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January 16, 2018

Seema Verma

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Hubert H. Humphrey Building, Room 445-G

200 Independence Avenue, SW

Washington, DC 20201

**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, November 28, 2017**

Dear Administrator Verma:

On behalf of Dialysis Clinic, Inc. (DCI), we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services’ (CMS) Medicare Advantage (MA) and Part D Proposed Rule. DCI is a nonprofit kidney health provider. We were founded forty-seven years ago, two years before Medicare covered dialysis, and currently care for more than 19,000 patients (15,000 of these patients are on dialysis and more than 4,600 patients have Chronic Kidney Disease (CKD)) in more than 245 locations in 28 states. For those patients with CKD, our primary goal is to keep them off dialysis, or at least delay their start of dialysis. For those who do start dialysis, we work to ensure that they are as prepared as possible for this transition in care.

We believe that transplant is the optimal therapy for many patients with kidney failure. Our founder, Keith Johnson, MD began working to increase access to transplantation in 1969, was the original President of SEOPF (the precursor organization to UNOS) and is a prior President of UNOS. To increase access to transplantation, we currently operate three organ procurement organizations (in Tennessee, New Mexico and Northern California). Because of the hard work of the staff of DCI Donor Services, more than 600 people received a kidney transplant in 2016.

Despite the fact that the USRDS has found that DCI’s mortality rates and hospitalization rates for patients on dialysis are the lowest of the national providers for fourteen years in a row, we know that we can provide better care for our patients on dialysis. Starting in 2011, we worked with CMMI in the development of the ESCO and many of our patients now benefit from care under the ESCO. We currently operate six ESCOs. We would have expanded the number of ESCOs in 2018 if we had been given the opportunity to apply for more ESCOs in 2017. Instead, we have

expanded our current ESCOs and anticipate that more than 2,900 DCI patients (29% of our Medicare patients on dialysis) are receiving care in an ESCO as of January 1, 2018. A little more than two years ago none of our patients benefitted from integrated care; we are excited that next year nearly 1/3 of our Medicare patients will benefit from this care and hope to expand this care to more patients if given the opportunity.

We have one comment on the Proposed Rule, detailed below.

**Comment Regarding Specific Provisions of the MA and Part D Proposed Rule**

*Section 12. Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types (§§ 423.100, 423.505)*

We support the proposed Part D plan sponsor’s standard terms and conditions for Any Willing Pharmacy requirement for All Pharmacy Business Models and the proposed revisions of the Definitions of Retail and Mail Order Pharmacy. As described in the Federal Register, the pharmaceutical distribution and pharmacy practice landscape continues to evolve rapidly and many pharmacies no longer fit traditional pharmacy classifications such as “retail” and “mail order”. The traditional interpretations of these pharmacy types by Part D plans and/or affiliated Pharmacy Benefit Managers (PBM) oftentimes prohibit beneficiaries from utilizing their pharmacy of choice. This was done through creation of “preferred pharmacy networks” in which terms and conditions excluded willing pharmacies from network participation.

We agree that Part D plan sponsors should permit the participation of ‘‘any pharmacy’’ that meets the standard terms and conditions. We also agree that 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. If the definition of “any willing provider” is changed as proposed, more beneficiaries would be able to use their pharmacy of choice.

Unfortunately, many Medicare beneficiaries experience both types of poly-pharmacy; be it defined as taking a lot of medications or defined as utilizing several pharmacies to fill required prescriptions. Oftentimes use of multiple pharmacies is not due to beneficiary choice; it is due to Part D interpretation of pharmacy network rules. DCI has two pharmacies negatively impacted by the current interpretations and application of “retail” and “mail order” definitions. Both pharmacies primarily serve patients with chronic kidney disease (CKD) or those that require dialysis.

Our main pharmacy in Nashville, TN principal role is to provide all End-Stage Renal Disease (ESRD)-related medications as defined under the ESRD Prospective Payment System to Medicare beneficiaries in our clinics across 28 different states. That pharmacy ships the ESRD-related medications to the patient’s clinic or home for use. The DCI Nashville Pharmacy is considered a “retail pharmacy” by State of Tennessee. DCI’s Nashville pharmacy would like to provide beneficiaries their other chronic medications however is prohibited to fill these prescriptions as the pharmacy is not permitted by many Part D plans and/or PBMs to participate in pharmacy networks. DCI Nashville pharmacy would also like to dispense prescription drugs to the walk-in general public from which Part D beneficiaries could purchase a covered Part D drug at retail cost sharing without being required to receive medical services from a provider affiliated with that pharmacy.

DCI has another pharmacy located in Kansas City, MO. Although that pharmacy can dispense acute and chronic medications to all Part D beneficiaries, it can serve the Kansas City metropolitan area only, as it is considered by Part D plans as “retail” and therefore to date has not been able to on any material scale “mail” prescriptions to beneficiaries and receive reimbursement (from Part D plans) for such prescriptions. The DCI Kansas City pharmacy has the capabilities to provide acute and chronic medications to more beneficiaries however it is excluded by many Part D plans and/or affiliated PBMs from mail order pharmacy network participation.

Allowing a Medicare beneficiary to select or continue to use a pharmacy of their choice and allowing their pharmacy to participate in all beneficiary pharmacy networks will result in overall improved medication safety. The proposed changes will allow better coordination of dispensed medications and will increase access to medications, minimize medication misadventures and ultimately may lower overall cost of care in the Medicare beneficiaries we serve.

**Conclusion**

Thank you for the opportunity to comment on the Medicare Advantage and Part D Proposed Rule. We would be glad to discuss this comments in greater detail at any time. If you have any questions, please feel free to contact Doug Johnson at 615-342-0435 or doug.johnson@dciinc.org.

Sincerely,

Douglas S. Johnson, MD