

December 31, 2018

VIA E-MAIL

Demetrios Kouzoukas

Principal Deputy Administrator & Director of
the Center for Medicare
Demetrios.Kouzoukas@cms.hhs.gov

Re: August 7, 2018 Step Therapy Memorandum

Dear Mr. Kouzoukas:

On behalf of the undersigned organizations, we are writing to follow-up on our November 14, 2018 meeting, where we discussed our concerns regarding the agency's August 7, 2018 policy memorandum allowing Medicare Advantage ("MA") plans to implement step therapy for plan beneficiaries ("the 2018 Memo")¹ and requested that CMS withdraw the memo and not allow MA plans to implement step therapy programs in 2019.

In this connection, we were pleased to see that the agency decided that the step therapy policy announced in the 2018 Memo should be subject to notice-and-comment rulemaking, initiated via the Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses Proposed Rule (CMS-4180-P) published on November 30, 2018 ("the Proposed Rule"). Included are a proposed definition of "step therapy" at 42 C.F.R. § 422.2 and proposed requirements for MA plans to set up a step therapy program at 42 C.F.R. § 422.136. *See* 83 Fed. Reg. 61252-62201 (Nov. 30, 2018) (proposing various step therapy-related amendments and additions to Chapter 42 of the Code of Federal Regulations).

Because CMS is using the rulemaking process to define step therapy and the requirements for MA plans to establish step therapy programs, CMS clearly recognizes that under 42 U.S.C. § 1395hh, the August 8, 2018 policy memorandum does not provide a legally sufficient basis for MA plans to implement such programs. Section

¹ Memorandum from Seema Verma, Administrator, to Medicare Advantage Organizations (Aug. 7, 2018), at https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf.

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1395hh(a)(2) provides: “No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under [Title 42 of the U.S. Code] shall take effect unless it is promulgated by the Secretary by regulation” Among other things, the Proposed Rule recognizes that step therapy regulations could, without adequate “safeguards,” deprive enrollees of “timely access to all medically necessary Medicare Part B medications.” 83 Fed. Reg. at 62169. Therefore, the Proposed Rule clearly addresses substantive legal standards governing the scope of benefits available to enrollees.

We acknowledge that the ongoing rulemaking process does not violate the Social Security Act. However, the 2018 Memo does. Its step therapy policy is identical to the Proposed Rule in its implications for enrollees. Because the 2018 Memo embodies a substantive policy that did not go through the process of rulemaking, it would be unlawful for the agency to implement the 2018 Memo and allow MA plans to implement step therapy in 2019. *See generally Allina Health Servs. v. Price*, 863 F.3d 937 (D.C. Cir. 2017), *cert. granted in part*, 139 S. Ct. 51 (2018). Although the distinction between legislative and interpretive rules is not relevant to the § 1395hh analysis, *see id.* at 944, by initiating the rulemaking process, CMS has implicitly agreed that the 2018 Memo is a “legislative rule” whose substantive provisions have not been properly promulgated via regulation. *See generally Am. Hosp. Ass’n v. Bowen*, 834 F.2d 1037 (D.C. Cir. 1987) (distinguishing between “legislative” and “interpretive” Medicare rules). Thus, regardless of how the Supreme Court eventually decides *Allina*, the 2018 Memo is legally deficient.

In addition to this new concern, our coalition continues to have the same concerns we discussed during our meeting. In particular, implementation of a step therapy program is a violation of §§ 1852(a)(1)(A) and (a)(B)(1), which require that MA plans “provide to members enrolled under [Medicare Advantage] . . . benefits under the original Medicare fee-for-service program option,” and which define these benefits as “those items and services (other than hospice care or coverage for organ acquisition for kidney transplants) for which benefits are available under parts A and B.” Implementation also violates the regulations at 42 C.F.R. §§ 417.414(b) and 422.101(a)-(b), which require MA plans to “provide coverage of . . . all services that are covered by Part A and Part B of Medicare . . . and that are available to beneficiaries residing in the plan’s service area.”

We believe that the next best steps are for CMS to withdraw the August 7, 2018 memo, announce that MA plans are prohibited from implementing step therapy in 2019,

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and announce that CMS will continue with the rulemaking process started on November 30, 2018 in order to obtain comments from interested parties on the issue of step therapy. This would be consistent with the concerns that beneficiaries in MA plans have access to medically necessary Part B drugs, and would also allow stakeholders (including our coalition) to make recommendations to CMS on step therapy programs.

If CMS does not withdraw the August 7, 2018 memorandum, it opens the MA program and MA plans that implement step therapy in 2019 to litigation that physicians and patients may deem necessary to protect Medicare beneficiaries from unlawful implementation of step therapy programs. If CMS does withdraw the memorandum and continues the rulemaking process, our coalition will review the final rule and postpone any action until that time.

We would like to meet with you at your earliest opportunity to discuss these issues further, in the hopes that we can advance our common goals and avoid unnecessary problems for Medicare Advantage. You may contact myself or Cathy Grealy Cohen on behalf of the undersigned organizations to arrange for a meeting:

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Cathy Grealy Cohen

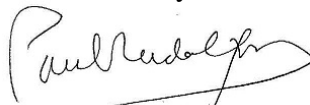
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Sincerely,



Paul M. Rudolf

On behalf of and cc to:

American Academy of Ophthalmology

American College of Rheumatology

American Glaucoma Society

American Society of Cataract and Refractive Surgery

American Society of Retina Specialists

The Retina Society