



January 16, 2018

Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4182-P
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted electronically via 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 Programs, and the PACE Program” — ExactCare Pharmacy Comments

Dear Administrator Verma:

ExactCare is pleased to offer comments on the Centers for Medicare & Medicaid Services (CMS) proposed rule 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” published in the *Federal Register* on November 28, 2017.

The ExactCare model was designed to cater to the specific needs of chronic, high-risk patients in a home-based environment. As such, our approach differs greatly from more traditional, commonly recognized models of pharmacy. ExactCare partners with health care organizations—including Medicare plans—to provide comprehensive medication management for medically complex, high-risk patients with multiple chronic conditions. ExactCare utilizes a high-touch medication management model coupled with proprietary technology to provide customized care tailored to each patient’s individual needs.

Our patients tend to have institutional-level of care needs; however the focus of their care is in the home. As such, our model has some attributes of long-term-care (LTC) pharmacy, but we are not a typical LTC pharmacy serving institutional patients. Additionally, while we package and deliver medications directly to patients, we are not a retail, mail-order, or specialty pharmacy provider. Rather, our model is an innovative hybrid that delivers a combination of customized clinical pharmacy services to meet patients’ needs within the continuum of care in their homes.

Our comprehensive approach helps patients overcome the challenges of polypharmacy through high-touch clinical pharmacy services, such as an in-home patient assessment and medication reconciliation; customized compliance packaging; holistic prescriber outreach program to coordinate a plan of care; and a proprietary clinical platform to customize treatment for each patient—while enabling health care organizations to achieve better clinical and economic outcomes, including proven substantial total cost-of-care savings demonstrated for Medicare beneficiaries.ⁱ

ExactCare is encouraged by the focus CMS is placing, through this proposed rule, on policies that will build a patient-centered system of care that increases competition, quality and access. We share a common focus on empowering patients to take ownership of their health; driving improvements in care for better patient health; and delivering outcomes that deliver substantial cost savings.

In the following pages, ExactCare offers comments on three sections of the proposed rule:

1. Flexibility in the Medicare Advantage Uniformity Requirements
 2. Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types
 3. MTM in MLR
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Flexibility in the Medicare Advantage (MA) Uniformity Requirements

ExactCare supports the intent and direction of this section. We are pleased to see the proposed rule offering MA plans increased flexibility to eliminate barriers to beneficiaries getting the care they need—through the most effective programs—to maintain and improve their health.

As is commonly understood, the longer a beneficiary can remain independent and age in place at home, the better for the beneficiary and the payor (Medicare, Medicaid or both). Improved access to the appropriate level of care for their health needs will make this possible. ExactCare shares this important focus.

ExactCare was founded in 2009 on the core tenant of driving better health for the most complex and costly patients. Since our founding, ExactCare has focused on helping high-risk patients with multiple chronic conditions overcome the challenges of polypharmacy. We accomplish this through a high-touch medication management model coupled with a case management approach to managing patients' health. This approach not only results in better health outcomes but also proven, significant total cost-of-care savings, documented through a recent study conducted by an independent third-party.ⁱ

Unfortunately, patients most likely to benefit from the ExactCare model are often challenged by cost sharing/patient copay differentials—especially when preferred networks exist. For many patients, incurring higher monthly costs is not an option due to financial constraints.

While copay differentials may seem nominal, the difference quickly adds up for a patient taking 10 or more medications daily—the typical profile of an ExactCare patient. This creates a significant access barrier, preventing patients from utilizing a program that will provide the optimal care for their health needs and drive optimal cost savings for CMS.

We are confident the following combination will lead to further adoption of this type of comprehensive medication management program and increased interest to offer these impactful services to this critical subset of the population:

- Ensuring high-touch medication management models are copay neutral or, ideally, offered under a preferential copay structure, which will improve patient access.
- Ensuring the most complex, high-cost groups of patients have access to these types of programs, which will be critical to successfully driving improved health and savings. We believe there would be significant benefit for MA plans to have broader flexibility in defining the groups of beneficiaries in need of the special treatment proposed in this CMS rule.
- Obtaining support from MA plans to motivate beneficiaries through healthy rewards to participate in these types of programs, which will improve adherence.
- Providing PBMs (that build and maintain the networks) the flexibility, motivation and, perhaps, incentives to customize networks in accordance with how plan sponsors define beneficiaries eligible for preferential treatment, which will maximize adoption.

RECOMMENDATIONS:

1. **ExactCare requests that CMS expand the criteria used to define a group of beneficiaries eligible for special treatment beyond a single disease state, including language in the proposed rule to expressly define “medically complex patients” as a group eligible for special treatment.** Defining medically complex patients may include a combination of factors such as number of medications, number and type of disease states, recent ALF or SNF stays, utilization of home health services or other characteristics. By doing this, CMS will make sure this very costly and vulnerable population can obtain the optimal care for their needs. In turn, this will drive improved patient health and total cost-of-care savings for CMS, as evidenced by data collected through a third-party study of CMS beneficiaries using ExactCare.¹
2. **In addition, ExactCare requests that CMS include specific requirements for MA plans to demonstrate how their contracted networks meet the needs of medically complex patients (or other targeted groups). Plan sponsors should have the flexibility, motivation and incentives to customize the networks for beneficiaries eligible to receive preferential treatment, and contractual arrangements that are specifically tied to improved outcomes for this population.** This increased level of accountability is a critical component to success.
3. **ExactCare requests that CMS encourage plan sponsors to go beyond copay neutrality and implement zero copays and/or rewards for healthy behaviors, such as improved medication adherence.** This combination will help motivate high-risk patients to participate in these types of programs, in turn driving better health for beneficiaries and lower costs for CMS.

Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types

We are pleased to see CMS addressing the challenges outlined in this section and focused on fostering an environment that will encourage innovation in pharmacy business and care delivery models.

We agree with the philosophy outlined by CMS in this section that the “Any Willing Pharmacy Standard Terms & Conditions” are meant to be an entry-level set of minimum conditions for pharmacies to participate in plan sponsors’ networks. In conjunction with this, we believe the following factors are critical to success:

1. These standard terms and conditions should be neither arbitrary nor overly rigid.
2. The standard terms and conditions should be broad enough to allow for and encourage innovative models for improving beneficiary health and lowering total cost of care for CMS.
3. Where standard terms and conditions don’t work, plan sponsors should offer pharmacies non-standard reasonable and relevant terms and conditions.

We agree with the definition of mail-order pharmacy and the proposed modified definition of retail pharmacy as outlined by CMS in this proposal. We also agree with the proposal by CMS to forego defining specialty and non-retail pharmacy to avoid being overly constraining and restricting innovation. That said, as noted, ExactCare utilizes an innovative model of care that does not fit cleanly into the existing construct of pharmacy definitions utilized by CMS.

The ExactCare model was designed to meet the unique high-touch medication management needs of chronic, high-risk patients in a home-based environment. Our focus is to keep these patients out of the emergency room, out of the hospital and out of LTC facilities, enabling them to age in place at home, the optimal environment for their health. We accomplish this through a distinct combination of service features, including the following:

- In-home patient assessments for every patient at start of care and ongoing home visits, as needed, to build strong patient relationships and ensure we collect the most complete and accurate information.
- Customized compliance packaging, helping to ensure the right medication is taken at the right time and driving safer, more effective medication regimens.
- Holistic, collaborative prescriber outreach program to develop an individualized plan of care for each patient.
- Proprietary clinical platform to customize treatment for each patient.
- Providing the benefits of key MTM activities to our patients each month for safer and more effective medication regimens.
- Eliminating transportation barriers by delivering all medications to patients’ homes each month.



This comprehensive approach has been proven to yield better health and financial outcomes for medically complex patients. A recent study conducted by a third-party revealed substantial total cost-of-care savings per member per month for Medicare beneficiaries using ExactCare.ⁱ

While this distinct approach is essential for these high-risk patients to achieve optimal health, it differs greatly from the existing defined pharmacy services types.

- **Mail Order.** ExactCare offers medication delivery to the patient's home to overcome transportation barriers that can negatively impact medication adherence. However, ExactCare does not deliver extended days' supplies (e.g., 90-day supplies) of medications. Because we serve patients prone to medication changes, extended days' supplies can result in excessive waste. We are also limited by legal requirements that regulate days' supply provided through multi-dose compliance packaging. Therefore, it is clear we are not a mail-order pharmacy and should not be forced to participate in a plan sponsor's network as a mail-order pharmacy.
- **Retail.** ExactCare is a closed-door pharmacy. We do not have a store front and are not open to the "walk-in general public." Therefore, we do not fit within the proposed definition of retail.
- **Specialty.** While ExactCare does dispense some specialty drugs, our service model is not aligned with the definition of specialty pharmacy.
- **Long Term Care (LTC).** Our model is most closely aligned with LTC pharmacy but still maintains distinct differences from LTC, as ExactCare is focused on serving patients in their homes. To do so, we provide an additional level of clinical support to keep patients out of the ER, out of the hospital, out of LTC facilities and at home. This is not only best for beneficiaries, but also drives substantial savings for CMS, as shown in our recent study.ⁱ

So while we agree with the pharmacy definitions outlined by CMS in this proposal, this still leaves pharmacies like ExactCare without a clear definition. Our proposed solutions are outlined below.

Another challenge is that current pharmacy contractual arrangements do not include quality and reimbursement terms and conditions that facilitate true value-based payment incentives for optimal use of high-touch, high-cost pharmacy models like ours. Contractual arrangements that promote innovation and align incentives for cost, quality and patient-centered outcomes need to be developed. This will drive increased adoption of the pharmacy models that deliver the most favorable health and financial outcomes for high-risk patients—and ultimately achieve the goals outlined by CMS.

To accomplish this:

- Plan sponsors must have the flexibility and motivation to include innovative pharmacies in their networks with reasonable and relevant terms and conditions.
- Pharmacy Benefit Managers (PBMs) must also be engaged. PBMs can either serve as a barrier or an enabler. PBMs must be willing to contract with innovative pharmacies at reasonable and relevant terms and conditions reflective of the economics of those pharmacies. The economics

are relevant in both (a) the cost structure of the high-touch/high-cost models and (b) the value they drive in lowering overall total cost of care for plan sponsors, CMS and taxpayers.

RECOMMENDATIONS:

1. **ExactCare requests that in the final rule CMS acknowledge that contractual terms and conditions that do not directly address unique features and cost drivers of a pharmacy business and service model would likely not be reasonable and relevant.** For instance, it would be helpful for CMS to clarify intent through the example that offering retail reimbursement rates for comprehensive, high-touch medication management services for medically complex, home-based patients that include the combination of services listed below would be inconsistent with CMS guidance and likely not be reasonable and relevant. This combination of services would include in-home patient assessments; holistic clinical medication review monthly; customized compliance packaging; collaborative prescriber outreach program to develop individualized care plans; monthly home delivery; and technology tools to promote adherence. It would also be helpful for CMS to define these medically complex patients; this may include a combination of factors such as number of medications, number and type of disease states, recent ALF or SNF stays, utilization of home health services or other characteristics.
2. **ExactCare also requests that CMS clarify expectations that to be consistent with guidance in this area, plan sponsors (and/or their PBMs) should either (1) develop standard terms and conditions applicable to unique and innovative pharmacy business models as they arise or, (2) engage in individual negotiations to determine mutually acceptable reasonable and relevant terms with such pharmacies.**
3. **ExactCare recommends CMS explore policy options to encourage plan sponsors to offer medically complex patients reduced/zero copays when utilizing high-touch pharmacy models to support both patient-centered care and the goals of MTM.** Only a portion of a plan sponsor's members will meet this criteria. However, this portion of the population is often the most costly, with just 5% of the population—health care “super-users”—accounting for more than half of health care spending. Removing financial barriers to adhering to optimized medication regimens is a key strategy to preventing hospitalizations and institutionalization for this population.

MTM in MLR

ExactCare fully supports more robust and effective Medication Therapy Management (MTM) programs and the role organizations like ours can play in driving this forward—specifically for the most vulnerable, at-risk and high-cost beneficiaries.

ExactCare utilizes a high-touch medication management model combined with a case management approach to managing patients' health. Our model was designed specifically to meet the unique needs of chronic, high-risk patients in a home-based environment. This includes effectively completing a



Comprehensive Medication Review (CMR) upon enrollment and key MTM activities each month for every patient we serve.

This is a key benefit to plan sponsors. Notably, while most patients served are MTM eligible, even beneficiaries that are not MTM eligible (based on the plan sponsors' criteria) still receive the benefits of a CMR and monthly MTM activities when on service with ExactCare.

We strongly believe programs like ExactCare's achieve maximum effectiveness for all constituents—patients, plan sponsors, PBMs and CMS—with this type of robust MTM approach as a core component of service. An effective approach includes completing key MTM activities on every patient each month they are on service. This is necessary to drive optimal health for the most vulnerable beneficiaries.

RECOMMENDATION:

ExactCare applauds the focus by CMS on encouraging MTM for as many beneficiaries as possible and strongly agrees with this approach. We also agree with the proposed changes to clarify that compliant MTM program costs should be included in the Medical Loss Ratio (MLR) numerator as QIA. ExactCare encourages CMS to move forward with finalizing this policy as it is proposed.

Again, we appreciate the opportunity to offer comments on the proposed 2019 Part C and D Proposed Rule. We remain committed to our common focus on empowering patients to take ownership of their health; driving improvements in care for better patient health; and delivering outcomes that deliver substantial cost savings.

Sincerely,

A handwritten signature in dark ink, appearing to read "Dale Wollschleger", with a long horizontal flourish extending to the right.

Dale Wollschleger, R.Ph.
Founder, President & CEO
ExactCare

ⁱ A recent study conducted by an independent third party revealed substantial monthly savings for members using ExactCare as compared with propensity matched Medicare members using other pharmacies. Savings reflected total cost-of-care, comprised of medical spend and pharmacy spend, with documented savings of \$700+ per utilizing member per month.