Regulatory Education and Action for Patients

• Seeking Common Ground

July 27, 2015

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2390-P
P.O. Box 8016
Baltimore, MD 21244-8010

Re: CMS-2390-P—Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability

Dear Administrator Slavitt:

The Regulatory Education and Action for Patients (REAP) coalition applauds the Centers for Medicare & Medicaid Services' (CMS) efforts to modernize the Medicaid managed care regulations by issuing the proposed rule, "Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability" (CMS-2390-P). We agree with CMS' objective to update its regulations to reflect the changes in the delivery system that have taken place over the last decade, and to strengthen the program's ability to serve diverse populations.

Comprised of patient advocacy organizations representing an array of patient issues and conditions, REAP's mission is to ensure that the patient experience is reflected in the federal regulatory and rule-making process. Our coalition convenes the nation's leading patient advocacy and public health organizations to advocate for the implementation of policies that will improve outcomes, affordability and access to health care for patients across the country. By bringing together a broad cross-section of patient-driven organizations, REAP is able to evaluate and build consensus on a wide range of patient concerns and ensure that those concerns are considered in policy development and implemented with a patient-centric focus.

REAP strongly supports the proposed rule's intent to strengthen program integrity safeguards, and ensure beneficiary protections in the areas of provider networks, coverage standards, and treatment of appeals. REAP believes that a modernized Medicaid managed care regulatory structure is essential to facilitate necessary system reform initiatives, and advance the delivery of health care for tens of millions of people. As you work to finalize this proposed rule, we offer the following comments:

I (B)(1) Alignment With Other Health Coverage Programs

(b) Appeals and Grievances (§438.400, §438.402, §438,404, §438.406, §438.408, §438.410, §438.414, §438.416, §438.424, §431.200, §431.220 and §431.244)

REAP strongly supports CMS's efforts to enhance beneficiary protections by aligning Medicaid managed care rules with Marketplace or Medicare Advantage (MA) standards to manage health care delivery across different product lines. By aligning Medicaid managed care with other programs when possible, enrollees will experience smoother transitions and have fewer disruptions to care when they transition between sources of health care coverage.

In particular, our coalition supports the changes to the grievance and appeals system for Medicaid managed care in order to increase uniformity between rules for Medicaid managed care and rules for MA managed care plans, and rules applicable to private health insurance and group health plans. A streamlined grievance and appeals process that applies across the market would make navigating the appeals system more manageable for patients and consumers in an increasingly fluid health care market. As such, we support the proposed rule's clarification of members' right to their case file, medical records, and other documents such as the plan documents used to conduct coverage determinations, as well as the tightening of the expedited appeal time frame and notice and recordkeeping requirements.

We are, however, concerned by the requirement that patients must first appeal an adverse coverage determination to their managed care organization (MCO) and exhaust the internal appeals procedures, before finally being able to appeal through the state Medicaid fair hearing process. The requirement to go through an internal review in all cases may ultimately pose barriers for many patients—who may already be overburdened by the physical and emotional effects of an illness— and may represent an unnecessary extra step in many cases.

I (B)(2) Standard Contract Provisions (§438.3, §438.6)

REAP applauds CMS for seeking to strengthen the complex contract structure governing managed care arrangements, as well as the federal oversight and approval process. We support the addition of standards for contracts with MCOs that are contractually obligated to provide coverage of covered outpatient drugs, and the clarification that plan contracts covering outpatient prescription drugs must adhere to federal Medicaid requirements, included in section 1927 of the Social Security Act, applicable to state programs directly.

In order to maximize access to medicines for patients in need, we encourage CMS to clarify that MCO formularies must satisfy the formulary rules set forth in section 1927. CMS should also clarify patients' rights to obtain off-formulary medications, and address the process for obtaining such medications in a manner that is both clear and understandable for patients and providers alike. While prior authorization requirements can serve an important purpose of standardizing care in a system that varies widely in terms of cost and quality, such requirements are often particularly burdensome for patients and create tremendous access problems. Patients whose conditions are well-managed on a

given therapy should be protected from such utilization review methods as prior authorization or step therapy throughout their tenure in a particular plan or as they transition to a new one.

I (B)(5) Beneficiary Protections

(a) Enrollment (§438.54)

REAP strongly supports CMS's efforts to address the gap in the current managed care regulations regarding the enrollment process. We agree that the absence of federal regulations governing enrollment of beneficiaries into managed care programs has yielded a variation among the states' approaches to enrollment, and that in order to ensure an appropriate, minimum level of beneficiary protection and consistency across programs, basic federal standards for enrollment are necessary. Furthermore, REAP supports CMS's position that beneficiaries are best served when they affirmatively exercise their right to make a choice of delivery system or plan enrollment. However, we believe that the proposed 14-day period for potential enrollees to make an active choice of their managed care plan does not provide sufficient time for many beneficiaries to become adequately educated about their plan options in order to select the plan that best suits their needs. To that end, we encourage CMS to revise the proposed timeframe and extend it to the suggested alternative of 45 days for beneficiaries to make an election.

(c) Beneficiary Support System (§438.71)

We applaud CMS for their recognition that certain beneficiaries may need additional assistance when evaluating their choices of the appropriate managed care plan to best suit their needs. We support the proposed requirement that states establish beneficiary support systems that provide services to beneficiaries before and after they enroll in a plan, including assistance services that would help patients and beneficiaries understand which factors to consider when choosing among managed care health plans and primary care providers. These support systems will be integral to helping beneficiaries navigate an otherwise overwhelming health care delivery landscape.

(d) Coverage and Authorization of Services and Continuation of Benefits While the MCO, PIHP, or PAHP Appeal and the State Fair Hearing Are Pending (§438.210 and §438.420)

REAP strongly supports the proposed rule's requirement that managed care contracts adhere to the program's reasonableness standards and use service authorization standards that are appropriate for and do not disadvantage patients with chronic conditions. As more managed care programs include enrollees with ongoing and chronic care needs, it is critical for the health and wellbeing of these patients and their families that any authorization periods avoid disruptions in care. The establishment of such standards for states will ensure that clinical services be authorized in a manner that reflects the patient's continual need for such services and support.

(e) Continued Services to Beneficiary and Coordination and Continuity of Care (§438.62, §438.208)

Our coalition supports the proposed rule's strengthening of coordination and continuity requirements plans, including ensuring a primary care provider for all beneficiaries, and the adoption of transition standards for beneficiaries moving into managed care or from one form of managed care to another. There should be transition of care standards for all Medicaid beneficiaries transitioning from one delivery system to another within Medicaid, and such transition policies should be a contractual part of a state's comprehensive quality strategy. Standards must include minimum requirements, including allowing beneficiaries to continue to receive care and services—including prescription drugs— from current providers for a specified time period; and ensuring that medical records are transferred to the new provider.

I (B)(6) Modernize Regulatory Requirements

(a) Availability of Services, Assurances of Adequate Capacity and Services, and Network Adequacy Standards (§438.206, §438.207, §438.68, §440.262)

REAP applauds CMS for seeking to bolster requirements for states to assess the adequacy of provider networks and the quality of care provided to individuals enrolled in Medicaid managed care plans. Many of the patients served by our respective organizations are too sick to travel long distances to receive treatment, and shortages of essential health care providers in the vicinity can dramatically change a patient's treatment plan, if not completely derail it. To that end, we strongly support the proposed rule's requirement that states establish network adequacy standards that ensure access to all services included in managed care contracts, and in particular the establishment of time and distance standards, as well as anticipated Medicaid enrollment; expected utilization of services; accounting for the characteristics and health needs of the covered population; number and types of health care professionals needed to provide covered services; number of network providers that are not accepting new Medicaid patients; and the geographic location and accessibility of the providers and enrollees. The adoption of such standards that are similar to the rules for private plans and MA programs will not only help to minimize confusion among beneficiaries, but more importantly, ensure that patients have timely access to covered services.

However, while we are greatly encouraged by the requirement that states, at a minimum, establish time and distance standards, certain types of Medicaid patients may need additional protections to ensure that they have access to appropriate care. Patients often require medically necessary treatment, only to find that a provider is unavailable within their plan's network. Disparities in access to care related to demographic factors such as race, ethnicity, language, or disability status are, in part, a function of the availability of the accessible providers who are willing to provide care and are competent in meeting the needs of populations in medically underserved communities. Additionally, new enrollees in Medicaid managed care may suffer from multiple chronic conditions and require the services of multiple

specialists. As such, we encourage CMS to stipulate that, in addition to time and distance standards, states should also define provider-to-enrollee ratios to ensure sufficient levels of network providers to reflect the different needs of the population. It is critical that affordable comprehensive coverage be made available to all patients who need it, and all efforts to ensure that robust networks are in place must be encouraged.

(b) Quality of Care (subparts D and E of part 438)

Ensuring quality care is of the utmost importance to patients and an effort that involves all stakeholders, and health plans play a critical role. As such, REAP strongly supports the proposal's expansion of quality improvement efforts, in accordance with principles of transparency and public reporting, alignment with Medicare and Marketplace standards, and consumer and stakeholder engagement. We support the proposal's requirement that states have plans that establish performance improvement projects for the purpose of improving quality of care; develop and implement a Medicaid quality rating system that would reflect the type of system developed for Marketplace plans; and establish a comprehensive quality improvement strategy to encompass its quality-related activities.

We support the requirement that states use a robust public engagement process when developing their quality rating system, and consider relative clinical quality management, plan efficiency, affordability, and member experience when doing so. Moreover, REAP believes that this new quality rating system provides an opportunity for alignment so that quality can be compared between programs, and thus aid beneficiaries who may move between programs to be able to better select appropriate care options. However, we are concerned by the proposal that states may elect to use an alternative quality rating system, which may also utilize different components to measure and report on performance data. While we understand that this flexibility is intended to allow states to design their activities to meet their own quality needs, we believe that this proposal would yield little or no alignment between state quality metrics, and therefore hinder comparability. Standardized, reliable, and meaningful quality information would increase transparency regarding Medicaid managed care health plan performance, and the accessibility of such information will contribute to patients' ability to select a plan that provides adequate coverage and network adequacy to meet their individualized health care needs. Improved transparency and standardization will serve to increase both state and health plan accountability in the quality of care provided to Medicaid beneficiaries, and help stakeholders (including patients, advocates and consumers) engage in informed advocacy, compare the performance of providers and health plans, and make more informed program and plan choices.

Conclusion

REAP appreciates the opportunity to provide comments on this proposed rule. We hope that as you review and finalize the proposed rule, you continue to ensure that all patients are able to access the affordable and comprehensive health coverage they need. We look forward to working with CMS in

the future to advance a regulatory framework capable of supporting such a role. REAP members stand ready to answer questions and provide any additional information about the patient groups for whom we advocate.

Sincerely,

American Autoimmune Related Diseases Association
American Brain Tumor Association
Arthritis Foundation
Cancer Support Community
COPD Foundation
Cutaneous Lymphoma Foundation
Epilepsy Foundation
Fight Colorectal Cancer
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
Lymphoma Research Foundation
Men's Health Network
National Alliance on Mental Illness
National Multiple Sclerosis Society
National Organization for Rare Disorders
National Patient Advocate Foundation
National Psoriasis Foundation
National Viral Hepatitis Roundtable
Ovarian Cancer National Alliance
Parkinson's Action Network
RetireSafe
Susan G. Komen
U.S. Pain Foundation
ZERO - The End of Prostate Cancer