

## **Regulatory Education and Action for Patients**

# • Seeking Common Ground

### Submitted electronically to EssentialHealthBenefits@cms.gov

January 31, 2012

Mr. Steve Larsen **Deputy Administrator and Director** Center for Consumer Information and Insurance Oversight Centers for Medicare and Medicaid Services

#### RE: **Essential Health Benefits Bulletin**

Dear Mr. Larsen:

Regulatory Education and Action for Patients (REAP) is an umbrella coalition comprised of patient advocacy groups whose goal is to strengthen current relationships and build new relationships with government agencies that have the responsibility for implementing provisions of the Patient Protection and Affordable Care Act<sup>1</sup>, as amended, (PPACA) and to ensure that implementation of the Act's provisions is patient-centric. The unique experience and expertise of each REAP member organization allows REAP 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 that regulate, develop, manage and/or impact health delivery, coverage, cost and availability of services to the United States population. REAP will, through its member organizations, contribute information and perspectives regarding important health care decisions to a degree that has not been possible heretofore by health care advocacy groups in the regulatory arena.

REAP appreciates the opportunity to submit comments on the Essential Health Benefits (EHB) Bulletin. The Essential Health Benefits definition is an important one as it identifies a minimum standard of benefits that must be covered by all qualified health plans and other non-grandfathered small group and individual insurance plans by 2014, pursuant to section 1302 of the Patient Protection and Affordable Care Act and is expected to impact over 70 million Americans. REAP recognizes the Bulletin does not have the force of law, and was intended to provide states with information regarding the approach that the Department of Health and Human Services (HHS) plans to pursue in a proposed rule to be issued in the future to define Essential Health Benefits. While we understand that, as a guidance document the Bulletin need not comply with the

requirements of the Administration Procedure Act<sup>2</sup>, greater specificity is warranted to allow for meaningful comment. REAP advises that if a Bulletin approach will be included in guidance the agency plans to release on plan cost sharing and the calculation of actuarial value, that it likewise be released with sufficient detail.

The Bulletin notes the Center for Consumer Information and Insurance Oversight (CCIIO) intends to propose that EHB be defined by a benchmark plan selected by each State. The selected plan serves as a reference plan that reflects both the scope of services and any benefits offered by a "typical employer plan" in that State. This approach which allows for State discretion in choosing a benchmark directly impacts which health benefits will be defined as essential in that State. It also allows for considerable variability among the states regarding essential health benefit definition. REAP advises that there needs to be Federal oversight of State decisions that influence or impact its EHB definition and that such oversight must be meaningful yet not unduly intrusive.

Meaningful Federal oversight includes providing guidance by identifying minimum standards that must be met to be in compliance with the PPACA. For example, CCIIO should provide an informative standard regarding how the term "medical necessity" might be defined by the plans. The standard should allow for definitions that incorporate clinically valid and reliable criteria which are compatible with generally accepted standards of care. The standard should allow for reasonable State flexibility and should not be prescriptive. Likewise, Federal guidance should be provided to the States regarding acceptable plan definition of an appeals process, particularly for consumers challenging the definition of medical necessity or equivalent benefit. The Federal guidance approach might be reflective of the approach found in Federal programs, such as the Medicaid program guidelines that specify a minimum set of services that must be provided to beneficiaries.

While REAP generally supports meaningful, yet not intrusive Federal oversight of State benchmark selection and review processes, the flexibility afforded benefit design requires more focused Federal oversight and clearly-defined Federal standards as its approach offers the potential for enrollee discrimination. The Bulletin states HHS intends to require that a health plan offer benefits that are "substantially equal" to the benefits of the benchmark plan selected by the State. . . ." This approach is also intended to be promoted across benefit categories. Absent clear federal guidance regarding what constitutes plan benefits that are "substantially equal," States have the opportunity to define the term in a manner that may not be in the best interest of patients at best, and preclude patients from accessing appropriate therapies at worst.

Another benefit design identified in the Bulletin that affords States substantial flexibility concerns formulary design. The Bulletin language asserts that, "If a benchmark plan offers a drug in a certain category or class, all plans must offer at least one drug in that same category or class, even though the specific drugs on the formulary may vary." When implemented at the minimum level, this approach potentially undermines access to the drug with the greatest therapeutic benefit for the patient and the best value to the health system. The standard of care for many conditions and diseases is a multi-drug regimen. Further, many patients experience drug intolerance or resistance immediately, for example with an allergy or genetic difference, or over time, as in with progressive

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<sup>&</sup>lt;sup>2</sup> 5 U.S.C. 551 et. seq.



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diseases or infections. The inability to access the appropriate drug to combat their illness with the greatest efficacy benefits neither the individual nor the system. As noted above, Federal guidance should be provided to the States regarding acceptable plan definition of an appeals process for consumers. In addition to requesting greater Federal oversight of the flexibility offered to states in benefit design, REAP also advises stricter adherence by States to benefit design standards promulgated by HHS.

Essential Health Benefit definition considerations should not be limited to mere text. The PPACA provides an important role for Exchange Navigators in educating consumers about plan benefits. Navigators will be responsible for advising consumers on how best to select affordable plans that meet their medical needs. Because Navigators have the potential to influence market behavior, REAP encourages CCIIO to include detailed information regarding Exchange Navigator eligibility as well as the scope of Navigator practice in upcoming proposed regulations.

In closing, REAP members thank CCIIO for the opportunity to provide the above comments. We look forward to reading the upcoming guidance regarding plan cost sharing and calculation of actuarial value.

Sincerely,

Alliance for Aging Research
Arthritis Foundation
COPD Foundation
HealthHIV
Hypertrophic Cardiomyopathy Association – HCMA
Men's Health Network
National Alliance on Mental Illness
National Osteoporosis Foundation
National Patient Advocate Foundation
Ovarian Cancer National Alliance
Parkinson's Action Network
Prevent Cancer Foundation
RESOLVE: The National Infertility Association
Zero - The Project to End Prostate Cancer