



January 10, 2017

Centers for Medicare & Medicaid Services, Department of Health and Human Services
Attention: CMS-4182-P
P.O. Box 8013
Baltimore, MD 21244-8013

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

To whom it may concern:

As a licensed pharmacist and the CEO of PillPack, Inc. ("PillPack"), an independent national pharmacy, I am writing to voice my strong support for the proposed rules in CMS-4182-P. Specifically, I support the proposed definition of "mail-order pharmacy" and the proposed modified definition of "retail pharmacy" because they strike the right balance to address and acknowledge recent innovations in pharmacy and health care business models, resolve confusion in the marketplace, and offer Part D plan sponsors greater flexibility (Section 13, Parts a. and b., pgs. 262-272.)

In short, if adopted, the proposed rules will help improve conditions for free market competition. More competition will create better customer experiences and place downward pressure on overall costs. I commend the agency for soliciting comment on these powerful proposals and recommend rapid approval with all relevant provisions unchanged.

To provide context and urgency for my support, this comment will first describe why PillPack is a unique and important new entrant in the pharmacy space. Then, I will share systemic challenges within our current system that threaten our business and weaken the broader environment for innovation. Finally, this comment will illustrate how the proposed rules would mitigate these challenges.

About PillPack: the only independent pharmacy that delivers medications nationwide:

PillPack is a unique pharmacy. We are licensed nationwide, with customers in every state except Hawaii¹. Since launching service in 2014, PillPack has grown to serve tens of thousands of customers, while employing 700 professionals in six locations². Our mission is to serve customers living with chronic conditions, such as diabetes, heart disease, mental illness, COPD, and more. Approximately half of our customers are enrolled in Medicare plans and this number is growing.

Because PillPack customers have high medical needs, our goal is to make it easier for them to take their medications as prescribed, which significantly improves health outcomes. Studies find that for every dollar spent on medications that are taken as prescribed, the health system saves as much as \$10 in future treatment costs³. Clearly, therefore, medication adherence plays an important role in lowering the unsustainable burden of medical costs in the United States. Despite this evidence, there has been very little innovation in pharmacy business models. To my knowledge, PillPack is the only independent pharmacy delivering medications nationwide, at scale. All three of the largest "mail-order pharmacies" in

¹ PillPack is licensed in Hawaii, but does not ship there due to prohibitive shipping costs.

² Manchester, NH; Somerville, MA; Brooklyn, NY; Salt Lake City & Park City, UT; Miami, FL; Austin, TX

³ M. Christopher Roebuck, et. al., "Medication Adherence Leads To Lower Health Care Use And Costs Despite Increased Drug Spending," Health Affairs, January 2011, <https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2009.1087>, accessed January, 2018.

operation today are owned and operated by pharmacy benefit managers (“PBMs”), the large corporations that also decide how hundreds of millions of Americans access and pay for medications. The industry remains dominated by a handful of major players, each setting their own participation standards. Results are dismaying: 50% of medications are not taken as directed and 20-30% of medications are never even picked up from the pharmacy. Estimates suggest that non-adherence leads to at least \$100 billion, and up to \$290 billion, in additional care costs in the United States annually⁴.

PillPack’s approach is designed to address this problem. We package medications in individual packets labeled with the date and time they should be taken, mail medications to our customers’ homes once per month, and provide trained staff to secure refills and renewals, and help our customers navigate insurance issues. Additionally, PillPack offers online tools to support customers and caregivers so they have complete understanding and control over their medications⁵. Our “Net Promoter Score” (a standard measure of customer satisfaction, ranging from -100 to +100) is routinely over 70, compared to an industry average in the low 20s. Health plans, aware of our approach and success, are beginning to proactively seek out opportunities to work with us because they understand that their members may be more adherent with PillPack as their pharmacy. We are encouraged by early data from these health plan relationships and expect to publish findings in 2018.

Systemic challenges act as a barrier to competition:

Despite being fully compliant with all federal and state regulations and earning rigorous private accreditations such as VIPPS and URAC, PillPack nonetheless faces arbitrary challenges and roadblocks that prevent us from accessing the full consumer marketplace. Our ability to serve customers is determined by private payers and for-profit PBMs. Today, three PBMs control access to 180 million lives, which is over 80% of all customers served by a PBM⁶. These entities wield vast power to shape the medication delivery market, and they aggressively exercise that power to limit new entrants, particularly those like PillPack that offer home delivery. Certainly, this is at least in part to protect their own competitive mail-order pharmacies, which comprise 40% of total annual prescription sales⁷.

PillPack has been subjected to repeated attempts by multiple PBMs to block our pharmacy’s participation and access to their networks. If successful, these actions would jeopardize our business and deprive customers of our innovative solutions. The stated reason for many of these actions was that PillPack’s unique and innovative business model did not fit perfectly into an existing class of pharmacy trade. In each instance, we have either publicly⁸ or privately responded on behalf of our customers and our business model. These efforts have been successful to date and PillPack is currently in network with all major PBMs. Unsettlingly though, there is nothing to prevent PBMs from unilaterally revoking access in the future for no reason. As a result, we continue to spend considerable energy, time, and resources fighting repetitive bureaucratic battles and a seemingly ever changing set of rules for participation. Furthermore, the barriers to entry in the industry serve as a deterrent to other innovative companies looking to emerge with new ideas. We believe this is a disservice to customers and the industry. We would vastly prefer to spend our resources improving our innovative service and being pushed by competitors than fighting bureaucratic battles simply to access the market.

⁴ Jane E. Brody, “The Cost of Not Taking Your Medicine,” *New York Times*, April 17, 2017, <https://nyti.ms/2psUF6a>, accessed January 2018.

⁵ For a complete overview of PillPack services please visit www.pillpack.com

⁶ Health Policy Brief: Pharmacy Benefit Managers,” Health Affairs, September 14, 2017. DOI: 10.1377/hpb2017.1, https://www.healthaffairs.org/doi/10.1377/hpb20171409.000178/full/healthpolicybrief_178.pdf, accessed January 2018.

⁷ Adam J. Fein, “The Top 15 Pharmacies of 2015,” *Drug Channels*, January 28 2015, <http://www.drugchannels.net/2016/01/the-top-15-pharmacies-of-2015.html>, Accessed January 2018.

⁸ Sara Ashley O’Brien, “PillPack vs. Express Scripts: When business turns ugly, people suffer,” *CNNMoney.com*, April 14, 2016, <http://money.cnn.com/2016/04/14/technology/pillpack-express-scripts/index.html>, Accessed January 2018.

The proposed rule offers an elegant and powerful solution:

CMS-4182-P creates a clear definition of a mail-order pharmacy and clarifies the definition of a retail pharmacy. These changes will resolve confusion in the marketplace, provide stability for existing innovative businesses like PillPack, and create a more hospitable marketplace for other, new, patient-centric pharmacy business models.

Today, PillPack does not fit into an existing class of service. This is by design. Our research suggests that providing 30-day fills delivered to a multi-chronic customer's home in pre-sorted dose packaging is the best approach for adherence and compliance. From a cost-sharing standpoint, we are considered a retail pharmacy dispensing 30 day supplies but, because we utilize carriers to deliver medications, we have at times been targeted and bucketed into mail-order class of trade or prohibited from joining a network at all. As noted in the proposed rules, "[...] *it is not appropriate for Part D plan sponsors to offer standard terms and conditions for network participation that are specific to only one particular type of pharmacy, and then decline to permit a willing pharmacy to participate on the grounds that it does not squarely fit into that pharmacy type.*" Our experience at PillPack is that Part D plan sponsors have, in fact, attempted to use the lack of clarity around these definitions to prevent PillPack, a willing pharmacy, from network participation. This is likely to happen again to PillPack and certainly will impede any other similarly ambitious new entrants. Pharmacies should gain access to a network based on their ability to meet the required standards for care, not based on varying definitions of class of trade. The proposed rules recognize the need for innovation beyond the existing classes of business and provide the clarity needed for PillPack and other business to start and succeed. I urge that these rules be adopted rapidly.

I also commend the proposed rule's effort to clarify and reinforce the existing "any willing provider" regulations. As described above, at great cost and effort, PillPack has earned and maintains the two leading private pharmacy accreditations, VIPPS and URAC. We believe, however, these non-governmental barriers are unnecessarily burdensome. Other innovative pharmacies should not have to go through the same hurdles we did. In the proposed rule, CMS removes the ability for entities to use private credentialing as a requirement for network participation. If PBMs believe that state or federal regulations are not sufficient for network participation, then these measures should be amended by mutual agreement, such that the standards remain transparent and open. PillPack would welcome that dialogue and participate enthusiastically. PBM-specific credentialing is an expensive and unnecessary barrier to entry. I strongly support the proposal to ban this private credentialing.

My experience as a pharmacist, founder, and CEO suggests that the proposed rules will achieve the stated CMS goals and drive significant positive changes in the industry. For these reasons, I strongly support finalizing the proposed rule as written.

Sincerely,



TJ Parker

Co-founder & CEO, PillPack

(617) 794-3393 | tj@pillpack.com

250 Commercial Street, Manchester, NH 03101