



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

APR 21 2016

Administrator
Washington, DC 20201

Robert Wergin, M.D.
Board Chair
American Academy of Family Physicians
1133 Connecticut Ave, NW, Ste. 1100
Washington, DC 20036

Dear Dr. Wergin:

Thank you for sharing your concerns regarding the affordability of prescription drugs, and Medicare Advantage (MA) and Medicare Prescription Drug Plans' use of prior authorization as a means to control drug costs.

CMS is committed to working in partnership with stakeholders to find ways to continue to improve the affordability and accessibility of life-saving prescription medications for beneficiaries in Medicare, Medicaid, and other health insurance programs. This work includes, for example, the release of the [Medicare Drug Spending Dashboard](#), which provides additional information and transparency regarding Medicare spending on prescription drugs. The Dashboard is meant to help inform health care decisions, and policy considerations, and encourage collective problem solving around drug affordability.

All Part D sponsors, including MA organizations offering Medicare Advantage Prescription Drug (MA-PD) plans, are required to provide a basic level of prescription drug benefits to Medicare beneficiaries, but can vary from one another in benefit structure and cost. Each Part D sponsor, specifically its Pharmacy & Therapeutics (P&T) committee, is ultimately responsible for determining which drugs will be placed on the plan's formulary. The P&T committee must also review for clinical appropriateness the practices and policies for formulary management activities, such as prior authorizations (PA), step therapies, and other drug utilization activities. Formulary management decisions must be based on scientific evidence, and may also be based on pharmacoeconomic considerations that achieve appropriate, safe, and cost effective drug therapy.

The CMS requires Part D sponsors to submit utilization management requirements applied at point of sale, such as PA, for approval as part of their formulary submission. Part D sponsors are encouraged to consistently utilize PA for those drugs with the highest likelihood of non-Part D covered uses. This is defined in guidance as 1) high likelihood that coverage is available under Parts A or B; 2) high likelihood that the drug is excluded from Part D coverage; or 3) high likelihood of use for non-medically accepted indications. We also provide guidance on non-allowable PA practices, such as imposing requirements more restrictive than CMS-approved PA criteria.

Page 2 – Robert Wergin, M.D.

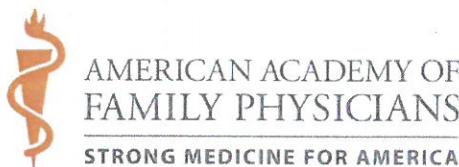
The CMS reviews each plan's formulary drug list, including tier placements, annually. These reviews validate that each plan offers robust access to medications across drug categories and classes. Consistent with 42 CFR §423.120(b)(2)(i), each formulary is reviewed for inclusion of at least two Part D drugs for each category and class submitted on the formulary file, except as noted in §423.120(b)(2)(ii). CMS continues to put forth considerable effort in ensuring that formularies are reviewed for robustness and are deemed non-discriminatory for Medicare beneficiaries.

CMS takes access to medications for Part D beneficiaries very seriously, as well as the administration of the program and providers' experience prescribing for Medicare enrollees. We appreciate you writing to express your concerns.

Sincerely,



Andrew M. Slavitt
Acting Administrator



March 30, 2016

Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave., SW
Washington, DC 20201

Dear Administrator Slavitt,

On behalf of the American Academy of Family Physicians (AAFP), which represents 120,900 family physicians and medical students across the country, I write to request that the Centers for Medicare & Medicaid Services (CMS) review and, if necessary, revise their requirements of Part D plans, specifically Medicare Advantage (MA) and Medicare Prescription Drug Plans (PDPs), so patients have a broader choice of adequate and affordable prescription drugs while reducing administrative burden for physicians.

Spiking drug prices have been well documented over the last year. These rising drug prices are necessitating Part D plans to alter formularies and cost increases are impacting seniors through higher premiums and co-pays. In response to the growing costs of pharmaceutical drugs, Part D plans and others have developed prior authorizations as a means to control costs. Prior authorizations and letter writing plague physicians by diverting physician time away from direct patient care.

The AAFP has a [policy](#) that supports a "physician and patient-friendly option to prescribe and receive drugs not included on the formulary using patient-centered, clinically-based criteria. Formularies should be designed to offer patients multiple levels of drug choice (from more to less restrictive) with accompanying patient cost sharing levels to account for variables including patient preferences."

The AAFP appreciates the attention you have given to this issue. If you or your staff have any questions about this matter or if we may further facilitate matters in this regard, please contact Robert Bennett, Manager of Federal Regulatory Affairs, at 913-906-6000 ext. 2522 or rbennett@aafp.org

Sincerely,

A handwritten signature in black ink, appearing to read "Robert Wergin, MD".

Robert Wergin, MD
Board Chair

www.aafp.org

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