Institute of Medicine
Essential Health Benefits
BIO Comments

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

   "Essential" in the context of an essential benefit package means ensuring that patients have access to the most medically appropriate, innovative therapies, diagnostic tools and vaccines that are used to treat and prevent disease and other illnesses. Patients must have access to all needed therapies, whether innovator or generic, as determined by the patient and physician. The essential health benefit requirements must protect the patient and provider relationship, and ensure a broad range of treatment options.

   In addition, a patient's treatment options should not be limited based on the coverage level that they choose. Beneficiaries should have access to the same therapies, diagnostics, and treatment options in all coverage levels outlined in the Patient Protection and Affordable Care Act (PPACA). For example, a beneficiary who chooses the Bronze Level coverage should have access to the same services and treatments as the Platinum Level, but only with variation in cost-sharing. Further, the accessibility of benefits deemed "essential" should not be limited by extreme cost-sharing arrangements regardless of the chosen coverage level or by care setting. For example, for therapies whether they are delivered in an outpatient, pharmacy or other health care setting.

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

   The Secretary must ensure that the definition of medical necessity is flexible to allow for the timely incorporation of new technologies and other medical breakthroughs in order to provide patients and their health care providers with the most appropriate tools to achieve the optimal quality outcome. Medical necessity should prioritize outcomes, patient satisfaction and management of a condition over cost. For example, one disadvantage of current approaches includes evaluating new technologies based on cost which leads to restricting patient access to novel therapies through placement on a specialty tier which may have high cost sharing and limited, or no, rights of appeal. Additionally, medical necessity determinations should incorporate consideration for unintended patient impacts, such as reduced adherence to prescribed therapies. Finally, no treatment should be universally excluded from coverage, particularly for FDA-approved indications and clinically accepted off-label uses. Moreover, appropriate payment adjustments must be available to hold patients and their physicians harmless in situations where choice of appropriate therapy results in an increased cost burden.

3. ***What criteria and methods, besides medical necessity, are currently used by insurers to determine which benefits will be covered? What are the advantages/disadvantages of these current criteria and methods?***

   The Secretary should look to existing methods that are well-adopted and have proven successful in facilitating timely patient access to needed therapies and preventative services. Methods and criteria adopted to update benefits packages should be consistent with timely access to quality care. For example, for immunization services, insurers use the recommendations of the Advisory Committee on Immunization Practices (ACIP) as approved by the Director of the Centers for Disease Control (CDC). These recommendations cover all ages and are rapidly and widely adopted by health

plans and States upon their dissemination. Similarly, the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology are an established and trusted resource for clinicians and insurers in helping to determine the most appropriate therapy for cancer patients and also to determine which benefits are covered. Other sources that may influence insurers benefit decisions include: United States Preventative Services Task Force (USPSTF) recommendations; CDC guidelines and recommendations for screening and treatments; and recommendations from professional medical societies.

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?***

   The development of each essential health benefit package should hinge on three principles: ensure patient access to the most medically appropriate therapies, vaccines and diagnostics; preserve incentives for continued innovation; and involve a transparent and inclusive process with public comment and rulemaking.

   When developing the essential benefit requirements, the Secretary must first and foremost ensure patient access to the most appropriate treatment and care based on an individual patient's needs. To achieve the best possible outcomes, providers must have the flexibility to tailor the appropriate course of treatment for each patient based on individual patient medical condition and clinical circumstances. Additionally, the Secretary should establish a clearly-defined appeals and exceptions process to ensure adequate beneficiary protections.

   Further, incentives for health care innovation must be preserved. In order to enhance and continue the discovery of new innovative diagnostic tools and therapies, consumers must have access to the most appropriate treatment options. This would include coverage for standard of care treatments when an individual is enrolled in a clinical trial.

   The process of determining the essential benefits package should include participation by a variety of interested parties and should occur in a timely and transparent process. In addition, the Secretary should consider recommendations by organizations recognized for their expertise in specific areas. The essential benefits package requirements should be updated on a routine basis to include such recommendations.

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?***

   PPACA eliminated lifetime caps on coverage and prohibited plans from imposing lifetime dollar limits on essential benefits because such policies unfairly discriminate against patients with the most devastating illnesses. Placing limits on specific services or items will restrict access to lifesaving therapies and treatments for patients who need them most, when they need them most.

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.

Access to the ten categories of care outlined in PPACA statute should be determined based upon individual patient medical condition and clinical circumstance. The Secretary must address the explicit needs of different patient populations when determining the requirements of the essential health benefit packages. Certain groups, such as women, children and people with disabilities, have very specific health care needs. "One-size-fits-all" policies that ignore the variability among individual patients in treatment efficacy, safety, and tolerability of treatment options must be avoided.

In addition, the value of some services, such as prescription drugs, vaccines and biologicals and preventive diagnostics and therapies, in reducing expenditures for hospitalizations and office visits should be considered and broad access to these services should be maintained.[1] Furthermore, studies have shown that, even for severe life-threatening diseases such as cancer, significantly more patients abandon treatment at higher co-pays. For example, a $200 co-pay showed three times more prescription abandonment than ≤$100 co-pays for oral cancer treatments.[2] In order to ensure that policies available through an exchange remain affordable, HHS may want to consider allowing flexible cost sharing across benefit categories, while ensuring that the essential benefits package is not designed with very high cost sharing for medications for patients with severe disease because to do so effectively puts the coverage out of reach for many lower income individuals.

7. How could it be determined 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?

All regulatory language should ensure 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 dependence or quality of life." Any process establishing essential health benefit requirements must ensure that individuals have clearly-defined rights to appeal decisions made by health plans. The appeals process should not be overly burdensome on either patients or providers. Further, the essential benefit requirements must be developed in a predictable and transparent manner with adequate stakeholder input, and through public comment and rulemaking.

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 Secretary must ensure that the essential health benefit requirements protect all patients, especially those with diverse needs. Many therapies targeting rare or "orphan" diseases, as well as severe, rapidly progressive, or life-threatening diseases, do not have an evidence base defined for

---

[1] See Nichol, K.L. The additive benefits of influenza and pneumococcal vaccinations during influenza seasons among elderly persons with chronic lung disease, Vaccine July 30 1999: 17 Suppl 1:S91-93 or Jha, Ashish, Performance measures, vaccinations, and pneumonia rates among high risk patients in Veterans Administration Care, American Journal of Public Health, Dec 2007, Vol 97, No 12, pp 2167-2172 or Lichtenberg, Frank R. "The Impact of New Drugs on US Longevity and Medical Expenditure, 1990-2003: Evidence from Longitudinal, Disease-Level Data." AEA Papers and Proceedings May 2007.

[2] Gleason PP, et al., "Oral Oncology Prescription Abandonment Association with High Out-of-Pocket Member Expense," Journal of Managed Care Pharmacy, 2010;16:161-162.

the general population due to the vulnerabilities, small size, heterogeneity, and other characteristics of these patient populations, and access to the most appropriate course of treatment must be preserved. When developing essential health benefit requirements, policymakers must recognize that there is no "average" patient, and individuals with unique health care needs should not be penalized with "one-size-fits-all" policies.

One approach that may help to reduce disparities and increase access to quality care is to ensure that patients have access to and coverage for various types of healthcare providers. In addition to physicians, access to pharmacists, nurse practitioners and other alternative care community sites should be allowed, within the confines of State laws, as providers of key services and care to patients. Patients should also have access to specialty providers to ensure quality care for all patient populations, especially the most vulnerable.

In addition, where possible, health plans, hospital systems and providers, should be strongly encouraged to invest in health information technology that captures key information, such as that captured in the Medicare Personalized Prevention Plan created by PPACA. Continued commitments to expanding the use of electronic medical records will help providers work with their patients to select the proper preventive and therapeutic options appropriate for their age, gender and underlying conditions. These technologies can also help ensure consistency across health systems thereby reducing the likelihood of 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?***

The Secretary should evaluate state mandates to determine how they address patient access to important and innovative therapies and treatments for vulnerable populations. States will have experience with these programs due to past administration and may be able to help the Secretary evaluate the patient care implications as they relate to an increase in prevention, improve patient quality of life and/or decrease long-term healthcare costs.

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?***

The essential health benefits package should be updated in a regular and timely way to maintain relevance to current medical practice and ensure consistency with the evolution of scientific evidence and advancements. Package requirements must be disseminated to patients, providers, and other stakeholders in a timely and efficient manner. For example, for the Medicare Part D program, CMS's regulatory guidance to PDPs is that they make a reasonable effort to review a new FDA-approved product within 90 days and make a decision within 180 days.

Patient choice and access to all therapies and services must be preserved and carefully monitored. A process should be in place for an external or governmental auditor to examine the impact of essential benefit requirements on patient access to needed therapies. In addition, a resource should

be made available to beneficiaries to register specific instances of reduced or limited access to treatments or therapies, as well as broader concerns with coverage policies.

With regard to benefits for drugs and biologicals, adequate patient safeguards must be in place to ensure that beneficiaries not only have a wide range of treatment options, but also access to those therapies that are most medically appropriate for their individual needs.. New prescription medicines can become available rapidly, and health plans should be positioned to extend coverage, particularly for lifesaving therapies, in an efficient manner.

Finally, updating the essential health benefits requirements should ensure the leveraging of best practices and coverage models that may be in place in the states or certain commercial plans. As the Secretary makes determinations on updates to the essential package, new and novel state programs that go above and beyond the current essential package should be considered on the national scale if states can show a positive effect on patients' access to new therapies or novel treatments. The same is true for some commercial plans outside of the exchange that may have novel programs and coverage designs in place, which have proven to benefit patients.