



January 10, 2018

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

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

JDRF 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.

ABOUT JDRF

JDRF is the leading global organization funding type 1 diabetes (T1D) research. Our mission is to accelerate life-changing breakthroughs to cure, prevent and treat T1D and its complications and we collaborate with a wide spectrum of partners in the community to achieve this mission. Founded in 1970 by parents of children with T1D, JDRF has invested nearly \$2 billion in research since its inception and employs over 20 scientists to manage its research portfolio.

T1D is an autoimmune disease that strikes suddenly and can be fatal. The disease prevents the body from producing sufficient insulin. Changes in diet or uptake of exercise cannot cure it. Until a cure is found, people with T1D have to test their blood sugar and give themselves insulin injections or infusions through a pump 24 hours a day every day in order to stay alive. Medicare beneficiaries with T1D are dependent on insulin to stay alive and thus have a considerable interest in a robust and affordable Part D program.

GENERAL COMMENTS

The cost of insulin has been growing dramatically. One study found that “Based on a nationally representative survey, the mean price of insulin increased from \$4.34 per milliliter in 2002 to \$12.92 in 2013.”¹ Another study found that out of pocket costs for all insulins increased 89% from 2000 to 2010.² A study of Medicaid reimbursement for insulin concluded that “Between 1991 and 2014, there was a near-exponential upward trend in Medicaid payments on a per-unit basis for a wide variety of insulin products regardless of formulation, duration of action, and whether the product was patented.”³ Data on Medicare’s Average Sales Price (ASP) made available by CMS shows that in 1Q2010, reimbursement for J1817, the code used to bill insulin delivered through an insulin pump, was set at \$2.349. By 4Q2017 the ASP figure had risen 424% to \$9.968.⁴

The significant rise in cost for insulin has negatively impacted people with T1D, including those with Medicare. It is a well-known fact that when patients face higher out of pocket costs for their medications they reduce the amount they use. This holds true even for people with T1D.⁵

It is our understanding that current market dynamics strongly incentivize manufacturers to increase their list prices solely for the purpose of being able to pay larger rebates to insurers/PBMs. As CMS’ own analysis has shown, these rebates are not being passed on to beneficiaries at the point of sale.⁶ Instead, beneficiary costs are increasing along with the rise in list price. JDRF is very concerned about this dynamic and we think it appropriate that CMS is considering taking action to address it.

JDRF has long held the position that rebates should be directly passed on to those who actually use the medications, thus reducing their out-of-pocket costs.⁷ Furthermore, we have extensively advocated to private commercial payers through our

¹ Hua X., Carvalho, N., Tew, M., Huang, E., Herman, W., Clarke, P. “Expenditures and Prices of Antihyperglycemic Medications in the United States: 2002-2013,” JAMA, April 5, 2016; 315(13):1400-1402.

² Lipska, K., Ross, J., Van Houten, H., Beran, D., Yudkin, J. Shah, N. “Use and Out-of-Pocket Costs of Insulin for Type 2 Diabetes Mellitus from 2000 to 2010,” JAMA, June 11, 2014; 311(22):2331-2333.

³ Luo, J., Avorn, J., Kesselheim, A. “Trends in Medicaid Reimbursement for Insulin from 1991 Through 2014,” JAMA Intern Med, October 2015; 175(10):1681-1687.

⁴ ASP data accessed at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html>

⁵ Iuga, A., McGuire, M. “Adherence and health care costs,” Risk Management and Healthcare Policy. 2014;7:35-44. Balkrishnan, R., Rajagopalan, R., Camacho, F., et al. “Predictors of medication adherence and associated health care costs in an older population with type 2 diabetes mellitus: a longitudinal cohort study,” *Clin Ther*. 2003 Nov;25(11):2958–2971.

⁶ 82 Federal Register 56420.

⁷ See JDRF’s statement of principles, “Achieving Insulin Access and Innovation,” available at: <http://advocacy.jdrf.org/wp-content/uploads/sites/111/2017/02/JDRF-Position-Statement-Access-to-Insulin-1.pdf>

“Coverage2Control” campaign to encourage them to use fixed-dollar copayments rather than coinsurance as a way of protecting their beneficiaries from growing list prices.⁸ Insurers, in both their commercial and Part D books of business, do not always choose to take these steps and their beneficiaries who use insulin are thus exposed to costs based on increasingly higher list prices.

SPECIFIC COMMENTS

JDRF Comments on “17. Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale”

In the proposed rule, CMS indicates a desire to establish a mechanism for using at least some portion of manufacturer rebates to reduce the negotiated price for Part D drugs. JDRF strongly supports this intention on the agency’s part. JDRF believes that CMS should establish mechanisms to ensure that the largest share possible of rebates be passed on to beneficiaries at the point of sale. The purpose of insurance is to protect the purchaser from large or irregular costs associated with their care. When a benefit design fails to do this and instead passes on ever increasing costs to the beneficiary, it calls into question the utility of that insurance. Allowing a subset of beneficiaries to carry very high costs for their care, rather than spreading risk among the entire pool defeats the purpose for which individuals purchase insurance.

We also believe that as a larger portion of the rebates is passed on to the beneficiary, there will be less incentive for insurers/PBMs to demand large rebates, because they will not be able to retain them. We would hope that without the pressure to produce larger rebates, manufacturers will face less pressure to increase prices. We encourage the agency to monitor this dynamic to see whether manufacturers do indeed rein in their price increases in response to a requirement that rebates be passed on to the beneficiary.

Finally, we believe that CMS’ decision to explore mechanisms for passing rebates on to beneficiaries will help alleviate financial pressures Medicare beneficiaries with T1D currently face and will help them better manage their condition, which is the appropriate role for an insurance program.

JDRF Comments on “d. Pharmacy Price Concessions to Point of Sale”

For reasons similar to our support for passing on manufacturer rebates, JDRF strongly supports CMS’ proposal to require that all pharmacy price concessions be passed on to the beneficiary at the point of sale in the form of lower negotiated prices. We believe that CMS is correct to be concerned about a possible perverse incentive driving Part D

⁸ See www.coverage2control.com

beneficiaries to poor performing pharmacies and therefore support the proposal to require that the negotiated price reflect the lowest possible price the pharmacy might receive. We believe that use of the lowest possible negotiated price with a later true up, as proposed by CMS, will adequately address this issue.

Thank you very much for your consideration of these comments. If you have questions, please do not hesitate to contact Jesse Bushman, Senior Director of Health Policy for JDRF at jbushman@jdrf.org or 202-465-4128.