



**National
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Health**

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Creative Health Benefits Solutions for Today, Strong Policy for Tomorrow

January 31, 2012

Submitted electronically via: EssentialHealthBenefits@cms.hhs.gov

Center for Consumer Information and Insurance Oversight
Department of Health and Human Services
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

**Re: Proposed Regulatory Approach to Defining “Essential Health Benefits”
under the Patient Protection and Affordable Care Act**

Dear Sir or Madam:

The National Business Group on Health is pleased to comment on the Department of Health and Human Services’ (HHS’s) proposed regulatory approach to defining “essential health benefits” (EHB) under section 1302 of the Patient Protection and Affordable Care Act (Affordable Care Act).

The National Business Group on Health represents approximately 340 primarily large employers, including 67 of the Fortune 100, who voluntarily provide health benefits and other health programs to over 55 million American employees, retirees, and their families. Our members employ and provide health benefits for employees under a wide variety of work arrangements, including full-time, part-time, seasonal, and temporary; usually offer their employees a choice of several plan options; and often operate multiple lines of business in multiple locations—often in all 50 states.

We support HHS’s efforts to balance comprehensiveness and affordability in establishing and implementing an EHB definition. We also believe and have testified that evidence of clinical effectiveness is critically important in developing an EHB definition. ***However, our members are deeply concerned that the regulatory approach described in the Essential Health Benefits Bulletin will result in over 50 different EHB definitions, thereby substantially increasing regulatory uncertainty and costs for multi-state employers who must apply the EHB definition.*** As our members implement the prohibitions on lifetime and annual dollar limits on EHB and other Affordable Care Act requirements, a primary concern will be minimizing administrative and cost burdens associated with these requirements. Allowing plan sponsors to use a single, uniform definition of EHB is critical to minimizing these burdens and will allow plan sponsors to

devote more resources toward maintaining and improving health benefits for their employees. **Therefore, the National Business Group on Health supports:**

- (1) Allowing plan sponsors to use a reasonable good faith interpretation of the term “essential health benefits” when complying with applicable Affordable Care Act requirements;**
- (2) In the alternative, allowing plan sponsors flexibility to use, for all plan participants, any single definition of EHB under any state’s benchmark plan or any multi-state qualified health plan offered through an Exchange;**
- (3) Allowing plan sponsors flexibility to maintain and implement plan design features that promote clinical effectiveness, efficiency, and value-based benefit design;**
- (4) Allowing self-insured group health plan sponsors the same benefit design flexibility that HHS proposes for issuers in meeting the EHB coverage standard;**
- (5) Exempting self-insured, ERISA-covered group health plans from any state benefit mandates in excess of the EHB applicable to those plans; and**
- (6) Evaluating and updating the EHB definition 6 months after implementation and annually thereafter.**

We believe that the above approach to EHB would promote efficient, uniform plan administration, reduce administrative and cost burdens, and allow plan sponsors much-needed flexibility in complying with Affordable Care Act requirements related to EHB. We provide further discussion of these recommendations below.

I. Regulatory Approach to Defining “Essential Health Benefits”

To accommodate the health care needs of their large and varied employee populations, National Business Group on Health members voluntarily provide a wide variety of self-insured health plan options at different cost and coverage levels. These group health plans provide benefits that often exceed those available in the small employer market.

Although the Affordable Care Act does not require self-insured group health plans to cover EHB, the definition nevertheless will have a significant impact on such plans. First, all group health plans must comply with the Affordable Care Act’s prohibitions on lifetime and annual dollar limits on EHB. Our members already have devoted significant financial, administrative, and staff resources to complying with Affordable Care Act and other federal requirements. Therefore, regulatory provisions that increase administrative and benefit costs are of particular concern for our members. In addition, some

participants in our members' plans likely will be eligible for Exchange coverage, which is subject to EHB requirements, at some time in the future. Finally, many employers and individuals will view any definition of EHB as the "floor" for all group health plan benefits, which may drive health care costs higher, especially if the definition of EHB includes state benefit mandates.

Our members are very concerned that HHS's proposed regulatory approach to defining EHB will significantly increase regulatory uncertainty and administrative and benefit costs for the following reasons:

A. Compliance with over 50 definitions of EHB

Defining EHB by a benchmark plan selected by each state could easily result in 50 definitions of EHB. In addition, any multi-state qualified health plan offered through an Exchange may have its own definition of EHB. Our members who maintain multi-state group health plans are deeply concerned that their plans will be required to review and comply with the EHB standard in every state in which they operate. Such a requirement would substantially increase administrative and benefit costs, particularly if states change their benchmark plans or the benefits offered in benchmark plans from year to year. In addition, costs associated with plan governance will likely increase if multi-state plans must incorporate different states' EHB definitions. For example, our members frequently conduct claims audits to ensure accurate claims payment and consistent plan interpretation. Having to build different states' EHB definitions into the auditing process will likely increase the cost of these audits.

B. Interference with Uniform Plan Administration

In ERISA's preemption provision, ERISA § 514, Congress explicitly provided for national, uniform administration of self-insured employee benefit plans. This provision is crucial to the efficient administration of multi-state group health plans such as those maintained by National Business Group on Health members. Uniform administration allows our members to offer standardized benefits packages for all employees, streamline administration and communications processes, and reduce costs by negotiating with providers on a multi-state or national basis. Requiring multi-state group health plans to comply with different state-based EHB definitions would severely hamper these efforts and run contrary to Congress's intent of allowing national, uniform plan administration.

C. Reasonable Good Faith Interpretation of EHB is Sufficient

In complying with the Affordable Care Act's prohibitions on lifetime and annual dollar limits on EHB, our members have, in accordance with guidance from the Departments of Health and Human Services, Labor, and the Treasury, applied a reasonable good faith interpretation of EHB. While doing so, our members have remained committed to offering a wide range of health benefits that often exceed those available in the small group market. Therefore, we believe it is unnecessary and costly to require compliance with state-based EHB definitions, as described in the Essential Health Benefits Bulletin.

We also believe that allowing a reasonable good faith interpretation of EHB would be consistent with HHS’s proposal to allow a health plan to offer benefits that are “substantially equal” to the benefits of a benchmark plan.

For the reasons described above, the National Business Group on Health recommends:

- (1) Allowing self-insured plan sponsors to apply a reasonable good faith interpretation of the term “essential health benefits,” as stated in § 1302 of the Affordable Care Act, when complying with applicable Affordable Care Act requirements; or
- (2) In the alternative, allowing plan sponsors flexibility to use, for all plan participants, any single definition of EHB under any state’s benchmark plan or any multi-state qualified health plan offered through an Exchange.

II. Benefit Design Flexibility

In addition to the above concerns involved with applying multiple definitions of EHB, our members are concerned that the regulatory approach described in the Essential Health Benefits Bulletin may not accommodate plan design features that promote clinical effectiveness, efficiency, and value-based benefit design. This result would run contrary to the Affordable Care Act’s—and our members’—goal of controlling the overall costs of health care. Therefore, we support HHS’s proposals to allow benefit design flexibility to allow greater consumer choice and promote plan innovation, including: allowing a plan to offer benefits that are “substantially equal” to the benefits of a benchmark plan; allowing flexibility to adjust benefits, including specific services covered and quantitative limits, provided all 10 statutory EHB categories are covered; permitting substitutions within each of the 10 categories specified by the Affordable Care Act and across benefit categories; and allowing plans to choose the specific drugs that are covered within categories and classes of prescription drugs. We recommend that HHS clarify in regulations that both self-insured and insured plans have such flexibility.

We also emphasize that any approach to defining EHB should incorporate and allow the following:

A. Demonstrated Evidence of Clinical Effectiveness

To prevent health care expenditures on unnecessary, redundant, and ineffective care, we strongly support basing EHB on services or treatments with demonstrated evidence of clinical effectiveness. To this end, EHB should align with generally accepted standards of medical practice and promote clinically appropriate care. For example, when evidence warrants, our members’ plans routinely use care and medical management tools based on clinical effectiveness, including:

- “Step therapy” for medications to encourage providers and patients to utilize proven effective drugs that are less costly or risky to patients’ health than new

“blockbuster” drugs with less evidence base. For example, many plans placed Vioxx, a high cost arthritis drug with links to serious cardiovascular problems, including heart attack and stroke, in a prescription drug formulary’s second or third tier unless physicians provided necessary medical information through the established medical exceptions process to justify prescribing it. Vioxx was initially favored by providers and consumers over other proven, lower-cost, and lower-risk non-steroidal anti-inflammatory drugs (NSAIDs).

- Radiology management programs to ensure that patients receive appropriate screening for their conditions or stages of treatment and are not subject to excessive radiation exposure or unnecessary scans. A number of studies have found that up to 50% of high-tech diagnostic imaging for a variety of conditions was redundant and that such imaging led to unnecessary radiation exposure, particularly for children and pregnant women.
- Dental plan limits—annual, frequency, age, and tooth structure—to provide low cost dental coverage, which has resulted in improved oral health with less than 3% of Americans reaching their annual dental limits. Without internal limits mitigating overutilization, the cost impact of providing oral health care services would rise considerably.

Other clinical effectiveness criteria, related to medical necessity, that plans commonly use include:

- Appropriateness of the service setting;
- Sufficient evidence of clinical effectiveness for services/procedures/devices;
- Sufficient evidence of meaningful clinical utility;
- Comparative effectiveness of the services/procedures/devices to alternatives;
- Cost and actuarial valuation of services/procedures/devices compared to alternatives;
- Demonstrated performance and quality of providers, e.g., Centers of Excellence; and
- Individual eligibility criteria, e.g., Herceptin for patients who meet genetic profile, disease state, and treatment history criteria; BMI \geq 40 for metabolic surgery.

In prioritizing clinical effectiveness, patients receive the highest-value, safest, and most medically appropriate health care services to meet their individual needs. Such a focus also would help group health plans maintain the balance between comprehensiveness and affordability of coverage while improving participants’ health and access to health benefits. Allowing employers to implement plan designs based on clinical effectiveness is

also consistent with HHS's efforts to promote evidence-based and value-based benefit designs.

B. Management Practices That Promote Efficiency

In addition to clinical effectiveness, we support promoting efficiency through best management practices that would keep EHB affordable. The following is a list of best management practices that leading-edge employer-sponsored plans incorporate to promote efficiency:

- **Evidence-Based Benefits.** Linking coverage to the effectiveness of treatments and setting cost-sharing, provider selection, and plan payments to support evidence-based care and discourage ineffective care. For example: reducing or eliminating copayments for maintenance drugs prescribed for diabetes, asthma, and hypertension where the evidence base for the drugs' effectiveness is strong.
- **Targeted Evidence-Based Preventive Care.** Providing incentives such as first dollar coverage (or little or no copayment) for evidence-based preventive care services for targeted populations to improve participant health and reduce future health care costs. Offering education programs to improve plan participant awareness of preventive care.
- **Emphasis on Primary Care.** Paying more for care coordination and patient management and evaluation services. Choosing providers who incorporate the "patient-centered medical home" concept and emphasize primary care coordination.
- **Meaningful Cost-Sharing.** Setting cost-sharing for plan participants at levels that reduce excessive and inappropriate utilization but ensure access to needed medical care when appropriate. Varying cost-sharing based on clinical necessity and therapeutic benefit. For example: Reducing cost-sharing when participants meet requirements fostering evidence-based care such as using medical consultation services and decision supports, participating in disease or case management, etc.
- **Prescription Drug Management.** Managing prescription drug use and pharmacy spending by establishing plan preferences for select generics and brand-name drugs. Considering "step" therapy, generic substitution requirements, or incentives, generic education programs for plan participants and physicians, a separate deductible for prescription drugs, preauthorization for selected drugs, reduced cost sharing for mail order compared to retail purchase, mandatory mail order of maintenance medications, tiered copayments, coinsurance rather than copayments for medications, dose optimization, and quantity-duration protocols for certain medications.

- **Health Improvement Programs.** Offering incentives such as premium discounts to participants who participate in health improvement programs and adopt healthier lifestyles.
- **Targeted Disease Management Programs.** Providing targeted disease management programs for certain chronic and potentially high-cost conditions where evidence demonstrates their effectiveness. Using incentives, rewards, and premium discounts to encourage participation.
- **Retail/Convenience Care Clinics.** Offering access to retail clinics for common, basic medical services to add convenience and reduce inappropriate emergency room visits. Promoting services at retail/convenience care clinics to plan participants through education campaigns and offering lower copayments for the services clinics provide.
- **Consumer Decision Support Tools.** Offering decision-support tools (plan selection and point-of-care) to help plan participants make informed decisions about their health. Tools include customized comparison and financial modeling to help individuals choose among plan options; hospital and physician report cards to assess provider performance against evidence-based standards; nurse lines; self-care guides; self-study modules; online information; health coaches, health advocates; and consumer medical information services to give plan participants more information about treatment options for conditions or illnesses. Requiring that plan participants use decision-support services before non-emergency surgery.
- **Pay-for-Performance.** Linking plans' provider payments to health care quality, paying more for better outcomes, greater efficiency, and better performance on prevention, chronic care management, and patient satisfaction measures. Providing financial incentives to plan participants to choose better performing providers.
- **High-Performance Networks.** Using high-performance networks to reduce costs and improve quality. Offering specialized services through facilities that meet criteria for volume and clinical outcomes, patient and family-oriented services, and evidence-based medicine. Implementing pay-for-performance arrangements and providing incentives to patients who select high-quality, cost-effective facilities. For example: Offering a preferred tier of medical groups and hospitals with differential copayments based on performance in quality and costs.
- **Health Information Technology (HIT).** Requiring health care vendors to use interoperable HIT wherever possible. Providing personal health records for plan participants.
- **Transparency (Cost and Quality).** Requiring plans and providers to publicly disclose information about the price and quality of care.

C. Reasonable Limits to Promote Effective Care, Prevent Unnecessary Care, and Keep EHB Affordable

We also strongly recommend that any definition of EHB take into account the significant role of limits on covered benefits in both employer and government-sponsored coverage. Employer-sponsored plans routinely place limits on a number of services, including the following, to keep care affordable:

- Bariatric coverage for weight loss;
- Chemical dependency;
- Chiropractic benefits;
- Dental coverage;
- Vision coverage;
- Durable medical equipment;
- Hearing aids;
- Home health care/hospice;
- Infertility benefits;
- Out-of-network benefits; and
- Physical and speech therapy.

Government health benefit programs, including Medicare, the Federal Employees Health Benefits Program (FEHBP), and Medicaid, also routinely place limits on benefits. For example:

- FEHBP's Blue Cross/Blue Shield basic option plan places a 75 visit annual limit on physical, speech, and occupational therapy sessions.
- Medicare utilizes a 190-day lifetime limit on inpatient psychiatric care; limits coverage for chiropractic care and a variety of other services; and does not cover acupuncture; dental care and dentures (in most cases); cosmetic surgery; custodial care (help with bathing, dressing, using the bathroom, and eating) at home or in a nursing home; health care while traveling outside of the United States (except in limited cases); hearing aids and hearing exams; or orthopedic shoes.

- Medicare prescription drug coverage (Part D) utilizes prior authorization, “fail first,” and “step therapy” requirements and quantity limits.

D. Exemption from State Benefit Mandates

For the above reasons, we also recommend that any definition of EHB not incorporate state benefit mandates. Such mandates would hamper the efficient, uniform administration of group health plans and be contrary to Affordable Care Act’s requirement that states defray the costs of state-mandated benefits. Furthermore, state benefit mandates often are the result of advocacy by provider, supplier, or patient groups rather than strong clinical evidence justifying coverage of the benefits at issue. For example, in the case of high-dose chemotherapy with autologous bone marrow transplantation (HDC/ABMT), this state-mandated care was found to be more harmful than the conventional treatment at the time.¹

For the reasons described above, the National Business Group on Health recommends:

- (1) Allowing plan sponsors flexibility to maintain and implement plan design features that promote clinical effectiveness, efficiency, and value-based benefit design;
- (2) Allowing self-insured group health plan sponsors the same benefit design flexibility that HHS proposes for issuers in meeting the EHB coverage standard; and
- (3) Exempting ERISA-covered group health plans from any state benefit mandates in excess of the EHB applicable to those plans.

III. **Updating Essential Health Benefits**

In the future, advances in personalized medicine will require a more individualized approach to coverage decisions. In addition, the speed at which new, costly medical technologies are coming to market will create a need for objective, evidence-based assessments to ensure patient safety, quality, and affordability. Both of these factors highlight the necessity of frequent and regular reevaluation of EHB. Such reevaluations should identify not only benefits to be added but also existing “essential health benefits” that may need to be eliminated because of new medical evidence.

Therefore, the National Business Group on Health recommends that HHS conduct an evaluation of EHB 6 months after implementation and annually thereafter. The initial evaluation should include an evidence-based, clinical review of the medical services and medical providers utilized (with an actuarial cost/benefit analysis), incorporate any new information based on credible, scientific evidence published in peer-reviewed medical

¹ Rettig, Richard. Litigating the Science of Breast Cancer Treatment. *Journal of Health Politics, Policy and Law*, Vol. 32, No. 5, October 2007.

literature, and result in removal of any benefits that are no longer supported by such evidence.

Annual reevaluations should take into account new evidence garnered from the comparative effectiveness research of the Patient-Centered Outcomes Research Institute. With a \$2.5 trillion dollar economy and another 32 million individuals gaining comprehensive coverage (some for the first time), the nation's health care delivery system will require timely action to ensure that there is budgetary room for new effective, evidence-based treatments, technology, and medications.

We also recommend that HHS regularly consult with outside organizations and utilize existing federal agencies, such as HHS's Office of Minority Health, for periodic updates on whether EHB is meeting the diverse needs of women, children, and persons with disabilities. In addition, after the first year, the HHS should request a report on the extent to which the definition of EHB is helping to eliminate health care disparities.

Thank you for considering our comments and recommendations on the proposed regulatory approach to defining "essential health benefits." We look forward to working with you as you continue to implement the various provisions of the Affordable Care Act. Please contact me or Steven Wojcik, the National Business Group on Health's Vice President of Public Policy, at (202) 558-3012 if you would like to discuss our comments in more detail.

Sincerely,

A handwritten signature in black ink that reads "Helen Darling". The signature is written in a cursive, flowing style.

Helen Darling
President