KIDNEY CARE PARTNERS

March 7, 2014

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Room 445-G
Washington, DC 20201

Re: Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs: CMS-4159-P

Dear Administrator Tavenner:

I am writing on behalf of Kidney Care Partners (KCP) to express concern about the way some oral medications are being withheld from Medicare beneficiaries also receiving treatment for End Stage Renal Disease (ESRD). The "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule" (Proposed Rule)[1] seeks to permit the use of prior authorization to determine whether a drug is appropriately covered under Part D or another part of Medicare. Given our members' experience with prior authorization in the context of the Medicare ESRD program, we are writing to encourage Centers for Medicare and Medicaid Services (CMS) to provide clarifications to such a policy to protect beneficiary access to medically necessary medications.

Despite guidance from the CMS, there appears to be ongoing confusion with regard to which oral medications are covered under Part B in the ESRD bundled payment and which other medications are covered under Part D. Our concern is twofold. First, beneficiaries have had difficulties obtaining necessary medications and, in some instances, physicians have had to hospitalize their patients so they can receive antibiotics for conditions unrelated to ESRD. Second, the fact that beneficiaries are being told that any oral medications, such as oral antibiotics, are part of the ESRD bundled payment when the prescription is from a nephrologist, inappropriately expands the bundle to include services that are not "for the treatment of end stage renal disease"[2] and is inconsistent with the authorizing

[1] 79 *Fed. Reg.* 1918 (Jan. 10, 2014).
[2] 42 U.S.C. § 1395rr(b)(14)(B)(iii).

statute. In sum, we strongly encourage CMS to provide clearer guidance and address these two problems, as described below.

I. The Congress specified which oral medications would be covered in the expanded ESRD bundle.

When the Congress authorized the ESRD Prospective Payment System (PPS), it expressly defined the items and services which were to be included in the expanded bundle. The statute states:

> the Secretary shall implement a payment system under which a single payment is made under this title to a provider of services or a renal dialysis facility for renal dialysis services (as defined in subparagraph (B)) in lieu of any other payment (including a payment adjustment under paragraph (12)(B)(ii)) and for such services and items furnished pursuant to paragraph (4).[3]

The Congress defined "renal dialysis services" as including:

> (i) items and services included in the composite rate for renal dialysis services as of December 31, 2010;
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> (ii) erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of end stage renal disease;
>
> (iii) other drugs and biologicals that are furnished to individuals **for the treatment of end stage renal disease** and for which payment was (before the application of this paragraph) made separately under this title, and any oral equivalent form of such drug or biological; and
>
> (iv) diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of end stage renal disease.
>
> Such term does not include vaccines.[4]

In the final rule implementing the ESRD PPS, CMS outlined a specific number of oral medications with intravenous (IV) equivalents that should be paid for by dialysis providers as part of the ESRD bundle.[5] It also delayed implementation of

[3] *Id.* § 1395rr(b)(14)(A)(i).
[4] *Id.* § 1395rr(b)(14)(B)(iii)(emphasis added).
[5] *See* 75 Fed. Reg. 49030 (Aug. 12, 2010).

the oral-only ESRD medications until 2014.[6] In the American Taxpayer Relief Act, the Congress further delayed implementation of these oral-only medications until 2016. CMS specified the oral IV equivalent medications by referencing the National Drug Codes (NDCs). The medications that come within this category are limited to a narrow category of drugs, such as oral Vitamin D therapy.

CMS developed a second list of oral medications, known as the "drugs that may be ESRD-related." These oral medications may be used either "for the treatment of ESRD" or to treat unrelated medical problems. The most common example of these drugs is oral antibiotics. While it is possible that an antibiotic may be needed to treat an infection related to a catheter (*i.e.*, ESRD-related), it is also likely that the antibiotic is prescribed to treat respiratory infections or similar non-ESRD-related infections. When CMS calculated the bundled payment it included only a minimal amount (0.2 percent of the then total spending of ESRD separately billed drugs) in the bundled payment rate to account for dialysis facilities providing such medications.

II. Recent guidance has created confusion and resulted in beneficiary access problems.

Beginning January 1, 2014, beneficiaries in the ESRD program began experiencing problems receiving certain oral medications through their Part D plans. This appears to be the result of changes made in the 2014 Call Letter.

The confusion arises because these "drugs that may be ESRD-related" are not clearly defined by a NDC list, nor are there concrete rules for determining if the drugs are being used for the treatment of ESRD or to treat some other condition. It is the prescribing physician only who can articulate when these medications are "for the treatment of end stage renal disease."

The original CMS guidance appeared to agree with this assessment. It stated:

> Given the likely small number of drugs in these categories that would not be payable under Part D, sponsors should not reject claims at point- of-sale, nor should sponsors employ prior authorization requirements solely for the purpose of verifying that the drug is ESRD-related. Rather, we strongly recommend that sponsors make conditional payment and then determine whether or not the drug was used for ESRD-related purposes.[7]

[6] 42 C.F.R. § 413.174(f)(6).
[7] CMS, "Clarification of Exclusion of Part D Payment for Drugs Included in the End-Stage Renal Disease Prospective Payment," (February 17, 2011).

This policy was designed to ensure that beneficiaries would not experience unnecessary delays in receiving their medications, which could compromise their health.

The most recent guidance,[8] however, introduces significant confusion into this circumstance by revising the instructions to allow Part D plans to implement prior authorization if the prescriber "receive[s] a monthly capitated payment for managing the ESRD patient's care." While agree that Part D plans should not restrict access for prescriptions written by a dentist, chiropractor, gynecologist, ophthalmologist, podiatrist, or hospital emergency room prescriber, the use of the term "monthly capitated payment" is simply too broad a term to protect beneficiary access. It is also important to clarify that nephrologist prescribers may prescribe medications to treat non-ESRD related conditions.

Our members have shared examples of physicians having to hospitalize patients not being able to receive, or being delayed in receiving, a medically necessary medication because the Part D plan would not cover the medications, leaving the patients responsible to obtain the medication through Part B. In addition, ESRD beneficiaries have also been denied oral-only medications as part of the ESRD bundle in some instances. We also understand that some prior authorizations are being denied solely on the grounds that beneficiaries have an ESRD diagnosis, rather than because the medication being prescribed is "for the treatment of end stage renal disease." While the recent guidance seems to have improved the situation, the examples cited above all occurred after the January 31 guidance was issued. This situation creates serious medical concerns about patients being able to begin treatment in a timely manner, as well as legal and financial concerns about the appropriateness of expecting that Part B providers will bear the cost of medications that were not adequately funded by the current payment rates.

III. Proposed recommendations to protect beneficiary access.

To address this problem and protect beneficiaries, KCP urges CMS to:

1) Clarify that non-nephrologist prescribers should be added to the list of prescribers that sponsors should accept from the pharmacy to establish that the medication is not "for the treatment of end stage renal disease." Indeed, there are very few non-nephrologist prescribers who would provide a prescription to a beneficiary "for the treatment of end stage renal disease." Thus, as with the other prescribers listed, prescriptions from non-nephrologist prescribers should not be subject to additional review. This clarification would

[8] CMS Guidance to HPMS List Serve, January 31, 2014.

place very little, if any, risk on the Agency and would protect beneficiary access.

2) As a short-term measure, clarify that sponsors should accept as fact from the pharmacy information on prescriptions written by nephrology prescribers that indicate whether or not the medication is "for the treatment of end stage renal disease." Nephrologists and nephrology practitioners are best positioned to designate whether the prescription is "for the treatment of ESRD" or not. There is no reason why a sponsor should deny coverage based solely on the fact that a beneficiary has a diagnosis of ESRD.

Both of these clarifications would provide a straightforward way for plan sponsors to answer the two questions set forth in the February 2011 guidance and would expedite the process of the beneficiary receiving their medication timely.

Finally, KCP would like to work with Agency to develop additional guidance to ensure that these medications are being covered by the appropriate part of the Medicare program.

IV. Conclusion

We appreciate the opportunity to work with you on resolving this problem as quickly as possible. Please do not hesitate to contact Kathy Lester at (202) 534-1773 or klester@lesterhealthlaw.com.

Sincerely,

Edward R. Jones, M.D.
Chairman
Kidney Care Partners

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