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March 2, 2018

Mr. Demetrios Kouzoukas
Principal Deputy Administrator and Director, Center for Medicare

Ms. Jennifer Wuggazer Lazio, F.S.A., M.A.A.A
Director, Parts C & D Actuarial Group
Office of the Actuary

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted Electronically: [https://www.regulations.gov \(docket number CMS-2017-0163\)](https://www.regulations.gov (docket number CMS-2017-0163))

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter

Dear Mr. Kousoukas and Ms. Wuggazer Lazio:

On behalf of Fresenius Health Partners (FHP), a subsidiary of Fresenius Medical Care North America (FMCNA), we would like to thank you for this opportunity to provide comments on the Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter (herein referenced as "2019 Advance Notice" or "2019 Call Letter").

FHP's mission is to improve both the value and quality of care for patients with Chronic Kidney Disease (CKD) and End-Stage Renal Disease (ESRD), which is highly aligned with the vision and goals of the Centers for Medicare & Medicaid Services (CMS). We currently carry out this mission through our involvement in ESRD Medicare Advantage Chronic Special Needs Plans (C-SNPs), as well as by our participation in Comprehensive ESRD Care (CEC) alternate payment model's ESRD Seamless Care Organizations (ESCOs, APM entities participating the CEC model). FHP has demonstrated that we are deeply committed to pursuing a more holistic, coordinated approach to better treatment for this special population.

Our comments are influenced by our history and experience with ESRD patients and their special needs. Our recommendations below specifically

address the proposals for 2019 ESRD Prospective Payment System (PPS), Out-of-Pocket Cost (OOPC) Model, STAR Rating and SNP-Specific Network.

I. ESRD PPS: Sensipar move from Part D to Part B

We have grave concerns about the impact of Sensipar's move from Part D to Part B on MA ESRD C-SNPs and the special population we serve. While CMS is proposing to reprice the ESRD Prospective Payment System (PPS) dialysis claims for the years 2014 – 2016 to account for the full implementation of the dialysis PPS system, CMS has not provided guidance or made the needed adjustment for Sensipar.¹ Beginning January 1, 2018, the injectable drug Parsabiv (etelcalcetide) is included in the ESRD PPS. With this inclusion, Sensipar is also included in the ESRD PPS and no longer payable under the Part D benefit when used for the provision of renal dialysis services.² CMS did allow Part D sponsors to modify their CY 2018 formularies to add a Part B versus Part D prior authorization, but CMS has not provided guidance for MA ESRD C-SNPs to accurately price for this move.³ For the reasons we set forth below, we strongly urge CMS to issue guidance for MA ESRD C-SNPs.

MA ESRD C-SNPs provide coordinated care to a population of chronically ill beneficiaries with the greatest need. Through renal-customized benefits and specialized clinical care, early results from MA ESRD C-SNPs show that tailored care for ESRD patients' can improve patients' outcomes and quality of life. MA ESRD C-SNP patients' outcomes are better than the ESRD national average. The hospitalization rate is 30% better, the readmission is 43% better and the catheter rate is 76% better. Finally, patients enrolled in an ESRD C-SNP are 43% more likely to receive a kidney transplant than those on Medicare FFS.⁴ FHP is deeply committed to pursuing a more holistic, coordinated approach to better treatment for this special population through MA ESRD C-SNPs and other value-based models of care. MA ESRD C-SNPs are relatively new, however, and though we are building capacity to serve more beneficiaries in the future, enrollment is small and dramatic year-to-year financial fluctuations will make it difficult or impossible to keep these important plan offerings on the market.

Calcimimetics are an important tool in the management of ESRD, and are often the largest single drug expense for patients on dialysis. They are frequently used to treat a common complication of dialysis treatment called secondary hyperparathyroidism. Most patients are treated medically using the oral drug Sensipar. Considering this is the first time CMS has moved a drug from Part D to Part B under a bundled payment structure, there are

¹ Centers for Medicare & Medicaid Services (CMS), Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter ("2019 Advance Notice" or "2019 Call Letter"), pg. 22-23.

² In 42 CFR 413.234 (d), an oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by the Food and Drug Administration.

³ Larrick Chavez-Valdez, Amy. *Sensipar® (cinacalcet) Furnished for the Treatment of ESRD Moving from Part D to ESRD PPS, Effective January 1, 2018*. HPMS Memo. August 18, 2017.

⁴ Sources: 2015 USRDS Annual Report, ESRD National Coordinating, SCAN and Humana ESRD C-SNP data: Las Vegas, NV Los Angeles, Orange County, Riverside and San Bernardino, CA.

numerous questions from stakeholders that CMS should clarify through guidance.

Below, we describe the crushing impact this policy will have if applied to MA ESRD C-SNPs:

- **Secondary hyperthyroidism develops in nearly all patients with ESRD**, which means most or all of our members are receiving therapy for this disorder.
- For each ESRD patient taking Senispar, this **cost is estimated to be between \$19,000 and \$20,000 per year** (\$1,585-\$1,667 per month).
- **Low Income Cost Sharing Subsidy (LICS) and Federal Reinsurance is only available for Part D**, and not for Part B; therefore, Senispar's cost will shift to patients (through increased cost sharing) and to MA ESRD C-SNPs. Under Part D, MA ESRD C-SNP is responsible for less than 20% of the cost, and under Part B, MA ESRD C-SNP will be responsible for 80% -100% of the cost.
- **Part B is subject to Medicare Advantage Maximum Out Of Pocket (MOOP)** requirements, and when MOOP is reached, MA ESRD C-SNP is responsible for 100% of claims. Additionally, MA ESRD C-SNP beneficiaries are estimated to reach their MOOP limit by the third month of the plan benefit year because of regular dialysis treatments;
- **ESRD Capitation is underfunded** because Senispar claims are not included in the FFS base claims experience for Part B bundle; and
- **MA ESRD C-SNP 2018 bid is underpriced and 2019 bid will be underpriced** because the ESRD bid required Senispar to be priced as Part D. As Part B, FHP estimates the additional plan cost per utilizing patient to be \$14,670 per year (or \$1,220 per month). Based on January 2018 data, with ~27% utilization of Sensipar, we estimate the additional costs to be \$225 PMPM.

We urge CMS to consider the crushing impact to MA ESRD C-SNPs and issue guidance clarifying coverage of drugs in the Transitional Drug Add-on Payment Adjustment (TDAPA) process for MA ESRD C-SNP plans.

Recommendations:

- Adjust ESRD Capitation to ensure Sensipar costs are appropriately funded.
- Provide opportunity and instructions to ensure Sensipar costs are priced accurately for both 2018 and 2019 MA ESRD CSNPs.

II. 2019 Out-of-Pocket Cost (OOPC) Model

CMS already acknowledges the unique bid needs of MA ESRD C-SNP by requiring ESRD specific bid instructions.⁵ We urge CMS also to recognize the need for a separate Out-of-Pocket Cost (OOPC) model for the MA ESRD C-SNP.⁶ The current OOPC tool does not support the MA ESRD C-SNP plan design for the following reasons:

- OOPC tool is built specifically excluding all utilization from ESRD beneficiaries;⁷
- OOPC tool does not accurately calculate cost sharing for ESRD patient dialysis services (\$0.30 PMPM in the OOPC model vs 20% x \$2,500 PMPM approximately);
- MA ESRD C-SNP exclusively enrolls ESRD beneficiaries⁸ and their services utilized are significantly different than non-ESRD FFS beneficiaries; and
- Small changes to rarely utilized benefits by ESRD population have large impacts on OOPC result (for example, dental – comprehensive and preventative).

We recommend for CMS either not to use the OOPC tool for MA ESRD C-SNPs or to create a separate OOPC tool for the ESRD population.

Recommendations:

- Do not use the OOPC tool for MA ESRD C-SNP, or
- Create a separate OOPC tool for MA ESRD C-SNP.

III. Enhancements to the 2019 Star Ratings and Future Measurement Concepts

As stated earlier, thank you for this opportunity to comment on the impact of advanced illness on Star Ratings. We appreciate CMS' efforts to ensure that beneficiaries with advanced illness receive proper and recommended treatment, and your openness to learning more about how ESRD treatment guidelines may not necessarily coincide with certain Star Rating measure sets. We support the establishment of a Technical Expert Panel (TEP) and strongly encourage the inclusion of ESRD expertise on this panel.⁹

As a Medicare Advantage (MA) organization focused exclusively on caring for ESRD beneficiaries through C-SNPs, we are concerned that the current Star

⁵ Instructions for Completing the Medicare Advantage Bid Pricing Tools for Contract Year 2018 (April 7, 2017), pg. 49.

⁶ 2019 Call Letter, pg. 171.

⁷ CY2018 Out-of-Pocket Cost Model Methodology (April 2017), pg. 2.

⁸ Medicare Managed Care Manual Chapter 16-B: Special Needs Plans, Section 40 – Enrollment Requirements.

⁹ 2019 Call Letter, pg. 106.

Rating methodology is not a true reflection of the performance and experience of our patients for the following reasons:

- ESRD is an advanced illness with a high mortality rate.
- ESRD patients requiring dialysis maintain a vastly different quality of life than those amongst the regular MA population, and as a result require substantially different medical protocols to be followed in comparison.
- MA ESRD C-SNPs require a unique model of care because of the special needs of the beneficiaries, but the applicable measurements do not reflect the special needs of these beneficiaries (which includes where and how services are provided).
- Treatment guidelines for ESRD patients do not support adherence to many of the Star Ratings measures, indicating that ESRD beneficiaries should therefore be excluded from many of the measures.
- While the ultimate Star Rating applies to the entire contract, sponsors with beneficiaries who are not special needs are able to absorb the impact of the special needs beneficiaries, while plan sponsors who only serve MA ESRD C-SNP members are not.

We additionally note that our FMCNA currently offers 24 ESRD ESCOs (APM entities participating in the Comprehensive ESRD Care (CEC) Model) across the country, which has enabled us gain insight into ESRD-quality specific measures that better coincide with CMS' goal of ensuring appropriate and quality care is carried out to all beneficiaries, particularly with regard to advanced illness. We welcome the opportunity to discuss ESRD-specific measures and rating methodology in more detail.¹⁰

Recommendations:

- Include ESRD expertise on the Technical Expert Panel (TEP).
- Exclude MA ESRD C-SNPs from measures that are not medically appropriate for patients with the advanced illness ESRD.
- Establish ESRD-specific measures to put in place of Star Ratings for MA ESRD C-SNPs, as done in the Comprehensive ESRD Care's ESCO Model.
- Compare MA ESRD C-SNP quality performance to other MA ESRD C-SNP plans (and specific Plan Benefit Package (PBP) when a MA ESRD C-SNP PBP is offered under a contract including MA and other SNP products), or compare at least to similar ESRD populations.

¹⁰ Centers for Medicare & Medicaid Services (CMS), Innovation Models, Comprehensive ESRD Care (CEC), Quality Performance Large Dialysis Organization (LDO), <https://innovation.cms.gov/Files/x/cec-qualityperformance-ldo.pdf>.

IV. SNP-Specific Networks Research and Development

We continue to support CMS' efforts to evaluate and establish separate network adequacy criteria for SNP-specific networks, but we do not agree with CMS that the current network adequacy criteria and exception request process account for the unique healthcare needs and delivery patterns for MA ESRD C-SNPs.¹¹ Because the quantitative measurements of the MA Network Adequacy Criteria methodology¹² are based on the entire MA population and Medicare fee-for-service (FFS) beneficiary, the ESRD Medicare beneficiary's unique data (e.g., utilization, location for time/distance requirement, and pattern of care) is obfuscated due to the small size of this special population. The ESRD Medicare beneficiary's data is not represented by the typical FFS and managed care population for the following reasons:

- Beneficiaries with ESRD only account for approximately 0.9% of the total Medicare enrollees.¹³
- While MA penetration is approximately 33.3% (20 million ÷ 60 million), MA ESRD C-SNP enrollment only accounts for 4,907 MA enrollees per CMS' February 2018 data.¹⁴
- Specialties, such as plastic surgery, chiropractic, allergy and immunology and dermatology, are seldom utilized by the ESRD population.
- While outpatient dialysis is typically already established with the MA ESRD C-SNP member, other facility services (such as mammography) are seldom utilized by the ESRD population.

Recommendations:

- Establish separate quantitative measurements for MA ESRD SNP-specific networks using the specific ESRD FFS and MA ESRD C-SNP data.
- Narrow required specialist types based on ESRD pattern of care for MA ESRD C-SNP.
- Remove services that are seldom utilized by the ESRD population from the facility network adequacy standards as applicable for the MA ESRD C-SNP.
- Revise minimum provider and time/distance requirements as applicable for the MA ESRD C-SNP population to be less stringent.

¹¹ 2019 Call Letter, pg. 186-187.

¹² Medicare Advantage Network Adequacy Criteria Guidance (Last updated: January 10, 2017), pg. 6 – 12.

¹³ <http://kff.org/medicare/state-indicator/enrollees-with-esrd/?currentTimeframe=0#>.

¹⁴ CMS February 2018 Reports, Medicare Advantage/Part D Contract and Enrollment Data, *Monthly Enrollment by State and Special Needs Plan (SNP) Data* (located on: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/index.html>)

- Establish specific exception request and review requirements for the MA ESRD C-SNP network.

Summary

FHP appreciates CMS' consideration of our comments and recommendations regarding the 2019 ESRD Prospective Payment System (PPS), Out-of-Pocket Cost (OOPC) Model, STAR Ratings and the need for MA ESRD C-SNP-specific network adequacy criteria. We urge CMS to recognize the adverse impact for MA ESRD C-SNPs without the appropriate adjustments to the ESRD PPS for Senispar, and additionally, we strongly urge the inclusion of ESRD expertise on the TEP. We are readily available for further discussion.

Sincerely,

A handwritten signature in blue ink, appearing to read "W. P. McKinney", is written over a light blue rectangular background.

William P. McKinney
President