The IOM is seeking public input to inform the committee’s deliberations and to identify potential sources for evidence/data that pertain to the specific questions. The IOM is governed by the Federal Advisory Committee Act; each response to the questions becomes part of a public access file. Please submit your comments by December 6 to ensure that they can be examined before the committee’s first meeting.

1. Contact Information
   U.S. Chamber of Commerce

2. For the purpose of these questions, do you consider yourself answering primarily from the viewpoint of a:
   - Consumer/Patient
   - Health care provider
   - Insurer
   - Employer
   - Health services researcher
   - State official
   - Other

   Please place your answers and recommendations for literature or data sources to support your view in the text boxes. You can copy text from another document to enter into the box; the boxes will hold up approximately 1,000 words each.

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

   The word “essential” is synonymous with basic, crucial, fundamental, vital and/or elemental. Within the context of the term “essential benefits package,” we believe that the word “essential” should be interpreted as benefits that are life-sustaining, rather than convenience-related. Any definition of an essential health benefit must balance the importance of providing reasonable coverage with the importance of managing the total future health care costs and accesses to coverage. When defining what constitutes an essential benefit package, a variety of factors related to affordability must also be considered. Creating an expansive set of categories and/or specific health care services to define “essential benefit package” will lead to more expensive coverage that will be less affordable for individuals and sponsors (particularly given the limitations on cost-sharing). While the definition must include the general categories of items and services established in §1302 of the Patient Protection and Affordable Care Act (PPACA), beyond that, if the definition is too inclusive and prescriptive, it will negatively impact
affordability for consumers. The more services a plan is required to cover, the more expensive the premiums for purchasing that plan will be. As a result, policymakers, regulators and the Secretary must be very vigilant against interpreting “essential” too broadly.

In order to maximize resources and the availability of basic coverage, we urge the Secretary to identify only general categories of care, rather than specific health care services, when defining “essential health benefits.” This approach will protect the flexibility to ensure that plans and sponsors can more responsively meet the evolving needs of individuals and employees.

- Essential is not all inclusive, and should not be interpreted to mean everything for everyone. Instead, an essential health benefit package should be a package of benefits that is reasonably designed to provide access to a set of health benefits that will substantially benefit the population.
- The definition of essential health benefits should be flexible and give plans the ability to define the manner, settings and circumstances under which covered services are delivered.
- Not every service or every service setting must be covered (e.g., plans should be allowed to incent enrollees to obtain services in the most cost effective setting, rather than cover services in all settings delivered by all providers). Also, the definition should not limit the ability to reward providers (based on performance) or exclude providers (based on performance) from delivering the essential benefits. Plans must be permitted to continue to manage their networks and assure quality and high performance.
- An emphasis should be placed on consumer choice when establishing the definition of essential benefits. Although insurers and employers must cover certain essential benefits, the purchasing of additional benefits should be a negotiation between the consumer and the insurer with the consumer ultimately deciding if they want to pay for richer benefits.

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

First, the Chamber would like to respectfully register concerns with the integration of such an extensive exploration of “medical necessity” in the context of a preliminary assessment of the essential benefit package. The Chamber appreciates the tangential importance of medical necessity within this issue; for benefits not included in the essential benefit package, there will be questions and interest as to whether beneficiaries will have access to other medically necessary services not delineated or included in the essential benefits package. Although this issue will be important to address, these are two different concepts. The high degree of focus within these initial questions appears to indicate a disturbing assumption as to nexus between essential benefit packages and medical necessity.

While “essential benefit package” is a critical piece of the Patient Protection and Affordable Care Act (PPACA), we stress that Congress did not include a definition of medical necessity in the PPACA. While the House bill included such a definition, a definition of medical necessity was not included in the final bill, as amended by HCERA. Failure to incorporate any such definition
into the final bill reflects Congressional intent to preserve flexibility in how this term is defined. In fact, Congress explicitly preserved the right of group health plans and health insurance issuers to employ “commonly used utilization management techniques like medical necessity and utilization review.” PPACA §1563(d). We respectfully urge that the Department of Health and Human Services (along with the Secretary, the Institute of Medicine and other Departments) in developing regulatory guidance remain focused on issues and topics addressed by the statutory language pursuant to Congressional intent.

We maintain that the definition of essential health benefits must not prevent an insurer or administrator from conditioning coverage of any benefit on "medical necessity", or medical appropriateness for a specific patient. Additionally, the IOM (HHS, the Secretary and other Departments) should not define medical necessity. To do so would be inconsistent with PPACA’s §1563, which preserves the right of group health plans and health insurance issuers to employ commonly used utilization management techniques in the provision of covered benefits.

After registering this concern and to answer the question, the Chamber would cite the following definition: Medical necessity is a tool that employers, insurers and governments use to determine whether or not to approve reimbursement for a particular benefit for a specific patient or classes of patients in their treatment plans. Medical necessity is not a tool for determining what items and services should make up a benefit package.

The commonly agreed upon standard in the medical, insurer and legal community for medical necessity is:

Medically necessary or medical necessity means health care services that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating illness, injury, disease or its symptoms, and that are:

a. In accordance with standards of medical practice that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations and the views of physicians practicing in relevant clinical areas and any other relevant factors;
b. Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient’s illness, injury or disease; and

c. Not primarily for the convenience of the patient, physician, or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.

Medical necessity determinations address the appropriateness of a specific medical service for an individual patient. This process is an effective way of reducing harm to enrollees/patients and ensuring that enrollees/patients receive the health services of greatest value for their individual needs. Again, the medical necessity process should not be used as part of the criteria for determining the standard set of categories included in the essential health benefits package; the medical necessity process is applied after the benefit design has been determined.
5. 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?

In general, insurers and administrators use protocols and medical management techniques to assure that the right care is delivered at the right time to the right patient.

One example of how quality and efficiency is evaluated occurs in the use of step therapy for pharmaceuticals. Pharmaceutical step therapy encourages providers and patients to initially use proven effective drugs that may be less costly with little to no cost-sharing before escalating to the use of the latest new breakthrough therapy.

Another medical management tool that has been successful is radiology management programs. These programs ensure that patients receive the appropriate screening for their condition or stage of treatment so that they are not subject to excessive radiation exposure needlessly. Studies show that an estimated 20% - 50% of high tech diagnostic imaging for a variety of conditions fails to provide information that improves patient diagnoses and treatment and may be considered redundant and unnecessary. As a result, radiology benefit management programs have been created to promote the appropriate use of imaging services, avoid redundancy and unnecessary exposure to radiation, and ensure that the patient receives the right service the first time. These programs focus on providing clinicians with the latest scientific evidence and evidence-based guidelines for specific imaging services through decision support tools and consultations with radiologists, and feedback on practice patterns. These programs have resulted in more appropriate utilization of imaging services while assuring that patients receive necessary care.

6. 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?

According to the statutory language (§1302(b)(2)(A)), the Secretary of HHS shall define the essential benefits package and ensure that it “is equal in scope to the benefits provided under a typical employer plan.” The Secretary is not charged with determining the details of each category of care. The survey of the employer marketplace, which PPACA requires the Department of Labor to conduct, should provide this information.

In assessing the scope of the typical employer plan, we urge the Secretary to evaluate the balance between covered services and cost of coverage. The interplay between these two elements for each plan must be carefully considered as the Secretary determines what basic benefits all plans will be required to cover. In employer offerings, plans covering desirable benefits at a cost that employees deem to be of value has lead to product differentiation. As stated in our initiate response, essential benefit packages must be comprised of the most basic and fundamental benefits. For various reasons, plans and employers will decide to offer richer benefit packages that build up from the essential health benefit package floor. However, requiring plans and employers to cover more expensive services as part of an essential benefit packages will make even the more basic plans offered more expensive. The more comprehensive the definition of...
“essential,” the more expensive the most basic plan offerings will have to be. This would thwart the primary goal of improving access to health care coverage and services for all Americans. A more comprehensive and detailed definition of essential benefits instead would perpetuate an empty promise of comprehensive coverage for all, when in fact that coverage would be increasingly unaffordable for more and more Americans.

Again, the decision to offer more extensive benefits should be consumer driven where the consumer has the choice to add or remove benefits based upon what the consumer is willing to pay. Fundamentally, this should be a negotiation between the insurer and the consumer.

7. **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?**

The Administration’s guidance on dollar limits for lifetime and annual benefits is very clear. Dollar limits on lifetime benefits are already prohibited, and annual dollar limits for “essential benefits” are being phased-out by 2014.

PPACA and corresponding regulations only prohibit dollar limits on lifetime and annual benefits; value based plans are specifically permitted under the PPACA’s preventive services requirement. Therefore to reflect these policy goals, it is critical to ensure that benefits care both incorporate the cost effective of care, and should not be manipulated or abused by those who might encourage inappropriate or unnecessary care. Therefore, flexibility needs to be maintained for employers and insurers to incorporate other types of limits on certain benefits, as they have been able to do historically. These include reasonable day limits, visit limits, step therapy for prescription drugs and value based plan designs that assure that enrollees/patients obtain services in proper settings with providers of high quality and greater efficiency. For value based benefit designs, plans must be permitted to increase the cost for an enrollee who chooses to obtain services delivered by higher cost providers with no better quality or access for the substantially same service (or similarly for pharmaceuticals); this practice should not be construed as a prohibited dollar limit. Affording plans and issuers flexibility will help ensure both quality and affordability for consumers.

Additionally, flexibility must allow plans and employers to innovate with new plan designs aimed at improving compliance with medical and/or drug protocols, such as value based plans. The establishment of essential health benefits should not interfere with:

- The use of medical necessity criteria to direct the consumer to the most cost efficient choice; or
- Limitations on out-of-network services and equipment.

8. **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.

Because the ten general categories are delineated in the law as categories that must be included in the essential benefit package, plans will be required to cover essential services in each category. Given the breadth of the categories, what is “essential” in each category should differ in scope. Instead, the more critical question is how to define “appropriate balance” (rather than how can we determine that “appropriate balance” has been met), given the different degrees of efficacy in rendering services in these broadly varying categories.

Appropriate balance is best be defined by looking to the marketplace and the needs of the average person including the total cost of providing the essential benefit and consumer choice. Generally today, if carriers design products that do not provide the balance of coverage that consumers want and need, then those products will not sell. In contrast, the best-selling products on the market today reflect the balance that best satisfies consumer demands. Similarly, employers develop and revise their health coverage offerings based on the needs and wants of their employees, as well as based on what their employees consider desirable for the cost.

The survey of the employer marketplace that the Department of Labor is required to conduct under the PPACA should provide this information. Using the marketplace as direct evidence of consumer demand is much more likely to accurately reflect needed and desired services than an untested, academic interpretation of “balance” which may not relate in any way to what consumers really want and need. However, there should be an independent assessment on how the benefit costs will be used and if consumers are willing to pay the costs.

PPACA’s §1302(b)(2) provides that HHS shall ensure that the scope of the essential health benefits under paragraph is equal to the scope of benefits provided under a typical employer plan. Because employer plans vary widely, we recommend that HHS recall the type of employers which will be most significantly impacted by how this term is defined. Essential benefits will primarily impact employers in two ways. First, small employers will be affected by the definition as it relates to requirements of plans offered in the exchange. Small employers that offer employee’s health care coverage through exchange plans will provide this essential health benefit package. Secondly, and more indirectly, all employers will be affected be this definition as it relates to annual limit prohibitions. All employers are prohibited from imposing annual limits on essential health benefits on a phased in basis until 2014.

Therefore, since the “typical” employer to which the essential benefit requirements will apply directly are smaller employers, the analysis of employer plans for this purpose should assess the scope of benefits offered by smaller companies. To rely on survey information that is heavily weighted toward large employers would be inappropriate and result most likely in a more comprehensive definition that most small employers would have difficulty affording.

9. 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?

Plans already have extensive, regimented processes in place to prevent the denial of covered services based on age, expected length of life, present of predicted disability, degree of medical dependency or quality of life. While a patient may refuse treatment, plans and insurers are prohibited now from denying covered services for these types of reasons.

Currently, decisions as to whether to provide a specific benefit is based largely on determinations of medical necessity and/or medical appropriateness, which necessarily take into account many factors, such as co-morbidities, age, expected lifespan and the ability of the patient to benefit from the service in question. Leaving these decisions to the regimented and legally determined medical necessity processes of insurers would help avoid scenarios that trigger the PPACA prohibitions related to denials based on age, life expectancy, disability to quality of life. In order to allow insurers to address coverage issues and situations appropriately on a case-by-case basis and to adapt quickly as needed to new technologies, these processes require flexibility. An overly prescriptive approach as to how such decisions are made could significantly undermine insurers’ ability to assure that the provision of medically inappropriate care is limited and that premiums are kept affordable through intelligent medical management. Lack of such oversight could also encourage fraud and abuse. The Chamber continues to argue that medical necessity should not be included in the definition of essential benefits.

10. 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?

Employers have a wide variety of beneficiaries for whom they offer coverage. Given the requirement that an essential benefits package mirror the typical employer plan in scope, we encourage the Secretary of Health and Human Services in defining the essential health benefits (as well as the Secretary of Labor in conducting the survey of employer sponsored coverage) to look to how employers evaluate and address the needs of their diverse workforces. The ten categories of covered benefits stipulated in §1302 are comprehensive and applicable to the health care needs of the entire population.

Advocates for certain groups will argue that they need specialized care or services where there may be little or no evidence. As a result, we urge that the Secretary considers such requests in the context of complex parameters, including the ten broad categories defined by PPACA, the limits placed on cost-sharing and the importance of affordability.

11. 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?

We believe that essential benefit packages should be viewed as the basic mandatory floor threshold and should be no more substantial than what is typically offered in scope by
employers. (As we discuss earlier, plans and employers will build richer benefit options up from this basic plan for those that would like to pay more money for richer coverage.)

State benefit mandates should not be considered as a criterion for benefit inclusion in the essential health benefit definition. Rather, evaluation of essential health benefits should be based on the best evidence.

However, if state mandates are evaluated, we urge the Secretary to strongly consider the following:

- Is there rigorous scientific evidence of the efficacy of the benefit?
- What are the utilization and cost impacts of the mandate? What are the business costs to comply with a mandate—that is, how much will it cost to implement and administer?
- How many people will the mandate affect? Benefits that affect a small population should not be mandated; the cost of implementing such a mandated benefit may far exceed the value given the few people who will be helped by the mandate.
- Several states (Maryland, Maine, California, New Jersey) require independent analysis of proposed mandates prior to enactment. These analyses consider the medical efficacy, social and financial impacts (including administrative costs) of the proposed mandates. However, it rarely is the cost of a single mandated benefit, but instead the cumulative impact of many mandates that causes material increases in premiums. Therefore, HHS should not only evaluate each mandate under consideration individually for its evidence-based support, but it should also complete a final study after all mandates are considered to ascertain the cumulative impact these will have on premiums, and the costs to taxpayers (by way of premium subsidies), employers and members. (As an example, see the following study published by the Maryland Health Care Commission http://mhcc.maryland.gov/health_insurance/mandated_1207.pdf)
- Inclusion of existing mandated benefits may add directly to the costs of PPACA. Even a small increase in the cost of the average plan will increase the government’s cost by billions of dollars in the form of higher premium subsidies.
- Each mandated benefit should be assessed to determine if it is designed to serve only a subset of individuals and is essentially a special interest add-on that will be subsidized by the population who pays the premiums of a given product.

12. 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 most critical method, both in the initial definition, and in subsequent updates to the essential benefit package, is that these processes be insulated, to the maximum extent possible, from
political pressure. Decisions about benefits must be evidence-based, and not influenced by industry or other groups to include coverage that lacks evidentiary support and is not “essential.” HHS should require at a minimum, an independent analysis of any proposed expansion of essential benefits. This analysis should include information from health plans, input from the medical community, and consideration of the medical evidence and literature. The analysis should evaluate the overall impact of the essential health benefits on the cost of subsidies for the government and affordability for consumers. It is important to differentiate between changes to the categories as established in the PPACA and actual covered benefit and services. Health plans should have flexibility to design covered benefits based on market feedback to assure that benefit packages appeal to consumers in light of costs.

In addition, HHS should periodically (e.g., every two or three years), study the cost of any proposed changes in the definition of “essential benefits,” and the impact of such changes on health insurance premiums. This updating process should also permit services, treatments or diagnostics to be excluded from essential health benefits in light of any new medical evidence on effectiveness, outcomes, etc. Both the initial and the cumulative impact of expansions of the definition of “essential benefits” should be tracked by HHS and considered when determining whether insurers’ proposed rate increases are “reasonable.”

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