

VIA ELECTRONIC SUBMISSION

Centers for Medicare & Medicaid Services

7500 Security Boulevard C1-13-07

Baltimore, Maryland 21244

www.regulations.gov

RE: 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 Program, and the PACE Program [CMS-4182-P]

FreseniusRx appreciates the opportunity to comment on the *Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Program, and the PACE Program* (hereinafter the Proposed Rule).¹

FreseniusRx is a pharmacy focused on renal medications that helps patients impacted by kidney disease. We are specialists in end stage renal disease (ESRD), and we work to maximize the impact of a patient's dialysis-related medications for improved overall health. FreseniusRx pharmacists are focused on keeping patients on their dialysis related medications and out of the hospital by improving medication adherence. As a pharmacy primarily servicing patients living with ESRD, an expensive, chronic condition, we understand the importance of transparency in drug pricing and affordability of drugs for our patients. We strongly support CMS efforts to address the growing inequities arising from the current definition of negotiated price and Direct and Indirect Remuneration (DIR) reporting requirements as they relate to performance based pharmacy arrangements. We supported the recent changes to the DIR reporting as required by the Final Medicare Part D DIR Reporting Requirements for 2016, and we are encouraged that CMS continues to explore program changes that will protect beneficiaries and the Medicare program from exploitation of loopholes in the rules. Our comments here are in response to your request for feedback on the treatment of pharmacy price concessions at the point of sale.²

As you identified in the Proposed Rule, performance contingent arrangements with network pharmacies have grown substantially since the Part D program was implemented. We share your concern regarding the reporting of pharmacy payment adjustments through DIR reporting methods and the negative effect on the

¹ 82 Fed. Reg. 56336

² Id. at 56426

Medicare program, beneficiary costs and access to affordable medications. We also note that the dramatic increase in performance contingent arrangements has disproportionately impacted small and independent pharmacies as well as specialized pharmacies serving a niche population such as FreseniusRx.

In our experience, as CMS notes in the Proposed Rule³, “performance” establishes the amount by which the original reimbursement is reduced and rarely, if ever, is there an additional incentive payment for high performance. Furthermore, Plan Sponsors and Pharmacy Benefit Managers (PBMs) are becoming more aggressive in the amount of reimbursement that is “clawed back” from pharmacies. Over a relatively brief period of time, FreseniusRx, has experienced a dramatic increase in the amount of reimbursement recouped, which we believe is a troubling trend. In some cases, PBMs reduce the original reimbursement by 85% or more and in many cases the reduction is less than the acquisition costs of the drugs dispensed to our patients. Putting aside the obvious problem of pharmacies continuing to serve Medicare beneficiaries below cost, CMS notes in the Proposed Rule that an analysis of “plan payment and cost data indicates that in recent years, DIR amounts Part D sponsors and their PBMs actually received have consistently exceeded bid-projected amounts.”⁴ Considering any DIR received that is over the projected amount factored into the plan bid goes to profits and not reduced premiums,⁵ we believe the current trend of increasingly aggressive recoupments will continue until the loopholes CMS identified in the Proposed Rule are addressed.

The trend of increasingly aggressive and unpredictable recoupments not only threatens access to pharmacies like FreseniusRx, which are better equipped to help managed high cost, chronic disease, but they threaten the health outcomes of the most vulnerable beneficiaries. CMS notes in the Proposed Rule that the current practice of accounting for pharmacy price concessions through DIR reporting shifts costs to beneficiaries by requiring them to cover a larger share of the actual cost of the drug, and that the cost shifting becomes more pronounced as pharmacy price concessions increase and continue to be applied outside of the negotiated price.⁶ CMS goes on to discuss how higher cost sharing can impede health outcomes by limiting access to therapy.⁷ FreseniusRx urges CMS to consider that this inverse relationship of outcomes to cost sharing is particularly important for Medicare beneficiaries living with ESRD. Socioeconomically disadvantaged populations are disproportionately burdened by kidney disease, and this is true of Medicare beneficiaries living with ESRD as well. Studies have positively correlated lower copays with increased adherence⁸, and our own experience is that patients make refill decisions based on their out-of-pocket costs. Economically disadvantaged patients struggle to afford the copays associated with their renal medications, which causes patients to delay refills. When patients are not adherent to their bone and mineral medications, patients experience difficulty with maintaining their calcium, phosphorus and parathyroid hormone levels within normal

³ Id. at 56427

⁴ 82 Fed. Reg. 56336, at 56420.

⁵ Id.

⁶ Id.

⁷ Id.

⁸ Duru OK, Edgington S, Mangione C, et. al. Association of medicare part D low-income cost subsidy program enrollment with increased fill adherence to clopidogrel after coronary stent placement. *Pharmacotherapy*. 2014;34(12):1230–1238

ranges, and this can lead to increased hospitalizations and cardiovascular mortality.^{9, 10} Our patients are particularly sensitive to increased out of pocket costs.

FreseniusRx supports the proposal CMS makes in the Proposed Rule to address the loopholes in the current rules. Specifically, we support the proposal to eliminate the exception at 42 CFR § 423.100 that allows PBMs and Plan Sponsors to reflect price concessions in the negotiated price when they can be “reasonably determined” at the point of sale.¹¹ We also strongly support the proposal to require PBMs and Plan Sponsors to include all pharmacy price concessions in the negotiated price by requiring the negotiated price to reflect the lowest possible reimbursement a network pharmacy could receive from a particular Part D sponsor for a particular Part D covered drug. We agree that a standardized approach to addressing pharmacy price concessions will help ensure Medicare beneficiaries share in the savings as well as create a simple and fair process for Plan Sponsors to account for all price concessions.

In the Proposed Rule CMS does not directly address the metrics by which Plan Sponsors and PBMs measure performance in performance contingent arrangements. However, as CMS continues to explore solutions, FreseniusRx urges you to consider that the metrics by which pharmacies are measured may be problematic as well. In our case, we service only patients with ESRD, a highly specific population with very specialized needs. Our experience has been that Plan Sponsors improperly apply broad metrics that do not accurately capture quality or performance as it relates to this population. For example, while current CMS guidelines call for the exclusion of ESRD patients from the Star Ratings related to Oral Diabetes and Hypertension medication adherence¹², PBMs continue to include these patients and drugs in their performance metrics. In doing so, PBMs improperly incentivize strict adherence to these medications which is not supported by the unique dosing needs of ESRD patients. Hypertension medications, for example, are often placed on hold before and after dialysis treatment based changes in the patient’s blood pressure that occur during and after treatment. CMS should consider its role in ensuring that Medicare beneficiaries are truly directed to high performing pharmacies when performance contingent arrangements are proposed by Plans Sponsors.

FreseniusRx appreciates the opportunity to share our thoughts on the proposed changes to the definition of negotiated price and DIR reporting. As we discussed, the trends with respect to pharmacy recoupments are troubling and problematic for the Medicare program, beneficiaries, and pharmacies who hope to continue to serve Medicare beneficiaries. We applaud CMS for taking another step towards addressing the regulatory

⁹ Roberts-Clary S, Larkin JW, Matzke GR, Rosen S, Reviriego-Mendoza MM, Fox T, Usvyat LA, Hymes JL, Ketchersid TL, Maddux FW. Improvements in MBD lab outcomes associated with improved pharmaceutical care in hemodialysis patients. *Nephrology News & Issues*. May 2017; 31:05:26-32.

¹⁰ Tentori F, Blayney MJ, Albert JM, et al. Mortality risk for dialysis patients with different levels of serum calcium, phosphorus and PTH: the dialysis outcomes and practice patterns study (DOPPS). *Am J Kidney Dis*. Sept 2008; 52(3):519-530

¹¹ 82 Fed. Reg. at 56426

¹² CMS, Medicare 2016 Part C & D Star Rating Technical Notes. April 2016; 61-62

loopholes that allow these abusive practices to continue, and we strongly urge CMS to quickly move forward in the rulemaking process. Please feel free to contact me at EMAIL or PHONE.

Sincerely,



Billy Kim, Vice President of Operations & Clinical Services