



March 7, 2014

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 21244-1850

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

Dear Administrator Tavenner:

The Regulatory Education and Action for Patients (REAP) Council would like to thank you for the opportunity to comment on the proposed rule entitled “Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs” (the “Proposed Rule”), which was published in the *Federal Register* on January 10, 2014.¹

REAP is an umbrella coalition comprised of 63 patient advocacy groups. The unique experience and expertise of each REAP member organization allows the coalition to provide the patient voice in a cross-disciplinary manner. REAP’s mission is to communicate issues to Federal and State regulatory bodies, Congress, health care insurers and others to regulate, develop, manage and/or impact health delivery, coverage, cost, and availability of services to the United States population. Through its member entities, REAP contributes information and perspectives regarding important health care decisions to a degree that has not been possible heretofore by individual health care advocacy groups in the regulatory arena.

While both REAP and its member organizations are pleased with many of the patient-centric proposals in the Proposed Rule and support the underlying concepts supporting such patient-centric proposals, we are significantly concerned that in its efforts to control Medicare spending and preserve the Medicare Trust Fund via the proposed elimination of select protected drug classes, the Centers for Medicare & Medicaid Services (“CMS”) has lost sight of the subsequent impact of such efforts on patients. While REAP members appreciate the daunting task of managing the significant costs associated with caring for the Medicare beneficiary population as it continues to expand, CMS nonetheless needs to ensure it is implementing any cost-control proposals or measures in the most patient-centric manner possible so

¹ 79 Fed. Reg. 1,918 (Jan. 10, 2014).

that patient access to quality care, opportunities for improved patient outcomes and the like are not impeded.

It is against this background that we offer the following comments to the Proposed Rule. We have organized our comments around three overarching principles—(1) proposals that may impact Medicare beneficiary access to needed drug therapies (both positively or negatively); (2) proposals focused on enhancing quality of care; and (3) proposals focused on enhancing beneficiary and stakeholder understanding of or simplifying the administration of the Medicare Part D benefit.

Proposals that May Impact Medicare Beneficiary Access to Needed Drug Therapies

Proposed Elimination of Some of the Protected Drug Classes

As highlighted above, REAP and its member organizations are concerned by CMS' proposal to remove immunosuppressants, antidepressants and antipsychotics from "protected class" status and the negative impact such a change would have upon a particularly vulnerable contingent of Medicare Part D beneficiaries who are suffering from mental illnesses or who have undergone organ transplants. Under the proposed criteria, the status of all the original six protected classes are threatened, including anticonvulsants, antineoplastics, and antiretrovirals. The proposed rule focuses on "typical individuals" yet Medicare beneficiaries are elderly persons, often with multiple co-morbidities, and some living with severe disabilities and very complex health care needs. As such, REAP, like many other patient advocate coalitions, health care organizations and members of Congress, urges CMS to reconsider its proposal to eliminate protected drug classes.² For the vulnerable patients in the six protected classes, it is essential that physicians be able to prescribe medications that are best for the patient, based on independent clinical judgment, and that patients are afforded access to these medications under Part D plan coverage. Therapies in the six protected drug classes are not necessarily interchangeable, and patients with these conditions need access to the medication or combination of medications most effective in treating the condition based on factors unique to the individual. Patients often react quite differently to the available treatments. As a result, managing these serious—often chronic and life-threatening—conditions requires access to the full range of therapies available. Failure to manage these conditions effectively will result in decreased quality of life and health complications for patients, as well as higher costs to the Medicare program and society through increased hospitalizations, relapses, deteriorating conditions which necessitate additional and expensive care, and loss of productivity.

Removing certain therapeutic classes from protected class status would result in myriad negative effects for Medicare Part D beneficiaries due to the elimination from Medicare Part D plan formularies of drug therapies that are currently depended upon by the most vulnerable of Part D beneficiaries. While many beneficiaries may be able to switch to Medicare Part D plans which cover their respective drug therapies, other beneficiaries, particularly those suffering from multiple chronic conditions and utilizing multiple drugs to treat such conditions, may not find an alternative Medicare Part D plan which covers all of their drugs. As such, many beneficiaries, particularly those stabilized on drug therapies to treat mental health or neurologic conditions, will be forced to pay out-of-pocket for such drugs, and

² See Medicare Access for Patients Rx Coalition Protected Classes Memorandum, available at <http://www.aahd.us/wp-content/uploads/2014/02/MAPRx-Protected-Class-Memo-021014.pdf>; February 5, 2014 letter from the United States Senate Committee on Finance to Administrator Marilyn Tavenner, available at http://naminc.org/wp-content/uploads/2014/01/SFC-Letter-to-CMS_Protected-Classes.pdf; January 28, 2014 letter from House Energy & Commerce Oversight Subcommittee Chairman Tim Murphy to Administrator Marilyn Tavenner, available at <http://murphy.house.gov/latest-news/murphy-reviewing-cms-decision-to-cut-off-access-to-lifesaving-mental-health-drugs/>.



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potentially incur medical debt. Others will switch to another medication in the therapeutic class covered by their respective Medicare Part D plans, which may potentially lead to destabilization, loss of therapeutic effect, and unwanted side effects. For some patients, the ability to switch drugs within a drug class may make the difference between a therapeutic and non-therapeutic treatment. Some beneficiaries might simply stop their drug therapy altogether. In fact, CMS itself cited similar concerns in Chapter 6 of the Medicare Prescription Drug Benefit Manual, which addresses its policy mandating coverage of “substantially all” the drugs in each of the six protected classes, noting that such coverage would “mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations.”³

While REAP appreciates the challenge CMS faces in containing Medicare spending, REAP does not believe that eliminating the current “protected class” policy will effectively achieve such a result. In fact, given that eliminating protected drug classes might result in lapses in adherence to drug therapies, implementation of CMS’ proposal to eliminate some protected drug classes might have the unintended consequence of increasing Medicare costs due to more frequent physician visits and hospitalizations. It has been estimated that non-adherence to medication regimes contributes \$100 billion in direct costs to the United States health care system annually and costs the United States over \$1.5 billion annually in lost patient earnings and \$50 billion in lost productivity.⁴ In November 2012 the Congressional Budget Office (“CBO”) released a report concerning the impact of adherence to drug therapies on medical spending by the Medicare program in which the CBO concluded that a one percent (1%) increase in the number of prescriptions filled by beneficiaries under Medicare Part D caused roughly two-tenths (.2%) of a percent reduction in medical services under the Medicare program.⁵ As such, CMS should be cognizant that while elimination of some or all of the “protected drug classes” might reduce Medicare Part D spending, such a policy could actually increase overall Medicare spending on health care.

We are also concerned that the resulting reductions in choice diminish the important doctor/patient relationship, removing treatment decisions from the hands of doctors and patients. As such, REAP urges CMS to abandon its proposal to eliminate the protected class status for antidepressants, immunosuppressants, antipsychotics or any other therapeutic class of drugs which currently is afforded protected status and maintain its current, long-standing protected class policy.

Proposed Mandatory Enrollment of Prescribers

As noted above, many REAP member organizations focus their efforts on serving patients with specific chronic conditions and illnesses, many of which are incurable. As such, REAP is particularly sensitive to

³ Medicare Prescription Drug Benefit Manual, Chapter 6- Part D Drugs and Formulary Requirements, § 30.2.5, *available at* <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter6.pdf>.

⁴ Andrew M. Peterson, Liza Takiya, Rebecca Finley, “Meta-Analysis of Trials of Interventions to Improve Medication Adherence,” *American Journal of Health-System Pharmacy* 2203: 60(7).

⁵ Congressional Budget Office, “Offsetting effects of Prescription Drug Use on Medicare’s spending for Medical Services,” November 2012, *available at* <http://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf>.

balancing the legitimate needs of patients suffering from incurable or painful illnesses to obtain drugs needed to relieve pain, with the needs of the health care and law enforcement systems to thwart prescription drug abuse. We appreciate the challenge CMS faces in implementing policies which aim to balance these two divergent goals. However, we are troubled by CMS' proposal to grant itself the ability to revoke a prescriber's Medicare enrollment if CMS determines there is a "pattern or practice of prescribing Part D drugs that- [i]s abusive and presents a threat to the health and safety of Medicare beneficiaries," thereby resulting in no coverage for Part D drugs prescribed by such a provider to Medicare Part D enrollees. Specifically, REAP is concerned that CMS has chosen not to define "abusive" or what is meant by a "threat to the health and safety of Medicare beneficiaries." Without precise definitions and adequate criteria by which potential prescribing practices can be uniformly evaluated, REAP is concerned that certain types of prescribers who often treat incurable or painful illnesses, such as oncologists who treat patients with cancer and anesthesiologists specializing in pain management, or health care professionals providing palliative or hospice care to patients at the end of life will be excluded from Medicare inappropriately and at disproportionate rates due to the types of patients they treat and their prescribing practices, even though high prescriptions of opioids, narcotics and other pain medicines may be legitimately required by their patients.

One option to avoid the unintended consequence of improper exclusion of certain classes of physicians and other prescribers primarily treating incurable or painful illnesses or providing palliative or hospice care to patients, might be to exempt certain classes of physicians/prescribers from review by CMS under the "pattern or practice of prescribing Part D drugs that- [i]s abusive and presents a threat to the health and safety of Medicare beneficiaries" standard. Another alternative might be for CMS to adopt different criteria for a "pattern or practice of prescribing Part D drugs that- [i]s abusive and presents a threat to the health and safety of Medicare beneficiaries" for those treating incurable or painful illnesses, such as oncologists, pain management specialists and those focused on providing palliative or hospice care to patients nearing the end of life.

REAP also recommends that CMS adopt a due process, complete with opportunities for prescriber and patient input and appeal rights, that must be conducted prior to CMS revoking a prescriber's Medicare enrollment related to a "pattern or practice of prescribing Part D drugs that [i]s abusive and presents a threat to the health and safety of Medicare beneficiaries." This will ensure that CMS' conclusions as to whether certain patterns or practices are indicative of overprescribing/utilization are formed with input from prescribers and patients who will ultimately be impacted by CMS' determinations. In addition, we recommend that CMS institute a notice period prior to revoking a prescriber's enrollment such that beneficiaries who will be impacted by CMS' decisions to revoke their prescriber's Medicare enrollment will have time to refill prescriptions for needed maintenance medications and switch health care providers as may be warranted.

Proposed Recharacterization of Preferred and Extended Day Supply Networks

Under the Proposed Rule, CMS has proposed requiring that each Medicare Part D plan sponsor create three (3) designated sets of template rates, terms and conditions to be offered to pharmacies—(1) standard- for drug supplies of 34 days or less; (2) preferred- for drug supplies of 34 days or less; and (3) extended- for drug supplies greater than 34 days. Any pharmacy willing to accept the standard rates, terms or conditions for the respective designation must be allowed to participate in the pharmacy network for the designation. REAP supports CMS' proposals which are aimed at reducing costs to beneficiaries, Medicare Part D plans and the Medicare program alike and improving beneficiary access by increasing the number of pharmacies offering preferred cost-sharing and extended day supplies. In



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In addition, we believe CMS' recharacterization of "preferred pharmacies" or "preferred networks" to preferred cost-sharing pharmacies will result in less beneficiary confusion as to what the designation means.

Proposed Disaster Planning and Access Exceptions During Disasters

REAP commends CMS for its commitment to ensuring beneficiary access to needed drug therapies during natural disasters and emergencies, as evidenced by its proposed requirement that all Medicare Part D plans maintain business continuity plans. However, CMS has proposed that Medicare Part D plans aim to restore all critical functions within twenty-four (24) hours of experiencing a disaster or emergency. We urge CMS to adopt a more fluid standard, such as the restoration of critical Part D functions as soon as possible, given that restoration of critical functions within a twenty-four (24) hour timeframe might be untenable depending on the disaster or emergency experienced.

In addition to commending CMS for requiring Medicare Part D plans to maintain business continuity plans, we likewise commend CMS for proposing to codify existing guidance requiring that Medicare Part D plan sponsors relax "refill-to-soon" edits in the event of an imminent or occurring disaster or emergency which might hinder an enrollee's access to covered Part D drugs for a period of time. The need for access to critical, potentially life-saving, drug therapies does not stop in times of crisis, and by CMS' proposals it is evident that CMS is attempting to ensure that beneficiaries' health needs are still met during emergencies.

Proposals Focused on Enhancing Quality of Care

Proposed Expansion of the Medication Therapy Management ("MTM") Program

REAP members are well-versed in the positive impact proper management of chronic conditions can have on patient care and quality of life. Medication adherence is a substantial component of proper management of many chronic conditions and debilitating illnesses. REAP has long supported CMS efforts aimed at incentivizing health care providers and health plans, whether under Medicare, the Medicaid program or under Qualified Health Plans offered through Exchanges, to dedicate resources to the effective management of chronic conditions. By expanding the Medicare Part D enrollee population to which Medicare Part D plans are required to offer MTM services to those suffering from two (2) or more chronic conditions and taking two (2) or more drug therapies, down from four (4) or more chronic conditions and three (3) or more drug therapies, CMS will ensure that Medicare Part D plans dedicate sufficient resources to ensuring patient adherence to critical drug therapies and to effectively managing chronic conditions.

While CMS has specified a list of conditions deemed "chronic" for purposes of assessing an enrollee's qualification for a Medicare Part D plan's MTM program, CMS has not designated the source of such a list, nor does the list appear inclusive of all conditions that might be deemed "chronic" by the health care community. The World Health Organization ("WHO") defines a "chronic disease" as a "disease of

long duration and generally slow progression.”⁶ While most, if not all, forms of cancer, Multiple Sclerosis and Amyotrophic Lateral Sclerosis would certainly meet that WHO’s definition of a “chronic disease,” they are absent from CMS’ designated chronic conditions list. We encourage CMS to adopt the WHO’s definition of “chronic disease” and work with the WHO, other global health organizations and federal government agencies to obtain, or if necessary compile, a more thorough and comprehensive list of chronic conditions.

Furthermore, while CMS’ proposal to require that MTM services be offered to enrollees suffering from two (2) or more chronic conditions is a substantial improvement over the existing four (4) or more chronic condition criteria, REAP recommends that CMS eliminate the dual chronic condition requirement. Depending on the chronic disease, the patient’s lifestyle and individual characteristics of the patient, managing even one chronic condition can require extensive care coordination, education and counseling, of which medication adherence is a substantial component. As such, we recommend that CMS consider requiring Medicare Part D plans to conduct MTM for their enrollees suffering from one chronic condition when multiple drug therapies are utilized.

Proposed Inclusion of Quality of Care Requirements in Sponsor Contracts with CMS

CMS has proposed requiring that all Medicare Part D plan sponsors contractually agree to provide “good quality health care” to their enrollees. CMS plans to define “good quality health care” by the achievement of three (3) or more stars for performance measures in the following five categories under the Star Ratings Program—(1) patient outcomes; (2) intermediate outcomes; (3) patient experience; (4) patient access to care; and (5) process. REAP has long advocated for quality health care on behalf of patients, and we commend CMS for further evidencing its commitment to quality health care through its proposal. However, we caution CMS that there is a need to balance quality with patient access to affordable health care. As such, we believe CMS should afford Medicare Part D plan sponsors an opportunity to cure poor quality health care within a reasonable and specified time frame, as evidenced by a failure to achieve three (3) or more stars on certain performance measures, prior to terminating sponsor agreements with CMS.

Proposals Focused on Enhancing Beneficiary and Stakeholder Understanding of or Simplifying the Administration of the Medicare Part D Benefit

Proposed Transparency in Pricing for Generic Drugs

CMS has proposed an update to the definition of “prescription drug pricing standard” to include Maximum Allowable Cost (“MAC”) prices and methodologies. As such, Medicare Part D plan sponsors will be required to update MAC prices at least weekly and make such prices available to consumers and pharmacies in advance of reimbursement. REAP has long been an advocate for full pricing transparency. Beneficiaries should be able to learn via the Medicare Part D plan finder tool or otherwise their precise cost-sharing obligations at a given pharmacy for a given drug prior to arriving at the pharmacy to pick up a prescription. Generic drugs subject to a MAC by a Medicare Part D plan sponsor or pharmacy benefit manager should not be held to a different standard than brand and single-source generic drugs which are not typically reimbursed on a MAC basis. As such, REAP applauds CMS for extending pricing transparency to all Part D drugs, regardless of the basis for reimbursement.

⁶ See WHO definition of “chronic disease” at http://www.who.int/topics/chronic_diseases/en/ (last visited Aug. 28, 2013).



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Proposed Enhanced Publication of Prescription Drug Event (“PDE”) Data

CMS has proposed broadening its release of de-identified PDE data. Specifically, CMS would no longer encrypt plan, prescriber or pharmacy identifiers in PDE data released to “legitimate researchers.” REAP and its member organizations are committed to advancing public health research and believe CMS possesses many unique data sets, including PDE data, which are valuable to researchers in conducting research aimed at advancing public health. We commend CMS in expanding the data fields available to public health researchers and urge CMS to consider broader publication of PDE data so long as individual patient privacy is protected and preserved.

Proposed Revisions to Broker Compensation

In the Proposed Rule, CMS has outlined amendments to the current permitted broker compensation structure. CMS has always capped any broker commission paid by Medicare Part D plan sponsors to fair market value for initial placements and thirty-five percent (35%) of the published fair market value for renewals, regardless of the renewal year. CMS has proposed publishing, on an annual basis, the fair market value of broker commission, which must be utilized by all Medicare Part D plan sponsors. REAP applauds CMS on this proposed amendment. Ensuring that broker commission/compensation is the same by and among all Medicare Part D plans and sponsors will help to ensure that brokers are not financially motivated to enroll a beneficiary in one Medicare Part D plan over another merely because the available commission is greater from a certain sponsor.

Again, we appreciate the opportunity to share our perspective on the Proposed Rule with you. REAP members all stand ready to answer questions and provide any additional information about the patient groups for whom we advocate.

Sincerely,

Alliance for Aging Research
Alpha-1 Association
Alpha-1 Foundation
American Brain Tumor Association
American Kidney Fund
Bladder Cancer Advocacy Network
Cancer Support Community
C-Change
COPD Foundation
Cutaneous Lymphoma Foundation
Epilepsy Foundation

Fight Colorectal Cancer
Friends of Cancer Research
Global Healthy Living Foundation
Huntington's Disease Society of America
Hypertrophic Cardiomyopathy Association
International Myeloma Foundation
Kidney Cancer Association
Leukemia & Lymphoma Society
Lung Cancer Alliance
LUNGevity Foundation
Mended Hearts
National Alliance on Mental Illness
National Organization for Rare Disorders
National Patient Advocate Foundation
National Psoriasis Foundation
Ovarian Cancer National Alliance
Prevent Cancer Foundation
Sisters Network
Susan G. Komen for the Cure
U.S. Pain Foundation
Us TOO International Prostate Cancer Education and Support Network
Zero - The Project to End Prostate Cancer