Essential Health Benefits White Paper

September 2010

Executive Summary

Defining the essential health benefits package is one of the most important responsibilities of the federal government in implementing the Affordable Care Act of 2010 (ACA). ACA outlines some overarching requirements for the essential health benefits package and requires the Secretary of HHS to further define the concepts through rulemaking. Once established, the new requirements for essential health benefits will govern what plans offer in the new Exchanges and individual and small group coverage more broadly. In addition, these requirements have the potential to have a broader impact on the private insurance market and other coverage.

Purpose. The purpose of this paper is to consider the approach the Secretary may take in defining the federal essential health benefits package. This paper:

- Provides a background on insurance mandates;
- Describes the essential health benefits package created in ACA;
- Explores the potential challenges in defining 'essential';
- Considers the Medicare program and the Blue Cross Blue Shield Standard Option available to federal employees through the Federal Employees Health Benefits Program (herein referred to as BCBS-SO) as potential frameworks for the federal standard; and
- Evaluates benefits mandated at the state level, including those established under Medicaid's Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Program for children.

Key Findings and Conclusions. The goals of engagement by the patient community in essential health benefits may include:

- *Ensuring the definition of 'essential' includes services vital to patients with chronic conditions.* The definition of 'essential' will set the foundation for how all services will be evaluated. Similar concepts such as 'medical necessity' and 'reasonable and necessary' are inadequately defined today, but could serve as potential starting points for defining 'essential.'

- *Ensuring categories of benefits are comprehensive.* ACA establishes 10 general categories of services that, at a minimum, must be included in the benefits defined by the Secretary. A review of the benefits provided under Medicare, BCBS-SO, state mandates, and the Medicaid EPSDT program for children suggests that the categories described in ACA may not adequately capture the range of services necessary for a comprehensive benefits package.

- *Ensuring an approach to developing the essential health benefits package that includes protections from discriminatory practices.* The Secretary appears to have three options to develop the essential health benefits package: 1) define benefits narrowly within each category; 2) define categories of benefits broadly but establish additional process-oriented requirements that would impose additional requirements on the development of coverage policies; or 3) define categories of benefits broadly, allowing plans to determine coverage within each category. Narrowly defining the benefits could be an approach used by the Secretary to ensure greater accountability for health plans. However, such an approach could limit plans' flexibility to adapt to changes in the evidence base for an intervention, as well as restrict their ability to accommodate advances in technology. At the same time, granting insurers with too much flexibility creates the risk that plans will exclude vital services from the package, even those that are evidence-based.

The second scenario may represent a compromise, in which plans are granted some flexibility in developing coverage policies, but additional processes or requirements would serve as checks to ensure that plans do not violate the spirit of the law with respect to depth of coverage and discriminatory practices.

- *Ensuring a transparent evaluation process of the benefits package.* The Secretary is required to periodically review the benefits package and assess if enrollees are experiencing difficulty accessing services. An open, transparent process will be critical to ensuring the patient perspective is incorporated in the development of measures used to evaluate the essential health benefits package.

Background

A central goal of health care reform is to ensure individuals have access to affordable and adequate insurance. To ensure adequacy in insurance coverage, the Affordable Care Act of 2010 (ACA) requires the Secretary of HHS to establish an essential health benefits package, a minimum standard for benefits that all qualified health plans[1] and other non-grandfathered small and individual insurance plans must cover by 2014.

Mandated benefits are certainly not new to the health insurance industry, but until recently, most benefit mandates were established at the state level. In addition, benefits mandated by states have typically been for discrete health care items and services, providers, or patient populations. However, the essential health benefits package seeks to establish a new federal standard that will serve as a floor for a comprehensive benefit package.

Insurance mandates

A health insurance mandate requires a health insurance company or health plan to offer or provide coverage for: a treatment by a particular type of health care provider; a certain treatment or service (including procedures, medical equipment, or drugs that are used in connection with a treatment or service); and the screening, diagnosis, or treatment of a particular disease or condition.[2]

An insurance mandate can take two forms: (1) a law may require the health plan to cover the service; or (2) a law may state that *if* the health plan covers the service, it must meet certain minimum requirements. Today, there are federally mandated benefit laws related to mental health parity, pregnancy benefits, minimum hospital stays for newborns and mothers, and reconstructive surgery after mastectomy. However, with the exception of mastectomy reconstructive surgery, these federal laws only require that *if* a health plan offers the benefit, it must comply with minimum requirements. Some health plans opt to exclude the benefit category entirely in order to avoid the requirements associated with the mandate (e.g., excluding coverage for mental health.)

Most mandated benefits are established by state legislatures since private insurance regulation has historically been the responsibility of the states. The number and types of mandates placed on health plans

[1] A "qualified health plan" is a health plan that is certified by each Exchange through which the plan is offered; provides the essential benefits package; is offered by an issuer that is licensed and in good standing in each state in which the plan is offered; agrees to offer at least one qualified plan in the silver and gold levels; agrees to charge the same premium whether the plan is sold through the Exchange or outside the Exchange; and complies with other requirements developed by the Secretary and the Exchange. Section 1301, *Affordable Care Act of 2010*.

[2] Laugesen MJ, Paul RR, et al. *A Comparative Analysis of Mandated Benefit Laws, 1949-2002.* Health Serv Res. 2006 June; 41(3 Pt 2): 1081–1103.

varies greatly by state. According to a tracking survey conducted by the Council for Affordable Health Insurance, Idaho has the fewest benefit mandates with 6, while Rhode Island has the most with 44.[3]

ACA Creates a New Benefits Concept at the Federal Level

ACA creates an essential health benefits package that all qualified health plans must cover by 2014. In addition, all individual and small group plans (regardless of whether they meet the qualified health plan definition) must cover the essential benefits package. The benefit requirements do not apply to grandfathered plans, large group, or self-insured plans.[4] As conceived in ACA, the essential health benefits package will be a comprehensive coverage policy that is intended to ensure that individuals have adequate coverage for a range of specific services when they purchase insurance. The scope of benefits must be equal to the scope of benefits provided under a typical employer plan. To inform the Secretary's determination, the Secretary of Labor is required to conduct a survey of employer-sponsored coverage to determine the benefits typically covered by employers. Because the essential benefits package represents a minimum for coverage, states still have the flexibility to mandate more generous benefits if they so choose. If a state mandates benefits in addition to the federal benefit package, then the state must assume the increased cost of the mandates.[5]

The Secretary is given several parameters for developing the essential benefits package.

- The benefits must include, at a minimum, 10 categories of services:
  - ambulatory patient services;
  - emergency services;
  - hospitalizations;
  - maternity and newborn care;
  - mental health and substance use disorder services, including behavioral health;
  - prescription drugs;
  - rehabilitative services and devices;
  - laboratory services;
  - preventive and wellness services; and chronic disease management; and
  - pediatric services, including vision and oral care.

- In defining the benefits, the Secretary must:
  - ensure that such essential health benefits reflect an appropriate balance among the categories described above, so that benefits are not unduly weighted toward any category;
  - not make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life;
  - take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups; and
  - ensure that health benefits established as essential not be subject to denial to individuals against their wishes on the basis of the individuals' age or expected length of life or of the individuals' present or predicted disability, degree of medical dependency, or quality of life.

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[3] Bunce VC, Wieske JP. *Health Insurance Mandates in the States 2009.* Council for Affordable Health Insurance.
[4] Sec. 2707 of the Public Health Service Act, as amended by Sec. 1201 of the *Affordable Care Act* of 2010.
[5] Sec. 1311, *Affordable Care Act of 2010.*

- Coverage of emergency services cannot be subject to prior authorization requirements or be limited because the provider of services does not have a contractual relationship with the plan.

ACA also establishes financial protections for beneficiaries:

- The cost sharing may not exceed the cost sharing for Health Savings Accounts.[6] For the small group market, deductibles may not exceed $2,000 for individuals and $4,000 for families. Out-of-pocket maximums are indexed by the percentage increase in average per capita premiums.[7]

- Plans must satisfy the actuarial value requirements outlined below[8]:
    - Bronze: Plan covers 60 percent of health care costs
    - Silver: 70 percent of health care costs
    - Gold: 80 percent of health care cost
    - Platinum: 90 percent of health care costs
    - Allows catastrophic coverage policies for individuals 30 or younger or those exempt from the individual mandate due to financial hardship

[6] For 2010, maximum out-of-pocket costs for HSAs are $5,950 for individual coverage and $11,900 for family coverage.
[7] The amount is increased by twice the percentage increase in average per capita premiums for family coverage.
[8] Child-only plans must be offered at the same level of coverage.

Challenges in Defining 'Essential'

A challenge for the Secretary in establishing the essential health benefits package will be defining the term 'essential' and establishing criteria for determining qualifying health care items or services. Although 'essential' is widely understood as a concept, the term has eluded definition, primarily because patients, providers, payers, and policymakers differ in their assessment of 'essential' in the context of a health care service.

As a benchmark, medical necessity, a term similar and related in concept to 'essential,' is ambiguously defined as services that are needed to diagnose or treat a medical condition and that meet accepted standards of medical practice. Defining medical necessity was less controversial prior to managed care, when payers rarely challenged physicians' decisions. However, in the past several decades, medical necessity has evolved into a term of art that has enabled health plans and physicians to make judgments about coverage that were largely unchallenged by patients.[12] Medical necessity and similar terms continue to be incorporated into legislation and regulations as a way to guide medical coverage decisions but lack of a consistent definition has led to variations in decision making. Past attempts to define medical necessity and similar concepts such as Medicare's "reasonable and necessary" standard suggest that the Secretary's task in defining 'essential' will hardly be straightforward. At the same time, however, establishing a clear definition of 'essential' will be crucial to building confidence in the Secretary's process for defining the essential health benefits package and for gaining public support.

Medicare's Attempts to Define "Reasonable & Necessary"

For the past four decades, Medicare coverage decisions have been based on the statute that established the program: ". . . no payment may be made . . . for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury." In enacting the Medicare program, however, Congress stopped short of further defining what constitutes "reasonable and necessary."

Since Medicare's inception, CMS has struggled to define criteria for how it determines whether an item or service is "reasonable and necessary." Three separate attempts by CMS to promulgate coverage criteria through the rule-making process have each been met with resistance by varying stakeholders.[9]

Past attempts by CMS to define "reasonable and necessary" have failed, in part, due to the inability of stakeholders, such as patients, payers, providers, and manufacturers, to reach a consensus on its definition.[10] However, a more fundamental obstacle has been that every attempt to define "reasonable and necessary" has sparked considerable public debate.[11]

Federal Health Programs as a Benchmark

While the results of the Secretary of Labor's survey of employer-sponsored health benefits will inform the development of the essential health benefits package, existing federal programs, such as the Federal Employee Health Benefits Plan (FEHBP) and Medicare, may be instructive in determining the potential approaches the Secretary may take to develop the benefits package as well as in identifying the items and services that could be included.

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[9] Foote SB. Why Medicare Can't Promulgate a National Coverage Rule: A Case of *Regula Mortis*. *Journal of Health Politics, Policy and Law* 2002 27:707-730.

[10] Tunis S. *Why Medicare Has Not Established Criteria for Coverage Decisions.* N Engl J Med 2004; 350:2196-2198.

[11] Ibid.

[12] Bergthold, LA. *Medical Necessity: Do We Need it?* Health Affairs 1995: 14-4; 180-190.

The FEHBP is the largest employer health insurance program in the United States, insuring eight million current and former federal employees and their families. FEHBP is a system of competing private health plans that is often viewed as a working model for providing decent, affordable coverage.[13]

While there is no prescribed minimum benefit package for FEHBP plans,[14] an often mentioned benchmark standard for adequate coverage is the Standard Option offered by Blue Cross Blue Shield under the FEHBP (BCBS-SO).[15] The benefit package provided under BCBS-SO offers comprehensive coverage for hospital, medical, surgical, diagnostic, preventive, maternity, and emergency services; prescription drugs; mental health; treatment therapies; physical and rehabilitation therapy; and home health, skilled nursing, and hospice care.

A review of the services covered under the Medicare program shows that Medicare covers substantially the same services as BCBS-SO, barring age-specific services such as pediatric care. The services provided in the Medicare program and in BCBS-SO (according to their respective 2010 service brochures) are summarized in the Appendix. The list of services is not comprehensive, as it includes only services that would fall in the 10 general categories in ACA, suggesting that the categories described in ACA are insufficient in capturing the range of services that could be included in the essential health benefits package.

Coverage of Prescription Drugs

Differences in the coverage of prescription drugs by Medicare Part B, Medicare Part D, and BCBS-SO provide insight into three potential approaches the Secretary can take in developing the essential health benefits package. While Medicare (primarily through the Part D program) and BCBS-SO cover substantially the same prescription drugs, the approaches used to develop their formularies and processes to ensure adequate coverage differ.

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[13] David K, Cooper BS, Capasso R. *The Federal Employee Health Benefits Program: A Model For Workers, Not Medicare.* November 2003. The Commonwealth Fund.

[14] Merlis M. *The Federal Employees Health Benefits Program: Program Design, Recent Performance, and Implications for Medicare Reform.* May 2003. Kaiser Family Foundation.

[15] Karen Pollitz statement to the Hearing on The Tri-Committee Draft Proposal for Health Care Reform on June 25, 2009. In June 2010, Karen Pollitz was appointed Deputy Director for Consumer Support, Office of Consumer Information and Insurance Oversight in the Department of Health and Human Services.

Table 1. Prescription Drug Coverage

Medicare Part B	Medicare Part D	BCBS-SO
• Drugs furnished in the context of a professional service that are not usually self-administered • Durable medical equipment supply drugs (e.g., inhalation drugs which are administered in the home through the use of a nebulizer) • Immunosuppressive drugs • Hemophilia clotting factors • Oral anti-cancer drugs • Oral anti-emetic drugs • Pneumococcal vaccine • Hepatitis B vaccine • Influenza vaccine • Antigens • Erythropoietin • Parenteral nutrition • Intravenous Immune Globulin Provided (IVIG)	• Formularies must include drug categories and classes that cover all disease states • Off-label anti-cancer drugs (use must be supported in designated compendia)	• Drugs that require prescription for their purchase • Clotting factors and anti-inhibitor complexes for the treatment of hemophilia • Contraceptives

Sources: Medicare Prescription Drug Benefit Manual, Blue Cross Blue Shield 2010 Service Plan Brochure.

The Medicare Part B program provides limited benefits for outpatient drugs. The program generally covers drugs that are not usually self-administered and when furnished in the context of a professional service. In addition, the Part B program covers several drugs for which coverage has been established by statute.[16] (See Table 1)

Medicare beneficiaries' primary means of access to outpatient prescription drugs is through the Part D program, which is administered by private plans. The Medicare Modernization Act and subsequent CMS regulation and guidance provides several parameters for the development of the formulary, including: 1) formularies must include drug categories and classes that cover all disease states; 2) each category or class must include at least two drugs (with exceptions); and 3) formularies must include all or substantially all drugs in the immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes.

While these formulary requirements leave plans with plenty of flexibility, CMS has established specific requirements for pharmacy and therapeutics (P&T) committee membership, conflict of interest, and formulary management, as well as created a rigorous formulary review process. CMS reviews all Part D formularies on tier placement to ensure they do not discourage enrollment of certain beneficiaries and to assess whether appropriate access is afforded to drugs or drug classes addressed in widely accepted treatment guidelines.[17] These process-oriented requirements serve as a layer of protection to ensure that formularies are consistent with best practice formularies in widespread use.

Unlike private plans in Medicare Part D, BCBS-SO (like all plans in FEHBP) is not required to meet a minimum standard for drug benefits and is given significant leeway in establishing its drug formulary.

[16] Section 1861(s), *Social Security Act*.
[17] Medicare Prescription Drug Benefit Manual. Accessed at http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter6.pdf on August 22, 2010.

Coverage of prescription drugs by the Medicare Part B and D programs and BCBS-SO illustrate three potential options for the Secretary in her approach to developing the essential benefits package:

1) define benefits narrowly within each category, such as the Medicare Part B program;

2) define categories of benefits broadly and establish process-oriented requirements as a 'check' on plans, similar to the Medicare Part D program; or

3) define categories of benefits broadly, granting plans the flexibility to develop coverage policies within each category, such as the FEHBP.

Existing State-Level Mandates

State mandated benefit laws

Spurred in part by public anxiety about managed care practices, mandated benefit laws proliferated in state legislatures in the 1990s.[18] Mandates were used to override restrictions placed by managed care on services that did not meet "medical necessity" requirements.[19] In addition, growth of mandated benefits during this time appears to have been aided by a political calculation by state legislators that they could meet the needs of concentrated and organized interests represented by groups of health care professionals and patients with a specific medical condition, with little resistance from payers, for whom the costs of an individual mandate at the time were minimal.[20]

With time and as the number of mandates accumulated, concerns emerged that state mandates were increasing premium costs. The growth of state regulation on health insurance was also cited as causing employers to switch from offering commercial health plans to offering self-insured plans, due to the protections provided under the Employment Retirement and Income Security Act of 1974 (ERISA), which exempts self-funded plans from complying with state health insurance laws and regulation.[21]

Today, there are over 1,200 state mandated benefit laws.[22] Some states, such as Idaho and Alabama, mandate few benefits, while others like Minnesota and Massachusetts provide for a broader range of benefits. Table 2 lists common state mandates arrayed against the 10 categories described in ACA. As shown in the table, several mandated benefits do not have a category in the ACA framework.

While the services listed in Table 2 are commonly provided across most private health plans, treatment for autism merits additional discussion. Autism treatment has only recently emerged as a mandated benefit in states but has steadily been gaining ground, in large part due to the increased diagnosis and understanding of the autism spectrum disorders, improved treatment, and organization of autism groups. As of 2009, 23 states mandated some form of coverage for autism treatment.[23] While popular, mandated coverage of treatments for autism is controversial, as insurers have raised questions about whether autism is a health-related condition or a behavioral or educational challenge and whether treatments that are considered educational should be covered by health insurers.[24] Autism treatment may be considered by the Secretary as she develops the essential health package, but the lack of a clear standard of care to determine the appropriate therapy makes it likely that plans will be granted some flexibility. The

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[18] Laugesen et al.
[19] Laugesen et al.
[20] Bellow NM, Halpin HA, McMenamin SB. *State-Mandated Benefit Review Laws.* Health Serv Res. 2006 June; 41(3 Pt 2): 1104–1123.
[21] Bellows et al.
[22] Bunce et al.
[23] Ibid.
[24] http://www.cahi.org/cahi_contents/resources/pdf/n152AutismTrend.pdf

Secretary will likely encounter other conditions for which treatment and diagnoses are evolving and that reflect substantial costs to individuals and insurers. These will be an ongoing source of controversy as essential benefits are required.

Table 2. Common State Mandates*

Category	Service
Ambulatory patient services	Ambulatory surgery Ambulance/transportation services Second surgical opinion
Emergency services	Emergency service
Hospitalization	Mastectomy minimum stay
Maternity and Newborn care	Maternity Maternity minimum stay Cleft palate Newborn hearing screening
Mental health/substance abuse	Alcoholism Drug abuse treatment Mental health general and parity
Prescription drugs	Contraceptives Off-label drugs
Rehab and habilitative services and devices	Orthotics and/or prosthetics Autism treatment
Laboratory services	None
Preventive and wellness; chronic disease management	Bone mass measurement Cervical cancer/HPV screening Colorectal cancer screening Diabetes self management and supplies HPV vaccine Mammography Prostate cancer screening
Pediatric, including oral and vision	Hearing aids for minors Well child care
No category	Bone marrow transplant Clinical trials Dental anesthesia Hair prosthesis for hair loss due to chemotherapy Home health care Hospice care In vitro fertilization Phenylkenoturia/metabolic disease formulas Temporomandibular joint disorders

* 10 or more states mandate the benefit.
Source: *Health Insurance Mandates in the States 2009*, Council for Affordable Health Insurance.

Interplay between state mandates and the essential health benefits package

Under ACA, states retain the ability to mandate benefits beyond those established by the federal mandate. In the event that a state wants to continue to apply mandates beyond the essential health benefits package, the state is required by law to either make payments to the qualified health plan enrollee or to the qualified health plan directly to defray the cost of these benefits.

Many of the existing state mandates are for benefits that are consistent with those provided in Medicare and BCBS-SO, making it likely that many state mandated benefits will fall under the scope of the essential health benefits package. For those state mandated benefits that do not, states may amend those laws so that they do not apply to qualified health plans or individual and small group plans offered outside the Exchange.

State experiences in defining benefits

Benefit mandates in Massachusetts account for 12% of premiums

Mandated benefits provide important protections for insured populations, but they can also hinder the ability of health insurers to offer affordable coverage options. As of January 1, 2006, the state of Massachusetts had 26 mandated benefits in effect, many of which were those commonly mandated by other states (as listed in Table 2).[25] The Massachusetts Division of Health Care Finance and Policy's report to the legislature indicated that total spending on mandated benefits in 2004-2005 was $1.32 billion, or 12% of health care premiums.[26] In Massachusetts, five mandates (maternity, mental health, home health, preventive care for children and infertility services) accounted for 80% of the total cost of the mandated benefits. In addition, one-third of the total cost was for maternity care, a benefit mandated by federal law. Excluding the costs of maternity care, which health plans must provide in the absence of any state mandate, the other mandated benefits accounted for about 8.5% of premiums.[27] Analyses by other states also show an increase in health care costs and premiums stemming from benefit mandates.[28]

Oregon's benefits package has undergone multiple iterations

In 1989, the state of Oregon, seeking to stem rising Medicaid costs and to expand coverage to the growing uninsured population, developed the Oregon Health Plan (OHP). The state planned to add uninsured people to the Medicaid program and to fund this expansion by reducing the scope of covered benefits.[29] To prioritize services, Oregon created the Health Services Commission (HSC), an 11-member committee charged with establishing priorities for coverage. Based on scientific evidence and expert opinion about treatment effectiveness, as well as public input, the HSC ranked more than 700 diagnoses and treatments in order of importance. The state legislature drew a line at item 587 on the list, and services above the line constituted the benefits package; participating health plans were required to cover all services above the line.[30]

The OHP, and the prioritized list, went into effect in 1994. As health care costs rose, the state used the list to reduce the number of covered services. In the late 1990s, however, the Health Care Financing Administration (present-day CMS) began denying Oregon's requests to move the line upward (so that fewer treatments are covered), and the number of people covered by Medicaid steadily declined.[31] While Oregon's plan has subsequently been dismissed as a failure, the prioritized list was adopted in 2007 as the basis for an essential benefits package in legislation mandating that the state develop a universal coverage plan for all Oregonians.[32] In the proposed benefits package, the list of covered benefits is categorized in four tiers with higher cost sharing for lower-priority services:[33,34]

I. Preventive services and highly effective care for severe chronic disease and life-threatening illness and injury;

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[25] Division of Health Care Finance and Policy. *Comprehensive Review of Mandated Benefits in Massachusetts Report to the Legislature*. July 7, 2008 Commonwealth of Massachusetts, Executive Office of Health and Human Services, Division of Health Care Finance and Policy.
[26] Ibid.
[27] Ibid.
[28] Cauchi, R. *Health Insurance Coverage Mandates: Are They Too Costly?* May 28, 2009. National Conference of State Legislatures. Accessed at http://www.ncsl.org/portals/1/documents/health/MandatesCauchi09.pdf on August 20, 2010.
[29] Boddenheimer T. *The Oregon Health Plan—Lessons for the Nation.* N Engl J Med 1997; 337:651-656.
[30] Ibid.
[31] Saha S, Coffman D, et al. *Giving Teeth to Comparative-Effectiveness Research—The Oregon Experience.* N Engl J Med 2010; 362:e18.
[32] Ibid.
[33] Office for Oregon Health Policy and Research. *Oregon's Essential Benefits Package & Value-Based Services: Overview and Next Steps.* July 2010. Accessed at http://www.oregon.gov/OHA/OHPB/meetings/2010/ebp-presentation.pdf?ga=t on August 20, 2010.
[34] http://www.oregon.gov/OHPPR/HFB/docs/BenefitCommitteeFinal.pdf?ga=t

II. Effective care of other chronic disease and life-threatening illness and injury;
III. Effective care for non-life-threatening illness and injury; and
IV. Less effective care and care for self-limited illness and minor illness and injury.

The proposed package includes first dollar coverage for value-based services, which are evidence-based services that have been shown to reduce complications of disease and reduce the overall cost of care; basic diagnostic services; and comfort care services including hospice and palliative care.[35] If approved, this package will serve as a minimum set of covered benefits, beginning with public programs and health plans participating in a state insurance Exchange.[36]

Medicaid's Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Program as a benchmark for pediatric care

For essential health benefits for pediatric care, a relevant benchmark may be Medicaid's Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Program, a preventive health program for individuals under the age of 21. EPSDT is the most comprehensive set of health benefits for children and adolescents in the public or private sector.[37]

EPSDT provides screening and preventive care as well as any medically necessary service to correct health problems identified through screening, even if that service is not covered under the state's Medicaid plan.[38] Services are required to be provided at intervals that meet reasonable standards of medical practice.[39]

The EPSDT benefit must include the following services:[40]

- **Screening Services**
  - **Comprehensive health and developmental history** (including assessment of both physical and mental health development);
  - **Comprehensive physical exam;**
  - **Appropriate immunizations** (according to the schedule established by the Advisory Committee on Immunization Practices (ACIP) for pediatric vaccines);
  - **Laboratory tests** (statewide screening requirements for the minimum laboratory tests or analyses to be performed by medical providers for particular age or population groups);
  - **Lead Toxicity Screening**
- **Health Education**—Health education and counseling to both parents (or guardians) and children designed to assist in understanding what to expect in terms of the child's development and to provide information about the benefits of healthy lifestyles and practices as well as accident and disease prevention;
- **Vision Services**—At a minimum, include diagnosis and treatment for defects in vision, including eyeglasses.
- **Dental Services**—At a minimum, include relief of pain and infections, restoration of teeth and maintenance of dental health.

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[35] Office for Oregon Health Policy & Research. *Policy Brief: The Essential Benefit Package.* March 2009.
[36] Saha S, Coffman D, et al. *Giving Teeth to Comparative-Effectiveness Research—The Oregon Experience.* N Engl J Med 2010; 362:e18.
[37] Peters CP. *Issue Brief: EPSDT: Medicaid's Critical But Controversial Benefits Program for Children.* National Health Policy Forum. November 20, 2006.
[38] Apling RN, Herz EJ. *Individuals with Disabilities Education Act (IDEA) and Medicaid,* 2003. Congressional Research Service.
[39] https://www.cms.gov/MedicaidEarlyPeriodicScrn/
[40] Ibid.

- **Hearing Services**—At a minimum, include diagnosis and treatment for defects in hearing, including hearing aids; and
- **Other Necessary Health Care**—States must provide other necessary health care, diagnosis services, treatment, and other measures to correct or ameliorate defects, and physical and mental illnesses and conditions discovered by the screening services.

Key Findings

- **Defining 'essential' will be a task that the Secretary will find challenging, but necessary.** The definition of 'essential' is open to wide interpretation. The experience of defining 'medical necessity,' a similar concept, has been fraught with difficulties. Many payers define medical necessity as services that are consistent with the diagnosis and treatment of a condition and standards of good medical practice and set criteria to outline specific diagnosis and levels of care deemed as medically necessary.[41] CMS defines medical necessity as "services or items reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" but the definition of 'reasonable and necessary' is still ambiguous even 45 years after its establishment.

- **The Secretary has three potential approaches to developing the essential benefits package** (as illustrated in the case study on prescription drugs):

  1) Define benefits narrowly within each category, such as the Medicare Part B program;

  2) Define categories of benefits broadly but establish process-oriented requirements that would impose additional requirements on the development of coverage policies, similar to the Medicare Part D program; or

  3) Define categories of benefits broadly, granting plans the flexibility to develop coverage policies within each category, such as the FEHBP.

- **The Medicare program and BCBS-SO cover substantially the same services, barring age-specific services.** While comparisons of the actuarial value of benefits provided under Medicare to BCBS-SO conducted prior to the enactment of ACA has shown Medicare to be less generous,[42] a review of the services provided by Medicare and BCBS-SO reveals considerable alignment in the type and range of services offered. The Medicare program and BCBS-SO could serve as frameworks for a robust essential health benefits package if the Secretary chooses to define the benefits narrowly.

- **Health plans are subject to numerous mandates established at the state level.** State mandated benefits cover a broad range of items and services that may be instructive in the development of the benefits that will be included in the federal mandate. In particular, Medicaid's EPSDT program could serve as a framework for pediatric benefits.

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[41] Review of medical necessity criteria across several health insurers, including: www.anthem.com, https://www.magellanprovider.com/MHS/MGL/providing_care/clinical_guidelines/MNC.asp; http://www.westernhealth.com/members/downloads/fs_med_nec_criteria.pdf; http://www.amerihealth.com/providers/policies_guidelines/medical_necessity_criteria.html.

[42] Yamamoto D, Neuman T, Strollo M. *How Does the Benefit Value of Medicare Compare to the Benefit Value of Typical Large Employer Plans?* September 2008. Kaiser Family Foundation.

- **The 10 categories described in ACA may be insufficient.** In the 10-category framework, it is unclear how treatment therapies that are delivered in the inpatient setting, such as chemotherapy and radiation therapy, renal dialysis, and infusion therapy, as well as non-ambulatory surgeries, such as mastectomies, breast reconstruction after mastectomies (which is a federally mandated benefit today), and organ transplants, would be categorized. Further, it is unclear if and how services that are delivered in settings of care other than the inpatient and the ambulatory settings, such as skilled nursing facilities, home health, and hospice, would be categorized in the current framework. The categories described under ACA may also be insufficient when it comes to treatments for children, such as autism treatment and the range of services provided in the Medicaid EPSDT program.

- **Robust, specific mandated benefits can adversely impact plan affordability.** Mandated benefits provide protections for insured populations, but they can also impede health insurers' ability to offer affordable health care coverage options. In Massachusetts, 26 mandated benefits accounted for 12% of health care premiums.

Conclusions and Engagement by the Patient Community

The implementation of health care reform provisions for which deadlines are looming may take attention away from determining essential health benefits, but the patient community should begin to engage with the Secretary to define key concepts relating to the package. The goals of engagement by the patient community in essential health benefits may include:

- **Ensuring the definition of 'essential' includes services vital to patients with chronic diseases and disabilities.**

  The definition of 'essential' will set the foundation for how all services will be evaluated. Similar concepts such as 'medical necessity' and 'reasonable and necessary' are inadequately defined today, but could serve as potential starting points for defining 'essential.' It is also possible that the Secretary will adopt a modified version of the approach proposed in the state of Oregon, in which highest-priority, or 'essential,' services, are defined as those that are: 1) preventive services and highly effective care for severe chronic disease and life-threatening illness and injury or 2) effective care of other chronic disease and life-threatening illness and injury.

  While a strong evidence base is almost certain to be a primary criterion for qualifying as an essential benefit, a key question will be how the Secretary will deal with off-label products, for which evidence has not been developed. While off-label use of anticancer drugs is covered by the Medicare program under certain conditions, off-label drugs are considered experimental/investigational by many payers, and if categorized as such by the Secretary could be excluded in the essential health benefits package. Policymakers have long recognized that cancer is somewhat unique, so this may be a more relevant issue for off-label use of drugs for other diseases, such as HIV/AIDS, and devices.

- **Ensuring categories of benefits are comprehensive.**

  ACA establishes 10 general categories of services that, at a minimum, must be included in the benefits defined by the Secretary. The Secretary is not precluded from establishing additional categories of service. A review of the benefits provided under Medicare, BCBS-SO, state mandates, and the Medicaid EPSDT program for children suggests that the categories described

in ACA may not adequately capture the range of services necessary for a comprehensive benefits package.

- **Ensuring an approach to developing the essential health benefits package that includes protections from discriminatory practices.**

  As discussed earlier, the Secretary appears to have three options to develop the essential health benefits package: 1) define benefits narrowly within each category; 2) define categories of benefits broadly but establish additional process-oriented requirements that would impose additional requirements on the development of coverage policies; or 3) define categories of benefits broadly, allowing plans to determine coverage within each category.

  Narrowly defining the benefits could be an approach used by the Secretary to ensure greater accountability for health plans. However, such an approach could limit plans' flexibility to adapt to changes in the evidence base for an intervention, as well as restrict their ability to accommodate advances in technology. At the same time, an approach like the third option creates the risk that health insurers will exclude services vital to patients with chronic disease from the package, even those that are evidence-based.

  The second scenario may represent a compromise, in which plans are granted some flexibility in developing coverage policies, but additional processes or requirements would serve as checks to ensure that plans do not violate the spirit of the law with respect to depth of coverage and discriminatory practices. Such processes or requirements could include:

  - Adopting a rigorous review process to ensure appropriate access is afforded to services or treatments that are consistent with best practices; and
  - Establishing protections from discriminatory cost-sharing practices, such as eliminating specialty tiers in prescription drugs covered in the essential health benefits package.

- **Ensuring a transparent evaluation process of the benefits package**

  The Secretary is required to periodically review the benefits package and assess if enrollees are experiencing difficulty accessing services. Several states have adopted mandated benefit review laws, which may serve as models for the different approaches the Secretary can take. The primary review criteria used across states that have such a process include: *cost impact* (e.g., impact of the total cost of health care in the state and costs for stakeholders affected by the mandate); *social impact* (e.g., utilization, insurance coverage, demand, availability, and need); and *medical efficacy* (e.g., verification of the effectiveness of the service or treatment in the prevention or treatment of disease or disability).[43] An open, transparent process will be critical to ensuring the patient perspective is incorporated in the development of measures used to evaluate the essential health benefits package.

[43] Bellows et al.

Appendix. Summary of Services Explicitly Covered Under Medicare and BCBS-SO

	Medicare	BCBS-SO
Ambulatory patient services	• Ambulatory surgical centers • Outpatient hospital services • Outpatient medical and surgical services and supplies • Second surgical opinions • Diagnostic tests, including X-rays, MRIs, CT scans, EKGs • Outpatient treatment therapies: ○ Chemotherapy and radiation therapy ○ Renal dialysis ○ IV therapy ○ Outpatient cardiac rehabilitation • Chiropractic services	• Ambulatory surgical centers • Outpatient hospitals services • Outpatient medical and surgical services and supplies • Second surgical opinions • Diagnostic tests, including X-rays, MRIs, CT scans, EKGs • Outpatient treatment therapies: ○ Chemotherapy and radiation therapy ○ Renal dialysis ○ IV therapy ○ Outpatient cardiac rehabilitation • Neurological testing • Chiropractic services
Emergency services	• Ambulance services • Emergency department services	• Ambulance services • Emergency department services
Hospitalizations	• Inpatient care	• Inpatient care
Maternity and newborn care	• Maternity care	• Maternal care • Congenital anomalies • Newborn screenings
Mental health and substance abuse services	• Outpatient mental health care • Smoking cessation	• Inpatient and outpatient professional services • Screening and behavioral change interventions for tobacco use and alcohol/substance abuse • Smoking cessation drugs
Prescription drugs	• Under Part B: ○ Durable medical equipment supply drugs (e.g., inhalation drugs which are administered in the home through the use of a nebulizer) ○ Immunosuppressive drugs ○ Hemophilia clotting factors ○ Oral anti-cancer drugs ○ Oral anti-emetic drugs ○ Pneumococcal vaccine ○ Hepatitis B vaccine ○ Influenza vaccine ○ Antigens ○ Erythropoietin ○ Parenteral nutrition	• Drugs that require prescription for their purchase • Needles and disposable syringes for the administration of covered medication • Clotting factors and anti-inhibitor complexes for the treatment of hemophilia • Contraceptives

	Medicare	BCBS-SO
	○ Intravenous Immune Globulin provided (IVIG) ○ Off-label anti-cancer drugs (use must be supported in designated compendia) • Under Part D: ○ Formularies must include drug categories and classes that cover all disease states ○ Off-label anti-cancer drugs (use must be supported in designated compendia)	
Rehabilitative and habilitative services and devices	• Occupational therapy • Physical therapy • Speech therapy • Durable medical equipment • Prosthetics/orthopedic devices	• Occupational therapy • Physical therapy • Speech therapy • Cognitive rehabilitation therapy • Durable medical equipment • Prosthetics/orthopedic devices
Laboratory services	• Certain blood tests • Urinalysis	• Blood tests • Urinalysis • Genetic testing (diagnostic only)
Preventive and wellness services and chronic disease management	• Abdominal aortic aneurysm screening • Bone mass measurement • Cardiovascular screenings (cholesterol, lipid, triglyceride) • Cancer screenings • Colorectal cancer screenings • Cognitive impairment (detection) • Mammograms • PAP tests and pelvic exams • Prostate cancer screening • Diabetes ○ screenings ○ self management ○ supplies ○ eye exams ○ foot care • EKG screening • Glaucoma tests • HIV screening • Immunizations ○ Influenza ○ Hepatitis B shots ○ Pneumococcal shot • Kidney disease education services • Nutrition therapy services • Pulmonary rehabilitation	• Allergy care • Abdominal aortic aneurysm screening • Bone mass measurement • Complete blood count • Cancer screenings • Colorectal cancer screenings • Mammograms • PAP tests and pelvic exams • Prostate cancer screenings • Cardiovascular screenings (cholesterol, lipid, triglyceride) • Diabetes ○ self-management ○ supplies ○ eye exams ○ foot care • Immunizations ○ Hepatitis immunizations (Types A and B) for patients with increased risk or family history ○ Herpes Zoster (shingles) vaccines ○ Human PapillomaVirus (HPV) vaccines ○ Influenza (one each flu season) ○ Pneumococcal vaccines ○ H1N1 Influenza (Swine) vaccines ○ Meningococcal vaccines ○ Tetanus-diphtheria (Td) booster — once every 10 years

	Medicare	BCBS-SO
		• Individual counseling on prevention and reducing health risks • Metabolic panel test
Pediatric services, including oral and vision care	Not Applicable	• Routine services as recommended by the American Academy of Pediatrics for children up to the age of 22: ○ Routine physical examinations ○ Routine hearing tests ○ Laboratory tests ○ Immunizations ○ Human Papillomavirus (HPV) vaccines ○ Meningococcal vaccine ○ Rotavirus vaccines ○ Related office visits • H1N1 Influenza (Swine) vaccines

Source: Blue Cross and Blue Shield Service Benefit Plan, 2010; Center for Medicare & Medicaid Services' *Medicare & You* 2010.