January 16, 2018

Ms. Seema Verma

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS–4182–P

Submitted electronically to: <http://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**

Dear Administrator Verma:

On behalf of the Premier healthcare alliance serving approximately 3,900 leading hospitals and health systems, hundreds of thousands of clinicians and 150,000 other provider organizations, we appreciate the opportunity to submit comments regarding the regulation proposed by the Centers for Medicare & Medicaid Services (CMS) for the 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. Premier healthcare alliance, a 2006 Malcolm Baldrige National Quality Award recipient, plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Premier maintains the nation's most comprehensive repository of hospital clinical, financial and operational information and operates one of the leading healthcare purchasing networks, which serves its members across the continuum of care, including long-term care facilities. Additionally, hospitals and health systems, working with Premier’s specialty pharmacies, provide a unique, patient-centric, cost effective model in caring for people with some of the most serious and costly diseases. Our comments primarily reflect the concerns of our owner hospitals and health systems. Below, the Premier healthcare alliance provides detailed comments with suggested modifications to the policies proposed by CMS.

**PHARMACY PRICE CONCESSIONS**

CMS invites comments on the application of pharmacy price concessions to the price of a drug at the point of sale. We strongly agree with the concerns raised by CMS that pharmacy price concessions, known as direct and indirect remuneration (DIR), as currently treated under Part D, are not reflected in the price of a drug at the point of sale.

In recent years, DIR fees have become increasingly problematic for beneficiaries, pharmacies and the government for a number of reasons. When DIR fees are applied retroactively and not captured at the point of sale, beneficiaries pay a higher copayment that does not reflect a reduction once DIR fees are assessed retrospectively to the pharmacy. In other words, a beneficiary’s copayment is based on a higher rate than the actual cost of the drug for the plan. Pharmacies are adversely impacted because they cannot determine their actual reimbursement rate until well after they have dispensed the medication. Further, for Medicare Part D and other government-funded drug coverage programs, DIR fees lead to inaccurate information on the drug costs that are reported to government entities because of differences in costs reported by plans and the amounts paid by the plans after DIR fees are taken into account. For these reasons **we urge CMS to eliminate all DIR fees from the Part D network**. This approach would generate savings for the Medicare program, provide cost-sharing relief for beneficiaries, and restore fair business practices to pharmacies.

Additionally, we are concerned about the unintended consequences that are likely to accompany the proposed “Lowest Possible Reimbursement” method that would attempt to capture at the point of sale the lowest possible reimbursement that a network pharmacy could receive for a Part D drug. **We urge CMS to abandon its “Lowest Possible Reimbursement” method as described in the proposed rule** that attempts to shift how these inappropriate fees are paid and pass-through some portion of the fee reductions to beneficiaries. CMS’ outlined approach is unlikely to achieve its policy goals of improving the quality of pricing information available or of market competition because unfair remuneration practices would still be in play. Rather, it would create incentives for plan sponsors and their Pharmacy Benefit Managers (PBMs) to adjust pricing practices in a way that could be harmful to beneficiaries and pharmacies.

**ANY WILLING PHARMACY STANDARDS**

CMS makes several proposals to clarify the requirement that plans permit participation of “any willing pharmacy” provided standard terms and conditions are met. Importantly, CMS proposes that plan sponsors may tailor their standard terms and conditions to different types of pharmacies, but they cannot exclude “unique or innovative” pharmacies from participating in their contracted pharmacy network on the basis of not fitting in the correct pharmacy type classification. We applaud CMS for providing this clarification that will foster a more inclusive and fair marketplace for beneficiaries and pharmacies.

**CMS should finalize the requirement that plan sponsors not exclude pharmacies that meet their standard terms and conditions from participating in their contracted pharmacy network**. Narrowing pharmacy networks disadvantages Medicare beneficiaries by limiting choice and availability of pharmacy options. To ensure beneficiary access and a level playing field for all pharmacies that meet contractual requirements, we support CMS in its efforts to clarify any willing pharmacy standards as proposed.

**PHARMACY LOCK-IN EXEMPTIONS**

CMS proposes to implement provisions of the Comprehensive Addiction and Recovery Act of 2016 (CARA) that require the Administration to establish a regulatory framework for PDPs to tackle the opioid crisis. As part of the framework, PDPs may establish a drug management program that “may limit at-risk beneficiaries’ access to coverage of controlled substances that CMS determines are ‘frequently abused drugs’ to a selected prescriber(s) and/or network pharmacy(ies),”[[1]](#footnote-2) known as pharmacy lock-in programs, beginning with the 2019 plan year. Prior to CARA’s passage, we urged Congress not to apply pharmacy lock-in programs to residents in long-term care Facilities (LTCFs) or other facilities that contract with a single pharmacy because it would disrupt current safeguards that are already in place for this population and would have unintended negative consequences for the ability of LTCFs to properly monitor and coordinate beneficiaries’ medications. We were pleased that Congress recognized the unique needs of patients residing in these settings by creating proper beneficiary exemptions.

In this rule, CMS appropriately proposes that an exempted beneficiary, with respect to a drug management program, is an enrollee who: (1) has elected to receive hospice care; (2) is a resident of an LTCF, of a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or (3) has a cancer diagnosis. We applaud CMS for recognizing the operational realities of exempting certain beneficiaries and **recommend that CMS finalize these conditions as proposed**. However, we are disappointed by CMS’ explicit rejection to exempt residents in assisted living facilities (ALFs[[2]](#footnote-3)) and urge CMS to reconsider. **We urge CMS to clarify “another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy” to include assisted living facilities.** Similar to LTCFs, these entities are at low risk for drug abuse and misuse and have a single pharmacy model to optimize the efficient provision of quality care.

We further support an exemption for these beneficiaries because quality of care may be undermined if a plan locks an ALF beneficiary into a pharmacy other than the contracted single pharmacy already working with the facility. Many ALFs adopt the single pharmacy model because it creates a highly efficient and coordinated system of care whereby the pharmacy provides oversight and management of all medications utilized by the beneficiary. The current process would be interrupted if a beneficiary were locked into a different pharmacy because the ALF’s single contract pharmacy would no longer be able to serve the beneficiary’s full medication management needs. This includes specialized packaging to reduce medication errors, 24/7 delivery for timely access to medications, drug utilization review to minimize adverse events, and other medication management services provided to the ALF. Such interruptions would impede optimal patient care, create operational inefficiencies and unnecessary burden for facilities.

**LONG-TERM CARE TRANSITION SUPPLY**

Current law requires that Medicare Part D Plans (PDPs) cover a transitional supply of non-formulary drugs and drugs with utilization management requirements within the first 90 days of a transition. This is to ensure that beneficiaries have consistent access to medications upon enrolling in a new plan or as a result of changes in their current drug coverage. In the outpatient setting, a plan must cover at least 30 days of medication. Since 2011, CMS has recognized that beneficiaries in long-term care (LTC) settings tend to have more complex medical conditions and therefore requires PDPs to allow them up to 91-98 days of non-formulary medication (through multiple refills) upon plan transitions. CMS now proposes to change this 90-day transition period and limit the transition supply in both settings to a one month’s supply. Such a shift represents a significant policy departure for beneficiaries in long-term care settings and threatens access to necessary medications.

While CMS comments that a transition for a Part D beneficiary in the LTC setting does not take any longer than it does for a beneficiary in the outpatient setting, we respectfully disagree. We support CMS’ prior assertion that LTC residents often have complex needs that frequently involve multiple drugs and in turn necessitate a longer period of time in order to successfully transition to new drug regimens. It is for these reasons that the longer transition period is indeed necessary. We echo CMS’ earlier concerns that residents of LTC institutions are more limited in access to prescribing physicians hired by LTCFs due to a limited visitation schedule and are more likely to require extended transition timeframes in order for physicians to work with facilities and pharmacies on transitioning residents to formulary drugs. It is for these reasons that w**e request that the transitional supply policy remain at 90 days for long-term care beneficiaries so that consistent access to necessary medications is maintained.**

Lastly, the reduction in the transition supply will have a minimal impact on reducing drug cost and waste as CMS suggests. The transition policy provides for only a one-time transition supply in clinically appropriate situations so that long-term care beneficiaries are able to work with their multiple prescribers to switch to the drugs covered by the plan or to request a formulary exception so that the plan will continue to cover the necessary drugs. If anything, ensuring an appropriate transition policy will help prevent adverse health events, including costly and preventable rehospitalizations, for this vulnerable population. If CMS should disregard these concerns and insist on reducing the transition supply, **we would ask that CMS consider a reduction from 90 days to at least two months.**

**FLEXIBILITY IN MA UNIFORMITY REQUIREMENTS**

CMS has determined it has the authority to permit MA organizations (MAOs) to: reduce cost sharing for certain covered benefits; offer specific tailored supplemental benefits; and offer lower deductibles for enrollees that meet specific medical criteria, provided that all enrollees who meet the identified criteria are treated the same. Additionally, MA plans would be able to exercise the uniformity flexibility within each segment of an MA plan. CMS says that these flexibilities will be available to plans beginning in CY 2019 and that the upcoming Call Letter will address the operational details of this policy. CMS also notes that the Value Based Insurance Design (VBID) demonstration will provide it with insights into future VBID innovations for the MA program. **Premier supports the VBID demonstration and appreciates that CMS has used its authority to expand certain aspects of VBID to all MA plans**. We believe such tools allow MA plans to provide services to beneficiaries that are associated with improved patient satisfaction and outcomes. Similarly, **providers could furnish enhanced care by leveraging such tools, so we encourage CMS to allow use of similar beneficiary engagement tools for ACOs and providers participating in other CMMI demonstrations.**

**MA AND PDP QUALITY RATING SYSTEM**

CMS seeks public comment on whether and how it should account for low socioeconomic status (SES) and other social risk factors in Part C and D Star Ratings. CMS says it seeks to balance accurate measurement of plan performance, effective identification of disparities and maintenance of incentives to improve the outcomes for disadvantaged populations. We strongly believe that every patient who seeks care should receive the same high-quality care; however, it is also important to understand the numerous and variable risks associated with socio-demographic factors that are outside of the control of the provider that can effect outcomes. When using measures to reward plans and provide plan feedback to consumers via Star Ratings, we must consider the context within which the providers contracted with the plans are working.

Use of social risk factors in risk adjustment allows for fair cross-comparisons and does not penalize one plan over another based on having a patient population with increased risk of poor outcomes due to endogenous factors. Payment rewards that lack socio-demographic adjustment can create a perverse cycle, wherein CMS denies resources (both lower payments and by discouraging beneficiaries from using these plans) to plans, and ultimately their network providers, that care for such patients, subsequently leading to unequal care for those patients due to lack of equal resources to treat them. **We encourage CMS explore adjusting for social risk factors at the measure-level or for the overall Star Rating system.**

**CONCLUSION**

In closing, the Premier healthcare alliance appreciates the opportunity to submit these comments 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 Programs, and the PACE Program proposed rule. If you have any questions regarding our comments or need more information, please contact Danielle Lloyd, VP, policy & advocacy and deputy director DC office, at [danielle\_lloyd@premierinc.com](mailto:danielle_lloyd@premierinc.com) or 202.879.8002.

Sincerely,



Blair Childs

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Premier healthcare alliance

1. <https://www.gpo.gov/fdsys/pkg/FR-2017-11-28/pdf/2017-25068.pdf>, page 56339 [↑](#footnote-ref-2)
2. Ibid, pg. 56347 [↑](#footnote-ref-3)