



December 6, 2010

RE: the Request for Information by the Institute of Medicine (IOM) on Essential Health Benefits Study

1. What is your interpretation of the word “essential” in the context of an essential benefit package?

Services and supplies that effectively evaluate, diagnose, cure or improve health outcomes due to illness or injury and services that reduce health risks. In addition, the Affordable Care Act requires the Secretary of Health and Human Services (HHS) to ensure that the benefits are equal to the scope of benefits provided under a “typical employer plan”.

2. How is medical necessity defined and then applied by insurers and self-insured plans in coverage determinations? What are the advantages/disadvantages of current definitions and approaches?

Insured and self-insured plans typically define medical necessity as health care services that a provider, using prudent clinical judgment, would provide to a patient for the purpose of evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are aligned with generally accepted standards of medical practice, clinically appropriate, and not primarily for the convenience of the patient or provider.

Advantage: The medical necessity determination is based on what is clinically appropriate for the individual.

Disadvantage: Common standards of medical practice are often based on professional consensus rather than objective evidence of effectiveness.

The term “medical necessity” is often misunderstood, implying the plan is using medical necessity to deny coverage, and underplaying the science base and attention to patient protection. A better term and principle to use is medical appropriateness.

3. What criteria and methods besides medical necessity are currently used by insurers and self-insured plans to determine which benefits will be covered?

Insured and self-insured plans use several criteria in addition to medical necessity to determine coverage, including the following:

- Appropriateness of the service setting;
- Sufficient evidence the service/procedure/device is effective;
- Sufficient evidence of meaningful clinical utility;
- Comparative effectiveness of the service/procedure/device to alternatives;

- Comparative cost and actuarial valuation of the service/procedure/device to alternatives;
- Demonstrated performance and quality of the provider, 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.

Advances in personalized medicine will require a more individualized approach to coverage decisions. The speeds at which new, costly medical technologies are coming to market emphasize the need for objective evidence assessments to ensure patient safety, quality and affordability.

4. What principles, criteria, and process(es) might the Secretary of HHS use to determine whether the details of each benefit package offered will meet the requirements specified in the Affordable Care Act?

In addition to evidence measures mentioned in #3, affordability of health care coverage should be considered in determining the benefit package details. One key consideration is consumer-directed health plans (CDHPs) – a high-deductible health plan coupled with a health savings account. These plans have emerged as a new plan type that gives individuals more control over their health care while maintaining affordability for those subsidizing health care coverage. More importantly, CDHPs are beginning to show evidence of increased adherence in chronic care, a reduction in unnecessary services and further engagement in health improvement programs. The compelling research, detailed below, illustrates that CDHPs should be permitted as a health option under the essential health benefits requirement.

In comparing members in a traditional plan with those in a CDHP, Blue Cross Blue Shield of Minnesota found that CDHP enrollee's accessed preventive services at a higher rate, had shorter hospital stays and fewer inpatient admissions. CDHPs have been covering preventive care communications at 100% years before health care reform came into fruition. Additionally, research published in the Journal of the American Medical Association observed that avoidable hospitalizations declined by almost a third in the CDHP group. Individuals with CDHPs also use health improvement programs at a higher level with 43% receiving a health screening (with 30% of those with traditional coverage doing so). CDHP enrollees are also 11% more likely to participate in an exercise program.

Lower premiums attract individuals to these types of plans. On average, employees with a CDHP contribute \$632 to the plan cost, compared to the overall cost all plans at \$899. With the lower upfront costs, individuals are able to set aside these monies into a tax-advantaged account to pay for future health care costs.

5. What type of limits on specific or total benefits, if any, could be allowable in packages given statutory restrictions on lifetime and annual benefit limits? What principles and criteria could/should be applied to assess the advantages and disadvantages of proposed limits?

Benefits could have a variety of limits applied through some type medical management (medical settings, duration of treatments, and approved treatment plans) limits. Health plans should be designed to encourage medical treatment that is both medically effective and also cost effective for both the plans and participants. Limitations should be based on clinical outcome studies to identify the best practice methods, medical settings, treatment durations, provider credentials, and also to identify areas of high utilization of and unnecessary use of medical services by participants that leads to abuse. Additionally, HHS should establish a formal ongoing medical management review process established to incorporate new advances in medical technology and in medical treatment plans to assure that plans cover the appropriate medical services in the appropriate settings. This will prevent ineffective medical treatment, inappropriate health benefits and avoid a financial burden for both the plan and participants.

6. How could an “appropriate balance” among the ten categories of essential care be determined so that benefit packages are not unduly weighted to certain categories? The ten categories are: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorders services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; pediatric services, including oral and vision care.

Health plans should be designed to provide benefits for appropriate and effective medical care for patients and at that same time medical services need to be cost effective for both the plan and participants. The ten categories, outlined in the above question include care provided in both a medical setting (ambulatory care, hospitalization, etc.) and also care that is provided for certain health conditions (behavioral, health, maternity, etc.). “Appropriate balance” must focus on treatment plans with high outcome levels, proper settings, appropriate provider credentials, and also normal utilization patterns.

7. How can it be determined that that essential benefits are not "subject to denial to individuals against their wishes" on the basis of age, expected length of life, present or predicted disability, degree of medical dependency or quality of life? Are there other factors that should be determined?

In order to be considered an essential benefit, the service or treatment must have demonstrated evidence of effectiveness and be clinically appropriate for the individual. Patient decision aids should be required (and their development funded) for essential benefits.

Patient decision-aids use the available evidence about relative risks and benefits of treatment choices to help patients arrive at an informed decision about the best course of action based on their risks, preferences, and circumstances such as age, expected length of life, present or predicted disability, degree of medical dependency and quality of life. Most decision aids are designed to be used in consultation with a clinician, commonly referred to as shared decision making.

Evidence suggests that helping patients choose treatments aligned with their preferences leads to better outcomes and may even reduce variations due to supply- and preference-sensitive interventions.

In addition, inappropriate denials can be avoided by using a timely appeals process that allows patients and their providers to demonstrate a service or treatment is appropriate.

8. How could it be determined that the essential health benefits take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups?

The Agency for Healthcare Research and Quality (AHRQ) and other existing federal agencies should continuously support research to monitor the affects of the “essential health benefits” on specific populations, possibly with regular reporting requirements.

The federal government should also regularly consult with outside organizations, such as the March of Dimes, and utilize existing federal agencies like the Department of Health and Human Services’ (HHS) Office of Minority Health and require them to submit periodic updates from their research to the HHS Secretary on whether the “essential health benefits” package is meeting the diverse needs of women, children and persons with disabilities and eliminating health care disparities without producing any adverse consequences for these groups.

Appropriate collection and utilization of data to close the gaps in health care disparities is essential. Communicating data findings and health messages are key factors as well.

The federal government should also apply any “lessons learned” and evaluate the “essential health benefits” package to determine if it accounts for the needs of the diverse segments of these groups using the new data collection and analysis standards that the HHS Secretary will establish under the Affordable Care Act for any federally conducted or supported health care or public health program, activity or survey to collect, report and analyze data on race, ethnicity, sex, primary language, and disability status at the smallest geographic level to detect and monitor trends in health care disparities.

9. By what criteria and method(s) should the Secretary evaluate state mandates for inclusion in a national essential benefit package? What are the cost and coverage implications of including current state mandates in requirements for a national essential benefit package?

State mandates are not the place to start. In fact, the federal government should evaluate many state mandates because they are often adopted for political reasons, not based on clinical evidence. In many cases, such as high-dose chemotherapy with autologous bone marrow transplantation (HDC/ABMT), Rettig, et. al (2007), they turned out to be harmful to patients. In addition, actuaries often find that mandates increase the cost of coverage.

We recommend that HHS very carefully weigh the additional costs against the clinical evidence-base and value of any additional benefits it adds to the “essential health

benefits” package and consider the impact on the affordability of coverage for American employers, employees and their families.

10. What criteria and method(s) should HHS use in updating the essential package? How should these criteria be applied? How might these criteria and method(s) be tailored to assess whether: (1) enrollees are facing difficulty in accessing needed services for reasons of cost or coverage, (2) advances in medical evidence or scientific advancement are being covered, (3) changes in public priorities identified through public input and/or policy changes at the state or national level?

HHS should conduct a 6 month evaluation that includes a review of medical services utilized, medical providers utilized, and benefits costs analysis, with appropriate updates implemented on an annual basis. HHS should establish a 6 month monitoring process to evaluate utilization of medical providers and facilities by medical conditions to assure that individuals are accessing medical services at the appropriate settings.

HHS should review medical management reporting, including information from utilization review, case management, and the appeals process on a 6 month basis to identify required changes and to update essential benefit on an annual basis. Also, HHS should use actuarial cost analysis to identify cost issues and to assure cost effective plans.