017, <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html>.

deep discounted rebated drugs—CMS must now enforce 100% pass through of all negotiated manufacturer rebates and other price concessions, using the same calculation for beneficiaries that it uses for its own net cost accounting between Part D sponsors and the Medicare program. For people with type 1 and other insulin-dependent diabetes, the alternative under the dual-pricing scheme created by CMS's innovatory regulation and subsequently sanctioned by CMS, is ongoing and increasing barriers in access to insulin, resulting in financial harm, long-term medical harm, and even death from lack of affordable access to insulin or emergency rescue glucagon kits.<sup>39</sup>

The resolution of this cost-sharing crisis is first and foremost a matter of political will and moral rectitude. Some Part D or private insurance premiums may slightly increase in the short run, but this is a necessary price to pay for transparency that is essential to the longterm sustainability of health insurance programs—and any such increases, as stated above, are likely to be offset via significant reductions in other short-term and long-term health care costs associated with cost-induced prescription drug non-adherence. Removing corporate moral hazard—the type of moral hazard that was at the core of the housing crisis—is now essential to protecting America's public-private health insurance system.<sup>40</sup>

Thank you very much for your consideration of these comments. If you have questions, please do not hesitate to contact us if we can be of any assistance. Your staff can reach Charles Fournier, Director of Legal Advocacy for T1DF.

Sincerely,



Julia Boss  
President

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<sup>39</sup> Glucagon is the first-line defense against severe insulin-induced hypoglycemia, a potential side-effect of insulin therapy. List/POS prices for glucagon have risen in parallel to prices for insulin, with list prices rising to around \$300 and rebating reportedly on the same scale as for insulin (a 2015 article authored by Lilly employees stated the price to insurers as approximately \$55.00 per vial). Many Medicare beneficiaries who need the kits simply do not purchase them, with cost likely a factor in this decision (only 0.2% of Medicare recipients with diabetes were prescribed glucagon in 2014). Lack of access to glucagon significantly increases the risks of severe hypoglycemia, a life-threatening emergency condition. <http://annals.org/aim/article-abstract/2667621/underutilization-glucagon-prehospital-setting>; <https://www.jwatch.org/na45804/2018/01/04/glucagon-underprescribed-and-underutilized>

<sup>40</sup> A fraction of the cost-sharing overpayment under Medicare Part D now accounts for the net profit of the entire health insurance industry.

[About T1DF](#) The Type 1 Diabetes Defense Foundation is a nonpartisan Oregon-based 501(c)(3) nonprofit dedicated to advancing equal rights and opportunities for Americans with type 1 and other forms of insulin dependent diabetes. T1DF accepts no funding from the pharmaceutical, medical device, pharmacy benefit management, or insurance industries or from any organization they fund. We support regulatory frameworks in which manufacturers compete directly on innovation and price to consumers and where drug channel actors can engage in open and efficient price arbitraging, without price discrimination and asymmetries of information.