



January 16, 2018

VIA ELECTRONIC DELIVERY

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington D.C. 20201

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 Programs and the PACE Program [CMS-4182-P]

Dear Administrator Verma:

Sempre Health appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) 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 Proposed Rule (Proposed Rule), published in the Federal Register on November 28, 2017.¹

Founded in 2015, Sempre Health is a health technology company offering an innovative prescription drug copayment structure to patients and third-party payors. Sempre Health works collaboratively with third-party payors and pharmaceutical manufacturer business partners to introduce, develop, and operationalize dynamic copayment structures that allow patients to lower their copayment costs by engaging in certain behaviors aimed at improving medication adherence, such as refilling prescriptions by a particular time or consistently over time. Sempre Health supports CMS's efforts to make changes to the Medicare Advantage, Medicare Fee-for-Service, and the Part D Prescription Drug Benefit Programs to encourage more transparent prescription drug costs and uniform benefits. Our comments, detailed below, encourage CMS to finalize changes that do not stifle innovation in patient engagement.

Our comments focus on the following areas, which we address below in additional detail:

- Request for Information to Require Pass through of Manufacturer Rebates at the Point of Sale to the Beneficiary; and
- Flexibility in the Medicare Advantage Uniformity Requirements.

¹ 82 Fed. Reg. 56,336 (Nov. 28, 2017), hereinafter "Proposed Rule."

1. Sempre Health encourages CMS to allow plans flexibility to use rebate pass through to encourage patient adherence

Sempre Health agrees with CMS's concerns stated in the Proposed Rule that higher beneficiary cost-sharing obligations can impede beneficiary access to necessary medications, leading to poorer health outcomes and higher medical care costs for beneficiaries and Medicare.² Sempre Health also agrees that beneficiaries benefit when manufacturer rebates are passed through to the cost of the drug at the pharmacy counter. We would like to encourage CMS to consider ways in which pass through of a manufacturer rebate can be used to incentivize patient adherence to drug therapies, thereby improving patient outcomes and reducing overall cost of care.

Sempre Health has designed a dynamic copay program that delivers the optimal copay prices at particular times as a means of encouraging patients to fill prescriptions for selected drugs in a manner consistent with how the drugs are prescribed. Payors select drugs for inclusion in the dynamic copay program, focusing on where sustained adherence to an included drug therapy is expected to improve patient outcomes and, thus, reduce overall costs of care. This is consistent with CMS's proposed alternative approach, under which the point-of-sale rebate policy would apply only for specific categories or classes of drugs.³ While CMS proposes that this alternative approach would focus on higher priced drugs, Sempre has found that plans also are interested in targeting therapeutic areas that may not have the highest price drugs but for which adherence failures can result in higher health care costs. We urge CMS to consider allowing plans to target therapeutic areas based on factors such as the impact of adherence on overall health care (and thus plan) costs.

The dynamic copayment structure is funded by manufacturer discounts passed through at the point-of-sale in the form of lower cost-sharing. For example, an eligible patient may receive a text message that his or her copayment for a prescription will be a particular lower price (e.g., \$10) before her expected refill date and a different higher price (e.g., \$25) after her expected refill date. At the point of sale, the patient pays the amount pre-determined by Sempre's algorithm, according to the patient's coverage under the participating payor's health plan. This effective discount to the payor ultimately inures to the enrollee, in the form of a lower copayment targeted to facilitate adherence. These goals are consistent with the Part D program's goals related to medication therapy management programs, incentivizing patient adherence, by ensuring beneficiaries share in plan discounts via lower cost-sharing obligations and doing so in a manner that allows plans to focus on improving outcomes.

Sempre Health supports CMS's interest in encouraging plans to pass through manufacturer rebates in the Part D program. In considering potential pass through models, Sempre Health encourages CMS to ensure that plans have the flexibility to adopt pass through models that have the added benefit of supporting patient adherence. While Sempre Health supports CMS's underlying goals in recommending a required pass through, we urge CMS to adopt any requirements in a manner that allow plans to take advantage of innovative approaches to beneficiary adherence such as dynamic cost-sharing.

² *Id.* at 56,420.

³ *Id.* at 56,423.

2. Sempre Health encourages CMS to clarify that the flexibility in the Medicare Advantage uniformity requirements also apply to Medicare Part D

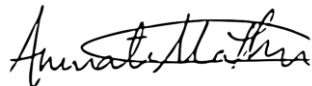
Sempre Health appreciates the steps CMS has taken in the Proposed Rule to clarify that Medicare Advantage plans may reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria.⁴ As CMS notes, this approach is permitted under the current statutory and regulatory framework. Sempre Health urges CMS to clarify that this same flexibility is consistent with the Part D uniform benefit requirements. Part D plans today offer differential benefits to differently situated beneficiaries, consistent with the Part D rules. For example, plans may offer lower cost-sharing on drugs, such as diabetes drugs, via formulary design as a means of encouraging adherence in a population for which adherence may pose a particular challenge. As long as the plan benefit design is not discriminatory, formulary structures designed to encourage adherence among certain patient groups is permissible. Plans also are permitted to target their medication therapy management programs to address specific medically needy populations. While these MTM programs must be available to all similarly situated beneficiaries, plans are not required to offer these benefits to all plan enrollees.

Similarly, differentiating cost-sharing via a dynamic copay program is consistent with the requirement for a uniform benefit design. Provided that dynamic copayments are made available in the same manner to all similarly situated beneficiaries, this variable cost-sharing is consistent with the Part D uniform benefit design requirement. For example, all patients enrolled in a particular plan that take a specific diabetes drug and have the same fill behavior are presented with the same copayment options, and thus the copayments are available uniform basis to all plan enrollees. The dynamic copay model is, in essence, a more innovative and complex approach to formulary benefit design – it allows plans to create more granular formularies than typically have been offered via traditional formulary tiering systems. Sempre Health urges CMS to clarify that Part D plans have the flexibility to reduce cost sharing for certain covered drugs for enrollees that meet specific medical criteria, provided that similarly situated enrollees are treated the same.

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We appreciate your consideration of our comments on the CY 2019 Medicare Advantage (MA) Program (Part C) and Prescription Drug Benefit Program (Part D) Proposed Rule. Please contact Anurati Mathur by phone at (408)550-5246 email at anurati@semprehealth.com if you have any questions regarding our comments.

Sincerely,



Anurati Mathur
CEO, Sempre Health

⁴ *Id.* at 56,360.