

May 19, 2014

Kathleen Sebelius
Secretary
Department of Health & Human Services
200 Independence Ave, SW
Washington, DC 20201

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

RE: Enforce Section 1876 Prohibiting Medicare Advantage Programs from Implementing Step Therapy Policies and Place a Moratorium on Payment Policies that Rely on the Continued Availability of Compounded Drugs

Dear Secretary Sebelius and Administrator Tavenner:

On behalf of the American Society of Retina Specialists (ASRS), our members, and patients, we urge the Centers for Medicare & Medicaid Services (CMS):

- to enforce Section 1876 Cost Contractors, Section 1833 Health Care Prepayment Plans, and PACE Organizations, prohibiting the imposition of additional requirements for access to certain Part B drugs or services, such as step therapy requirements, unless also required through Original Medicareⁱ and
- to place a temporary moratorium on Medicare Advantage plan payment policy changes that in part incentivize the use of compounded drugs until such time as the U.S. Food and Drug Administration (FDA) has promulgated the rules pursuant to Drug Quality and Security Act (P.L. 113-54).

The ASRS is the largest retinal organization in the world, representing over 2400 fellowship trained members. Retina specialists are board certified ophthalmologists who have completed fellowship training in the medical and surgical treatment of retinal diseases. The mission of the ASRS is to provide a collegial open forum for education, to advance the understanding and treatment of vitreoretinal diseases, and to enhance the ability of its members to provide the highest quality of patient care.

Medicare Advantage plans continue to use multiple strategies to establish explicit and implicit step therapy policies despite being prohibited by Section 1876. For example, Monarch Healthcare and Memorial Healthcare IPA's Clinical Practice Guidelines refer to Avastin as the "preferred agent," promote its off-label use, and encourage its use by systematically denying prior authorization requests for Lucentis and Eylea. Another implicit step therapy strategy, used by United HealthCare in Connecticut, is to reimburse below market value for the J codes for two FDA approved anti-VEGF treatments – Lucentis and Eylea. By doing so, retina specialists are forced to take a loss on two Part B covered drugs or switch to Avastin.

Another proposed payment policy by Cigna-HealthSpring Medicare Plan seeks to establish capitated rates for treatment of age-related macular degeneration (AMD) and other retinal diseases. Since the proposed capitated rate would only be feasible if the retina specialists used Avastin for the treatment of AMD and Avastin remained available at its current price, ASRS believes this type of payment policy violates Section 1876 (i.e., it implicitly establishes a step therapy requirement since retina specialists would lose money prescribing other FDA approved Medicare covered Part B drugs).

In addition, until the FDA finalizes its rules implementing the “Drug Quality and Security Act,” it is uncertain whether Avastin will continue to be available in a compounded form for ophthalmic use. During this time of uncertainty, many retina specialists have already reported difficulty obtaining compounded Avastin as many compounders have elected to no longer supply it. Moreover, now that the FDA is requiring compounding pharmacies to only dispense Avastin with a patient-specific prescription for office use, many retina specialists have been forced to switch to FDA approved drugs that can be ordered in advance of a patient visit instead of having to have the patient return to receive the prescribed injection of Avastin.

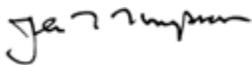
In summary, we strongly urge CMS to ensure that Medicare Advantage beneficiaries continue to have access to all Medicare covered services including Medicare Part B drugs. Medicare Advantage plans should not be able to outsource services to an entity that establishes policies that have explicit or implicit step therapy policies. Medicare Advantage beneficiaries in consultation with their physicians should continue to have the right to make wise and judicious choices based on their unique risk factors, clinical appearance, and economic requirements, as well as the availability of compounded drugs.

We look forward to a response from you. Please do not hesitate to contact the ASRS if you have any questions.

Thank you for your consideration.

Sincerely,

American Society of Retina Specialists Executive Committee



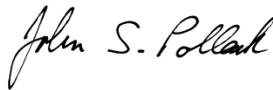
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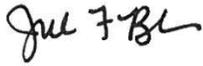
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Executive Vice-President

cc: Ms. Danielle R. Moon, J.D., MPA, Director, Medicare Drug and Health Plan Contractor Group

ⁱ http://www.asrs.org/content/documents/cms_step_therapy_memo_091712-2.pdf. Accessed May 13, 2014.